Aurora Xi Plasmapheresis System

Operator's Manual

SW v2.1

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Rx Only

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Chapter 1
Introduction

The Aurora Xi Plasmapheresis System can also be called Aurora Xi.

Section 1.1: About this Manual

This Aurora Xi Operator's Manual includes:

- **Table of Contents**
- **Chapter 1 — Introduction:** About this manual, intended use of Aurora Xi, indications, contraindications, donor requirements and care, expected performance, adverse effects, and warnings and cautions.
- **Chapter 2 — System Overview:** General description, safety systems, device components, disposable set components, touchscreen overview, barcode capability, and general description of manufacturer-approved data management system functionality.
- **Chapter 3 — Device ON/OFF and Set-Up Procedures:** Daily device setup and powering OFF the device.
- **Chapter 4 — Plasmapheresis Procedure:** Describes a typical plasmapheresis procedure, remote procedure setup, electronic transfer of Procedure Records, and optional tasks that may be performed during a procedure.
- **Chapter 5 — Troubleshooting:** How to troubleshoot the device and procedure.
- **Chapter 6 — Maintenance and Cleaning:** Device relocation, procedures for both routine and preventive device maintenance and care, how to contact service, and warranty information.
- **Chapter 7 — System Specifications:** Various device specifications, such as physical and electrical, standards compliance, and symbology.
- **Appendix A:** Nomograms, calculation of AC and plasma volume in collected product, and total residual blood loss.
- **Glossary of Graphics:** Categorizes and defines touchscreen elements.

Document Purpose

This manual provides the requirements and steps to successfully collect plasma using Aurora Xi. This manual assumes that operators are trained in the use of Aurora Xi and:

- Basic venipuncture skills
- Familiarity with the center's applicable guidelines and standard operating procedures (SOPs), including aseptic technique

Conventions

Actual screens and summary information may vary from the examples shown in this manual.

This manual uses bold text for the names of buttons, prompts, icons, or tabs.

Buttons, prompts, or icons may appear below instructional text of this manual to clarify operational instructions.

For example, tap the **Check** button:

Most of this manual applies to all centers (e.g., plasma collection centers), regardless of the type of disposable set or configuration used with Aurora Xi. Instructions that apply to the use of a feature that is only applicable to countries and regions (i.e., groups of countries that operate under a single regulatory authority) where appropriate regulatory approvals have been granted are placed in a gray box, with a statement in italics that describes the specific feature. For example:

> If the disposable set does not include a protective cap at the end of the plasma line, position the plasma line so that it is secured in the plasma line tubing guide.
>
> *Applies to disposable sets with an integrated collection container.*

This manual uses color-coded boxes to warn against potential hazards, caution against unsafe practices, and emphasize important information. Warnings alert the operator of potential hazards that can present a threat of personal injury. Warnings are highlighted in red and appear next to the ISO 7010-W001 symbol. For example:

WARNING

→ Used to alert personnel of potentially hazardous conditions that may cause serious adverse reactions, personal injury, or safety hazards, and convey situations in which the operator’s actions play a key role in preventing hazards.

Cautions notify the operator of conditions that could damage equipment, compromise results, or cause unnecessary alarms. Cautions are highlighted in orange and appear next to the ISO 7000-0434A symbol. For example:

CAUTION

➞ Used to alert personnel of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the donor or damage to the instrument or other property. It may also alert against unsafe use.

Notes provide additional information the operator may find useful. Notes contain non-critical information but should always be reviewed by the operator. Notes are highlighted in blue and appear next to a symbol depicting a pencil and paper. For example:

NOTE

➞ Used to provide additional information about the content.

Bold, underlined text indicates a link to another section in the manual. When viewing the manual on a computer or mobile device, you can select a link to jump to a new page. See **General Warnings on page 1-7.**

Descriptions of Service Roles

This manual identifies service roles throughout the manual.

- **Local Service Representative:** An employee of the device manufacturer that has been trained and certified for field service and technical support.
- **Authorized Service Personnel:** A center service technician that has been trained and certified for field service by the device manufacturer.

Operator Qualification and Training

For operator qualifications and manufacturer's training programs, contact your local service representative.

Section 1.2: Intended Use of the Aurora Xi Plasmapheresis System

The Aurora Xi Plasmapheresis System is intended for the automated collection of plasma by membrane filtration to be processed as Source Plasma. The Aurora Xi System is to be used with a single-use Plasmacell Xi Disposable Set and 4% sodium citrate anticoagulant and allows for Saline and No Saline Protocol options.

Section 1.3: Indications

The Aurora Xi Plasmapheresis System is indicated for donors determined eligible by a qualified licensed physician or by persons under their supervision and trained in determining donor eligibility in accordance with applicable eligibility requirements.

Section 1.4: Contraindications

The use of the Aurora Xi Plasmapheresis System is contraindicated in those cases where adequate anticoagulation cannot be achieved.

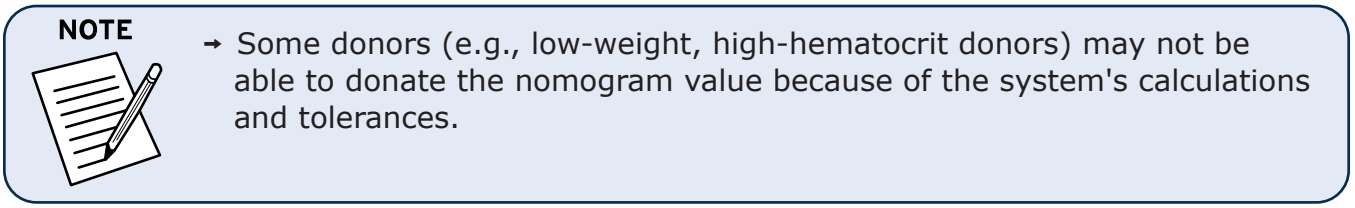
Section 1.5: Donor Requirements and Care

Patient Population

The Aurora Xi Plasmapheresis System is intended to be used with donors rather than patients. Donors should be selected based on applicable eligibility requirements, as well as institutional standard operating procedures (SOPs) for the individual plasma collection center.

Donor Requirements

Each center should select eligible donors based on the applicable eligibility requirements. Per the system requirements, the minimum allowable donor weight is 110 lb (50 kg) and the allowable hematocrit range is 36% to 55% (hemoglobin range 11.7 to 17.9 g/dL).



See **Appendix A** for a description of available nomograms.

Donor Care

Follow center guidelines and SOPs for venipuncture site and donor care.

➔ The donor should be informed of the basic procedure and understand the potential health risks associated with plasmapheresis.

Section 1.6: Expected Performance

Aurora Xi is expected to:

- Perform an automated plasmapheresis procedure using a single-needle, single-use, sterile fluid-path disposable set.
- Deliver anticoagulant (AC) solution automatically to mix with extracted whole blood at a nominal ratio of 1:16 (4% sodium citrate).
- Separate whole blood automatically into concentrated cellular components, return concentrated cellular components to the donor, and collect plasma up to a target collection volume of 200 mL to 1098 mL (depending on the center's configured limit as allowed by local regulations).
- Control the extraction rate of whole blood automatically based on donor vein capacity (draw rate is configurable up to 120 mL/min).
- Control the reinfusion rate automatically of concentrated cells to the donor based on donor vein capacity (reinfusion rate is configurable up to 150 mL/min).
- Limit the total maximum extracorporeal red blood cell volume at any time during a procedure to the configured limit.
- Maintain collection volume accuracy to within ± 10 mL, based on manufacturer's default plasma density configuration.
- Automatically signal the end of a procedure after the target collection volume is reached and the final reinfusion phase is complete.
- Infuse saline solution automatically to the donor based on the user-programmed volume (if a Saline Protocol is selected).

Aurora Xi, when set up for remote communication with a data management system, is expected to:

- Receive procedure setup files from the data management system to populate procedure parameters on the selected device.
- Send Procedure Records to the data management system to permit electronic storage of Procedure Record information on the center's donor management system.

Section 1.7: Adverse Effects

A donor may experience adverse effects similar to those experienced during routine blood collection.

- Dizziness/light headedness, pallor, nausea, hyperventilation, sweating, fainting, vomiting, rapid heart rate, tiredness/fatigue, or low blood pressure may occur. These reactions may be more common among certain donor populations (e.g., first-time, low weight, female, and/or younger donors), and among certain device configurations (e.g., those that increase the rate or magnitude of intravascular volume depletion).
- Due to venipuncture, the donor may experience pain, bruising/hematoma formation, or skin irritation at the site of phlebotomy. In rare cases, local or venous infection, arterial venipuncture, or peripheral nerve injury may occur.

Reactions associated with apheresis procedures may also occur.

- Reinfusion of saline or donor blood may induce chills or cause infiltration.
- Infusion of anticoagulants containing citrate may lead to hypocalcemia, which may manifest as a tingling feeling, often around the mouth of the donor. Other symptoms may include paresthesia (abnormal sensation of the skin), unusual smell or taste, a sensation of vibrations, muscle discomfort, and/or headache. In the rare case that severe hypocalcemia occurs, symptoms may include tetany, convulsions, or cardiac arrhythmia, which if untreated, could lead to death.
- The single-use tubing set includes 2-diethylhexyl phthalate (DEHP), a commonly used plasticizer in medical devices. Where required by local regulations, additional information regarding the risks associated with the use of products containing DEHP is provided in the disposable set product insert (i.e., instructions for use).

In the Aurora Xi New Nomogram clinical study, the rate of significant hypotensive adverse events (SHAEs) in donors using the new Adaptive Nomogram algorithm was less than twice the rate in donors using the Optimized Nomogram algorithm.

For many populations who traditionally experience a high SHAE rate (donors weighing 124 lbs or less, female donors, and donors 20 years old or younger), the incidence of SHAEs with the new Adaptive Nomogram was similar to that with the Optimized Nomogram. Among first-time donors, SHAE rates were slightly higher with the new Adaptive Nomogram, however, most SHAEs with the new Adaptive Nomogram occurred at collection volumes in-range for the Optimized Nomogram as well. The rate of severe injury was slightly higher with the new Adaptive Nomogram, however, the overall rate of this type of events was low; 8 events with Optimized Nomogram versus 10 with new Adaptive Nomogram in a study of over 50,000 donations.

Error conditions during blood donation may result in excessive citrate infusion, blood loss, damage to blood (hemolysis or clotting), and air infusion. This condition may lead to serious adverse reactions, including dyspnea. Error conditions that may be prevented or mitigated by operator action are included in applicable warnings.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the European Member State in which the user and/or patient is established.

Section 1.8: Warnings

Follow all warnings. These warnings are intended to alert the operator of potentially hazardous conditions that may cause serious adverse reactions or personal injury and convey situations in which the operator's actions play a key role in preventing hazards.

General Warnings

Warning:	If the system deviates from expected operation, press the **STOP** button to end the procedure without fluid return in order to mitigate the various risks associated with unexpected operation. Do not reinfuse reservoir contents, in order to mitigate the various risks associated with unexpected operation.
Warning:	Flat or bent tubing in the blood line or cell line may cause hemolysis. Do not use the disposable set if flat or bent tubing is present.
Warning:	Do not connect a donor if the instrument displays a red banner (task zone). This indicates a Test Mode which may have disabled safety systems.
Warning:	Do not use the Aurora Xi system in the presence of explosive gases (e.g., anesthetics, oxygen).
Warning:	Use only the power cord supplied with the Aurora Xi instrument, and plug into a polarized, grounded three-hole outlet, in order to prevent electrical hazards.
Warning:	Do not use the power cord if it is frayed or damaged, in order to prevent electrical hazards.
Warning:	Donors must be screened for eligibility by a medical professional. Donors with certain conditions (e.g., liver and renal diseases) may experience higher rates of reactions.

Context-Specific Warnings

These warnings are listed here for your convenience but require context-specific content to interpret. To fully understand these warnings, see the specific section where they are applied.

Warning:	Use only 4% sodium citrate anticoagulant. Other anticoagulants could lead to clotting or citrate reaction.
Warning:	Confirm that the correct donor weight, donor height, donor gender, and donor hematocrit or hemoglobin are displayed on the touchscreen when information is manually entered or scanned using a barcode scanner. Incorrect information may lead to additional red blood cell (RBC) loss, excess blood loss, over-collection of plasma, and/or higher than intended citrate infusion rate (CIR).
Warning:	The air detector and the outside of tubing installed in the air detector must be clean and dry during disposable set installation and the procedure, to ensure proper functioning of the air detector.
Warning:	If the donor line is removed from the air detector, ensure that the correct line is re-installed to maintain effective air detection.
Warning:	If an air in line alert (3102) is present and the procedure is going to be ended, inspect the donor line for air. If air is present in the donor line, end the procedure without fluid return, in order to mitigate the risk of air infusion.
Warning:	The system cannot prevent or detect all blood loss to the environment. Failure of the operator to perform alert recovery actions can increase the hazard for blood loss and increase the extracorporeal blood volume.
Warning:	If particulate matter is observed in the disposable set, end the procedure without returning fluids or reservoir contents.
Warning:	Confirm that the correct procedure ID or donation setup ID is displayed on the touchscreen. Incorrect information may lead to red blood cell (RBC) loss, hemolysis, and/or incorrect saline infusion volume.

Section 1.9: Cautions

General Cautions

Following is a list of general system cautions. These cautions are intended to inform the operator of potentially hazardous conditions which, if not avoided, may result in minor or moderate injury to the donor and/or operator, and/or cause damage to the instrument or other property. The caution may also alert against unsafe use.

Caution:	The donor should be instructed to alert the operator if symptoms of citrate infusion occur (see the **"Adverse Effects"** section). If symptoms occur, the operator should slow or halt reinfusion.
Caution:	Use aseptic technique throughout the procedure.
Caution:	The power cord, pressure cuff, and any other accessories, must be kept away from walkways to prevent tripping.
Caution:	Avoid wearing unrestrained long hair and jewelry so that they are not caught in moving parts of the instrument.
Caution:	Do not block the vent on the rear door of the instrument. Blocking the vent may cause the instrument to overheat.
Caution:	Do not reuse a disposable set. Reuse of a disposable set may lead to a donor being exposed to a potential biohazard from the blood of another donor.
Caution:	Treat all used disposable sets as potential biohazards.

Context-Specific Cautions

These cautions are listed here for your convenience but require context-specific content to interpret. To fully understand these cautions, see the specific section where they are applied.

Caution:	The correct solutions pole that corresponds to the appropriate disposable set and saline solution is to be installed and used to prevent cross-spiking of solutions.

Context-Specific Cautions

Caution:	Equipment connected to the Aurora Xi instrument's communication ports must comply with all appropriate UL/CSA/IEC standards for the equipment type in order to prevent electromagnetic interference (EMI) hazards. Furthermore, the combination forms a medical system and may also require standards compliance. Consult a trained representative if there are any questions.
Caution:	Do not operate the Aurora Xi Plasmapheresis System without training. Performing a procedure without proper knowledge of system components, controls, and instructions may increase the risk of harm to the operator or donor, or may cause damage to the instrument and may result in unsafe practices.
Caution:	The Aurora Xi Plasmapheresis System and data management system should be deployed within a secure network perimeter to prevent access from unauthorized external system(s).
Caution:	Do not touch the touchscreen with sharp objects, because sharp objects may cause damage to the instrument.
Caution:	Power OFF the instrument at the end of each day, in order to allow the system to self-test its safety systems.
Caution:	Failure to use the **STOP** button when powering OFF the instrument may cause the instrument to become non-functional.
Caution:	Do not operate the instrument unless the air filter and tray are installed.
Caution:	If the instrument has been moved or relocated, perform weigh scale checks before starting a plasmapheresis procedure to ensure scale accuracy.
Caution:	Position the front of the instrument away from direct sunlight to ensure proper function of the Hb detector.
Caution:	Both locking wheels should be locked when the instrument is stationary, in order to prevent unintended movement of the device, which may impact weigh scale readings.
Caution:	When placing the weight onto a weigh scale hanger, make sure the weight tabs are in proper orientation and align onto the hanger to prevent the weight from slipping through or falling off the hanger, potentially causing injury or damage.
Caution:	When unplugging the power cord from the mains supply outlet, grasp the power cord at the plug and not by pulling the power cord wire.

Context-Specific Cautions

Caution:	Verify that the expiration dates of all consumable materials (e.g., disposable set, saline solution, AC solution, plasma collection container, and apheresis needle) have not been exceeded.
Caution:	Do not use AC or saline solutions if they do not appear clear, are leaking, or contain particulate matter.
Caution:	AC and saline solutions should be used at room temperature or up to 37° C (98.6° F), and in compliance with the solution manufacturer's instructions.
Caution:	Only 16 gauge or 17 gauge thin-walled apheresis needles may be used.
Caution:	In order to ensure that safety systems perform as expected, the length of the apheresis needle set should be 6 inches (15 cm) to 12 inches (30.5 cm), inclusive.
Caution:	Do not use the disposable set if the protective caps are damaged, loose, or not intact or set integrity is compromised.
Caution:	Verify that the tubing is centered on the pump rollers. Push the pump lines as far back as possible in the pump. Slack in the line or forcing the pump handle to close over improperly positioned tubing may cause damage to the tubing.
Caution:	Ensure that the tubing keepers are loaded on the correct side of the tubing guides.
Caution:	Improper installation of tubing in the pumps may affect flow rate accuracy, impact efficiency of the procedure, cause leaks, or lead to hemolysis.
Caution:	An improperly loaded disposable set can cause kinks which can lead to hemolysis. Ensure there are no twists or kinks present in the disposable set that restrict the inner diameter of the tubing to smaller than the inner diameter of the needle.
Caution:	Do not let the separator lower support snap into place, as it may damage disposable set components and/or the instrument.
Caution:	Verify that the plasma collection container is properly installed and aligned to prevent inaccurate weight readings.
Caution:	Only use the longer plasma collection bag with the elongated container shroud to prevent inaccurate weight readings.
Caution:	After Install Check, do not disturb the reservoir, the cell line, or the reinfusion line to avoid reservoir scale alerts.

Context-Specific Cautions

Caution:	Ensure proper connection of solution containers so that there is no leakage at the connection site.
Caution:	While connecting solutions, do not interchange the AC and saline lines. Ensure the red AC connector is connected to the AC container.
Caution:	After spiking the AC solution container, ensure that there are no air pockets in the AC container around the ports.
Caution:	The donor venipuncture site must be positioned above the fluid in a connected AC container, in order to provide redundant means of protection against citrate infusion.
Caution:	The operator should monitor the venipuncture site for any adverse effects (e.g., hematoma formation).
Caution:	Secure the position of the fistula after venipuncture to reduce the likelihood of the needle being removed from the vein during the procedure.
Caution:	Do not exceed the configured sample volume when taking donor blood samples, as this may lead to excess blood loss.
Caution:	Do not attempt to clear the donor line, blood line or needle, or resolve a venipuncture problem by infusing saline to the donor.
Caution:	Ensure that the pressure cuff tubing is routed around the back of the instrument, not through the container shrouds, to avoid interference with the container weigh scales, which may lead to inaccurate weight readings.
Caution:	Do not take samples from the disposable set unless the disposable set includes a sampling pouch near the needle set. The remainder of the disposable set contains AC, which may dilute the sample.
Caution:	End the procedure without fluid return if set integrity is compromised. Do not manually reinfuse reservoir contents.
Caution:	To avoid inaccurate pressure sensor readings, end the procedure without fluid return if blood has touched or entered into the pressure sensor ports (P1 or P2).
Caution:	Do not push open any clamp at any time during the procedure, unless directed by troubleshooting instructions.
Caution:	If there is a leak from the plasma collection container, end the procedure with optional fluid return. Estimate and record the collection volume according to your center SOPs in order to ensure proper reporting of plasma loss.

Context-Specific Cautions

Caution:	Failure to monitor the AC container and end the procedure if air enters the AC line after a 3004 alert may lead to air infusion or blood clots.
Caution:	Plasma samples for testing are to be taken from the mixed collection container, not the plasma line, to prevent false negative infectious disease test results.
Caution:	If any solution containers have been exposed to blood, treat the containers as potentially biohazardous.
Caution:	Clean and disinfect blood spills immediately. Treat all spills and potentially contaminated surfaces as potential biohazards.
Caution:	If configured for use with a data management system and the procedure record is not transmitted to the data management system, the operator shall record appropriate procedural information (according to the center's SOPs) from the **Procedure Results** screen manually.
Caution:	Ensure the needle set to disposable set connection is tight to prevent air infusion and leaks.
Caution:	Repeatedly clearing a persistent alert/alarm by touching the **Check** button, without resolving the underlying condition, may lead to inaccuracies in the blood and AC monitoring safety systems.
Caution:	Do not replace a depleted AC container because it will impact the system's ability to manage the citrate infusion rate.
Caution:	Be sure to not kink the P1 or P2 lines when recovering from blood detection alerts.
Caution:	End the procedure without fluid return if there is unexpected noise from the separator.
Caution:	Before performing optional manual reinfusion of reservoir contents, inspect the donor line and reinfusion line between the reservoir and apheresis needle for air bubbles. If air is present, do not begin the manual reinfusion.
Caution:	While performing optional manual reinfusion of reservoir contents, the system will not be able to detect any air present in the line. Therefore, the donor line must be continuously monitored by the operator for air bubbles during the manual reinfusion process. If air is observed, immediately clamp the line and end manual reinfusion.
Caution:	Although the system is automated, plasmapheresis procedures must be monitored.

Context-Specific Cautions

Caution:	If damage to the tubing is observed, end the procedure without returning fluids or reservoir contents.
Caution:	If there is blood on the saline line or container side of the saline clamp, end the procedure with optional fluid return.
Caution:	Procedure results may be inaccurate if the power switch is turned OFF during a procedure. RBC loss must be estimated manually in order to ensure proper reporting.
Caution:	If blood has moved to the AC container side of the AC pump, end the procedure without fluid return.
Caution:	If a 3302 alert/alarm occurs, do not return fluids or reservoir contents.
Caution:	If two 3025 alerts occur in a saline procedure, the plasma product should be discarded due to possible dilution with saline.
Caution:	When performing offline saline administration, follow the saline administration set manufacturer's directions for use to avoid air infusion.
Caution:	Perform venipuncture according to the center's SOPs.
Caution:	After changing a needle set, prime the needle set and clear air from the donor line to prevent infusion of air to the donor.
Caution:	If red blood cells become visible in the plasma line or collection container, end the procedure with optional fluid return.
Caution:	The instrument must be used and stored in the proper operating environment (e.g., temperature, humidity, altitude, and surface incline requirements).
Caution:	Do not perform maintenance tasks while a procedure is in progress, to prevent unsafe practices.
Caution:	Only local service representatives or authorized service personnel should open or close the rear door of the instrument.
Caution:	Power OFF the instrument before replacing the air filter and tray, disassembling pump assembly components, or replacing the power cord.
Caution:	Allow cleaning and disinfecting agents to dry before installing the disposable set.

Context-Specific Cautions

Caution: Do not use solvents or abrasive cleaners (e.g., alcohol or 10% bleach solution) on the instrument or disposable set.

Caution: Allow the air filter and tray to dry completely after cleaning and before re-installing the filter onto the instrument.

Caution: Clean the separator motor cup thoroughly after a spill. When cleaning, be careful not to misalign the motor cup, because a misalignment in the motor cup will result in a malfunction. Do not insert a tightly wadded cloth or a sharp instrument into the cup. Clean the inside of the motor cup with a mild soap and damp towel. If blood remains after cleaning, do not use the instrument. The interface between the separator and the motor cup may not function properly.

Caution: Never attempt to clean foreign debris from the orifices of the pressure sensor ports (P1 and P2) with invasive probing of the ports, because this may damage the pressure sensors.

Caution: Clean the pressure transducers properly after a spill. If blood remains in the pressure transducers after cleaning, do not use the instrument. The pressure transducers may not function properly.

Caution: Do not remove or adjust the flags of the optical blood detectors; any adjustment could interfere with cover reassembly and proper functioning of the optical detectors.

Caution: Disinfect and clean the pumps properly after a spill. If blood remains in the pumps after cleaning, do not use the instrument. The pumps may not function properly.

Caution: When maintaining the instrument, use only replacement components, cables and accessories authorized by the instrument manufacturer and be sure to replace all shields, covers, screws, and gaskets in their exact locations as described in the Aurora Xi Service Manual. Failure to do so may result in increased emissions or decreased electromagnetic immunity of the instrument.

Caution: The backup battery should be properly handled and disposed to prevent exposure to harmful chemicals.

Caution: The Aurora Xi System is not intended for use as portable equipment.

Caution: Instrument performance may be affected by external electromagnetic fields generated by non-EMC compliant medical equipment and other electromagnetic sources (such as small hand-held radio transceivers).

Context-Specific Cautions

Caution: Exposure to Radio Frequency Radiation. The equipment contains a transmitter; see the instrument label near the antenna for the FCC ID. The antenna(s) used for this transmitter must be installed to provide a separation distance of at least 20 cm (0 feet 7.87 inches) from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter. End users must follow the instructions from this document for transmitter operating conditions to satisfy Radio Frequency exposure compliance.

Caution: Ensure that the disposable set is stored appropriately to mitigate kinks or deformation of the set during storage.

Section 1.10: Intended User

Specially trained healthcare professionals are required to operate the Aurora Xi Plasmapheresis System for blood component collection procedures.

Chapter 2
System Overview

This chapter provides an overview of Aurora Xi and describes how to use the touchscreen.

Section 2.1: General Description

The Aurora Xi Plasmapheresis System is an automated system that uses a disposable set to collect plasma to be processed as Source Plasma. Aurora Xi uses a rapidly rotating separator (membrane filter) to separate whole blood into plasma for collection and concentrated cells for reinfusion to the donor.

The donor is connected to the device throughout the procedure. A single venipuncture site and single apheresis needle are used to perform sequential cycles of alternating Collection and Reinfusion Phases.

- During the Collection Phase, blood is drawn from the donor and is separated into plasma and concentrated cells. The plasma is collected and the concentrated cells are pumped into a reservoir.
- During the Reinfusion Phase, the concentrated cells from the reservoir are reinfused to the donor using the same venipuncture site and apheresis needle as the Collection Phase.

The operator uses the touchscreen to control the procedure, gather status information, and handle error conditions. Device safety systems and alert/alarm functions help ensure donor and operator safety.

NOTE

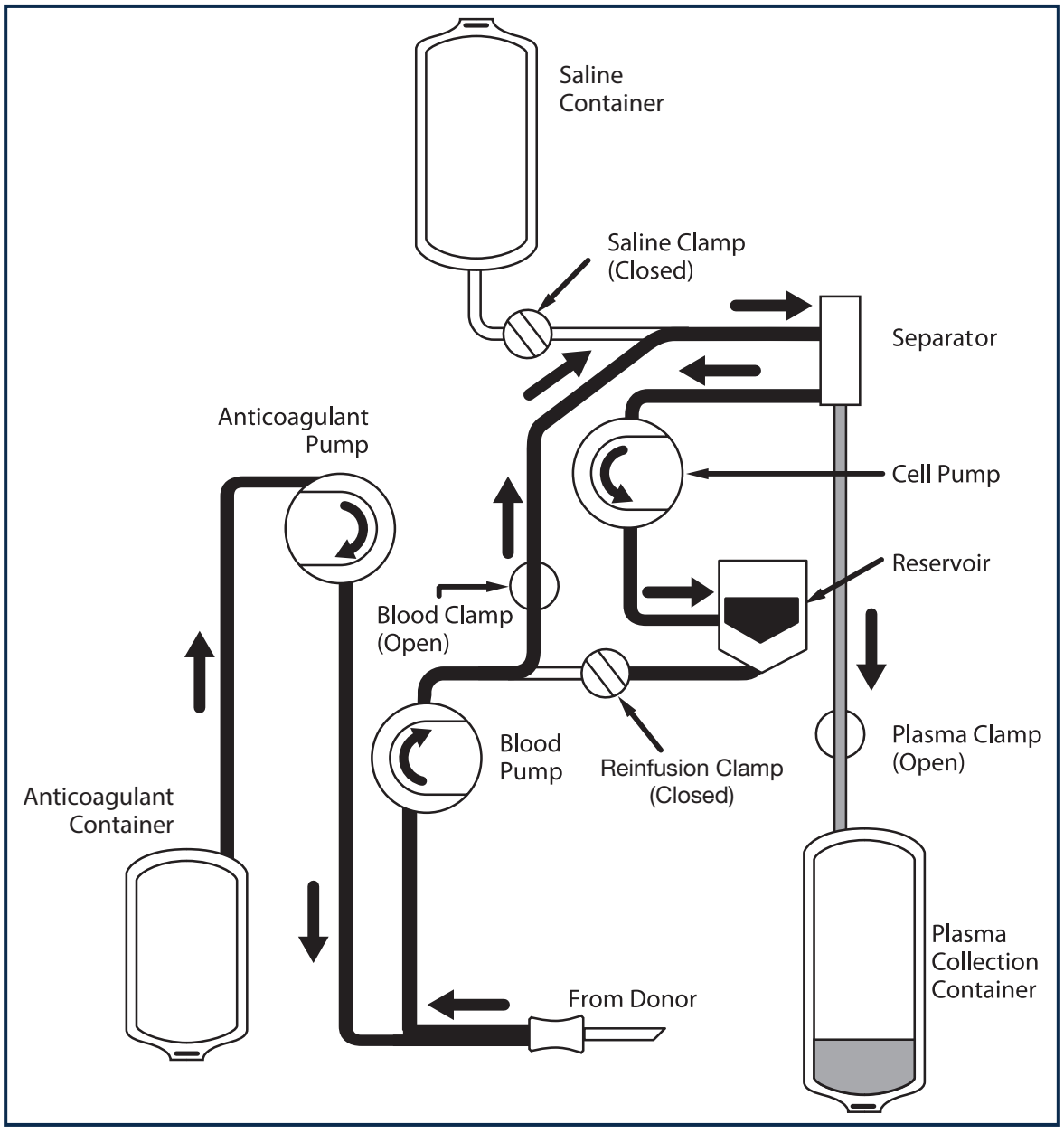
➞ The alert/alarm terminology also covers any advisories that occur.

Collection Phase

When the Collection Phase begins, AC solution pumps at a controlled rate and mixes with whole blood as it enters the disposable set from the donor's vein. The anticoagulated blood is pumped to the separator, where plasma separates from the cellular components and flows into an appropriate plasma collection container. The cellular components are pumped from the separator to a reservoir.

The Collection Phase stops when the reservoir reaches an expected volume of concentrated cells or if the target collection volume is achieved. The reservoir fill volume varies by center configuration and donor parameters. The Reinfusion Phase begins when the reservoir volume is full.

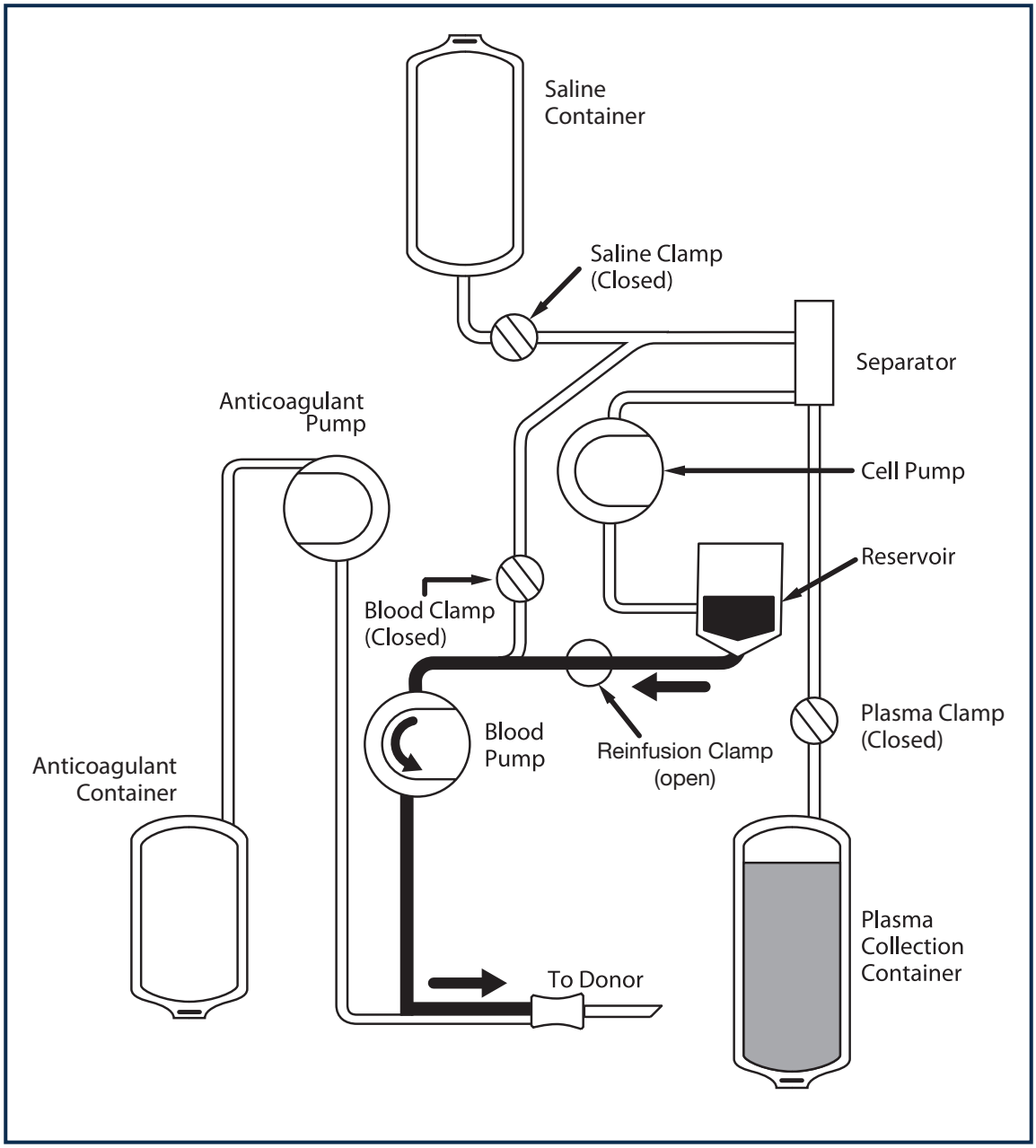
Figure 1: Collection Phase



Reinfusion Phase

During the Reinfusion Phase, the blood pump reverses, returning the concentrated cells in the reservoir to the donor using the same apheresis needle as the Collection Phase. If a Saline Protocol was selected, saline infusion follows the Final Reinfusion Phase.

Figure 2: Reinfusion Phase



Section 2.2: Safety Systems

The Aurora Xi automated operating protocol requires minimal operator involvement after venipuncture. Visual and audible signals notify the operator if attention is required.

NOTE

- Aurora Xi is for use in a plasma center.
- The device is intended to be operated from the front.

Install Check

The Install Check sequence identifies disposable set problems and set installation errors. This sequence verifies that:

- There are no leaks or other problems with the disposable set that would jeopardize donor safety or procedure completion;
- The disposable set is correctly installed; and
- System pumps, clamps, and pressure sensors are functional.

NOTE

- Not all areas of the disposable set are checked during the Install Check. See "Performing Install Check and Priming Solutions" on page 2-4 for a list of areas the system does not check.

Donor Safety

The device is designed to minimize conditions that affect donor safety. If a safety-related condition is detected during a procedure, the device safely pauses the procedure, stops all pumps, and alerts the operator if attention is required. Some donor safety features are:

- **Air Detector Assembly:** The air detector assembly prevents harmful air infusion to the donor. The system continuously monitors the air detector assembly during a procedure. Before donor connection, the system tests the air detector assembly's ability to sense fluid or air in the lines. If either test fails, the procedure cannot be started. The air detector senses air bubbles ≥ 50 µL. If air is detected while fluids are being reinfused to the donor, the procedure will not resume until air is manually or automatically purged from the donor line.
- **Hemoglobin (Hb) Detector:** An optical sensor continuously monitors the plasma line for changes in color. If a significant color change occurs, the system stops the procedure and notifies the operator with an alert. Operator intervention is required to continue the procedure.
- **Pumps:** The system continuously monitors and controls the AC pump, blood pump, and cell pump throughout device operation. In the event of a pump failure, the system stops the procedure and attempts to recover on its own or notifies the operator if the system cannot recover on its own.

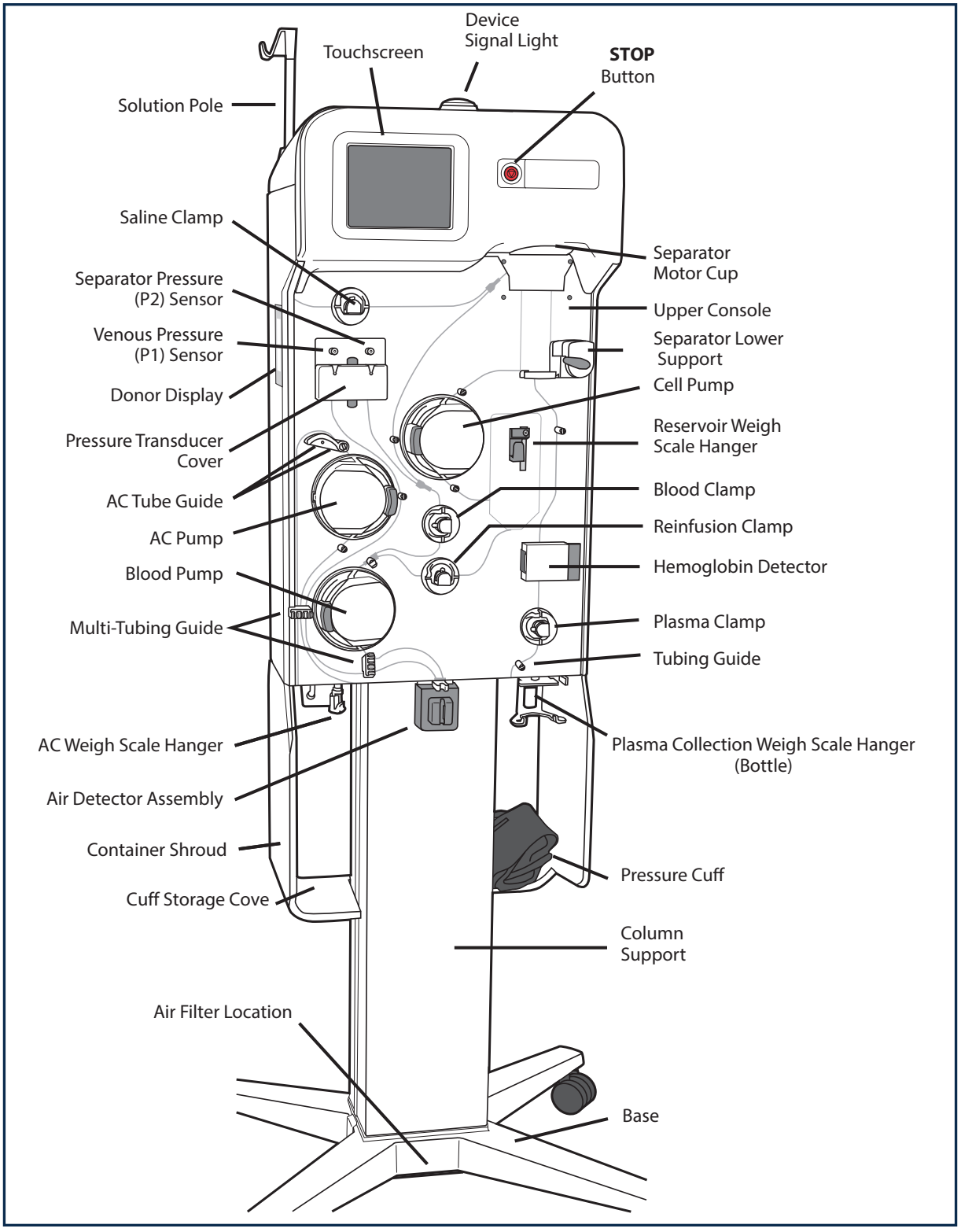
- **Disposable Set Solution Connections:** The SPIKESMART System is designed to reduce the chances of interchanging connections of the saline container and AC container. Aurora Xi consists of a Plasmacell Xi Disposable Set with a spike connector on the saline line to be used with a saline container with a suspension slot.
- **Separator Control System:** This system helps ensure proper plasma flow, in turn reducing the likelihood of hemolysis. The separator pressure (P2) sensor continuously monitors pressure within the separator. The control system helps ensure proper plasma flow, in turn reducing the risk of hemolysis.
- **Intelligent Flow Control (IFC):** This feature monitors and automatically responds to donor blood flow issues that can occur during the procedure. Flow rate and cuff pressure are automatically adjusted to attain maximum flow rates. Flow is stopped when occlusions are detected. The system can automatically recover from occlusions but notifies the operator if it is unable to do so.
- **AC Weigh Scale:** This scale monitors the volume of fluid throughout the procedure to ensure proper supply of AC. The citrate infusion rate is subsequently controlled by the system during the Reinfusion Phase.
- **Plasma Weigh Scale:** This scale monitors the plasma collection volume throughout the procedure. When the target collection volume is detected, the system transitions to the Final Reinfusion Phase.
- **Reservoir Weigh Scale:** This scale monitors the concentrated cells volume, specifically extracorporeal red cell volume, in the reservoir throughout the procedure. The Reinfusion Phase begins when the reservoir contents reach the configured volume or the target collection volume is achieved, whichever occurs first.

Operator Safety

- **Electromagnetic Compatibility (EMC):** Aurora Xi devices are in compliance with the applicable standards on electromagnetic compatibility (IEC 60601-1-2). See **"Section 7.7: Electromagnetic Compatibility"** for additional information.
- **Protection from Electrical Hazards:** The system is designed to minimize the potential for electrical shock. All line voltage electronics are enclosed in the column. The column is attached to the console and provides only low DC voltage to the device.
- **Protection from Rotational Hazards:** The rotational components of the three pumps and the separator are isolated to prevent hazard to the operator.
- **Protection from Potentially Infectious Agents:** The disposable set requires two connections in the blood processing pathway during set up and no open connections or disconnections during normal operation or cleanup. This minimizes operator exposure to potentially infectious blood-borne agents.

Section 2.3: Device Components

Figure 3: Typical Device – Front View



The following information describes the major device components.

Device Signal Light

A signal light located at the top of the device is a status indicator for the operator. For detailed information about the indicator signal, see **"System Status" on page 5-4**.

Touchscreen

The touchscreen is a graphical user interface by which the operator interacts with the device, controls the procedure, gathers status information, and handles error conditions. For detailed information, see the **"Section 2.5: Touchscreen Overview"**.

STOP Button

Before a Procedure

Pressing the **STOP** button before a procedure allows the operator the option to power OFF the device. For detailed information on how to power OFF the device, see **"Section 3.3: Powering OFF the Device"**.

During a Procedure

Pressing the **STOP** button during a procedure stops the procedure. If fluids are introduced to the disposable set without sealing it, the system stops all pumps and closes all clamps to isolate the donor from the device. Pressing the **STOP** button allows you to end the procedure, resume the procedure, and/or shut down the device, depending on the current status of the procedure. For detailed information, see **"Section 4.10: Using the STOP Button"**.

Pumps

Three peristaltic pumps are located on the front panel. The individual functions are described below.

- **AC Pump:** Delivers the AC solution at a controlled rate into the blood line as whole blood enters the set from the donor during the Collection Phase. This pump does not operate during the Reinfusion Phase.
- **Blood Pump:** Primes the disposable set and clears air from the donor line. Collects whole blood from the donor and delivers anticoagulated blood to the separator during the Collection Phase (see **Figure 1 — Collection Phase**). The blood pump reverses and pumps concentrated cellular components from the reservoir back to the donor through the same venipuncture site during the Reinfusion Phase (see **Figure 2 — Reinfusion Phase**). If a Saline Protocol is used, the blood pump also delivers saline to the donor during the Final Reinfusion Phase.
- **Cell Pump:** Delivers concentrated cellular components from the separator to the reservoir during the Collection Phase. It also primes the disposable set. This pump does not operate during the Reinfusion Phase except to clear blood from the separator during the Final Reinfusion Phase.

Clamps

There are four clamps on the front panel. The disposable set is installed on these clamps. The clamps open and close automatically during system operation. See **Figure 1 — Collection Phase** and **Figure 2 — Reinfusion Phase**.

- **Reinfusion Clamp:** Closes to block the reinfusion line during the Collection Phase. This clamp opens during the Reinfusion Phase, allowing the blood pump to reinfuse concentrated cellular components from the reservoir to the donor.
- **Blood Clamp:** Opens during the Collection Phase to allow anticoagulated whole blood to be pumped to the separator. The clamp closes to block the blood line during the Reinfusion Phase.
- **Saline Clamp:** Closes to block the saline line during the Collection and Reinfusion Phases. For a Saline Protocol, the clamp opens automatically to allow saline to flow during solutions priming at the beginning of the procedure, to flush concentrated cells from the disposable set back to the donor, and for saline infusion.
- **Plasma Clamp:** Opens during the Collection Phase to allow plasma to flow into the plasma collection container. This clamp closes at various points in the procedure, including the Reinfusion Phase.

Hb Detector Assembly

The Hb detector assembly consists of a hemoglobin detector and a door. The Hb detector uses an optical sensor which continuously monitors the plasma line for color changes. If a significant color change occurs, the system stops and notifies the operator with an alert. Operator intervention is required to continue the procedure.

NOTE

→ The Hb detector can be falsely triggered by lipids or air bubbles in the plasma line.

Pressure Transducer Assembly

The pressure transducer assembly consists of a venous pressure (P1) sensor, separator pressure (P2) sensor, optical blood detectors, and the pressure transducer cover.

- **Venous Pressure (P1) Sensor:** Monitors the pressure at the donor's vein in order to maximize flow to and from the donor.
- **Separator Pressure (P2) Sensor:** Monitors the separator pressure to maximize plasma collection efficiency.
- **Optical Blood Detectors:** Monitors the blood level in the tubing and stops the procedure if blood rises to this level in the tubing. This prevents liquid from entering the P1 and P2 sensor ports. The sensors also allow the system to detect the presence of tubing during disposable set installation and throughout the procedure. These optical sensors are located behind the pressure transducer cover.

Air Detector Assembly

The air detector assembly senses fluid or air in the donor line. If unexpected air is detected while the donor is connected, the procedure stops. If air is detected while fluids are being reinfused to the donor, the procedure will not resume until air is manually or automatically purged from the donor line.

Pressure Cuff

The pressure cuff inflates automatically during the Collection Phase and deflates during the Reinfusion Phase. The operator can inflate and deflate the cuff for vein examination, venipuncture site preparation, and donor comfort by using the touchscreen.

Weigh Scales

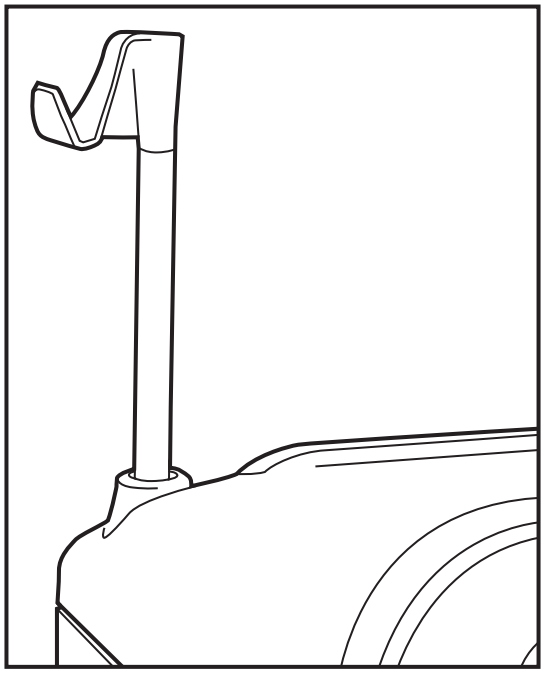
Three weigh scales monitor the current collection volume, AC solution volume, and concentrated cellular content volume in the reservoir.

- **Plasma Collection Weigh Scale:** Monitors the collection volume throughout the procedure. When the target collection volume is detected, the system starts the Final Reinfusion Phase. The device is supplied with a bottle hanger. An optional bag hanger is available.
- **AC Weigh Scale:** Monitors the volume of fluid in the AC container throughout the procedure to ensure proper supply of AC. The citrate infusion rate is subsequently controlled by the system during the Reinfusion Phase.
- **Reservoir Weigh Scale:** Monitors the volume of concentrated cells, specifically extracorporeal red cell volume, in the reservoir throughout the procedure. The Reinfusion Phase begins when the reservoir contents reach the configured volume or the target collection volume is achieved, whichever occurs first.

Solution Pole

The solution pole is used to suspend a saline container. It is not rated to support more than a 1000 mL container. The solution pole has a slot-shaped hook for use with SPIKESMART Disposable Sets and compatible saline containers.

Figure 4: Typical SPIKESMART Solution Pole



Container Shrouds

During a procedure, the container shrouds safeguard the plasma collection container and the AC container from any disturbances. Correctly hung containers should avoid touching the shroud.

Cuff Storage Cove

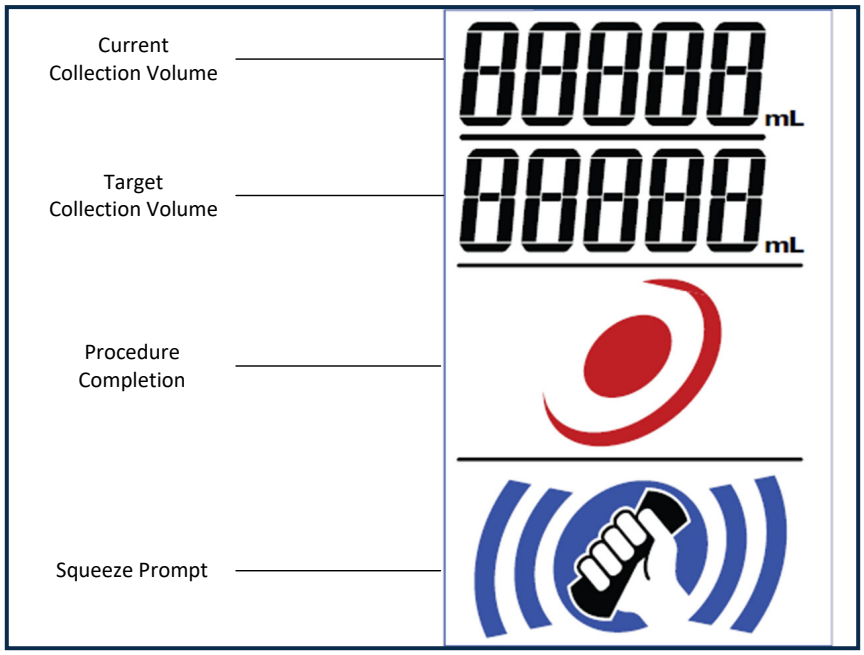
The cuff storage cove provides convenient storage for the pressure cuff.

Donor Display

There are two donor displays, one on each side of the device.

The donor display informs the donor of progress toward the target collection volume, and prompts the donor when to squeeze (i.e., during the Collection Phase) or stop squeezing (i.e., during the Reinfusion Phase).

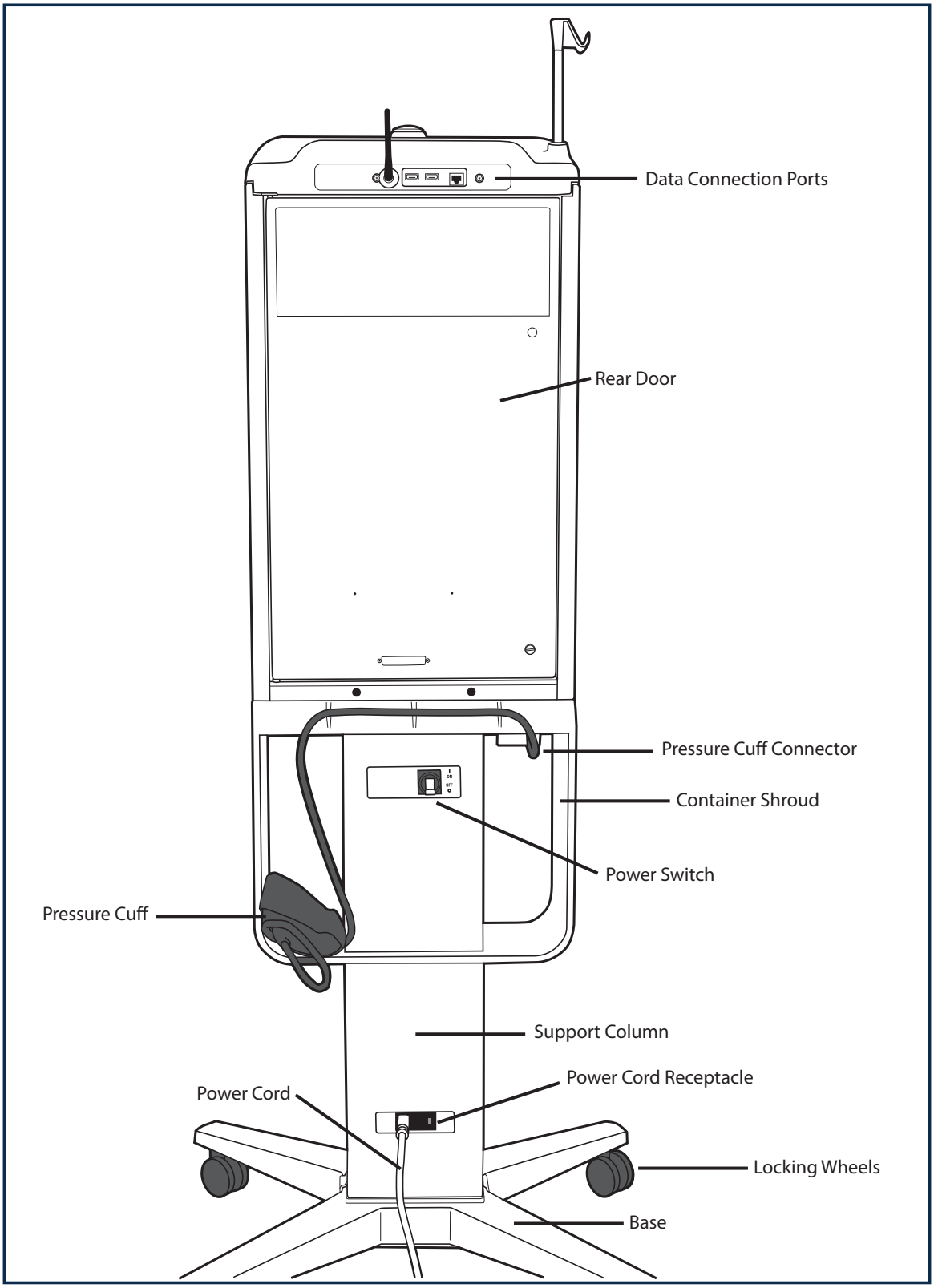
Figure 5: Typical Donor Display



The following table describes the donor display elements:

Display	Function
Current Collection Volume	Displays the current collection volume (including anticoagulant) in mL.
Target Collection Volume	Displays the target collection volume in mL.
Procedure Completion	Displays icon when the procedure is complete.
Squeeze Prompt	Donor should:  Squeeze (adequate venous pressure)  Increase squeeze (low venous pressure)  Increase squeezing (very low venous pressure) If the donor display does not display one of these prompts, the donor should stop squeezing.

Figure 6: Typical Device – Rear View



Data Connection Ports

The data connection ports are located on the upper-back of the device. Only connect approved communication devices to Aurora Xi.

CAUTION

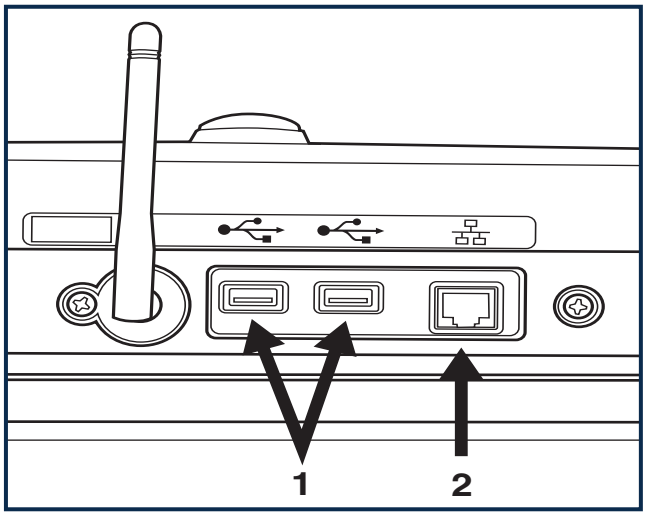
- When maintaining the device, use only replacement components, cables, and accessories authorized by the device manufacturer and be sure to replace all shields, covers, screws, and gaskets in their exact locations as described in the Aurora Xi Service Manual. Failure to do so may result in increased emissions or decreased electromagnetic immunity of the instrument.
- Equipment connections to the instrument's communication ports must comply with all appropriate UL/CSA/IEC standards for the equipment type in order to avoid interference issues between the system and other devices.

The data connection ports include:

USB ports (1) - These two ports should only be used to connect the barcode scanner and flash drives approved by the device manufacturer.

Ethernet port (2) - This port should only be used by device manufacturer-approved wired connections. ww

Figure 7: Device – Data Connection Ports



Rear Door

Only authorized service personnel or a local service representative is permitted to open the rear door.

Pressure Cuff

The pressure cuff inflates automatically during the Collection Phase and deflates during the Reinfusion Phase. The operator can also inflate and deflate the cuff for vein examination, venipuncture site preparation, and donor comfort by using the touchscreen.

Column and Base

The column and base supports the device upper console. All line voltage electronics are enclosed inside the column. The column also contains a backup battery to maintain computer memory and display in the event of a power loss. An air filter covers the vent at the bottom of the column.

Locking Wheels

There are two non-locking wheels and two locking wheels on the base. Engage both wheel locks while the device is stationary.

Power Switch and Power Cord Receptacle

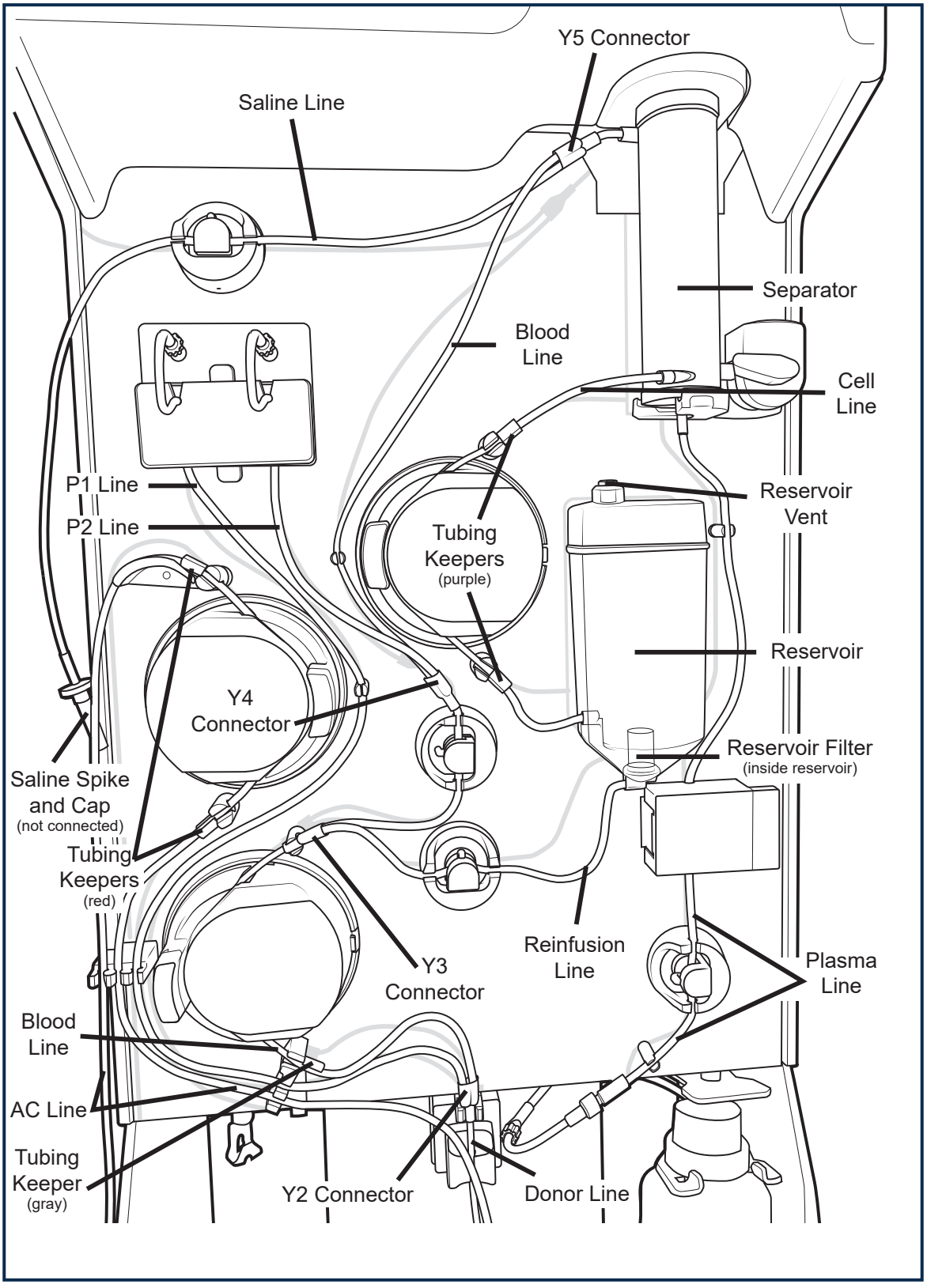
The power switch and power cord receptacle are on the back of the column.

- Ensure that the power switch is OFF before unplugging the power cord. Failure to do so will cause the backup battery to discharge.
- An audible tone will not sound in the event of a power loss alert.

Section 2.4: Disposable Set Components

The typical disposable set consists of a separator, reservoir, and tubing to transport blood and solutions within a sterile fluid pathway. Each component is integrally connected.

Figure 8: Typical Disposable Set Installation

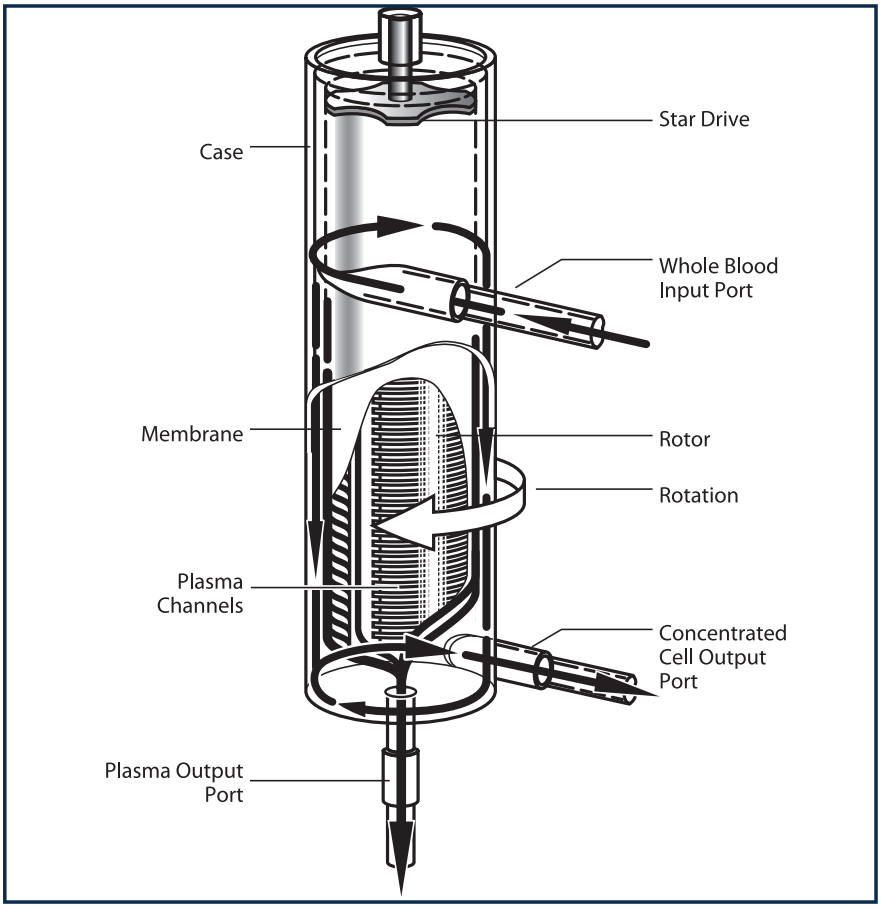


Separator

The separator has a membrane filter that splits blood into components. Anticoagulated whole blood enters the whole blood input port and plasma is separated by the spinning membrane filter.

The plasma then moves from the plasma output port, through the plasma line, and into the plasma collection container. Concentrated cells are pumped from the concentrated cell output port and into the reservoir.

Figure 9: Separator



Reservoir

Concentrated cells from the separator are collected and kept in the reservoir until reinfusion to the donor. The processing volume of the reservoir is based on administrative settings and donor parameters.

- **Reservoir Vent Filter:** Equalizes pressure in the reservoir during collection and reinfusion.
- **Reservoir Filter:** Filters reservoir contents before reinfusion.

Disposable Set Tubing

The disposable set also includes several tubing lines for transporting anticoagulated whole blood, concentrated cells, plasma, saline, or anticoagulant within the device during the Collection/Reinfusion Phases. The individual lines in a set are as follows:

- **AC Line:** Transports AC solution through the AC pump to the Y1-connector.
- **Blood Line:** Transports anticoagulated whole blood from the Y2-connector through the Y3- and Y4-connectors to the Y5-connector at the separator. Reservoir contents also pass through part of this tubing from the reservoir and go back to the donor (i.e., from the Y3-connector to the Y2-connector).
- **Cell Line:** Transports concentrated cells from the separator to the reservoir by using the cell pump.
- **Donor Line:** Transports anticoagulated whole blood from the Y1-connector to the Y2-connector. Reservoir contents also pass through this tubing section from the reservoir and go back to the donor.
- **Plasma Line:** Transports plasma from the separator to the plasma collection container.
- **Reinfusion Line:** Transports reservoir contents from the reservoir to the blood line.
- **Saline Line:** Transports saline from the saline container to the Y5-connector. The line does not transport fluids for a No Saline Protocol, although it may contain blood on the right side of the saline clamp while performing a No Saline Protocol.
- **P1 and P2 Lines:** Connect the disposable set to the two pressure sensors.

CAUTION

→ Ensure that the disposable set is stored appropriately to avoid kinks or deformation of the set during storage.

Section 2.5: Touchscreen Overview

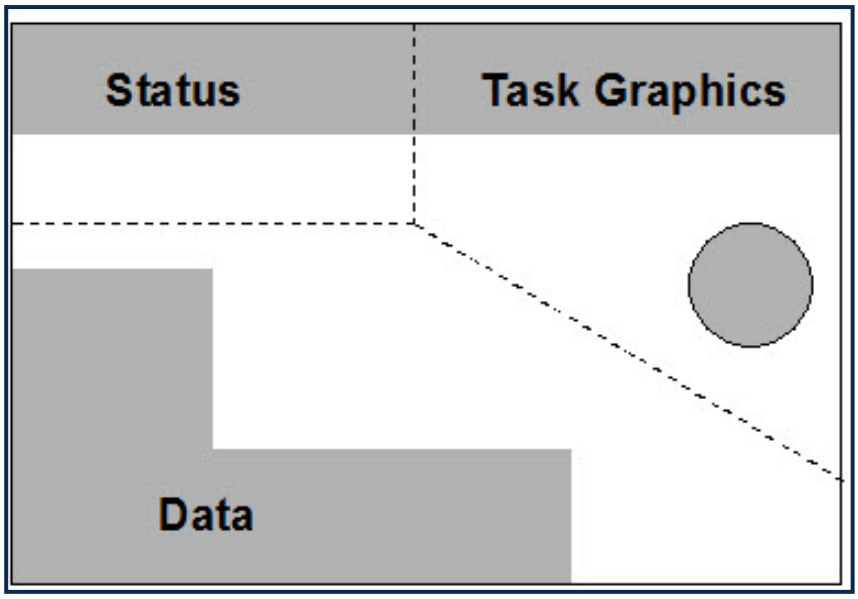
The Aurora Xi touchscreen prompts the operator to perform actions and displays information. This section describes the touchscreen format and typical elements that appear on screens and overlays.

Touchscreen Format

The touchscreen format has three zones. The function of each zone is described below.

- **Status Zone:** displays the Information button and the time, date, and operator identification information throughout the procedure.
- **Task Graphics Zone:** displays animated status graphics and operator prompts like "Install the disposable set," "Attach pressure cuff," or "Perform venipuncture." This zone also displays task confirmation buttons and other elements for making adjustments during a procedure.
- **Data Zone:** displays information about the procedure and has interactive elements for entering, viewing, and modifying data about the donor or the donation. This zone can also be used to adjust flow rate settings.

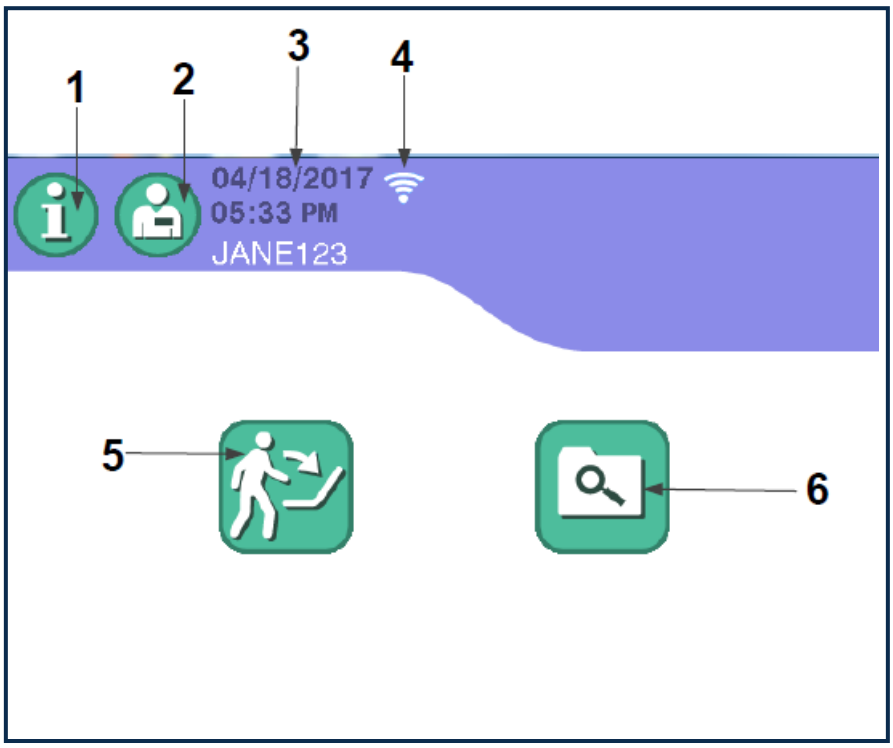
Figure 10: Touchscreen Zones



Home Screen Elements

Once all weigh scale checks are successfully completed, the **Home** screen displays. The **Home** screen is also displayed on wrap-around from a previous procedure. This section identifies and describes typical elements on the **Home** screen.

Figure 11: Typical Home Screen Elements



1. **Information Button:** Provides access to either the Procedure Information page or Instrument Settings page. For detailed information about the Procedure Information page, see **"Procedure Information" on page 4-78**. For detailed information about the Instrument Settings page, see **"Section 4.14: Instrument Settings"**.

2. **Operator ID Button:** For entering the operator ID information. For detailed information on how to enter the operator ID, see **"Section 4.11: Changing or Reentering the Operator ID During the Procedure"**.

3. **Date, Time, and Operator ID:** Displays the date, time, and operator ID. Date/time format and operator ID availability are set by the administrative settings. If needed, date and time can be changed by the operator. For detailed information on how to change the date and time, see **"Date/Time" on page 4-92**.

4. **Network Status Indicator:** Displays the device network connection status with the data management system. If the device is connected to a data management system, the **Network Connected** icon is displayed. If the device is not connected to a data management system (status is disconnected or limited), the **Network Not Connected** icon is displayed. See the **"Glossary of Graphics"** for **Network Connected** and **Network Not Connected** icons.

5. **New Procedure Button:** For starting a new procedure. For detailed information about how to start a new procedure, see **"Section 4.2: Starting a Procedure"**.

6. **Procedure View Button:** Provides additional procedure information.

Data Entry Screen Elements

This section identifies and describes typical elements that appear on the **Data Entry** screens, such as tabs, pages, buttons, and overlays. For detailed information about alert/alarm screen elements, see **"Section 5.1: Alert/Alarm Overview"**.

CAUTION

- Do not touch the touchscreen with sharp objects, because sharp objects may cause damage to the instrument.

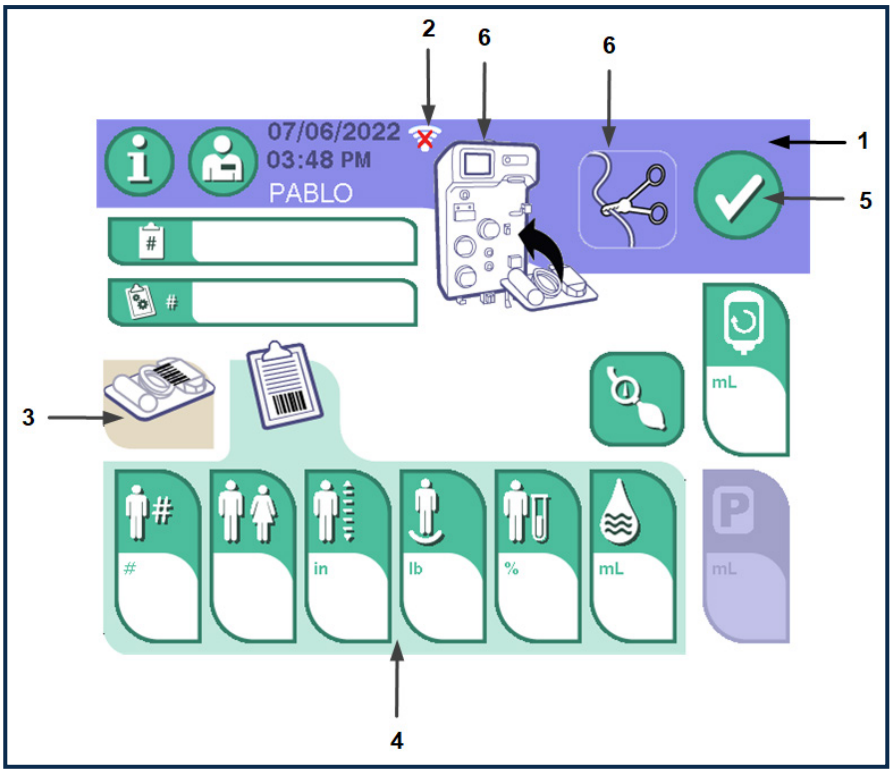
NOTE

- Touchscreen entries must conform to the device's administrative settings. Audible and visual indicators notify the operator of an unacceptable entry.
- The **Data Entry** screen for donor data uses the same type of screen elements defined in this section.

The **Main Data Entry** screen is displayed when the **New Procedure** button is tapped. For detailed information on screen elements, reference the elements described in this section
.

1. **Screen Header:** The color of the screen header indicates the status of the system. Lavender indicates a normal condition for pre-collection and post-collection. Blue is normal condition for collection. Yellow is a pause condition. Orange is a low to medium priority alert/alarm condition. Red indicates a high priority alert/alarm condition. For detailed information about the Alert/Alarm Screens, see **"Section 5.1: Alert/Alarm Overview"**.

Figure 12: Typical Data Entry Screen Elements



2. **Network Status Indicator:** Displays the device network connection status with a data management system. If the device is connected to a data management system, the **Network Connected** icon is displayed. If the device is not connected to a data management system (status is **Disconnected** or **Limited**), the **Network Not Connected** icon is displayed. See the Glossary of Graphics for **Network Connected** and **Network Not Connected** icons.

3. **Tabs:** Provide access to additional information and any controls related to that screen. Tapping a tab opens a page. A page remains open until the screen is closed or a different tab is selected.

4. **Data Entry Buttons:** Provides various buttons to access operator inputs, navigate sets of data, and confirm selections. When tapped, an overlay opens which requires operator input.

The button color indicates the current status of a button. The system displays three button colors: green, blue, and gray. The button turns dark green when it is being tapped. The color status and examples are listed below. For a complete list of buttons, see the **"Glossary of Graphics"**.

- Green: Enabled status

- Blue: Selected status

- Gray: Disabled status

NOTE

→ Buttons may be disabled due to administrative settings, procedure settings, and/or device status.

5. **Check Button:** Saves entries and closes the displayed screen or overlay. For detailed information, see **"Common Elements" on page 2-22**.

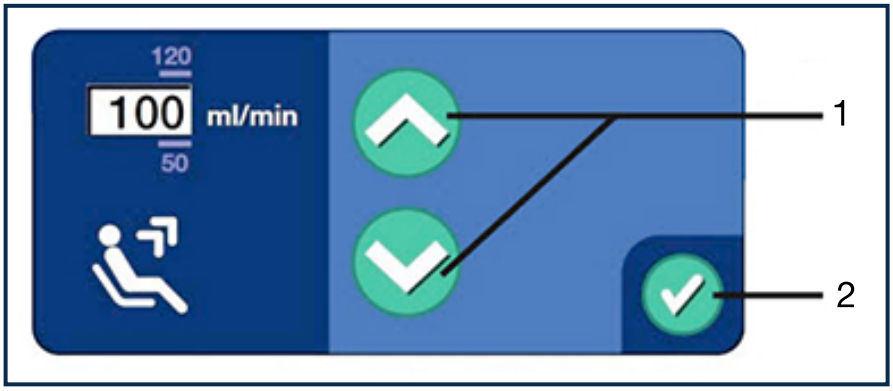
6. **Prompts:** Display when an operator is required to enter information or perform certain actions. They also display operational status and general information about a procedure. For a complete list of prompts, see the **"Glossary of Graphics"**.

Common Elements

Many screens and overlays contain common elements such as the **Up** and **Down** buttons and the **Check** button.

1. **Up** or **Down** Button: Increases or decreases the displayed value.
2. **Check** Button: Saves operator inputs and closes the screen or overlay.

Figure 13: Common Elements



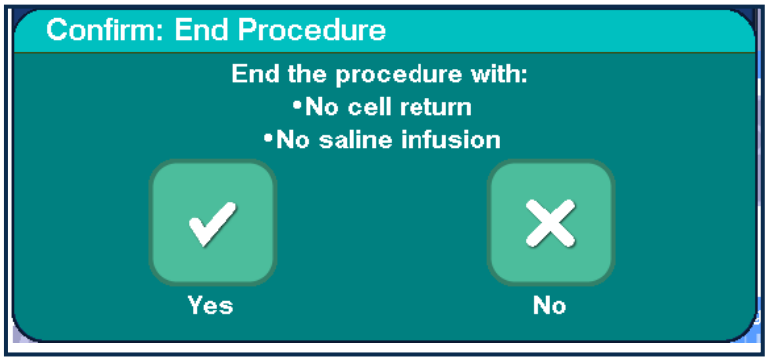
Overlays

This section describes typical elements that appear on overlays. Overlays open after tapping a button that requires a confirmation, decision, or any information entered through a keypad.

Confirmation Overlay

The confirmation overlay asks the operator to verify an action. Select the intended action from the overlay.

Figure 14: Typical Confirmation Overlay



Data Entry Overlay

Data Entry overlays allow the operator to view, enter, or change information. Tap the appropriate buttons to enter or change information. If applicable, a keypad overlay opens. For detailed information about the **Data Entry** overlay, see **"Entering Disposables Data" on page 4-5**.

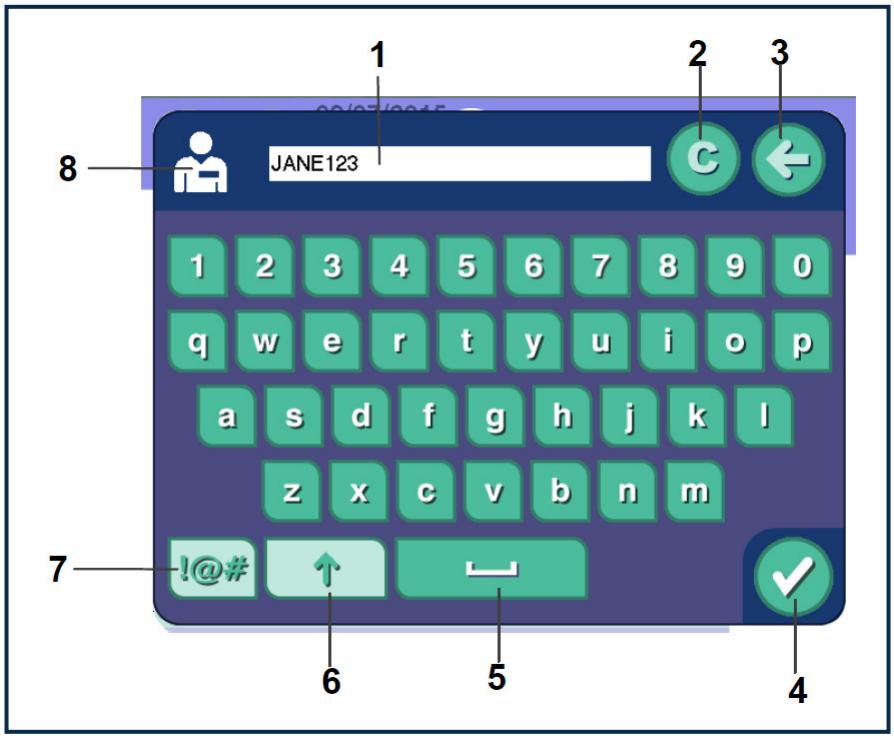
Keypad Overlays

The Aurora Xi device has several kinds of keypad overlays operators use to enter information. All keypad overlays function similarly even though their appearance and content differs. Some keypads have an option to select from preset values. Preset values are determined by administrative settings. Tap and hold a letter button to access more options, such as letters with accent marks.

Alphanumeric Keypad

1. **Data Entry Field:** Displays the keypad entry.
2. **Clear Button:** Deletes the entry from the **Data Entry** field.
3. **Backspace Button:** Deletes the last character from the **Data Entry** field.
4. **Check Button:** Saves the entry and closes the overlay.
5. **Space Button**: Inserts a space.
6. **Shift Button:** Toggles between uppercase and lowercase characters. The **Shift** button is uppercase when blue and lowercase when green.

Figure 15: Alphanumeric Keypad Overlay Elements



7. **Special Character Button:** Toggles between special characters and the alphanumeric keypad. When the alphanumeric keypad is displayed, the button shows **!@#**. When the special characters keypad is displayed, the button shows **ABC**. The button is always green.
8. **Icon (Varies):** Identifies the type of information to be entered (the Operator ID icon is illustrated in **Figure 15 — Alphanumeric Keypad Overlay Elements**). For a complete list of displayed icons, see the **"Glossary of Graphics"**.

Numeric and Preset Keypad Overlays

Some keypad overlays have an option to select from several preset values. Preset values are configured and available using the administrative settings.

1. **Preset View Button:** Opens the preset keypad overlay that contains any available preset values. The presets are configured in the administrative settings.
2. **Clear Button:** Deletes any entry in **Data Entry** fields.
3. **Check Button:** Saves the entry and closes the overlay.
4. **Icon (Varies):** Identifies the type of information to be entered (the **Collection Volume** icon is shown).
5. **Associated Data:** Displays data such as donor weight range.
6. **Minimum Indicator:** Displays the minimum allowable value for the **Data Entry** field.

Figure 16: Typical Numeric Keypad Overlay

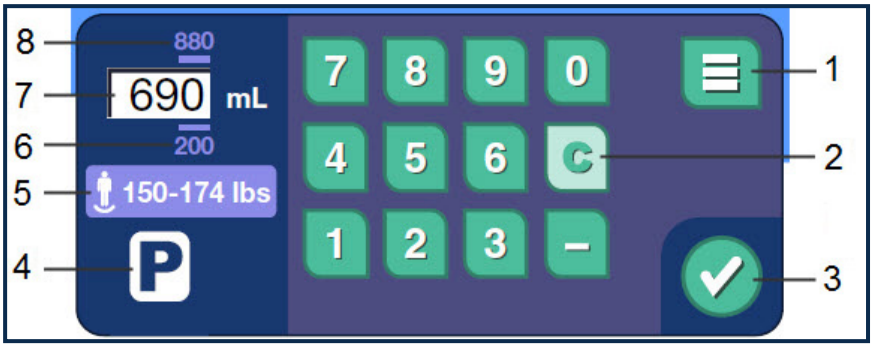
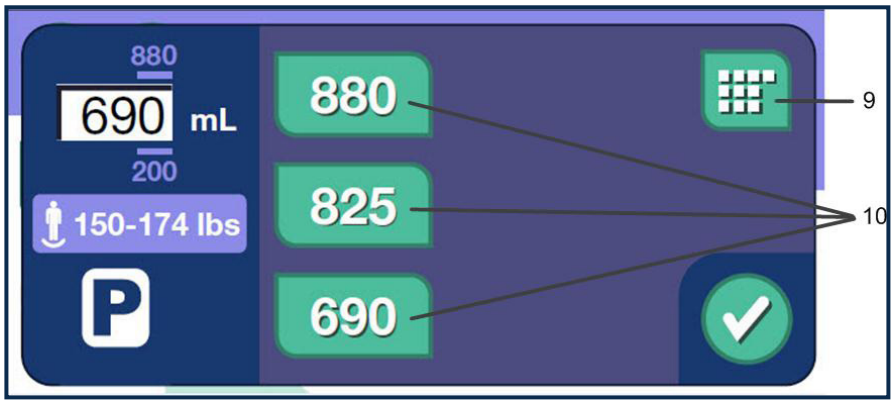


Figure 17: Typical Preset Keypad Overlay



7. **Data Entry Field:** Displays the preset selection.
8. **Maximum Indicator:** Displays the maximum allowable value for the **Data Entry** field.
9. **Numeric Keypad Button:** Opens the numeric keypad overlay.
10. **Preset Value Buttons:** Display the values preset by the administrator. The selected preset displays in the **Data Entry** field.

Section 2.6: Barcode Capability

Aurora Xi can be used with an optional barcode scanner approved by the device manufacturer. The barcode scanner connects to a USB port on the back of the device. The device is barcode compatible to easily and accurately enter information. A barcode scanner is used to scan the barcode on the disposable set and other configurable items (e.g., operator ID, procedure ID (aka donation ID), etc.) that may be required. These items need to be barcode enabled. Please refer to the Administrator's Guide for instructions on enabling barcode formatting. Refer to **"Entering Procedure and Donor Information" on page 4-4** for additional information on barcodes.

Section 2.7: Electronic Transfer of Procedure Files

Aurora Xi can be used with a data management system. Electronic transfer of procedure files between the data management system and the device is done to easily and accurately enter information during procedure set-up and permits electronic storage of Procedure Records onto the center's donor management system.

There are two types of procedure files:

1. The procedure setup file, which is transmitted from the data management system to the device for procedure setup, and

2. The Procedure Record, which is transmitted from the device to the data management system when the procedure is complete.

Depending on the transmit method selected for the device, the procedure setup file may contain:

- procedure references (e.g., operator ID, donor ID, procedure ID, and/or donation setup ID),
- procedure parameters (e.g., donor gender, donor weight, etc.), and
- procedure information (e.g., selected Saline Protocol, target collection volume, donor weight, donor height, etc.).

See the Aurora Xi Administrator's Guide — Procedure Setup Method section for additional information.

The procedure setup file can be retrieved through two methods:

- **Pull Method:** The operator can either retrieve the procedure setup file or can enter a procedure ID or donation setup ID on the device's touchscreen.
- **Push Method:** This file can be sent directly to the device from the data management system.

The Procedure Record is automatically sent to the data management system from the Aurora Xi device when the plasma container is removed. The Procedure Record (either a non-donation, donation, demo, or QC record) can contain procedure information (e.g., procedure time, collection volume, total cycles, etc.) or QC information.

Refer to the Aurora Xi Service Manual for instructions on connecting the device to the data management system and the Administrator's Guide to enable electronic transfer of data between the data management system and the device.

Chapter 3
Device ON/OFF and Set-Up Procedures

This chapter provides information on how to power ON and OFF the device, how to perform daily device set-up tasks, and perform device weigh scale checks.

CAUTION

- Do not operate the Aurora Xi Plasmapheresis System without training. Performing a procedure without proper knowledge of system components, controls, and instructions may increase the risk of harm to the operator or donor, or may cause damage to the device and may result in unsafe practices.
- Do not tap the touchscreen with sharp objects, because sharp objects may cause damage to the device.
- Power OFF the device at the end of each day, in order to allow the system to self-test its safety systems.
- Failure to use the **STOP** button when powering OFF the device may cause the device to become non-functional.
- Do not operate the device unless the air filter and tray are installed.
- If the device has been moved or relocated, perform weigh scale checks before starting a plasmapheresis procedure to ensure scale accuracy.
- Position the front of the device away from direct sunlight to ensure proper function of the Hb detector.
- Both locking wheels should be locked when the device is stationary, in order to prevent unintended movement of the device, which may impact weigh scale readings.

NOTE

- Procedure screens in this manual are typical and may vary from actual device screens.
- Do not power the device ON or OFF while the donor is connected. Disconnect and isolate the donor from the device when the device is powered ON or OFF.
- If the device is not plugged in and powered ON at least once every six months for 24 hours, the back-up battery may need to be replaced.

Section 3.1: Daily Device Set-Up

Gathering the Necessary Supplies

- 1200 g verification weight - used to verify the weigh scales
- 1500 g calibration weight - used to calibrate the weigh scales

Power the Device ON

1. Check that the device power cord is connected to a mains power outlet.

2. Check that the rear door is completely closed. If the rear door is open, contact your local service representative or authorized service personnel.

3. Position the power switch to ON (located on the back of the device support column). The screen displays software information, then displays the **Aurora Xi Logo** screen with an animated **Self-Check** icon in the upper-right corner. This screen displays until the device completes a self-check.

Figure 18: Typical Aurora Xi Logo Screen

4. Check that the displayed date and time at the top of the screen are correct. If the date or time is incorrect, see **Date/Time on page 4-92**.

NOTE

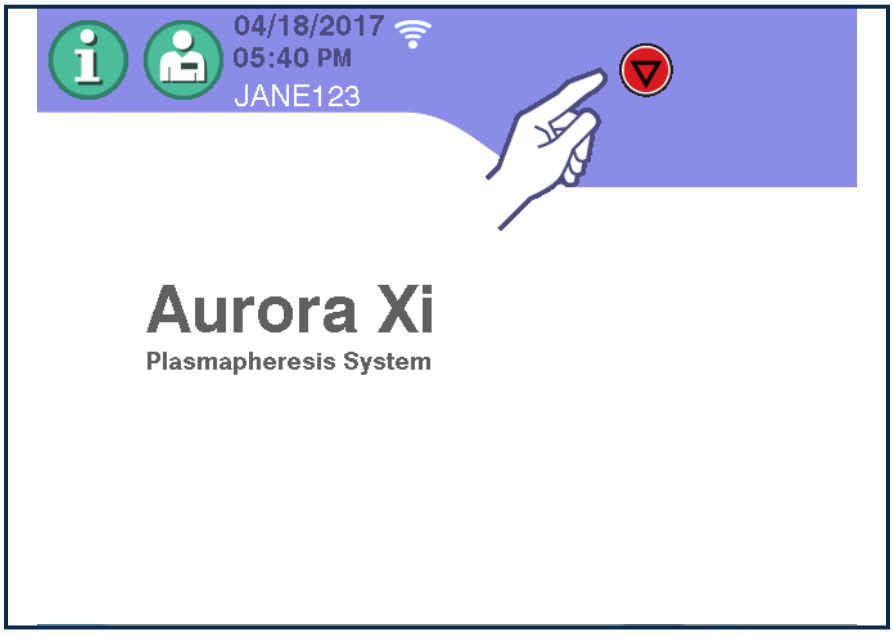
→ The system will detect a date prior to January 1, 2023 as alert 1003. Later incorrect dates are not automatically detected.

Daily STOP Button, Signal Light, and Audio Checks

Perform the following daily checks.

1. When the system self-check is complete, the **Press STOP Button** prompt is displayed on the **Aurora Xi Logo** screen.

Figure 19: Typical Aurora Xi Logo Screen – Press STOP Button Prompt



2. Press the **STOP** button on the device (to the right of the touchscreen). Then, the **Verify Audio/ Visual Signals** prompts and **Check** button are displayed on the **Aurora Xi Logo** screen.

Figure 20: Typical Aurora Xi Logo Screen – Verify Audio/Visual Signals Prompt

3. Verify that the device performs the following actions:

   - Illuminates the device signal light at the top of the device in green, yellow, and red
   - Sounds an audible tone

   If yes, the device signal light and audio check are successful.

4. Once all daily checks are successful, tap the **Check** button.

NOTE

➞ If any of the **STOP** button, signal light, or audible tone checks fail, contact your local service representative or authorized service personnel.

Verifying Weigh Scales

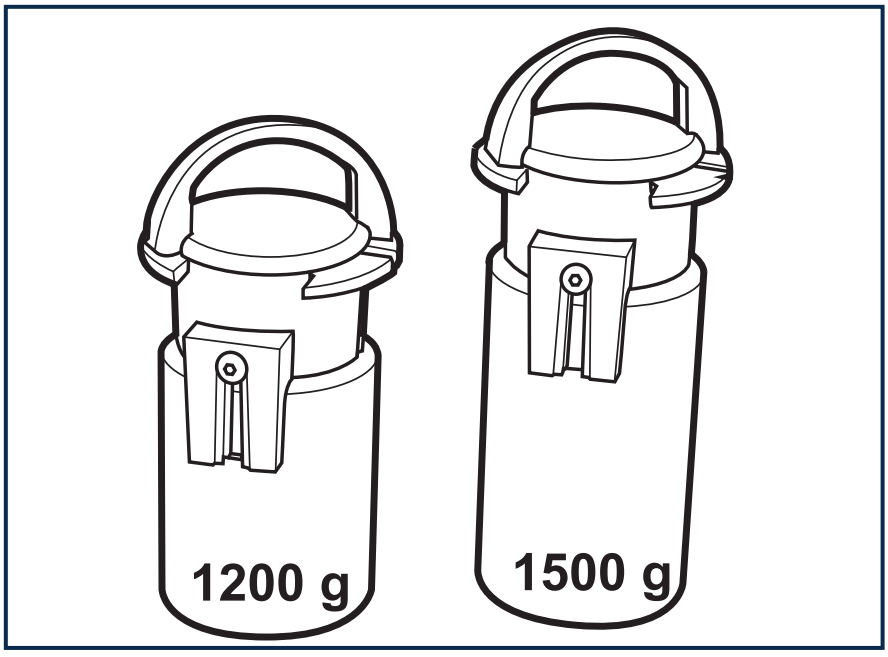
Aurora Xi has three weigh scales:

- AC
- reservoir
- plasma collection

The manufacturer recommends that all device weigh scales be verified daily. Administrative settings determine the frequency of prompting for verification of weigh scales.

Use weigh scale fixtures from the manufacturer for weigh scale verification (1200 g) and calibration (1500 g).

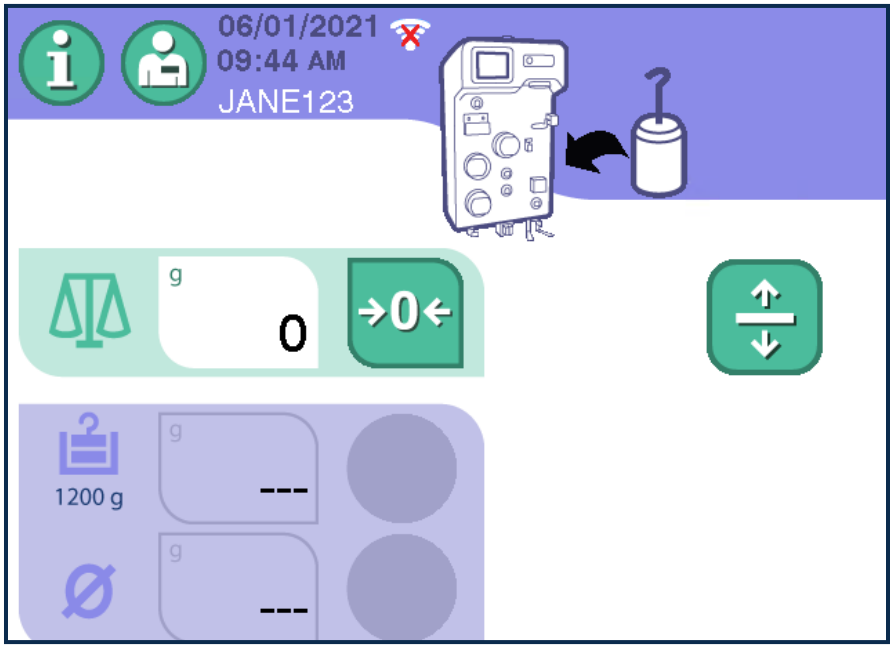
Figure 21: Typical Weigh Scale Fixtures



To perform verification for a weigh scale, perform the following:

1. The blinking screen indicator identifies the appropriate weigh scale to verify. If the scale check row (top row) does not display 0 g, tap the **Tare Scale** button. The system tares the scale and displays 0 g.

Figure 22: Typical Verification Weigh Scale Screen – Successful Tare



2. Place the 1200 g verification weight on the appropriate weigh scale hanger identified by the blinking screen indicator. Allow time for the device to verify the scale. When successful, the measured weight is between 1196 g to 1204 g (where 1196 g and 1204 g are both passing readings), and the following features are displayed as seen in **Figure 22**.

   - The live measured weight is displayed on the top row.
   - The saved measured weight is displayed on the second row.
   - The scale pass icon is displayed on the second row.

NOTE

→ Do not tap or move the scale or weight during verification.

CAUTION

→ When placing the weight onto the bottle hanger, make sure the weight tabs are in proper orientation and align onto the hanger to prevent the weight from slipping through or falling off the hanger, potentially causing injury or damage.

Figure 23: Typical Hanging Weigh Scale Fixture (AC Scale)

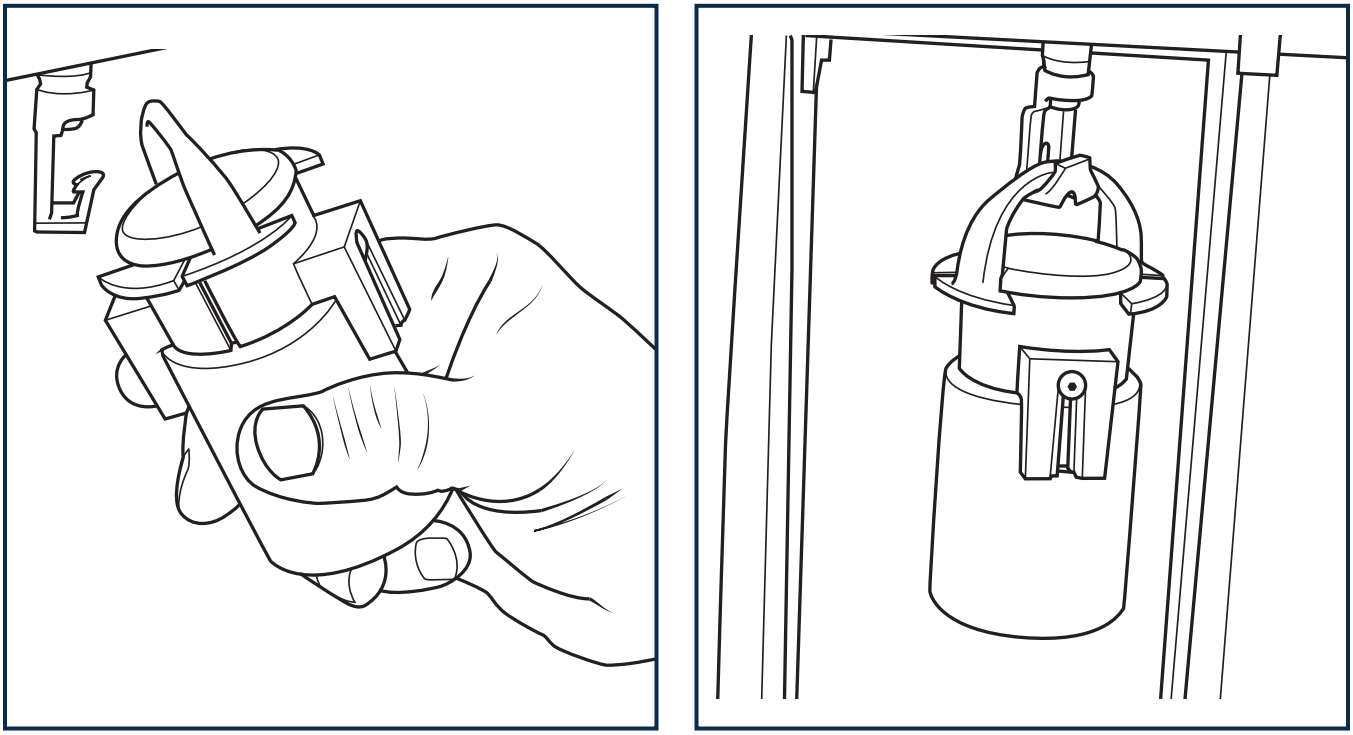


Figure 24: Typical Hanging Weigh Scale Fixture (Reservoir Scale)

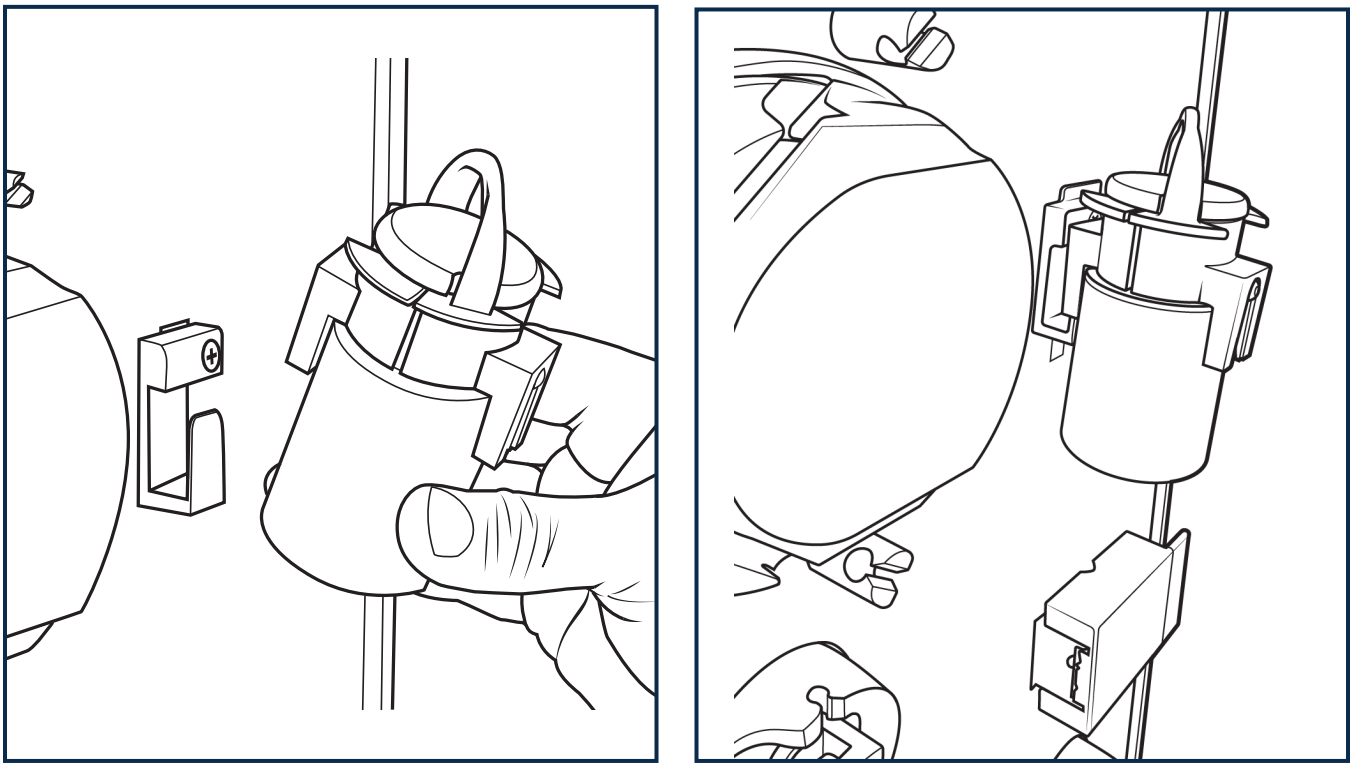


Figure 25: Typical Hanging Weigh Scale Fixture (Plasma Collection Scale – Bag Hanger)

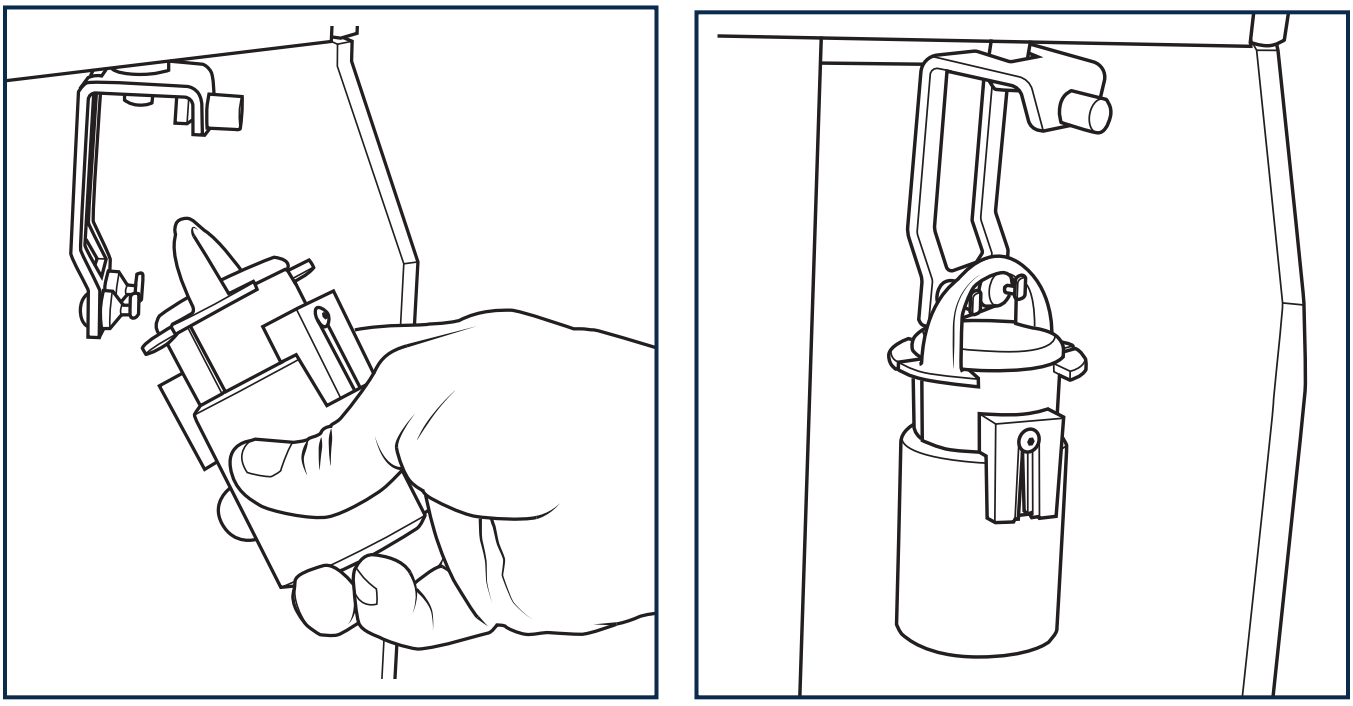
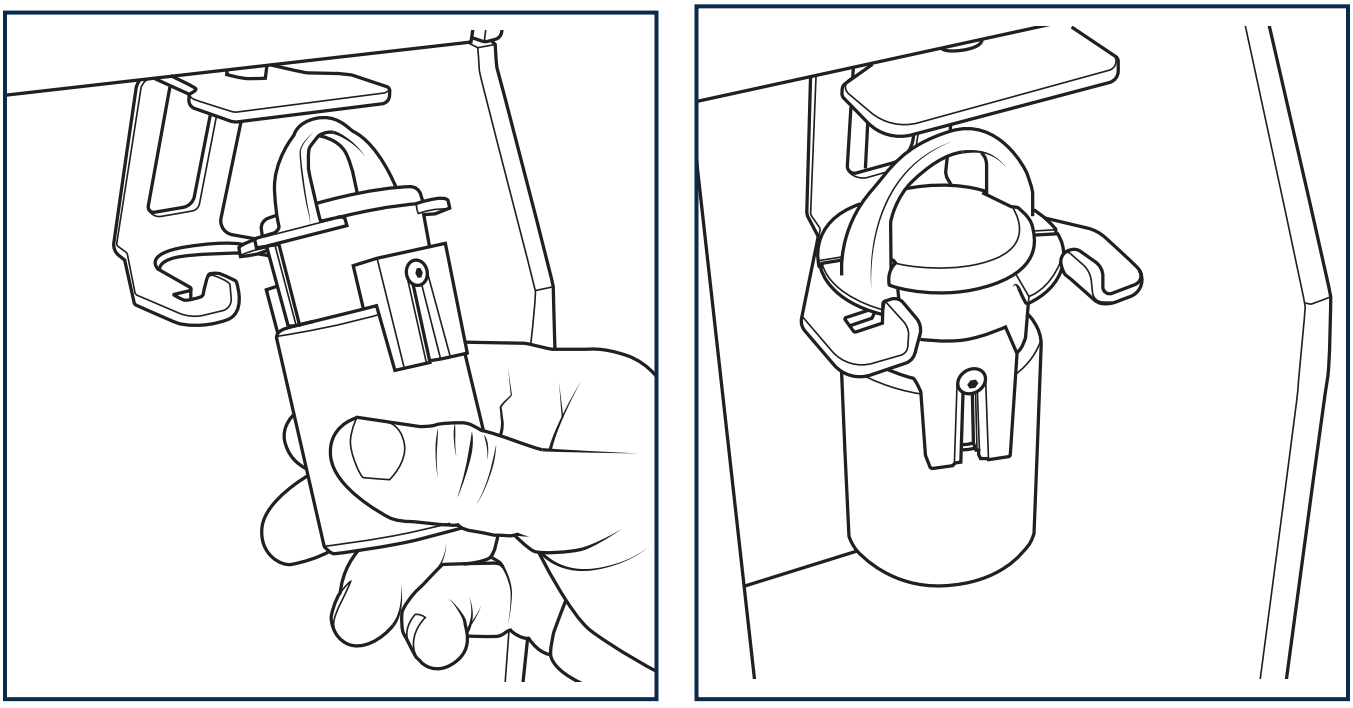
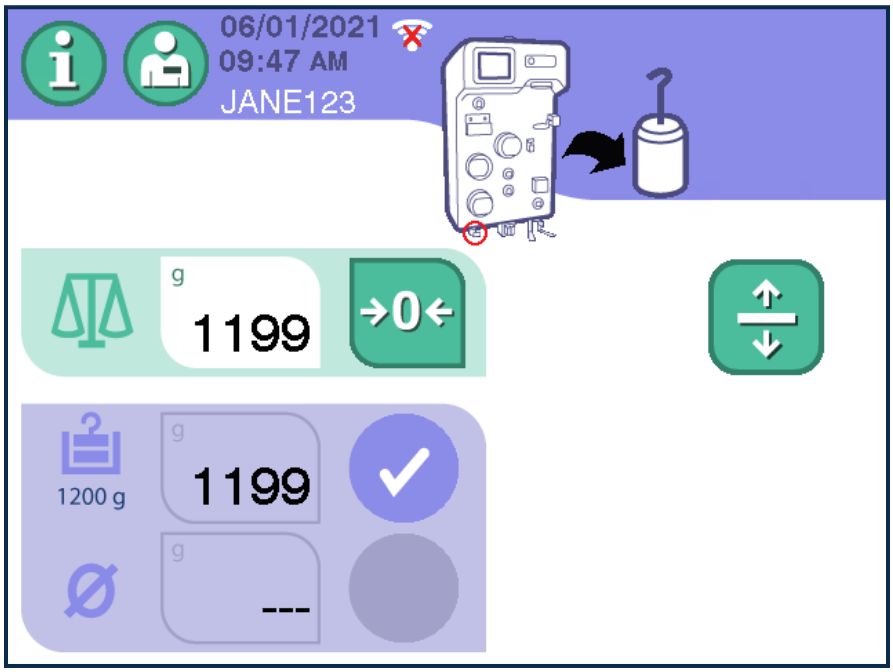


Figure 26: Typical Hanging Weigh Scale Fixture (Plasma Collection Scale – Bottle Hanger)



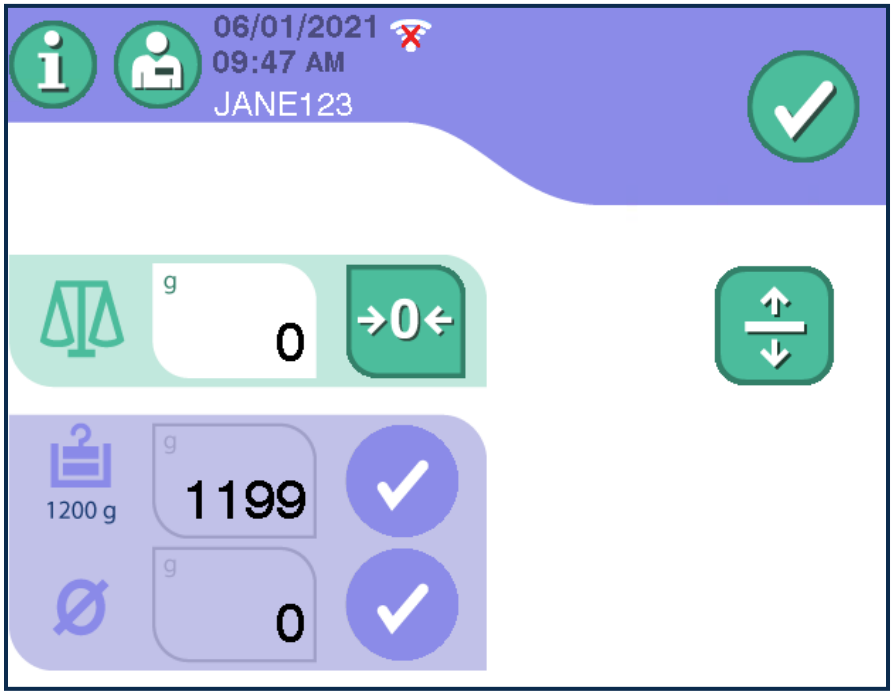
3. Remove the 1200 g verification weight from the weigh scale hanger. The system verifies for 0 g.

Figure 27: Typical Verification Weigh Scale Screen – Successful 1200 g



4. When successful, the measured weight is between -4 g to 4 g (where -4 g and 4 g are both passing readings), the **Scale Pass** icon is displayed adjacent to the measured weight on the third row, and the **Check** button is displayed in the task zone.

Figure 28: Typical Verification Weigh Scale Screen – Successful 0 g



5. Tap the **Check** button. If prompted, verify additional weigh scales.

When unsuccessful, the **Scale Fail** icon is displayed. For additional information, see Resolving an Unsuccessful Weigh Scale Verification.

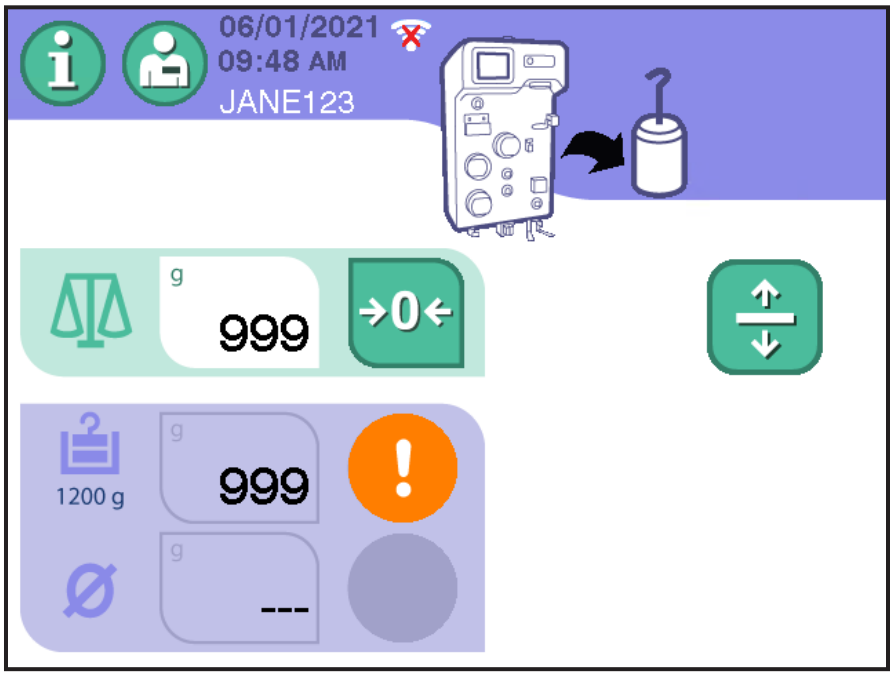
Resolving an Unsuccessful Weigh Scale Verification

For any unsuccessful weigh scale verification, the **Scale Fail** icon is displayed adjacent to the measured weight.

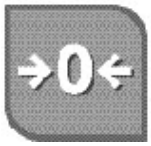
To resolve an unsuccessful weigh scale verification, perform the following:

1. Remove the verification weight from the weigh scale hanger and repeat the instructions for Verifying Weigh Scales. The number of times an operator can attempt to verify a weigh scale is configured through the administrative settings.

Figure 29: Typical Verification Weigh Scale Screen – Unsuccessful Verification



2. If the operator reaches the maximum number of times a weigh scale can be verified, the system disables the **Tare Scale** button.



3. When the **Tare Scale** button becomes disabled, calibrate the weigh scale or contact a local service representative or authorized service personnel.

4. For detailed weigh scale calibration instructions, see Calibrating Weigh Scales.

Calibrating Weigh Scales

If the **Calibration** button is enabled on the **Verification Weigh Scale** screen, operators can calibrate a weigh scale as necessary.

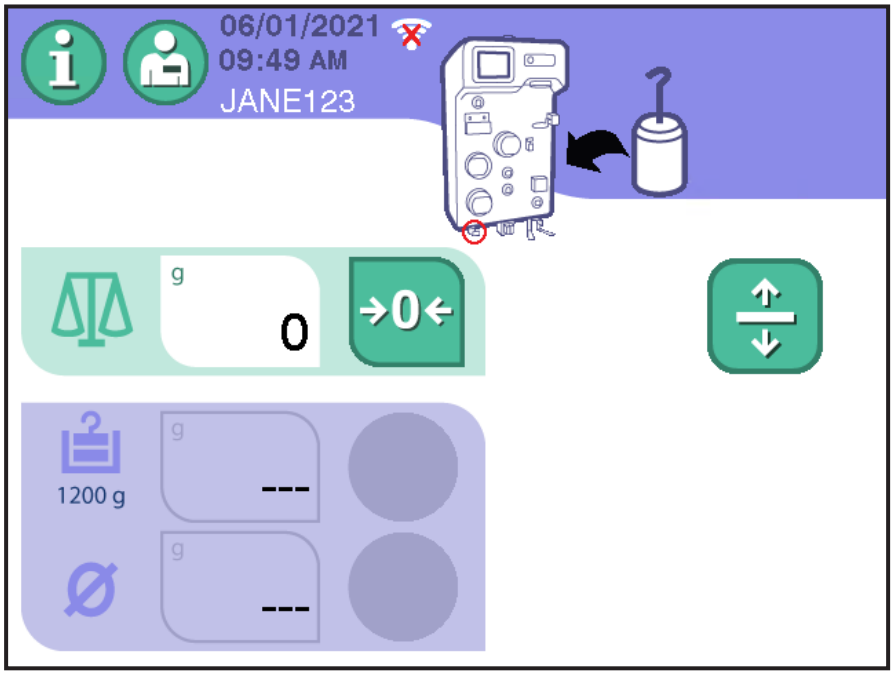
NOTE

- Possible causes for weigh scale inaccuracies include excessive force applied to the weigh scale when loading or unloading the container/ reservoir, and unintentional interference or impacts causing damage to the weigh scale assembly.
- If an issue with the weigh scale is suspected, perform weigh scale checks.

To perform calibration for a weigh scale, perform the following:

1. From the **Weigh Scale Verification** screen, tap the **Calibrate Scale** button.

Figure 30: Typical Weigh Scale Verification Screen – Calibration Button (Enabled)



If the **Remove Weight** prompt is displayed, remove any weights from the weigh scale hanger. The blinking screen indicator identifies the appropriate weigh scale hanger to check.

To return back to the **Verification Weigh Scale** screen, tap the **Back** button.

2. Tap the **Check** button on the first row to calibrate to 0 g (i.e., tare the scale).

3. The first row displays 0 g along with the adjacent **Scale Pass** icon.

4. The second row displays the **Check** button.

Figure 31: Typical Weigh Scale Calibration Screen – Remove Weights Prompt

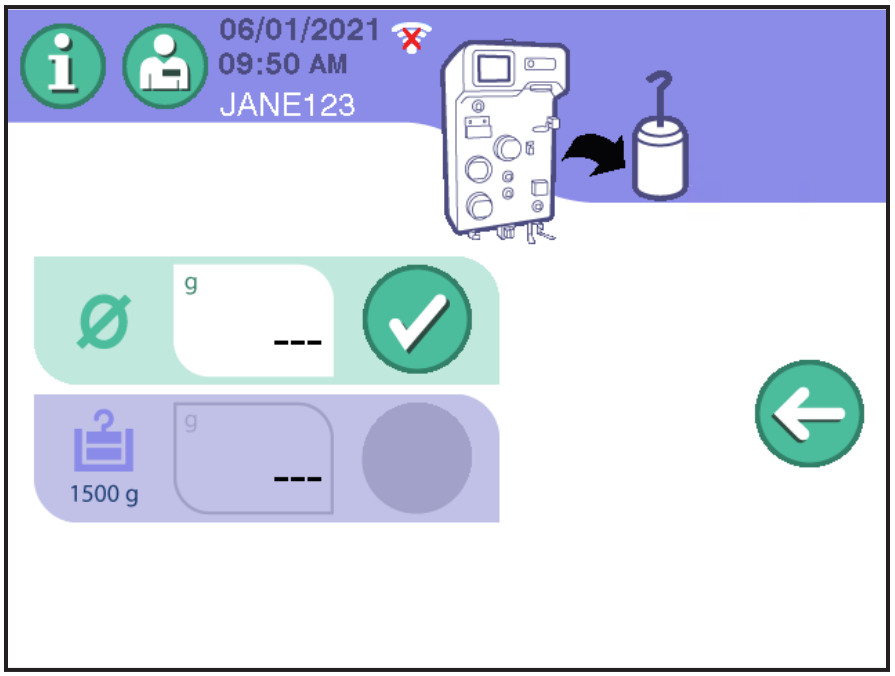
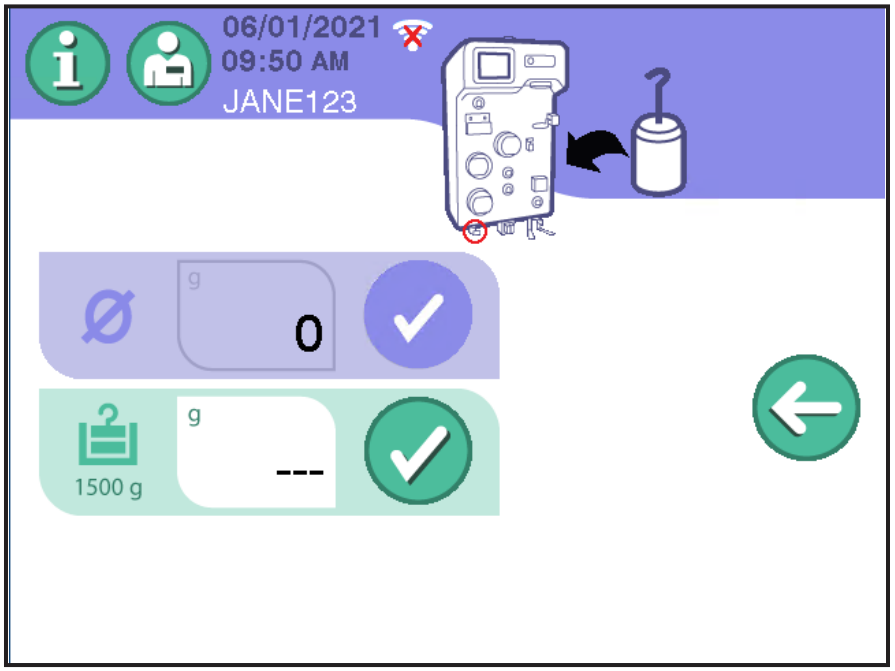


Figure 32: Typical Weigh Scale Calibration

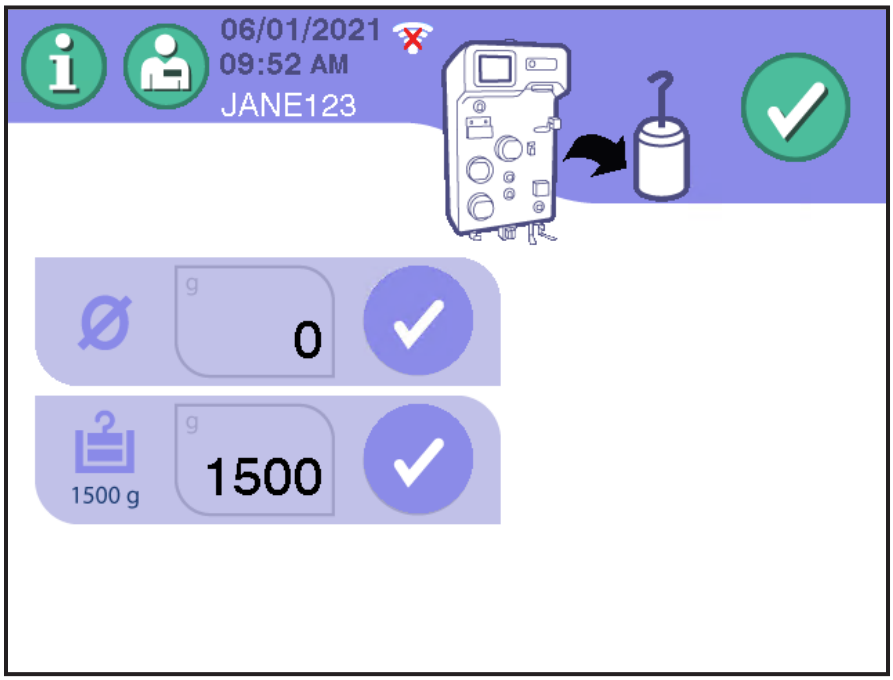


5. The blinking screen indicator identifies the appropriate weigh scale to calibrate. Place the 1500 g calibration weight on the appropriate weigh scale hanger.

6. Tap the second row **Check** button. When successful, the following occurs:

   - The second row displays 1500 g and the adjacent **Scale Pass** icon.
   - The task zone displays the **Check** button.

Figure 33: Typical Weigh Scale Calibration Screen – Successful 1500 g Calibration



7. Remove the 1500 g calibration weight from the device.

8. Once calibration has been completed, tap the **Check** button to perform Weigh Scale Verification with the 1200 g weight.

For any calibration that fails, an alert/alarm is displayed. For detailed information about alerts/alarms, see **"Section 5.1: Alert/Alarm Overview"**.

Section 3.2: Set-up Network Configuration for Remote Communication

This section provides information on how to register the Aurora Xi device to a manufacturer-approved data management system.

NOTE

- Initial configuration should be performed by local service representative or authorized service personnel.
- Prior to registering the device with a data management system, network configurations settings must be established.
- If needed, reference the Aurora Xi Service Manual "Network Configurations" for additional troubleshooting tips.

1. If the device is configured for remote communication with a data management system, then a Time-Based One-Time Passcode (TOTP) is required to be entered to register the device with a data management system. Refer to the data management system Instructions for Use on how to obtain the TOTP Passcode.

2. Once entered, tap the **Information** button on the **Home** screen to navigate to the **Device Setting** tab.

3. Within the **Device Setting** tab, tap the **Network Configuration** tab.

4. Ensure that the data management system status displays **Connected**.

5. If a data management system status displays **Limited**, invalid information may have been entered during network setup, or the TOTP Passcode was incorrect.

Figure 34: Typical TOTP Passcode Overlay

6. If the data management system status displays **Disconnected**:

   - The device may not be connected to the network internet
   - Invalid information may have been entered during network setup.

Section 3.3: Powering OFF the Device

This section provides information on how to power OFF the device before a procedure. To power OFF the device during a procedure, see Section **"Section 4.10: Using the STOP Button"**.

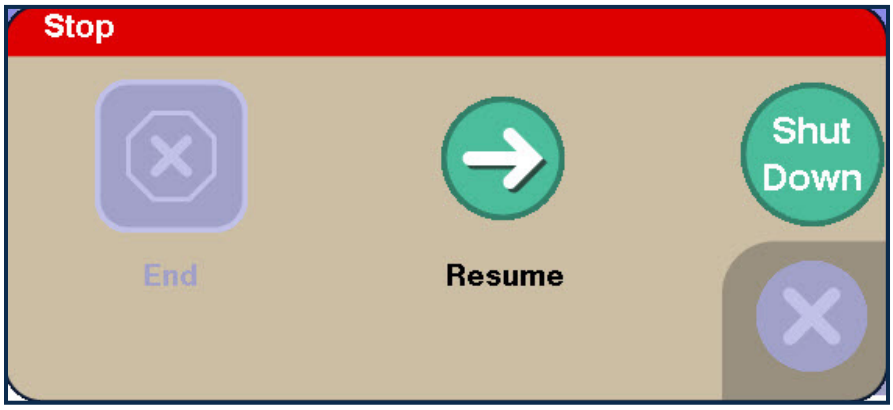
CAUTION

→ Failure to use the **STOP** button when powering OFF the device may cause the device to become non-functional.

Unless the screen indicates otherwise, the operator must use the **STOP** button when preparing the device to power OFF. Failure to do so may require service for the device. To power OFF the device before a procedure, perform the following:

1. Press the **STOP** button next to the touchscreen. The **STOP** overlay displays.
2. Tap the **Shut Down** button.

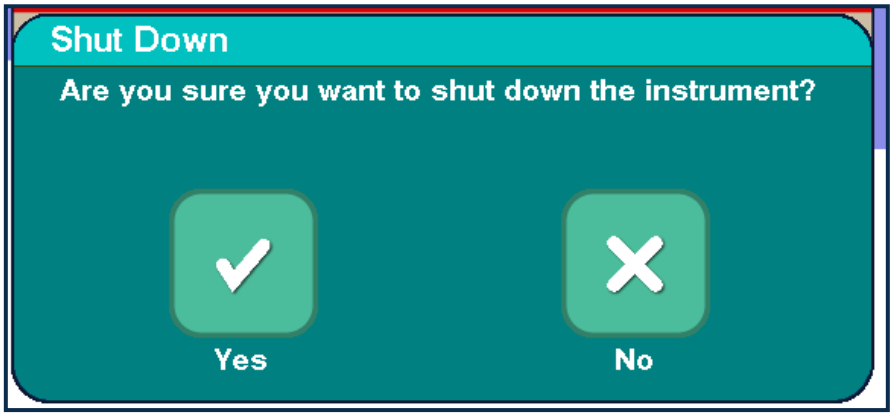
Figure 35: Typical STOP Overlay Before a Procedure



3. The **Shut Down** overlay opens.
4. Tap the **Yes** button. A message displays "Shutting down, please wait".

   - If the **No** button is tapped, the **Shut Down** overlay closes and the **STOP** overlay displays.

Figure 36: Typical Shut Down Overlay



5. When the **Power Aurora Xi Off** screen is displayed, position the power switch to OFF (located on the back of the device support column).

Figure 37: Typical Power Aurora Xi Off Screen

CAUTION

- When unplugging the power cord from the mains supply outlet, grasp the power cord at the plug and not by pulling the power cord wire.

NOTE

- Ensure that the power switch is in the OFF position before unplugging the power cord. Failure to do so will cause the system to run on battery backup.
- After positioning the power switch to OFF, wait at least 10 seconds before attempting to position the power switch back to ON.

6. When the device is powered OFF, if needed, unplug the device power cord from the mains power outlet.

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Chapter 4
Plasmapheresis Procedure

This chapter provides a description of a typical Aurora Xi Plasmapheresis procedure and optional tasks which may be performed during the procedure.

Section 4.1: Gathering the Necessary Supplies

WARNING

- Use only 4% sodium citrate anticoagulant. Use of other anticoagulants could lead to clotting or citrate reaction.

CAUTION

- Verify that the expiration date of all consumable materials (e.g., disposable set, saline solution, AC solution, plasma collection container, and apheresis needle) has not been exceeded.
- Do not use AC or saline solutions if they do not appear clear, are leaking, or contain particulate matter.
- AC and saline solutions should be used at room temperature or up to 37° C (98.6° F), and in compliance with the solution manufacturer's instructions.
- Only 16 gauge or 17 gauge thin-walled apheresis needles may be used.
- In order to ensure that safety systems perform as expected, the length of the apheresis needle set should be 6 inches (15 cm) to 12 inches (30.5 cm), inclusive.

NOTE

➞ Collection containers must meet the following conditions:
- Have a maximum weight of 200 g
- Can be correctly fitted to connect to the set
- Have a sterile fluid path
- Are large enough for the desired collection volume
- Are properly vented (according to the manufacturer's directions) or flexible
- Hang vertically and centered on the weigh scale hanger
- Fit on the device without contacting the column or shroud

➞ Always use a new AC container whenever a new disposable set is installed to avoid potential AC solution depletion.

➞ All solutions containers should be validated by the center for connections to the disposable set and device and for proper fluid flow.

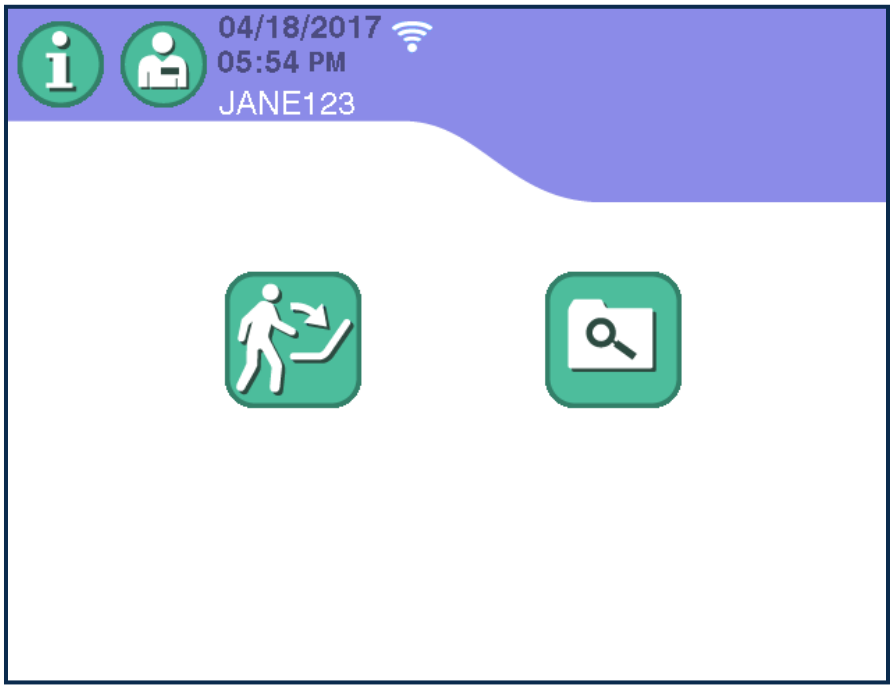
Gather the following before beginning a procedure:

Item	Quantity	Notes
Plasmacell Xi Disposable Set labeled for use with the Aurora Xi Plasmapheresis System	1	
Apheresis Needle Set	1	
Anticoagulant solution container		4% sodium citrate anticoagulant solution (250 mL – 500 mL) with fill volume as specified using the administrative settings
Saline Protocol: saline solution container		250 – 1000 mL with fill volume equal to or greater than the target saline infusion volume
Plasma collection container	1	Needed if not already provided as part of the disposable set
Hemostats	As needed	
Supplies needed for venipuncture site preparation and care	As needed	
Tube sealing equipment	As needed	

Section 4.2: Starting a Procedure

To start a procedure, tap the **New Procedure** button on the **Home** screen.

Figure 38: Typical Home Screen



The animated **Self-Check** icon is displayed on the **Home** screen until the device self-check is complete.

When the self-check is complete, the **Main Data Entry** screen is displayed.

Figure 39: Typical Home Screen – Self-Check

Section 4.3: Entering Procedure and Donor Information

An operator must enter data before beginning a procedure. This section provides instructions on entering data and performing Two-Pass Verification, if enabled by the administrative settings. Enter data using the touchscreen or barcode scanner, as set per the administrative settings.

NOTE

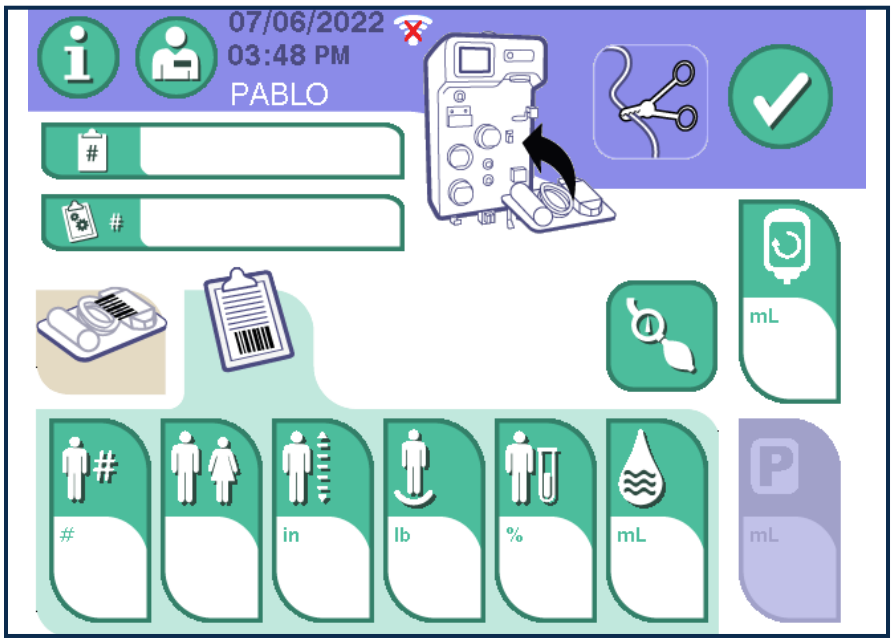
- The center can configure button availability and **Two-Pass Verification** overlays by changing the administrative settings (see the Administrator's Guide for more information). As a result, some buttons described in this chapter may be disabled or **Two-Pass Verification** overlays may not be displayed to the operator.
- Donor and procedure data may be entered in any order, before or after disposable set installation.
- If using the following barcode symbologies (GS1-128 (1D and 2D DataMatrix), EURO CODE, and ISBT-128), entry fields may not need to be selected prior to data entry. The device recognizes these barcodes and may automatically populate the appropriate field(s) based on administrative settings.

Entering Operator, Procedure, and Donation Setup ID Data

1. To manually enter or change the operator ID, tap the **Operator ID** button.

2. Enter data using the keypad overlay or the barcode scanner. When complete, tap the **Check** button.

Figure 40: Typical Main Data Entry Screen – Operator, Procedure, and/or Donation Setup ID



3. To manually enter or change the procedure ID, tap the **Procedure ID** button.

4. Enter data using the keypad overlay or barcode scanner. When complete, tap the **Check** button.

5. To manually enter or change the donation setup ID, tap the **Donation Setup ID** button.

6. Enter data using the keypad overlay or barcode scanner. When complete, tap the **Check** button.

Entering Disposables Data

This section provides information on entering disposable data using the elements on the **Data Entry** overlay. Tapping the **Disposables Data** button on the **Main Disposable Data Entry** screen opens the **Data Entry** overlay. You can also enter data from the **Procedure Information** page accessed through the **Information** button.

Disposables data entry may be enabled or disabled depending on the administrative settings. Enter data using the touchscreen or barcode scanner, per administrative settings.

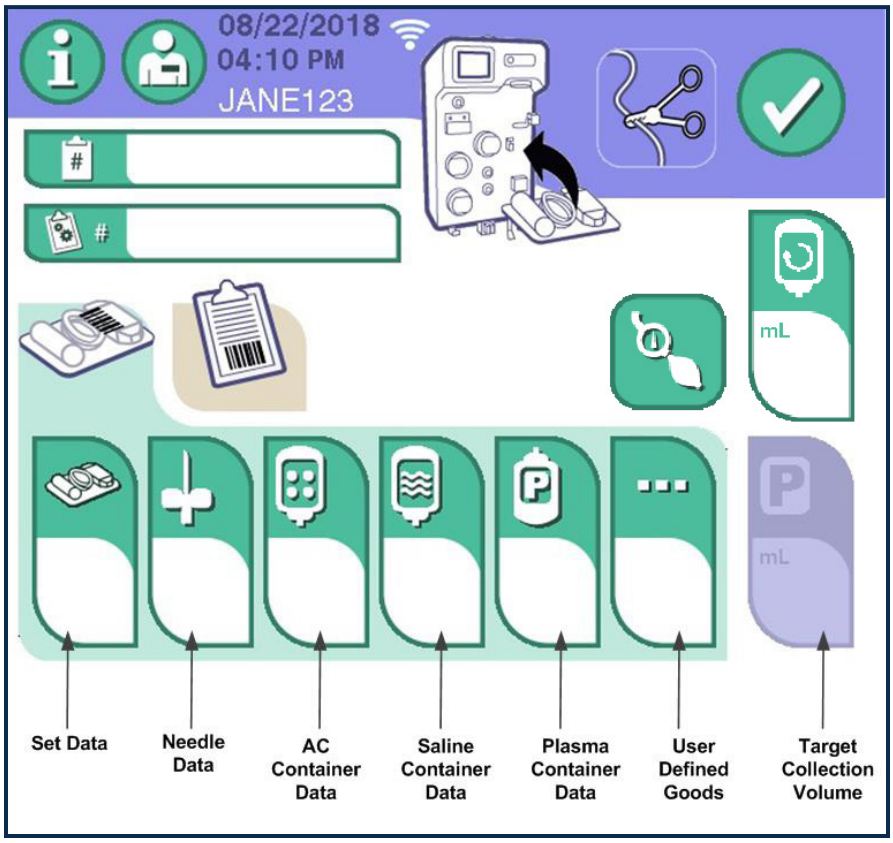
NOTE

- If using GS1-128 (1D and 2D DataMatrix) or ISBT-128 barcode symbology, entry fields may not need to be selected prior to data entry. The device recognizes these barcodes and may automatically populate the appropriate field(s).

Set Data Button: If enabled, allows entry of the code number, lot number, and expiration date information about the disposable set (per administrative settings). Enter the information using the touchscreen or barcode scanner.

Needle Data Button: If enabled, allows entry of the code number, lot number, and expiration date information about the needle set (per administrative settings). Enter the information using the touchscreen or barcode scanner.

Figure 41: Typical Main Data Entry Screen – Disposable Set Data



NOTE

→ If enabled, needle data can be entered at the **Pre-Collection** screen or at the **Venipuncture** screen using the touchscreen or barcode scanner.

AC Container Data Button: If enabled, allows entry of the code number, lot number, and expiration date information about the AC used during the procedure (per administrative settings). Enter the information using the touchscreen or barcode scanner.

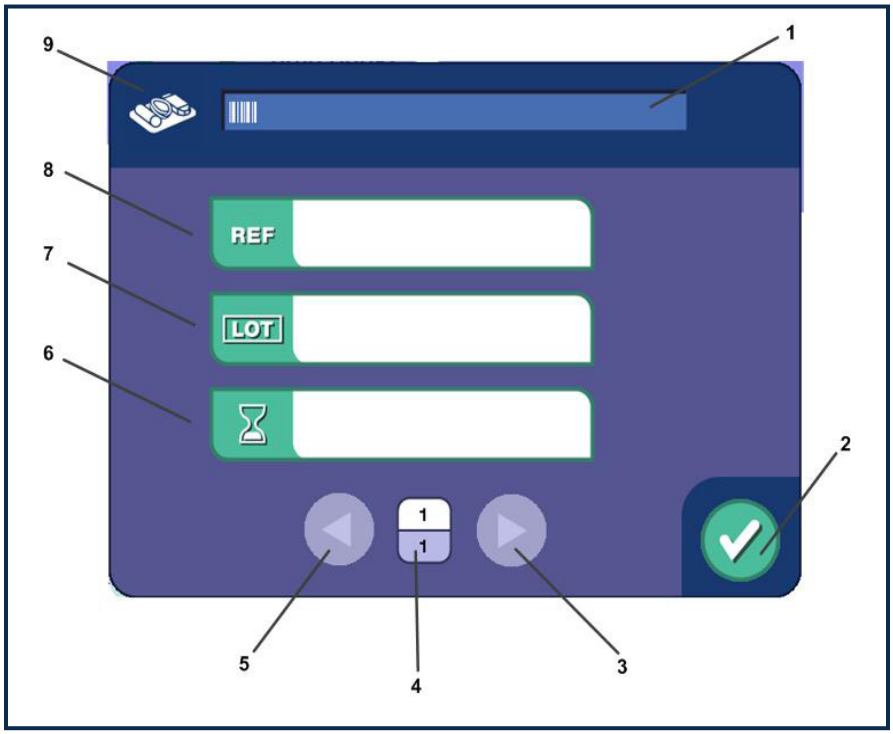
Saline Container Data Button: If enabled, allows entry of the code number, lot number, and expiration date information about the saline used during the procedure (per administrative settings). Enter the information using the touchscreen or barcode scanner.

Plasma Container Data Button: If enabled, allows entry of the code number, lot number, and expiration date information about the plasma container used during the procedure. Enter the information using the touchscreen or barcode scanner.

User-Defined Soft Goods Button: If enabled, allows entry of the code number, lot number, and expiration date information about user-defined soft goods used during the procedure (per administrative settings). Enter the information using the touchscreen or barcode scanner through the **Data Entry** overlay. Tapping a **Soft Goods Data** button opens the **Data Entry** overlay.

1. **Barcode Field:** Displays barcode information (if applicable).
2. **Check Button:** Saves screen entries and closes the overlay.
3. **Page Forward Button:** Displays the next Data Entry page.
4. **Page Number indicator:** Top number indicates current page, and the bottom number indicates the total number of available pages.
5. **Previous Page Button:** Returns to previously displayed page.

Figure 42: Typical Data Entry Overlay



6. **Expiration Date Field:** The **Expiration Date** overlay opens when this field is selected. Once an expiration date is entered, it displays in this field.
7. **Lot Number Field (LOT):** The extended keypad overlay opens when this field is selected. Once a lot number is entered, the current disposables lot number displays in this field.
8. **Code Number Field (REF):** The extended keypad overlay opens when this field is selected. Once a code number is entered, the current disposables code number displays in this field.
9. **Icon (Varies):** The displayed icon identifies the type of information to be entered.

Expiration Date Overlay

When the expiration date field is tapped from the **Data Entry** overlay, the **Expiration Date** overlay opens.

1. **Up Button:** Increases the numeric value displayed.
2. **Clear Button:** Deletes any entries in the data entry field.
3. **Down Button:** Decreases the numeric value displayed.
4. **Month/Year Field:** Tapping either field allows the operator to enter data by tapping **Up** or **Down**.

Figure 43: Typical Expiration Date Overlay

Entering Disposable Set Information

1. If the **Disposables Data** tab is not displayed, tap the **Disposables Data** tab.
2. Tap the associated button to enter disposables data, (set data, needle set data, AC container data, saline container data, plasma container data, or user-defined soft goods).

NOTE

- Only fields required per the administrative settings are enabled on this overlay.
- If using GS1-128 (1D and 2D DataMatrix) or ISBT-128 barcode symbology, entry fields may not need to be selected prior to data entry. The device recognizes those barcodes and may automatically populate the appropriate field(s).

3. When the desired button is tapped, an overlay displays with associated data entry fields.
4. Enter data using the touchscreen or barcode scanner into the corresponding overlay fields.
5. When complete, tap the **Check** button. The **Data Entry** overlay closes, and the **Main Data Entry** screen displays a check mark on the applicable button.

Saline Optional Protocol Selection

If the administrative settings default protocol is set for saline optional, perform the instructions in this section. Otherwise, proceed to **Entering Donor Data (Using the Touchscreen) on page 4-10**.

1. Tap the **Saline Container Data** button on the **Main Data Entry** screen.

2. (Optional) Tap the **Target Saline Volume** button on the **Donor Data Entry** screen.

Figure 44: Typical Protocol Selection Overlay

3. The **Protocol Selection** overlay displays.

4. Select the desired protocol.

5. The **Protocol Selection** overlay closes and returns to the previous screen.

NOTE

➔ If a Saline Protocol was selected, after this overlay closes, the system prompts the operator to enter a target saline infusion volume.

Entering Donor Data (Using the Touchscreen)

This section provides information on how to enter donor data using the elements on the **Data Entry** overlay. The **Data Entry** overlay opens when a donor data tab is tapped on the **Main Data Entry** screen.

Certain donor parameters may be enabled or disabled depending on the system's administrative settings. Donor and procedure data may be entered in any order, before or after disposable set installation.

Donor Information Overlays

Donor Height, Donor Weight, and Donor Hemoglobin/Hematocrit overlays all use the numeric keypad, which is described in Chapter 2. The donor ID uses the alphanumeric extended keypad, which is also described in Chapter 2.

Main Data Entry Overlay

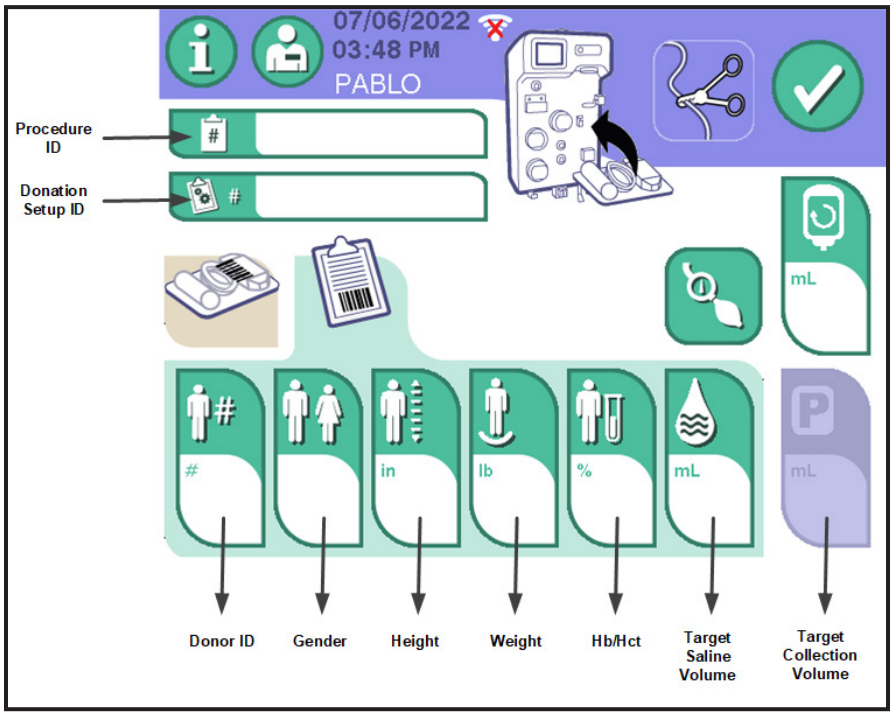
Donor ID Button: If enabled, allows entry of the donor ID number for the procedure.

Donor Gender Button: If enabled, allows entry of the donor's gender for the procedure.

Donor Height Button: If enabled, allows entry of the donor's height for the procedure. This can be in inches or centimeters, depending on the administrative settings.

Donor Weight Button: Allows entry of the weight of the donor. This can be in kilograms or pounds, depending on administrative settings.

Figure 45: Typical Main Data Entry Screen – Donor Data



Donor Hematocrit/Hemoglobin Button: Allows entry of the hematocrit or hemoglobin value of the donor. Note this displays as either hematocrit or hemoglobin, depending on the administrative settings.

Target Saline Infusion Volume Button: Allows entry of the target saline infusion volume for the procedure during a Saline Protocol.

Target Collection Volume Button: Displays Target Collection Volume. This button sets the target collection volume for the procedure. If the system is configured to use a standard nomogram (using the administrative settings), when donor weight is entered, the system automatically determines the Target Collection Volume (including plasma and anticoagulant).

If the system is configured to use an optimized nomogram (using the administrative settings), when donor weight is entered, the system determines the Target Plasma Volume (viewable only in the **Procedure Record** overlay if configured in administrative settings).

Once the donor hematocrit or hemoglobin are entered, the system automatically determines the corresponding Target Collection Volume.

- When using the new Adaptive Nomogram, donor hematocrit or hemoglobin is not used for the nomogram calculation; however, donor hematocrit or hemoglobin entry is required to begin a procedure.

If the system is configured to use the new Adaptive Nomogram (using the administrative settings), when donor weight, donor height, and donor gender are entered, the system determines the Target Collection Volume (including plasma and anticoagulant) directly, and this value is automatically populated.

The Collection Volume value can be adjusted (per the administrative settings) using the preset volumes (only available when using the standard nomogram) or the extended keypad, but cannot exceed the automatically populated volume. For information, see the preset keypad information in **Numeric and Preset Keypad Overlays on page 2-24**.

Procedure ID Button: If enabled, allows entry of the procedure ID for the procedure.

Donation Setup ID Button: If enabled, allows entry of the donation setup ID for the procedure.

ECV (Extracorporeal Volume) Limit Button: Provides access to set extracorporeal red blood cell volume (RBC) limit in mL. This setting is the maximum amount of red cells to be drawn by the device at any point during the procedure, where the extracorporeal RBC volume is no greater than 15% of the donor's estimated RBC volume. The maximum limit is an administrative setting. The operator may decrease this setting for donor comfort and/or to reduce donor reactions, per the center's SOPs. When using the new Adaptive Nomogram, the ECV Limit must be set to 200 mL for new and lapsed donors.

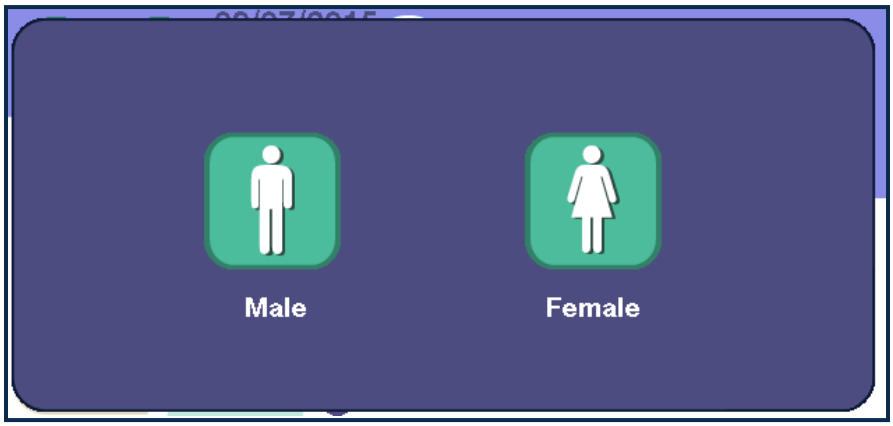
Entering Donor Information

1. If the **Donor Data** tab is not displayed, tap the **Donor Data** tab.

2. Tap the associated button to enter donor data (**Donor ID**, **Donor Gender**, **Donor Height**, **Donor Weight**, or **Donor Hb/Hct** button).

3. An overlay displays with the appropriate data entry fields for each button.

Figure 46: Typical Donor Gender Overlay



NOTE

→ For more information regarding selecting donor gender, refer to the Technical Information Document (TID) on Transgender and Non-Binary Apheresis Donors and Patients.

4. Enter data using the touchscreen or the barcode scanner in the corresponding overlay fields.

WARNING

→ Confirm that the correct donor weight, donor height, donor gender, and donor hematocrit or hemoglobin are displayed on the touchcreen when information is manually entered or scanned using a barcode scanner. Incorrect information may lead to additional red blood cell (RBC) loss, excess blood loss, overcollection of plasma, and/or a higher-than-intended citrate infusion rate (CIR).

5. Tap the **Check** button on the overlay. The overlay closes, and the **Donor Data Entry** screen displays the entered data on the applicable button.

6. If a Saline Protocol is selected, tap the **Target Saline Volume** button to enter the volume. The **Saline Volume** overlay displays.

Figure 47: Typical Saline Volume Overlay

7. Enter or select the target saline volume.

   - To use one of the preset values, tap the corresponding **Preset** button (if displayed, per administrative settings).

   - To enter the value manually, tap the **Keypad** button. The keypad overlay displays. Enter the target saline volume.

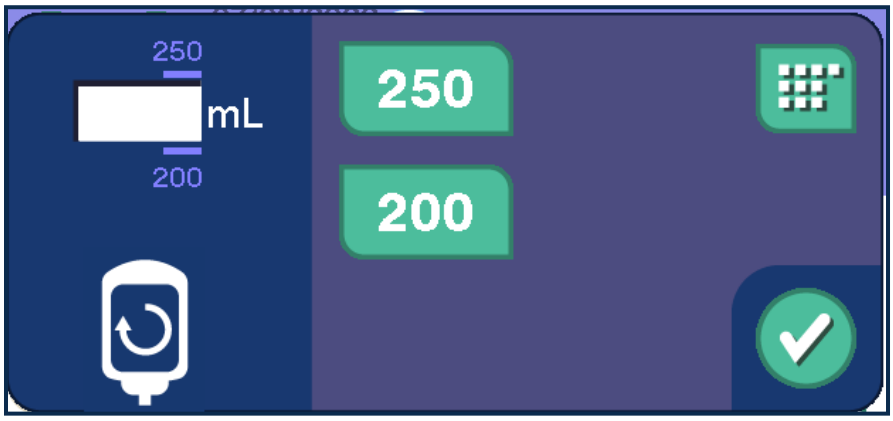
8. To confirm, tap the **Check** button.

The **ECV Limit** button provides access to set extracorporeal red blood cell (RBC) limit in mL. This setting is the maximum amount of red cells to be drawn by the device at any point during the procedure, where the extracorporeal RBC volume is also limited to no greater than 15% of the donor's estimated RBC volume. The maximum limit is an administrative setting. The operator may decrease this setting for donor comfort and/or to reduce donor reactions, per the center's SOPs. When using the new Adaptive Nomogram, the ECV Limit must be set to 200 mL for new and lapsed donors.

1. Enter or select the ECV Limit.

   - To use one of the preset values, tap the corresponding preset button (if displayed, per administrative settings).
   - To enter the value manually, tap the **Keypad** button. The keypad overlay displays. Enter the ECV limit.

Figure 48: Typical ECV Overlay



2. To confirm, tap the **Check** button.

The target collection volume is automatically populated based on: entered donor weight (if configured for the standard nomogram) or donor weight and donor hematocrit or hemoglobin (if configured for the Optimized Nomogram) or donor gender, donor height, and donor weight (if configured for the Adaptive Nomogram).

NOTE

- The upper limit of the **Collection Volume** overlay is the automatically populated volume; the operator cannot exceed this volume.
- Preset Collection Volumes are only displayed if configured in administrative settings and if configured for using the standard nomogram.

1. To change the target collection volume, tap the **Target Collection Volume** button.
2. Enter or select the target collection volume.
   - To use one of the preset values, tap the corresponding preset button (if displayed, per administrative settings).
   - To enter the value manually, tap the **Keypad** button. The keypad overlay displays. Enter the target collection volume.
3. To confirm, tap the **Check** button.

Figure 49: Typical Collection Volume Overlay (Standard Nomogram)

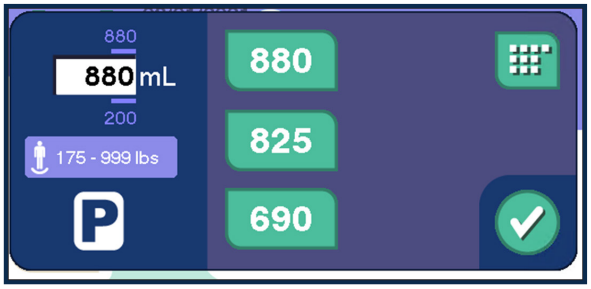


Figure 50: Typical Collection Volume Overlay (Optimized Nomogram)

Figure 51: Typical Collection Volume Overlay (Adaptive Nomogram)

Section 4.4: Installing and Checking a Disposable Set

This section provides instructions on how to install the disposable set. Installing the separator, followed by the reservoir, and then cell pump line is recommended to reduce the likelihood of kinks or twists in the cell pump line.

Installing a Disposable Set

CAUTION

- Do not use the disposable set if the protective caps are damaged, loose, or not intact, or set integrity is compromised.
- Verify that the tubing is centered on the pump rollers. Push the pump lines back as far as possible in the pump. Slack in the line or forcing the pump handle to close over improperly positioned tubing may cause damage to the tubing.
- Ensure that the tubing keepers are loaded on the correct side of the tubing guides.
- Improper installation of tubing in the pumps may affect flow rate accuracy, impact efficiency of the procedure, cause leaks, or lead to hemolysis.
- An improperly loaded disposable set can cause kinks which can lead to hemolysis. Ensure there are no twists or kinks present in the disposable set that restrict the inner diameter of the tubing to smaller than the inner diameter of the needle.
- Ensure that the pressure cuff tubing is routed around the back of the device, not through the container shrouds, to avoid interference with the weigh scales.
- Only use the longer plasma collection bag with the elongated container shroud to prevent inaccurate weight readings.

NOTE

- Do not open any pump handle at any time between disposable set Install Check and disposable set removal, except when directed by troubleshooting instructions.
- Do not open the Hb (Hemoglobin) detector assembly door at any time between disposable set Install Check and disposable set removal, except when directed by troubleshooting instructions.
- Do not open the lower separator support, adjust the alignment of the separator, or squeeze the separator at any time between disposable set Install Check and disposable set removal, except when directed by troubleshooting instructions.

NOTE

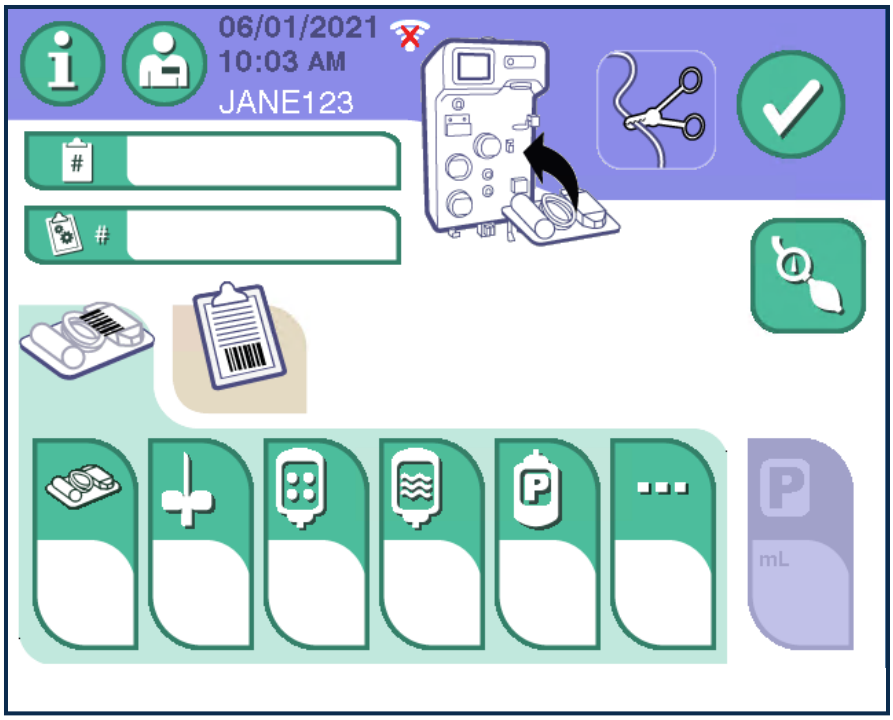
- Follow the tubing routing diagram on the front panel when installing the disposable set.
- When loading tubing into clamps, gently slide the tubing back and forth to ensure that the line is centered and taut in the clamp.
- Illustrations in this section are for reference only and may not represent all possible set configurations.
- The disposable set must be at room temperature to function properly. For detailed operating ranges, see **"Section 7.3: Recommended Operating and Storage/Shipping Requirements"**.
- Do not use sharp objects to open the disposable set packaging.

When the Install Set prompt is displayed on the **Main Data Entry** screen, install the disposable set. Perform the following steps.

Preparing the Disposable Set

1. Ensure the following device components are in the open position:
   - The Hb detector assembly door, pressure transducer assembly cover, separator lower support, and all three pumps.
   - For detailed information about the location of device components, see **"Section 2.3: Device Components"**.
2. Open the disposable set packaging.
3. Carefully pull on the package perforations and remove the set from the packaging.

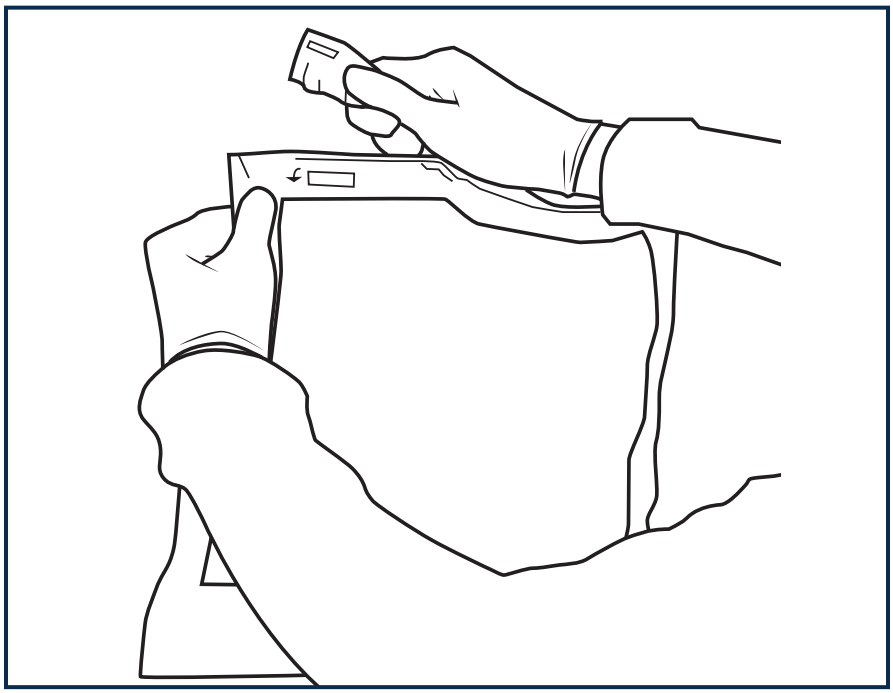
Figure 52: Typical Main Data Entry Screen – Install Set Prompt



4. The disposable set tubing is taped together at various places to ease installation and to prevent tubing from touching the floor. It is recommended to remove the tape in the sequence as instructed in the following sections.

5. Inspect the disposable set for integrity and damaged protective caps before use.

Figure 53: Open Disposable Set Packaging



CAUTION

→ Do not use the disposable set if the protective caps are damaged, loose, or not intact, or set integrity is compromised.

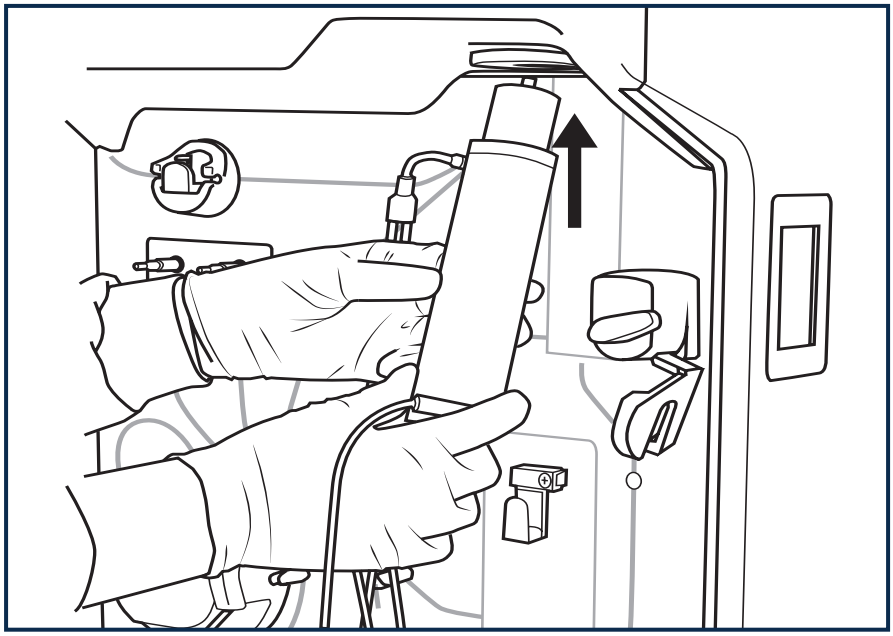
Install the Separator

1. Insert the separator top into the separator motor cup.

   - A magnet holds the separator in the separator motor cup.

2. Position the separator tubing side ports to the left side of the separator.

Figure 54: Insert Separator into Separator Motor Cup

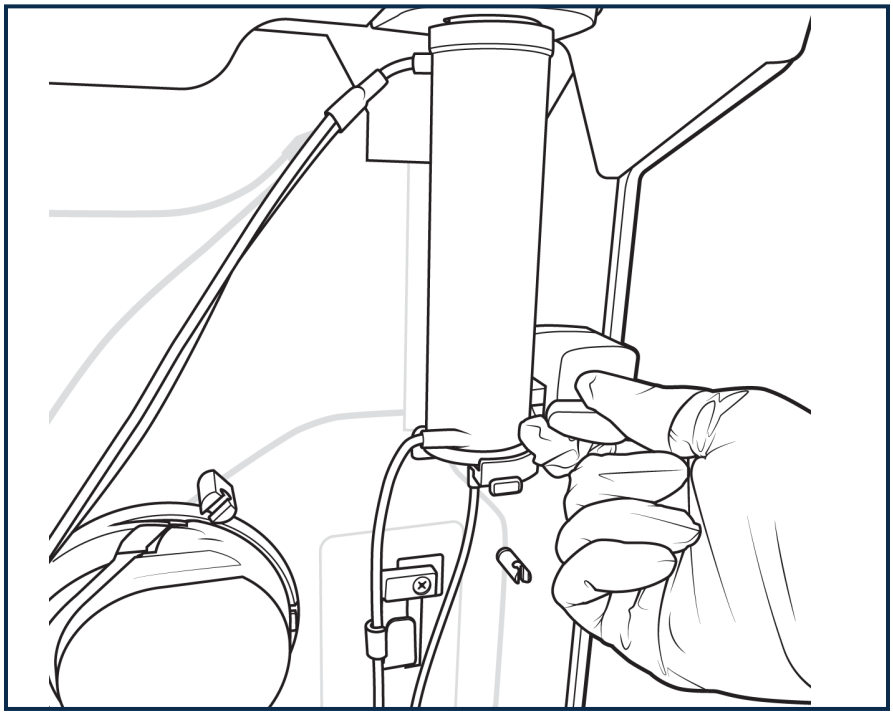


CAUTION

➞ Do not let the separator lower support snap into place as it may damage disposable set components and/or the device.

3. Carefully close the separator lower support by turning the support handle (blue) clockwise until the support stops.

Figure 55: Close Separator Lower Support



4. Check the position of the separator and ensure that it is centered and positioned properly on the support.

CAUTION

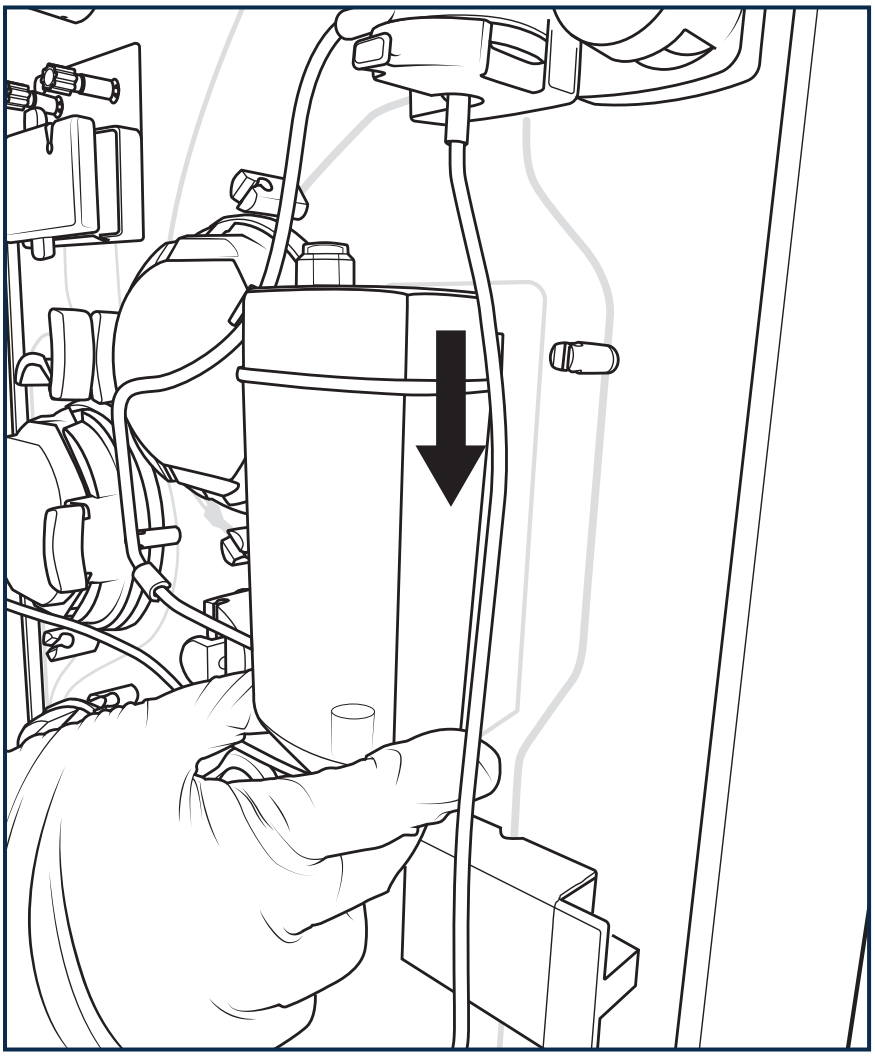
➞ An improperly loaded disposable set can cause kinks which can lead to hemolysis. Ensure there are no twists or kinks present in the disposable set that restrict the inner diameter of the tubing to smaller than the inner diameter of the needle.

Install the Reservoir

1. Gently slide the back of the reservoir down onto the reservoir weigh scale hanger until the reservoir is secure.

2. Use care when installing the reservoir to the weigh scale in order to avoid overload alerts.

Figure 56: Install Reservoir



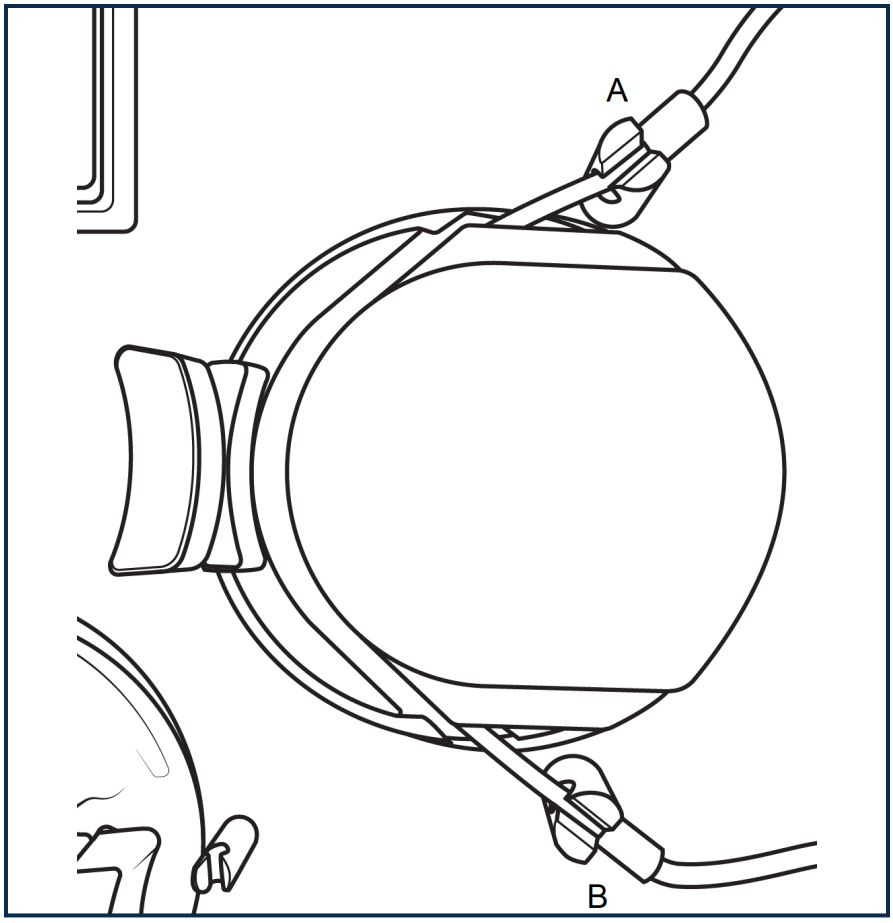
Install the Cell Line

NOTE

- When loading the cell line, either the bottom cell line keeper (Step 1) or the top cell line keeper (Step 2) may be installed first, as long as the reservoir weigh scale is not disturbed due to inadvertently pulling tubing during the cell line installation.

1. Insert the tubing from the bottom-left of the separator into the tubing guide above the cell pump (A).
2. Ensure the tubing keeper (purple) is touching the right (flat) side of the tubing guide.
3. Center the tubing on the cell pump rollers and insert the tubing into the tubing guide below the cell pump (B). Push the pump lines back as far as possible in the pump.
4. Ensure the tubing keeper (purple) is on the right (flat) side of the tubing guide.
5. Close the cell pump by turning the cell pump handle (blue) counterclockwise.

Figure 57: Install Cell Line



CAUTION

- Ensure that the tubing keepers are loaded on the correct side of the tubing guides.
- Improper installation of tubing in the pumps may affect flow rate accuracy, impact efficiency of the procedure, cause leaks, or lead to hemolysis.
- Verify that the tubing is centered on the pump rollers. Push the pump lines back as far as possible in the pump. Slack in the line or forcing the pump handle to close over improperly positioned tubing may cause damage to the tubing.

Install the Plasma Line

CAUTION

→ An improperly loaded disposable set can cause kinks which can lead to hemolysis. Ensure there are no twists or kinks present in the disposable set that restrict the inner diameter of the tubing to smaller than the inner diameter of the needle.

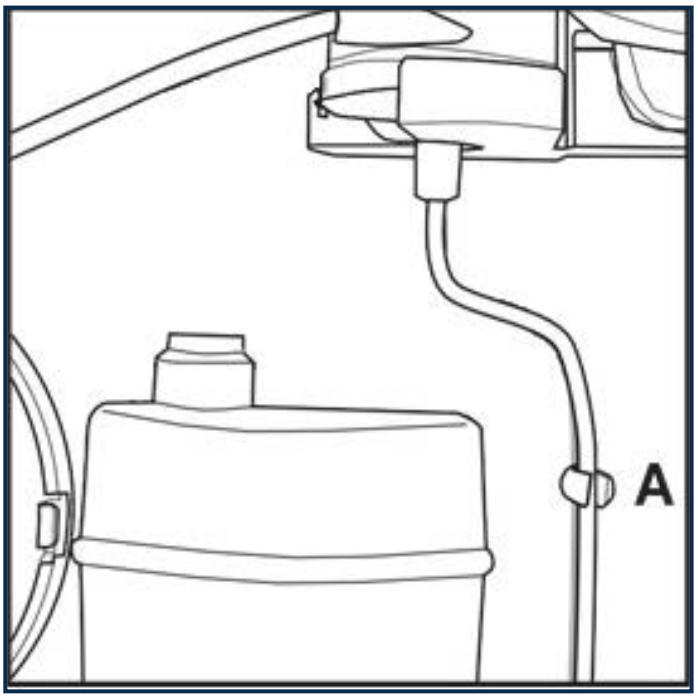
NOTE

→ The tubing guide on the plasma line should be used such that the plasma line is positioned around the reservoir. Tubing must not touch the reservoir, as this may cause errors in the reservoir scale reading.

1. Insert the tubing from the bottom of the separator into the tubing guide, right of the reservoir (A).

2. Position the tubing such that the line does not have any sharp bends or kinks.

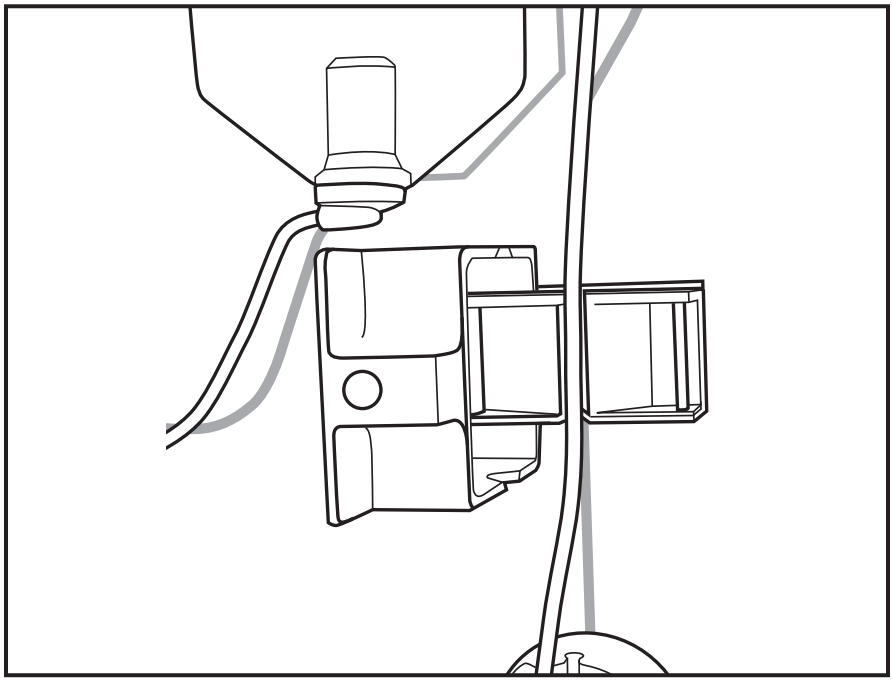
Figure 58: Insert Plasma Line into Tubing Guide



3. Insert the tubing into the Hb detector.

4. Ensure the tubing is fully seated in the Hb detector. Close the Hb detector assembly door using the Hb detector assembly door handle (blue).

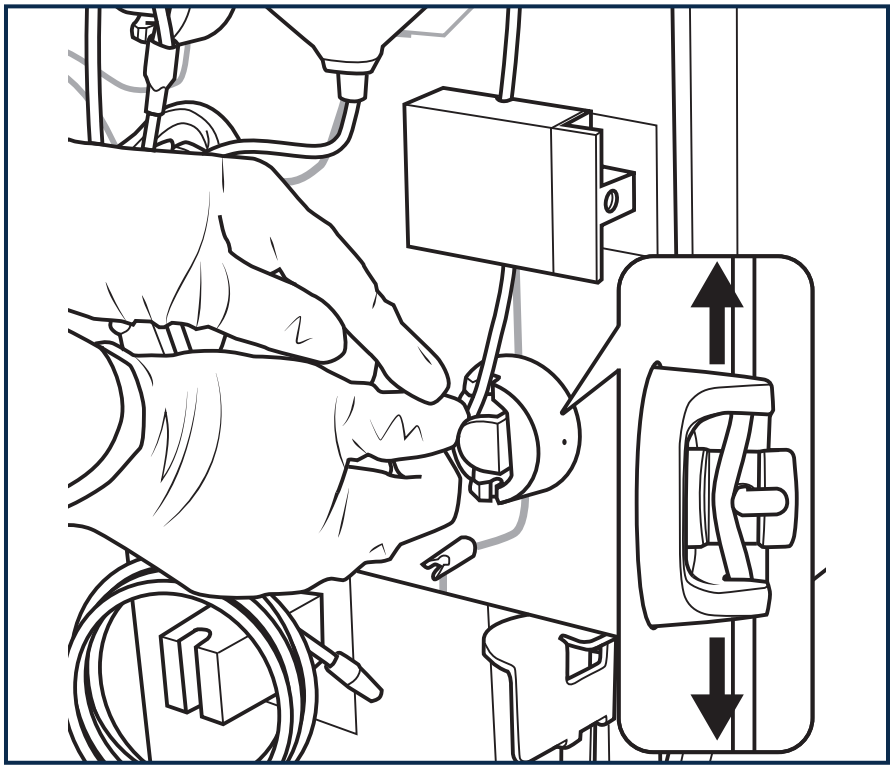
Figure 59: Insert Plasma Line into Hb Detector



5. Insert the tubing into the plasma clamp.

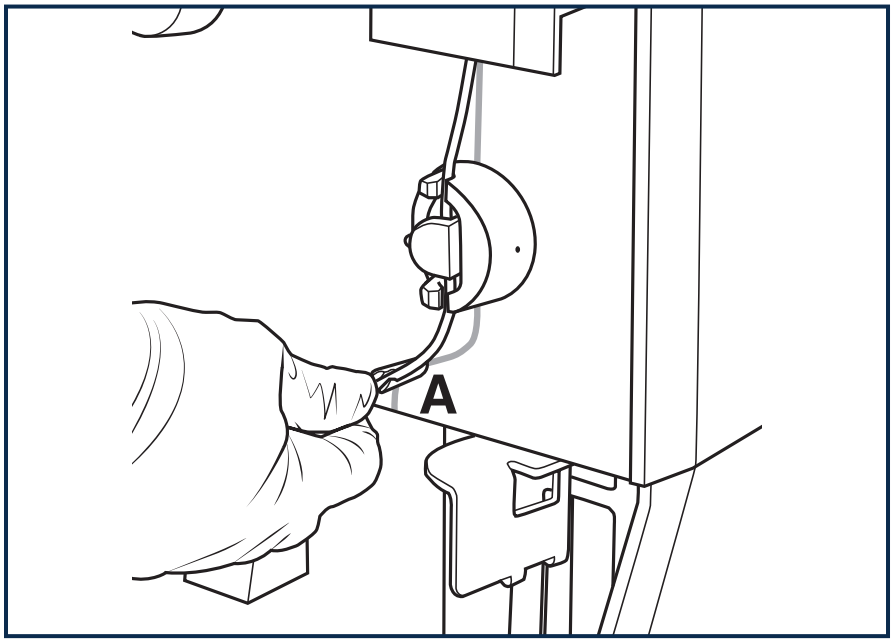
6. To properly center the tubing within the clamp, gently slide the tubing up and down until it is well aligned.

Figure 60: Insert Plasma Line into Plasma Clamp



7. Insert the plasma line tubing into the tubing guide (A), below the plasma clamp.

Figure 61: Insert Plasma Line into Tubing Guide



Install the Saline Line

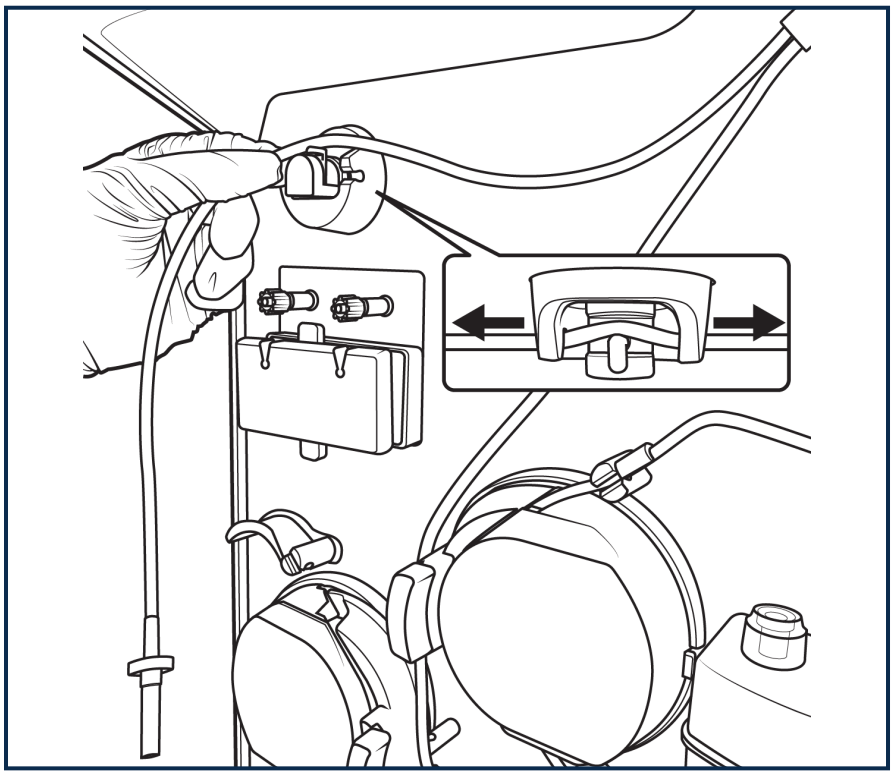
1. Remove the outermost disposable set tape that keeps all tubing together.

2. Remove the tape that includes the saline line.

3. Insert the tubing from the top of the separator into the saline clamp.

4. To properly center the tubing into the clamp, gently slide the tubing back and forth until it is well aligned.

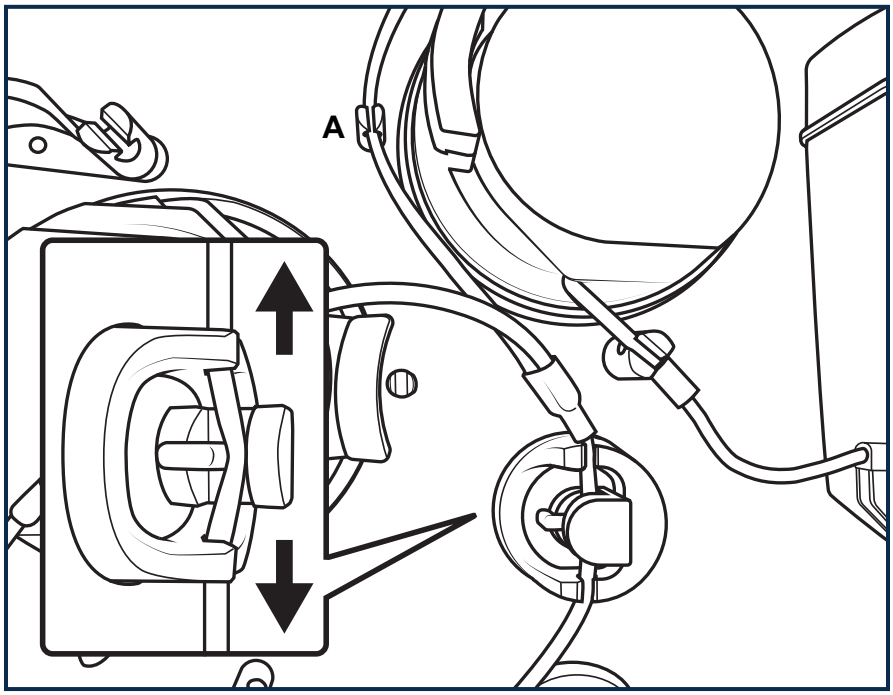
Figure 62: Install Saline Line



Install the Blood Line (Part 1 of 2)

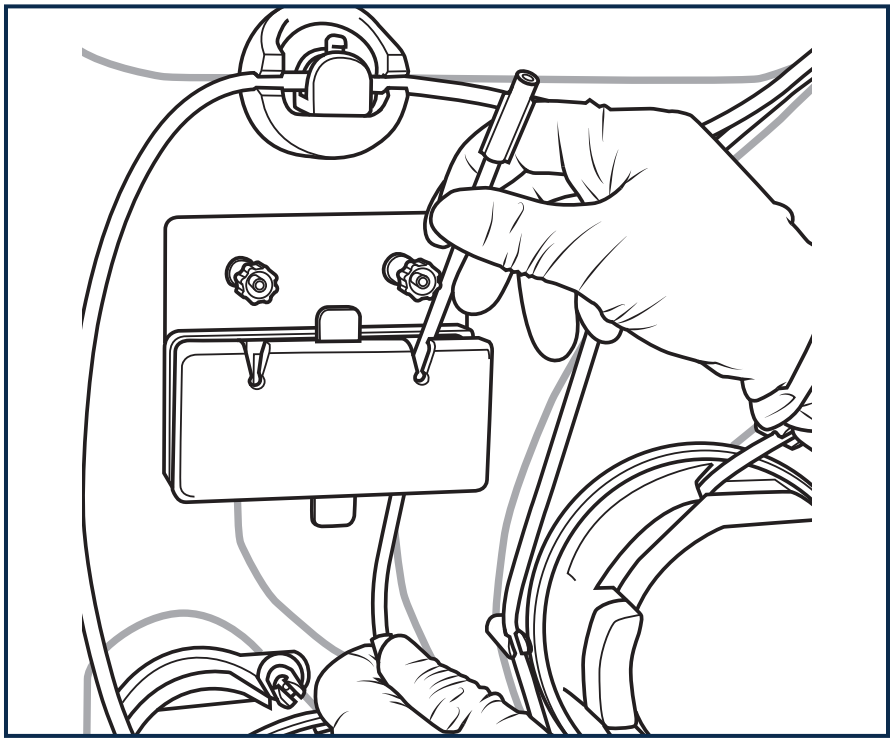
1. Insert the upper separator tubing into the tubing guide left of the cell pump (A), and insert the tubing through the blood clamp.
   - The Y4 connector should be supported by the blood clamp.
2. To properly center the tubing into the clamp, gently slide the tubing up and down until it is well aligned.

Figure 63: Install Blood Line into Tubing Guide and Blood Clamp



3. Install the P2 line.
4. Loop the P2 line tubing through the right side of the pressure transducer cover.
5. Align the tubing to the top and bottom right-side slots on the pressure transducer assembly.

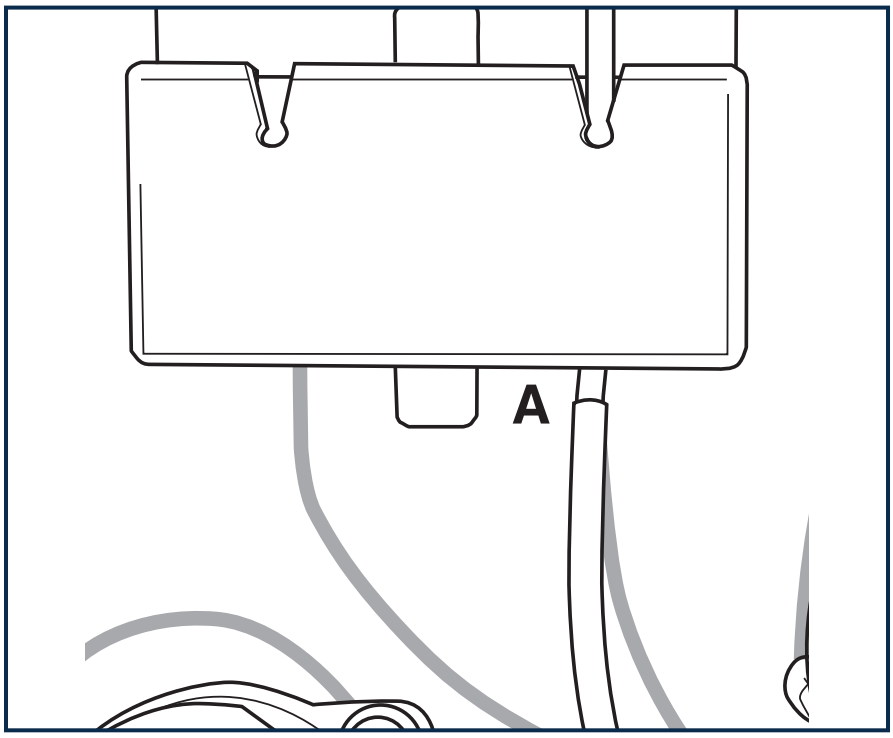
Figure 64: Insert P2 Line in Pressure Transducer Assembly



6. Check the P2 line position.

7. Ensure the larger diameter tubing section is completely below the pressure transducer assembly (A).

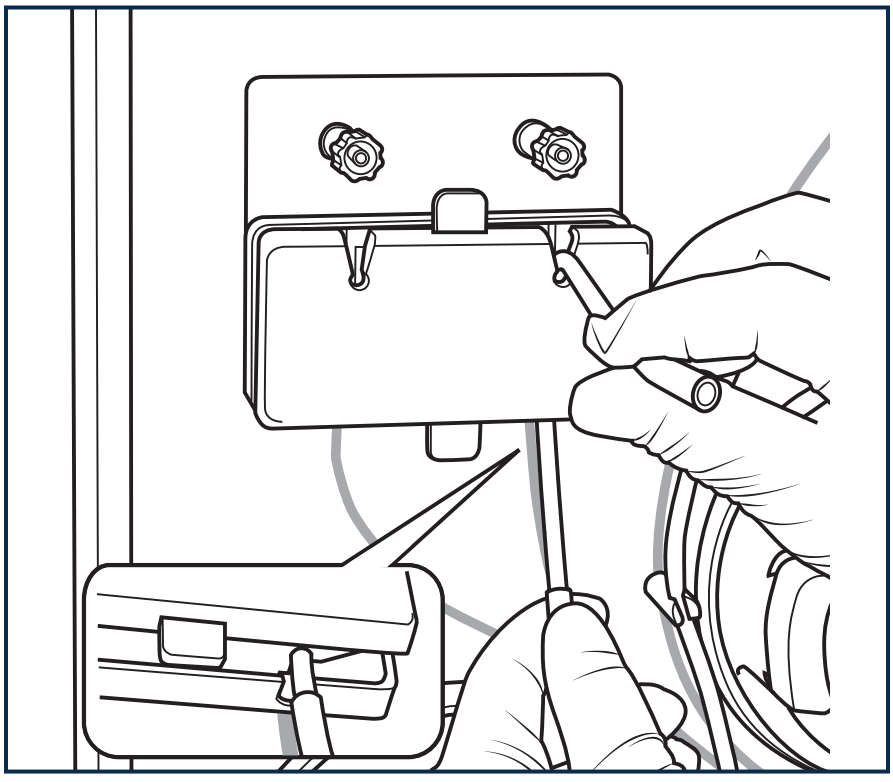
Figure 65: Check P2 Line Position



8. Seat the P2 line tubing in the top-right and bottom-right pressure transducer slots by pulling the tubing forward.

9. Ensure the tubing is seated in the bottom-right slot.

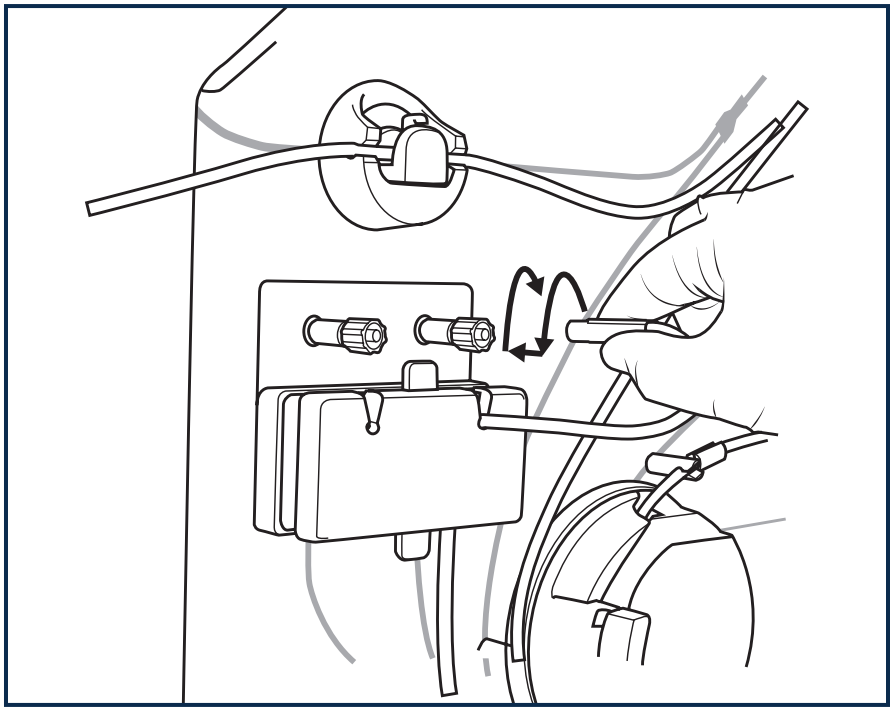
Figure 66: Seat P2 Line in Pressure Transducer Slots



Install the P2 Luer

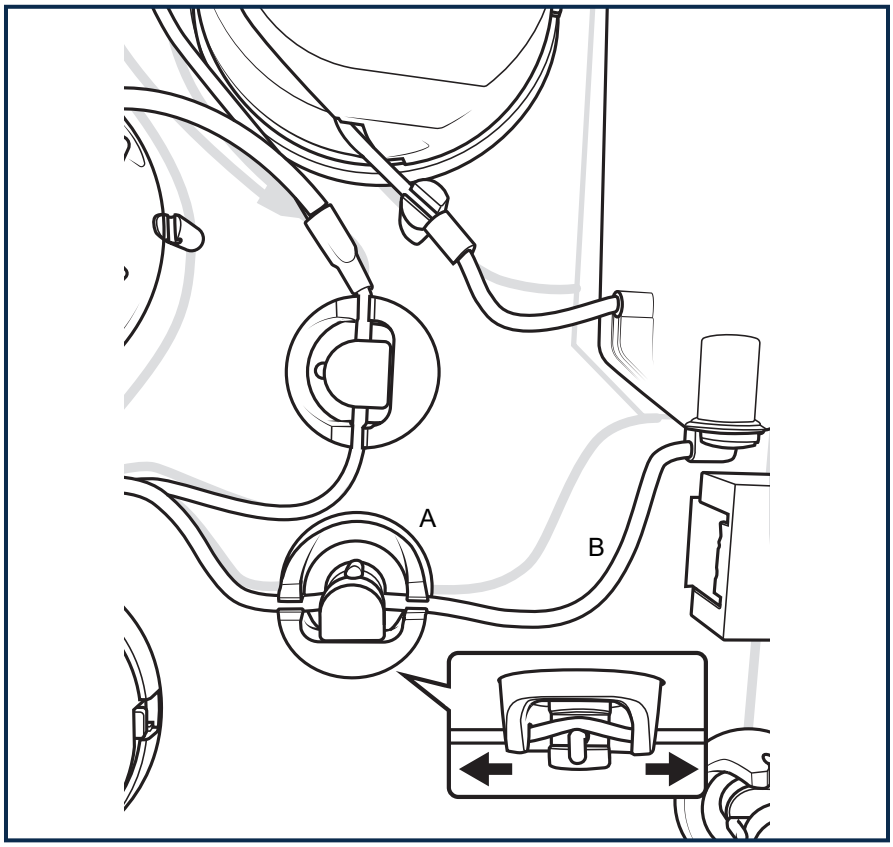
1. Position the P2 Luer in front of the P2 connector.
2. Turn the Luer counterclockwise approximately 1/4 turn, insert the Luer into the connector, and lock by turning clockwise.
   - Turning the Luer counterclockwise before install minimizes possible line kinks from the P2 Luer install.
3. Ensure the Luer is properly secured into the P2 connector.

Figure 67: Install the P2 Luer



4. Install the reinfusion line.
5. Insert the tubing from the bottom of the reservoir through the reinfusion clamp (A).
6. Gently slide the tubing in the reinfusion clamp so that the tubing from the reservoir to the reinfusion clamp (B) follows the tubing routing diagram on the front panel of the device.
   - This allows for a gentle curve in the line, which reduces the risk of unnecessary stress on the reservoir weigh scale.

Figure 68: Install Reinfusion Line



Install the Blood Line (Part 2 of 2)

CAUTION

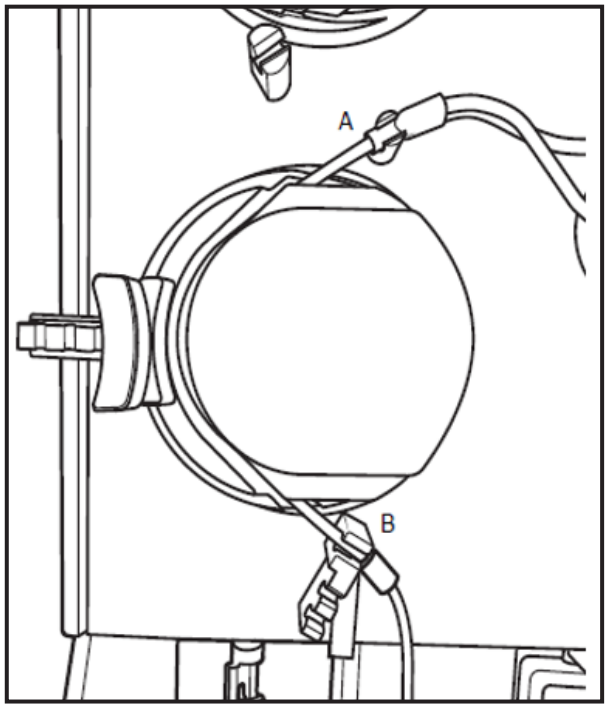
- Verify that the tubing is centered on the pump rollers. Push the pump lines back as far as possible in the pump. Slack in the line or forcing the pump handle to close over improperly positioned tubing may cause damage to the tubing.
- Improper installation of tubing in the pumps may affect flow rate accuracy, impact efficiency of the procedure, cause leaks, or lead to hemolysis.
- An improperly loaded disposable set can cause kinks which can lead to hemolysis. Ensure there are no twists or kinks present in the disposable set that restrict the inner diameter of the tubing to smaller than the inner diameter of the needle.
- Ensure that the tubing keepers are loaded on the correct side of the tubing guides.

1. If the blood pump top tube guide (A) is a small, round tube guide, insert the Y3 connector into the tubing guide (A) above the blood pump by threading the tubing into the Y; do not push the Y3 connector into the tubing guide from the front.

2. If the tube guide is a large tube guide, insert the blood pump tubing into the tubing guide (A) above the blood pump.

   - Positioning the Y3 connector perpendicular to the device panel minimizes the trapping of air in the Y3 connector.

Figure 69: Install Blood Line



3. Insert the tubing on the blood pump rollers. Ensure the position of the tubing is centered on the blood pump rollers. Push the pump lines back as far as possible in the pump.

4. Insert the tubing into the top-guide of the multi-tubing guide, below the blood pump (B). Ensure the tubing keeper (gray) is on the right (flat) side of the tubing guide.

NOTE

- If Y3 emerges from the top of the blood pump during the procedure, do not push it back in. The tubing guides are intended to allow excess tubing to emerge out.

5. Close the pump by turning the pump handle (blue) counterclockwise.

Install the Donor Line

WARNING

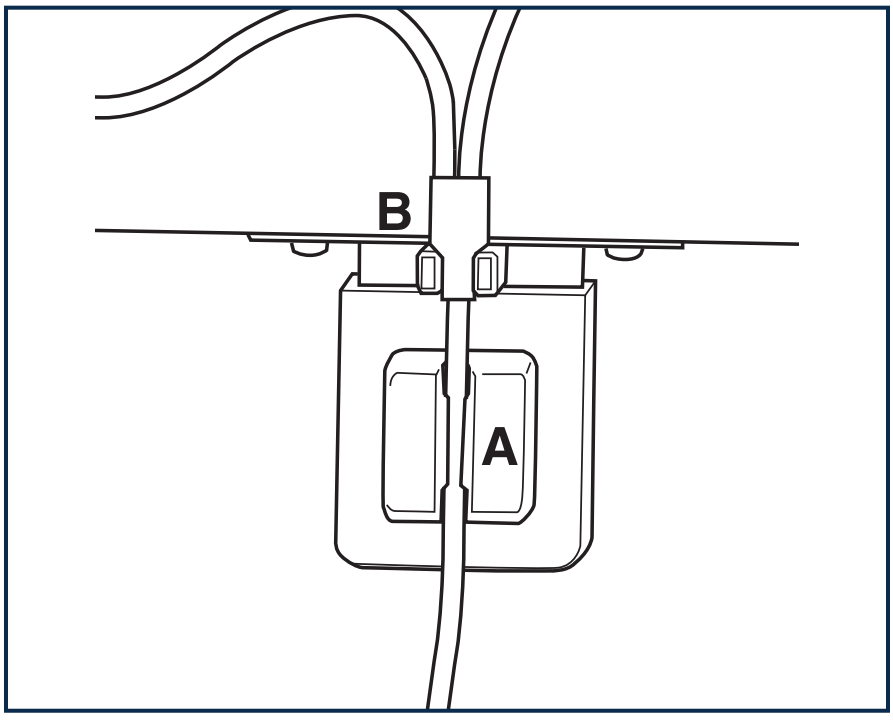
- The air detector and the outside of tubing installed in the air detector must be clean and dry during disposable set installation and the procedure, to ensure proper functioning of the air detector.
- If the donor line is removed from the air detector, ensure that the correct line is reinstalled to maintain effective air detection.

NOTE

- Do not use the device if air detector appears to be damaged (e.g., deformation or cracks).

1. Insert the donor line into the air detector assembly (A).
2. Gently slide the line up and down until it is secure in the assembly and the Y2 connector is supported by the tubing guide (B).
3. Ensure the tubing is fully seated in the air detector assembly (A).

Figure 70: Install the Donor Line

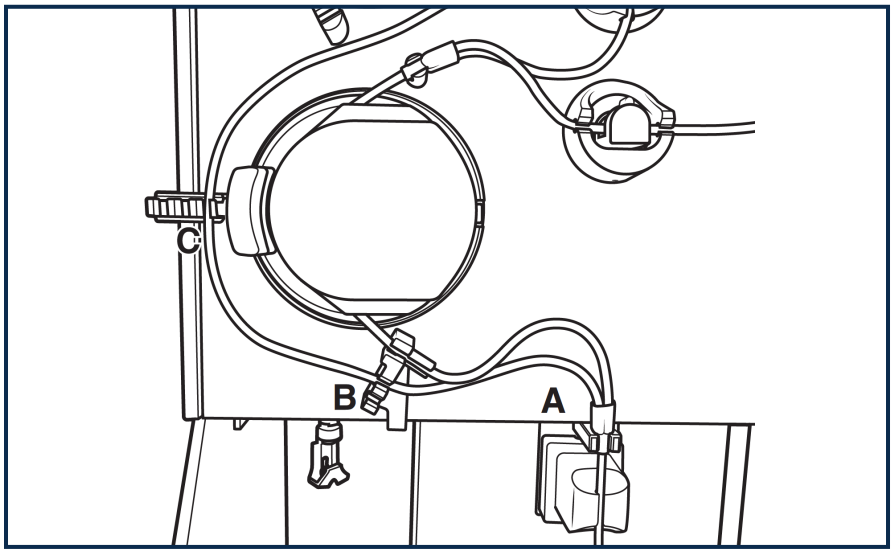


Install the P1 Line

1. Insert the tubing (A) into the middle slot of the multi-tubing guide (B), below the blood pump.

2. Insert the tubing into the right slot of the multi-tubing guide (C), left of the blood pump.

Figure 71: Insert P1 Line into Multi-Tubing Guides



3. Insert the tubing into the tubing guide (A), right of the AC pump.

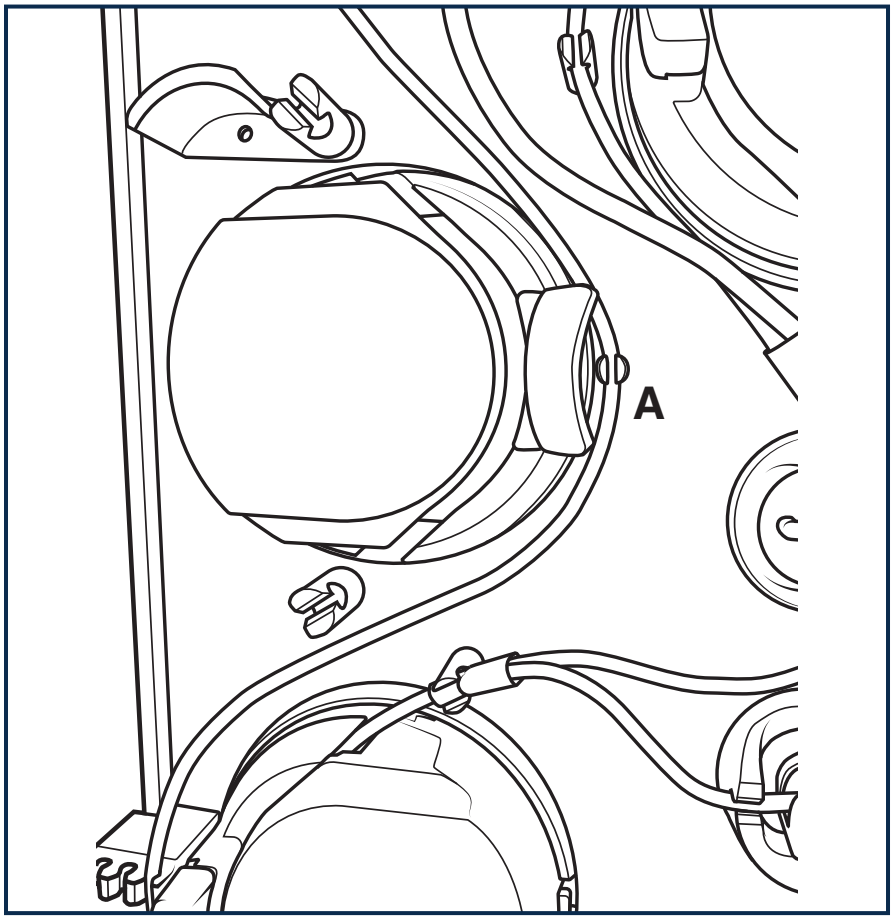
4. Loop the P1 line tubing through the left side of the pressure transducer cover.

5. Align the tubing to the top and bottom-left side slots on the pressure transducer assembly.

6. Seat the P1 line tubing in the top-left and bottom-left side pressure transducer slots by pulling forward, leaving approximately the same size loop as the P2 line.

7. Ensure the tubing is seated in the bottom-left pressure transducer slot.

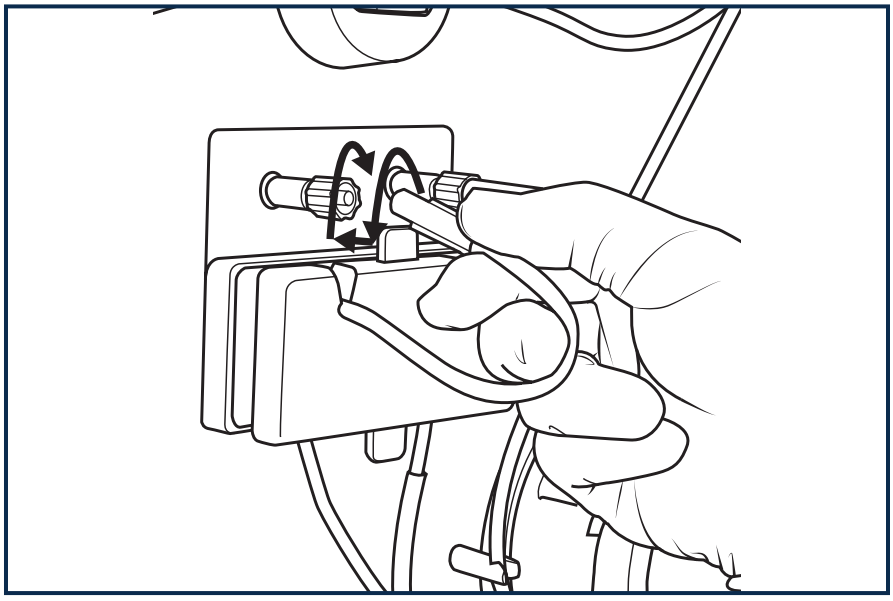
Figure 72: Insert P1 Line into Tubing Guide



Install the P1 Luer

1. Position the P1 Luer in front of the P1 connector.
2. Turn the Luer counterclockwise approximately 1/4 turn, insert the Luer into the connector, and lock by turning clockwise.
   - Turning the Luer counterclockwise before install minimizes possible line kinks from the P1 Luer install.
3. Ensure the Luer is properly secured into the P1 connector.

Figure 73: Install the P1 Luer

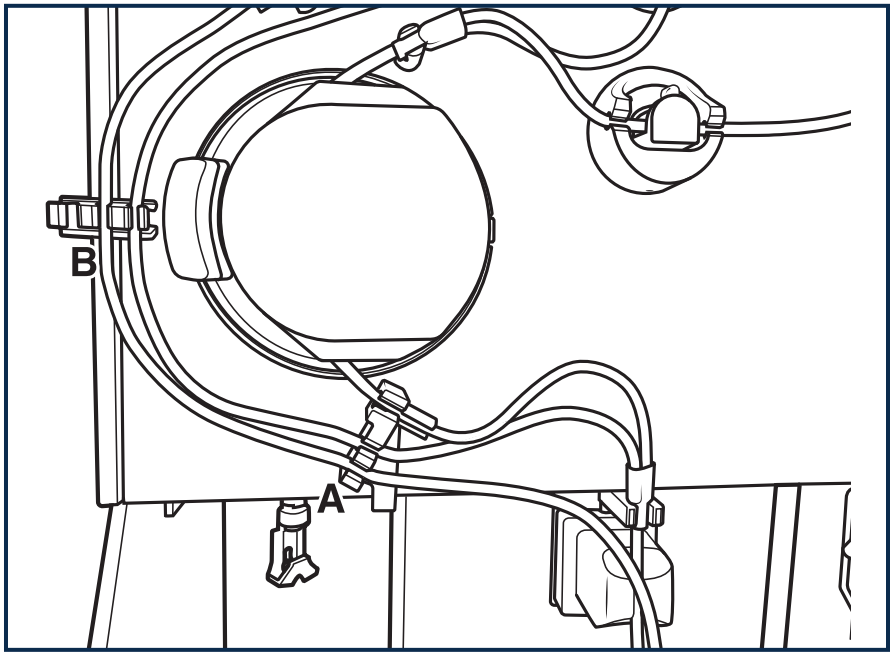


4. Close the pressure transducer cover by pushing gently on the top and bottom (blue) cover tabs.

Install the AC Line

1. Remove the AC line disposable set tape.
2. Insert the AC line into the bottom slot of the multi-tubing guide (A), below the blood pump.
3. Insert the tubing into the middle slot of the multi-tubing guide (B), left of the blood pump.

Figure 74: Insert the AC Line into Multi-Tubing Guides



4. Insert the tubing into the tubing guide below the AC pump (B).

5. Ensure the tubing keeper (red) is touching the left (flat) side of the tubing guide.

6. Insert the tubing on the AC pump. Push the pump lines back as far as possible in the pump.

7. Ensure the AC line is centered on the AC pump rollers.

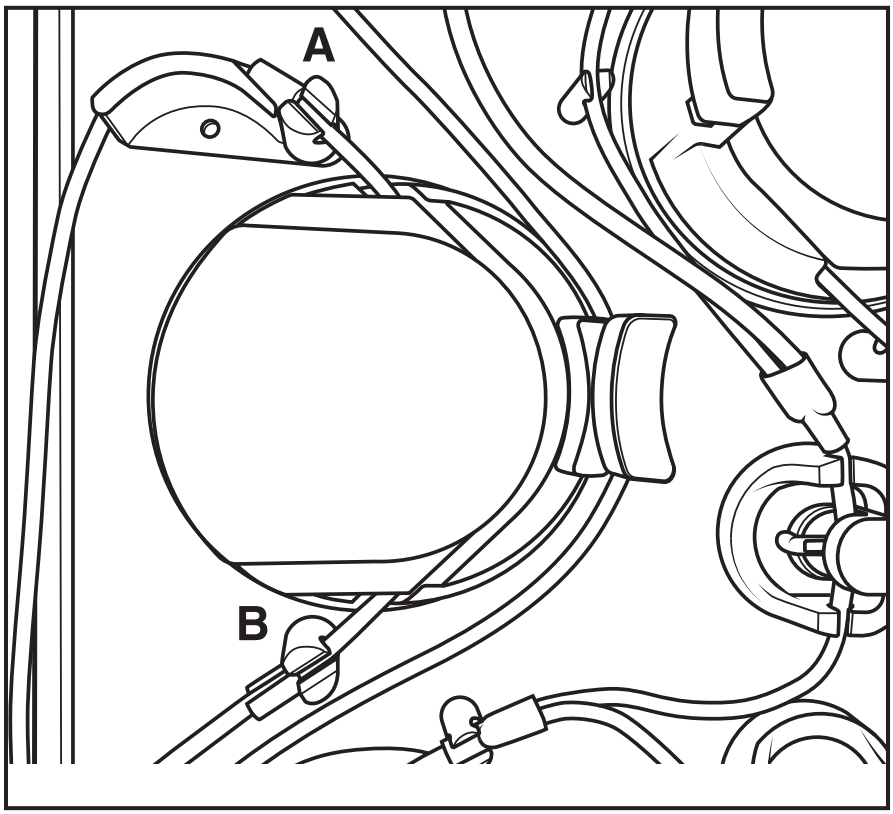
8. Insert the tubing into the tubing guide above the AC pump (A). Ensure the tubing keeper (red) is on the left (flat) side of the tubing guide.

CAUTION

- Verify that the tubing is centered on the pump rollers. Push the pump lines back as far as possible in the pump. Slack in the line or forcing the pump handle to close over improperly positioned tubing may cause damage to the tubing.
- Improper installation of tubing in the pumps may affect flow rate accuracy, impact efficiency of the procedure, cause leaks, or lead to hemolysis.
- Ensure that the tubing keepers are loaded on the correct side of the tubing guides.

9. Close the AC pump by turning the AC pump handle (blue) counterclockwise.

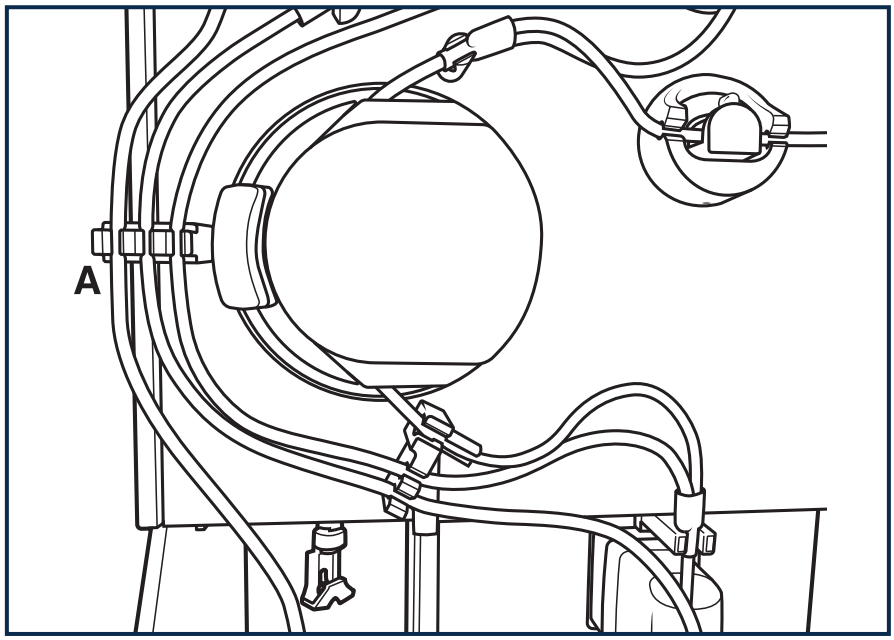
Figure 75: Insert the AC Line into Tubing Guides



10. Insert the AC tubing into the left slot of the multi-tubing guide (A), left of the blood pump.

11. Use caution not to pull the top AC tubing keeper (red) away from the tubing guide at the top of the AC pump.

Figure 76: Insert the AC Line into Tube Guide

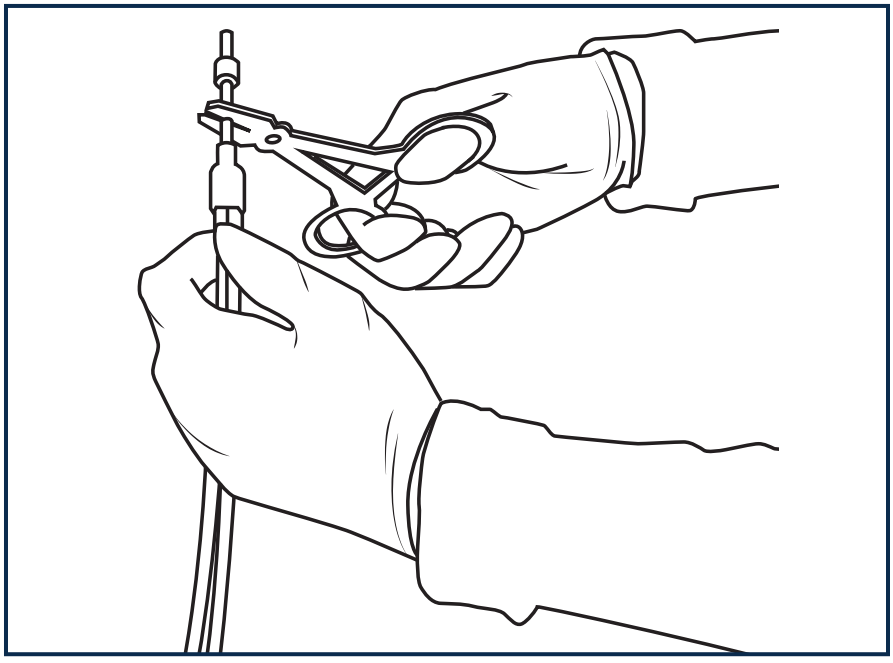


Kit Install Wrap-Up

1. Use a hemostat to clamp the donor short line between the Y1-connector and the needle connector.

2. Inspect the installed disposable set for twists and kinks.

Figure 77: Clamp the Disposable Set with Hemostat



NOTE

➔ Do not hang hemostats on any of the weigh scale hangers. Unexpected weight on any of the weigh scales may cause alerts/alarms.

CAUTION

➞ An improperly loaded disposable set can cause kinks which can lead to hemolysis. Ensure there are no twists or kinks present in the disposable set that restrict the inner diameter of the tubing to smaller than the inner diameter of the needle.

Installing a Plasma Collection Container

1. Place the plasma collection container on the plasma weigh scale hanger such that the weigh scale moves freely and there is no interference from a twisted plasma line or external objects (e.g., donor line tubing, cuff tubing, donor's clothing).

CAUTION

➞ Verify that the plasma collection container is properly installed and aligned to prevent inaccurate weight readings.

➞ Only use the longer plasma collection bag with the elongated container shroud to prevent inaccurate weight readings.

2. If the disposable set does not have an integral plasma collection container, use aseptic technique to connect the plasma collection container to the plasma line.

3. The plasma collection container and line must hang freely.

4. Ensure that there are no kinks in the plasma line.

Max Duration Time for Installed Disposable Set

This information concerns the length of time a Plasmacell-C Disposable Set can remain installed on the Aurora Xi device, or out of its protective pouch, prior to use.

The allowed time depends on if the disposable set has been installed on the device and if the solutions have been connected to the disposable set.

The allowed time is defined in the following examples:

Example 1: The disposable set has been installed onto the device, the solution(s) are connected to the set, and the disposable set is primed with either saline or anticoagulant.

The disposable set can remain unused on the device for no more than four (4) hours after the solution containers have been connected.

Example 2: The disposable set has been installed onto the device and the solution(s) have NOT been connected to the disposable set. The plasma collection container has not yet been connected to the plasma line.

The set may remain partially installed overnight (up to 24 hours), provided the following steps are followed.

Disposable Set Partial Uninstallation

1. After installing a Plasmacell-C Disposable Set, uninstall parts of the disposable set from the device as follows:
   - Remove tubing from all clamps
   - Open all pump covers
   - Disconnect both tubing lines from the P1 and P2 pressure transducers
   - Open the transducer cover

WARNING

→ All protective covers on the disposable set must remain intact to maintain the disposable set sterile fluid path.

2. Follow the proper shut down procedure per the current Aurora Xi Operator's Manual and turn the device power switch to the OFF position until the next procedure is scheduled to begin.

To resume and complete the disposable set installation:

3. Turn the device power switch to the ON position.

4. Proceed to the **Install Set** screen as defined in the current Aurora Xi Operator's Manual and perform the following steps:

   - Load tubing into clamps
   - Close all pump covers
   - Reconnect the tubing lines to the P1 and P2 pressure transducers
   - Close the transducer cover

5. Visually verify that the disposable set is correctly installed and touch the **Check** button to begin the Install Check.

WARNING

→ All protective covers on the disposable set must remain intact to maintain the disposable set sterile fluid path.

Example 3: The disposable set has been removed from its pouch but is not yet installed onto a device.

The set may remain out of its pouch overnight (up to 24 hours), provided that all protective covers on the disposable set remain intact to maintain the disposable set sterile fluid path.

CAUTION

→ The device must be used and stored in the proper operating environment (e.g., temperature, humidity, altitude, and surface incline requirements).

Section 4.5: Performing Install Check and Priming Solutions

Ensure that the disposable set is properly installed (e.g., separator installation, plasma collection container, and the collection container connection).

Start Install Check

CAUTION

- After Install Check, do not disturb the reservoir, the cell line, or the reinfusion line to avoid reservoir scale alerts.

NOTE

- Do not open any pump handle at any time between disposable set Install Check and disposable set removal, except when directed by troubleshooting instructions.
- Do not open the Hb detector assembly door at any time between disposable set Install Check and disposable set removal, except when directed by troubleshooting instructions.
- Do not open the lower separator support, adjust the alignment of the separator, or squeeze the separator at any time between disposable set Install Check and disposable set removal, except when directed by troubleshooting instructions.

The Install Check sequence does not verify the following parts of the system:

- Proper separator installation
- Proper disposable set integrity around reservoir
- Proper tubing installation to the air detector (checked in later procedure sequences)

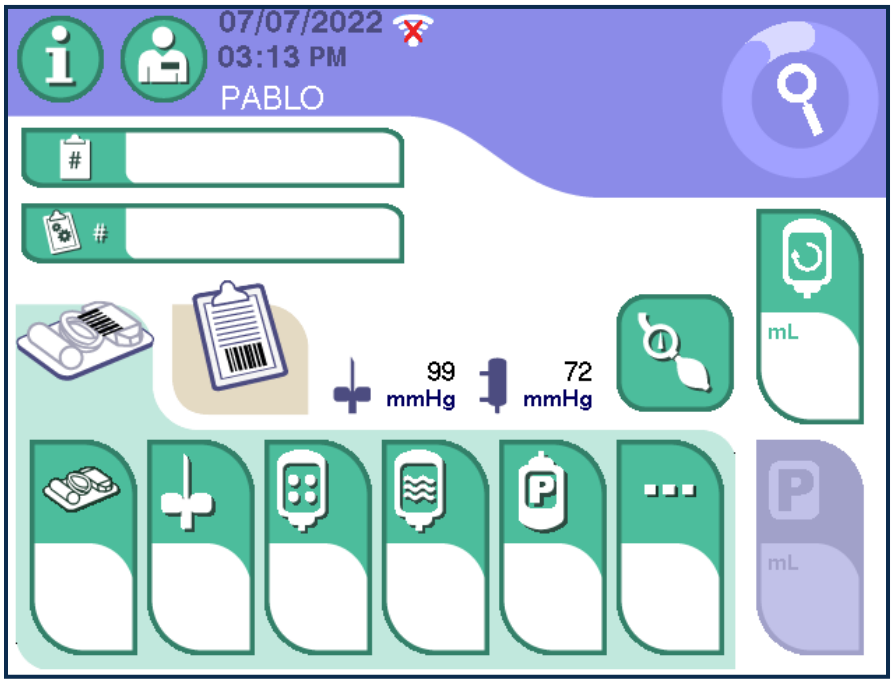
If Install Check is not successful, the corresponding alert/alarm messages are displayed. For detailed information about alerts/alarms, see **"Chapter 5 Troubleshooting"**.

After the disposable set is installed, tap the **Check** button to start Install Check.

The animated **Self-Check** icon is displayed until the Install Check is complete.

During Install Check, the pumps run intermittently and clamps open and close.

Figure 78: Typical Data Entry Screen – Install Check



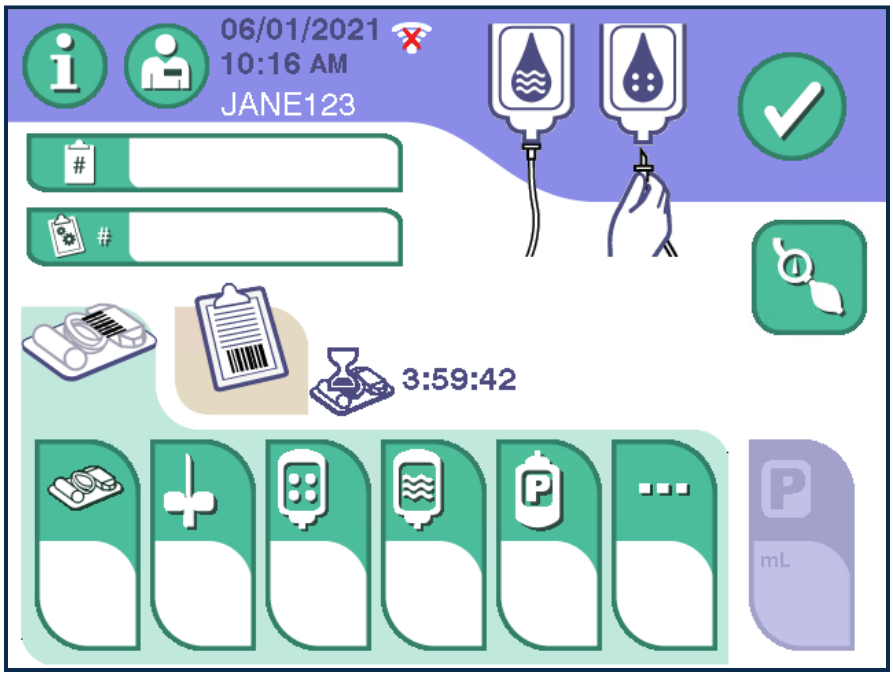
Disposable Set Timer

When Install Check is successful, the **Set Timer** icon is displayed.

The timer indicates the total time remaining to prime the set, enter donor data, perform venipuncture, and begin the procedure.

The disposable set timer starts to count down.

Figure 79: Typical Data Entry Screen – Set Timer

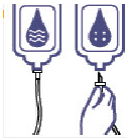


The disposable set can be installed up to four hours before beginning the procedure, per the administrative settings.

If the procedure has not yet started and when the disposable set timer reaches zero (0), an alert/alarm is generated. The disposable set and all connected ancillaries should be sealed, removed, and properly disposed. Start a new procedure and install a new disposable set (see **"Chapter 5 Troubleshooting"**).

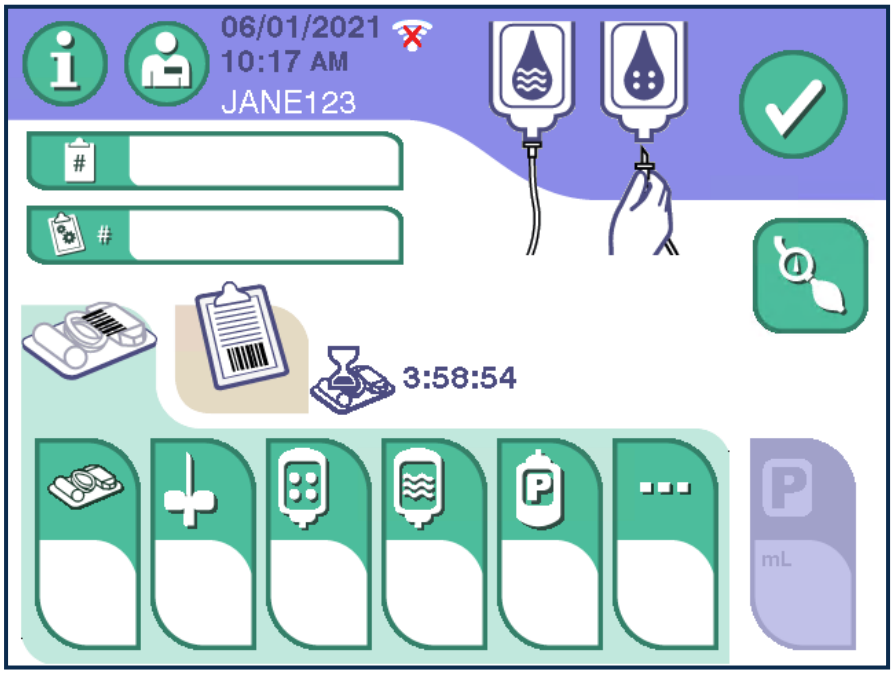
Connecting Solutions and Priming

When the Install Check is successful, the touchscreen displays a **Connect AC Container and Saline Container** prompt



or a **Connect AC Container** prompt.

Figure 80: Typical Data Entry Screen – Connect Solutions Prompt



CAUTION

- Ensure proper connection of solution containers so that there is no leakage at the connection site.
- While connecting solutions, do not interchange the AC and saline lines. Ensure the red AC connector is connected to the AC container.

NOTE

- For a No Saline Protocol, hang and connect only the AC container. The **Saline** icon will not appear on the **Connect AC Container** prompt.

AC Container

CAUTION

→ After spiking the AC solution container, ensure that there are no air pockets in the AC container around the ports.

1. Hang the AC container on the AC weigh scale hanger.
2. Remove the plastic protective cap from the AC spike.
3. Connect the red AC line spike completely to the AC container.
4. The AC container and line must hang freely.
5. Tap the bottom port of the AC container several times to dislodge any bubbles from the port.

Saline Container (Saline Protocol Only)

NOTE

→ Do not use the device if a solutions pole or compatible saline container hook is not installed.

1. Hang the saline container on the saline solution pole.
2. Remove the plastic protective cap from the saline connector.
3. Connect the clear saline spike/Luer to the saline container.
4. Ensure that the port and saline lines are not kinked.
5. Tap the bottom port of the saline container several times to dislodge any bubbles from the port.

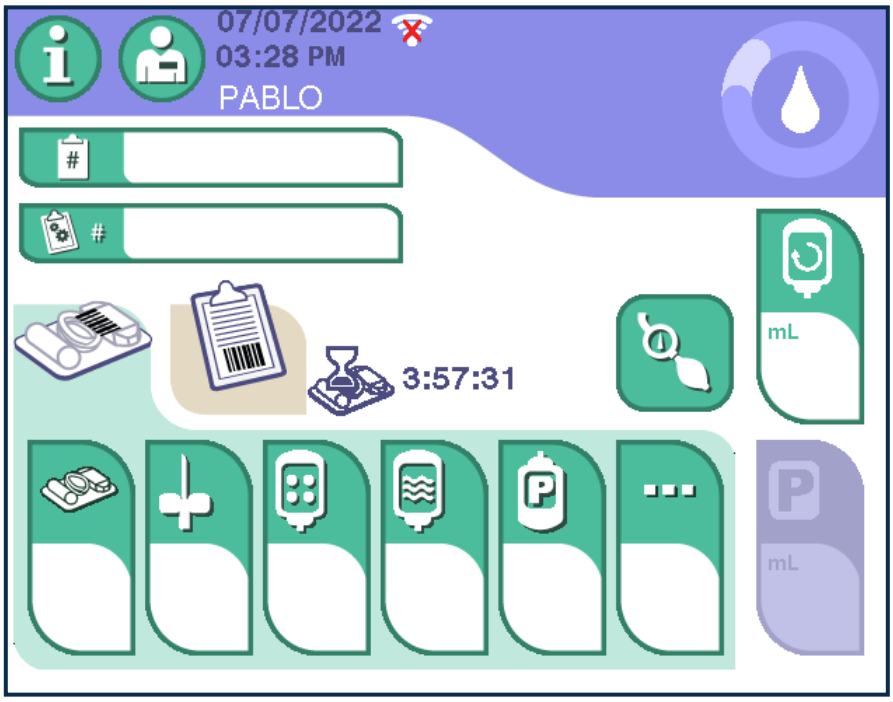
Prime Solutions

NOTE

- Solutions containers should be hung vertically when removing air pockets around the ports where the solution spikes/Luers are connected, in order to prevent alerts/alarms and/or improper priming.
- Verify the AC container is stable on the weigh scale and not moving before tapping the **Check** button.
- Alerts resulting from interference with the reservoir scale may require procedure termination.

1. Tap the solution container ports several times to dislodge any bubbles from the ports.
2. Tap the **Check** button. The animated **Prime** icon is displayed.

Figure 81: Typical Main Data Entry Screen – Prime Icon

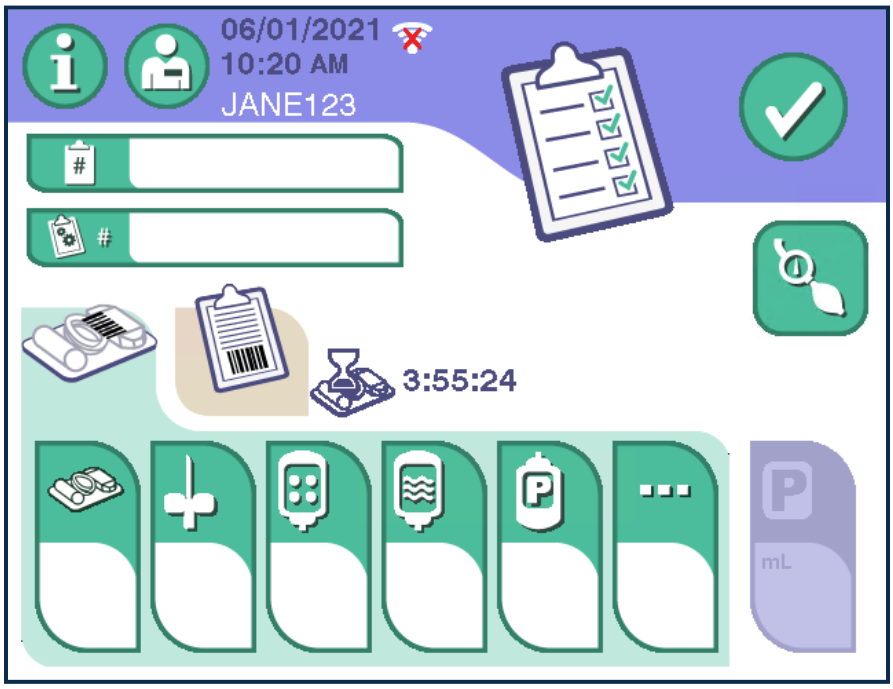


Entering and Confirming Data

After priming ends, the **Enter Data** screen displays on the touchscreen. View and make data entries on this screen.

Tap the appropriate data entry buttons to make changes or enter remaining data.

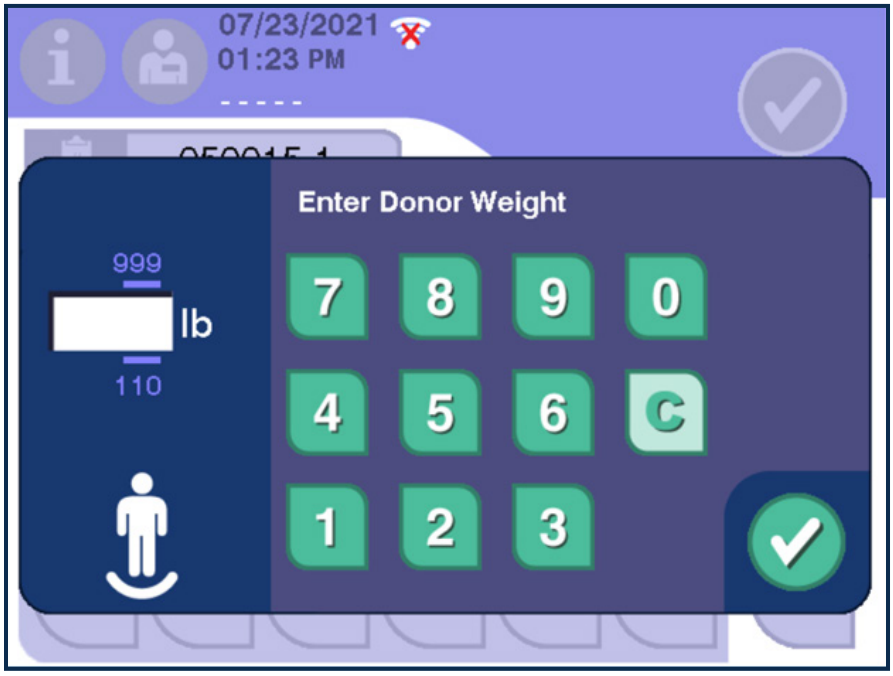
Figure 82: Typical Enter Data Screen



Tap the **Check** button once data is entered.

If Two-Pass Verification is configured in administrative settings, an overlay for re-entering donor data (donor gender, donor height, donor weight, and/or donor hematocrit or hemoglobin) displays.

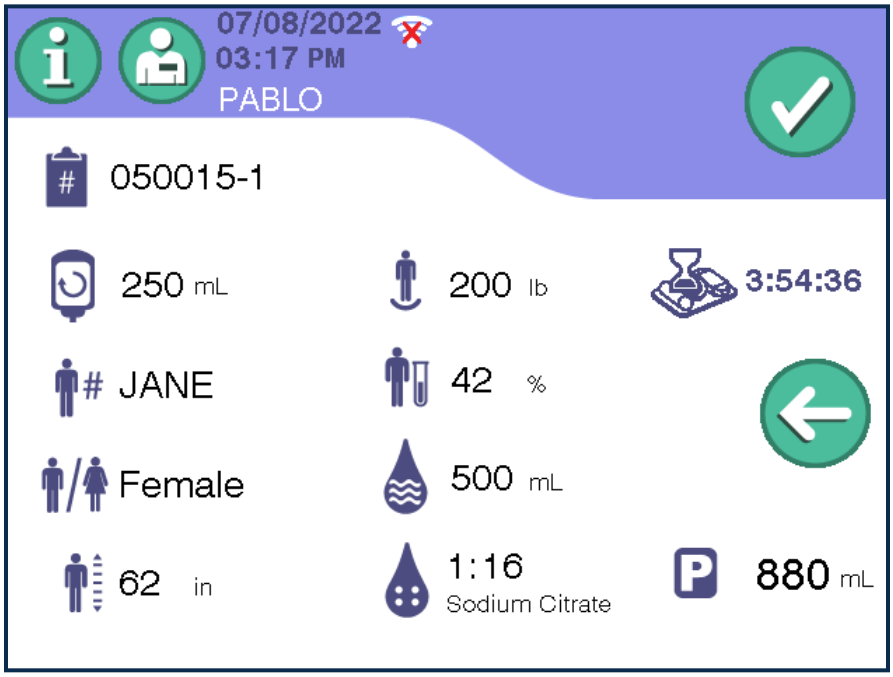
Figure 83: Typical Two-Pass Verification Overlay



Once Two-Pass Verification of donor data completes, or if Two-Pass Verification was not configured in administrative settings, the **Procedure Data Confirmation** screen displays.

If changes are needed, tap the **Back** button to return to the **Data Entry** screen.

Figure 84: Typical Procedure Data Confirmation Screen



WARNING

- Confirm that the correct donor weight, donor height, donor gender, and donor hematocrit or hemoglobin are displayed on the touchscreen when information is manually entered or scanned using a barcode scanner. Incorrect information may lead to additional red blood cell (RBC) loss, excess blood loss, overcollection of plasma, and/or a higher-than-intended citrate infusion rate (CIR).
- Confirm that the correct procedure ID or donation setup ID is displayed on the touchscreen. Incorrect information may lead to red blood cell (RBC) loss, hemolysis, and/or incorrect saline infusion volume.

NOTE

- Confirm that the correct target saline infusion volume is displayed on the touchscreen. Incorrect information may lead to over-infusion or under-infusion of saline.

Review all data entries displayed on the **Procedure Data Confirmation** screen. Tap the **Check** button to confirm all entries.

Section 4.6: Entering Donor and Procedure Information Using Remote Communication

If your system is configured to receive information through a communication system approved by the device manufacturer, the donor and procedure information can be imported using the following steps.

WARNING

➞ Confirm that the correct procedure ID or donation setup ID is displayed on the touchscreen. Incorrect information may lead to red blood cell (RBC) loss, hemolysis, and/or incorrect saline infusion volume.

NOTE

➞ The system will not proceed to the venipuncture display until all required donor and procedure information is entered.

➞ The device is set to PULL with procedure ID, PULL with donation setup ID, PUSH with procedure ID, or PUSH with donation setup ID (see the Administrator's Guide for more information).

1. If the device is set to PUSH with procedure ID or PUSH with donation setup ID, the administrator pushes a procedure setup file to a selected Aurora Xi device.

2. If the device is set to PULL with procedure ID or PULL with donation setup ID, enter the procedure ID or donation setup ID as required per the center's SOPs using one of the following methods:

   - scan the procedure ID or donation setup ID barcode, or
   - if unable to scan the procedure ID or donation setup ID barcode, tap the **Procedure ID** or **Donation Setup ID** button and enter the information manually.

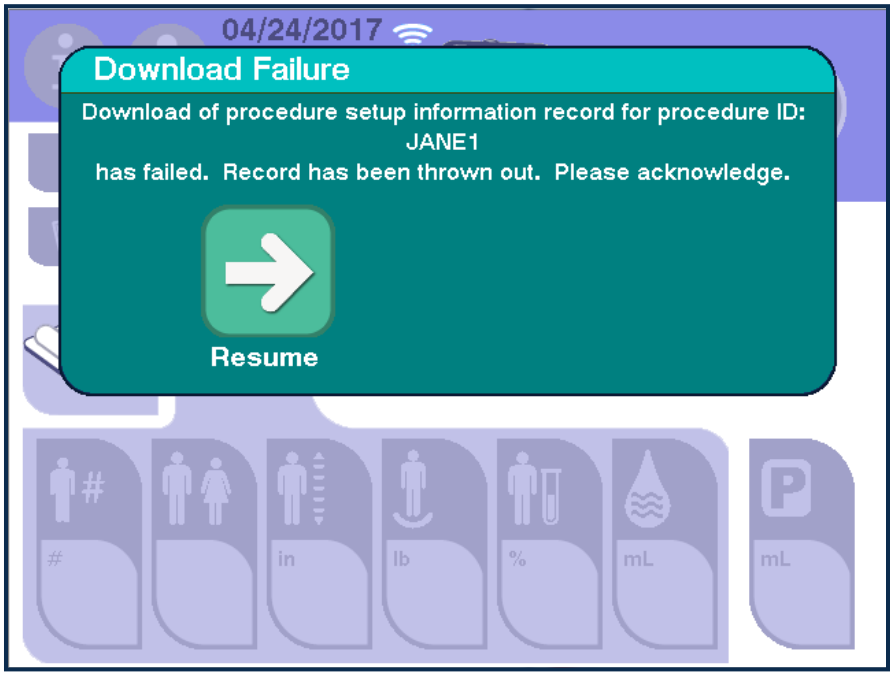
3. The entered procedure ID or donation setup ID is used to retrieve the corresponding procedure setup file from the data management system.

   - Retrieval of the procedure setup file from the data management system may take a few minutes. When complete, the **Retrieving Record...** overlay displays.

Figure 85: Typical Retrieving Record... Overlay

4. If the entered ID does not correspond to a procedure setup file on the data management system, the **Download Failure** overlay displays.

Figure 86: Typical Download Failure Overlay



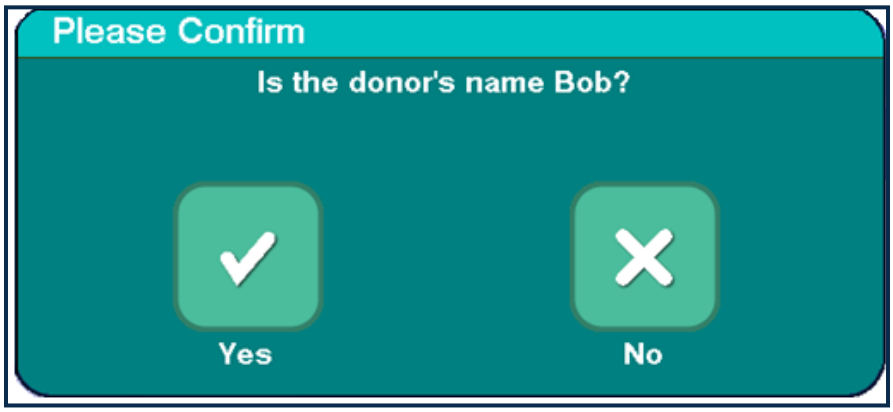
5. Once the procedure setup file is pushed or pulled onto the device, confirmation questions and/or questionnaires may be displayed on the **Main Data Entry** screen of the device.

NOTE

→ If the system is configured to require answers to questions to verify the donor, additional Confirmation and/or Questionnaire-type questions may appear on the touchscreen. If **No** is selected to any of the questions or a manually entered answer is incorrect, no procedure setup information is downloaded to the device. If the system does not populate the procedure parameters, manually enter the value by following the instructions in **"Section 4.3: Entering Procedure and Donor Information"**.

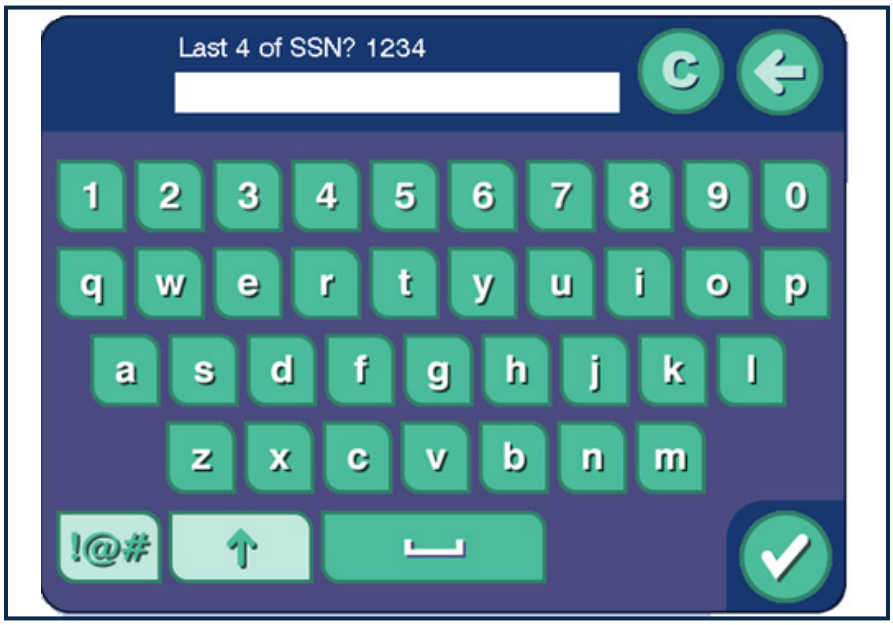
6. To answer a Confirmation Question, tap **Yes** or **No**.

Figure 87: Typical Confirmation Question Overlay



7. To answer a questionnaire, manually enter the answer using the keypad.

Figure 88: Typical Questionnaire Overlay



8. Once all questions are answered successfully, information contained in the procedure setup file populates the **Main Data Entry** screen.

WARNING

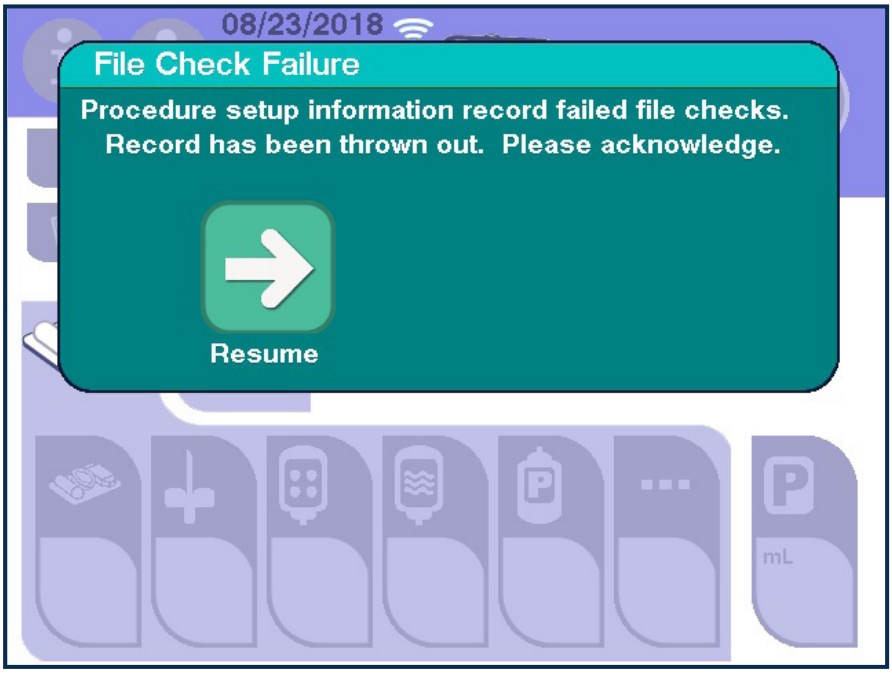
- Follow the center's SOPs for the appropriate target collection volume for the donor.

NOTE

- The device will not allow entry of touchscreen parameter inputs inconsistent with configured settings of the device's administrative settings. An audible tone and a flashing data button indicates entry of unacceptable data input.
- Procedure parameters present in the procedure setup file is displayed on the device touchscreen, even if the entry fields were disabled in Administrative Mode (see the Administrator's Guide for more information).
- If the Saline Protocol or parameter values (such as donor weight, donor weight units, and collection volume) fall outside the limits/settings, validation may fail. If any of the Confirmation Questions or Questionnaires were answered incorrectly, the procedure setup file will not populate on the **Main Data Entry** screen.

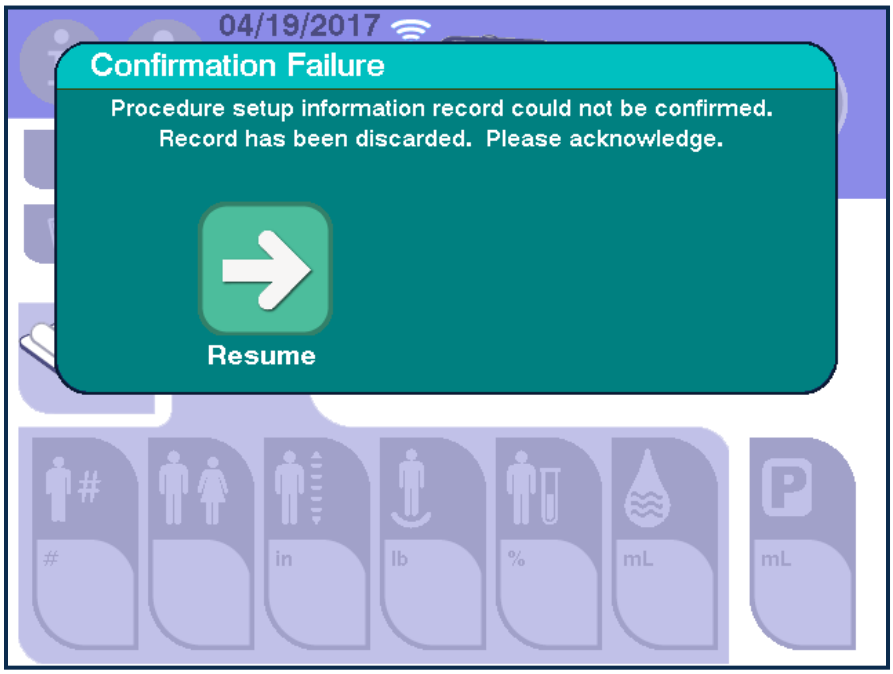
If any of the values contained within the procedure setup file are not within specified limits, file validation checks fail.

Figure 89: Typical File Check Failure Overlay



If a file check or confirmation failure occurs, information contained within the procedure setup file will not be populated on the **Main Data Entry** screen of the device.

Figure 90: Typical Confirmation Failure Overlay



Section 4.7: Performing Venipuncture and Starting Procedure

CAUTION

- Perform venipuncture according to center's SOPs.
- The operator should monitor the venipuncture site for any adverse effects (e.g., hematoma formation).
- The donor venipuncture site must be positioned above the fluid in a connected AC container, in order to provide redundant means of protection against citrate infusion.
- Secure the position of the fistula after venipuncture to reduce the likelihood of the needle being removed from the vein during the procedure.
- Do not attempt to clear the donor line, blood line or needle, or resolve a venipuncture problem by infusing saline to the donor.

NOTE

- Avoid contact with or disturbance to the device during venipuncture. Disturbance may lead to a weigh scale alert/alarm causing the cuff to deflate.

After the disposable set is installed and checked, the solution(s) are primed, and all the required procedure and donor data is entered and confirmed, the **Perform Venipuncture** prompt appears.

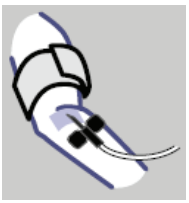
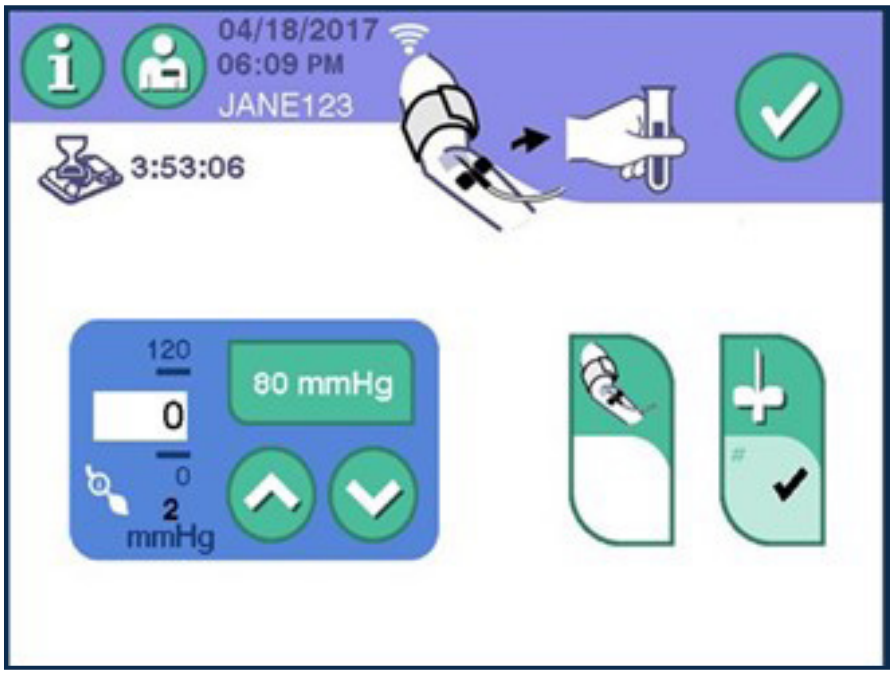


Figure 91: Typical Venipuncture Screen



When the **Venipuncture** screen displays, perform these steps:

1. Ensure that the pressure cuff is positioned properly and comfortably on the donor's arm.

CAUTION

- Ensure that the pressure cuff tubing is routed around the back of the device, not through the container shrouds, to avoid interference with the container weigh scales.

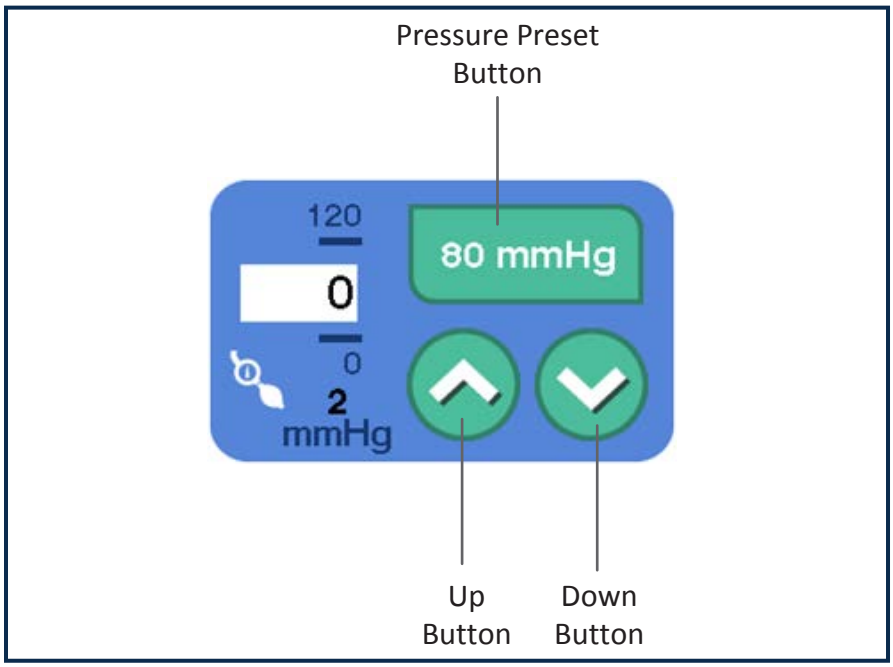
NOTE

- Use the appropriate cuff size range for the donor's arm. Use only cuffs that are approved by the manufacturer.
- Ensure that the pressure cuff tubing is free of restriction (e.g., kinks) when the cuff is attached to the donor.

2. Adjust the cuff pressure to the desired setting for determining venipuncture location and/or performing venipuncture. The actual cuff pressure is present to the right of the **Cuff** icon.

3. Use the **Up/Down** buttons or the **Pressure Preset** button on the **Venipuncture** screen.

Figure 92: Typical Cuff Pressure Adjustment Buttons



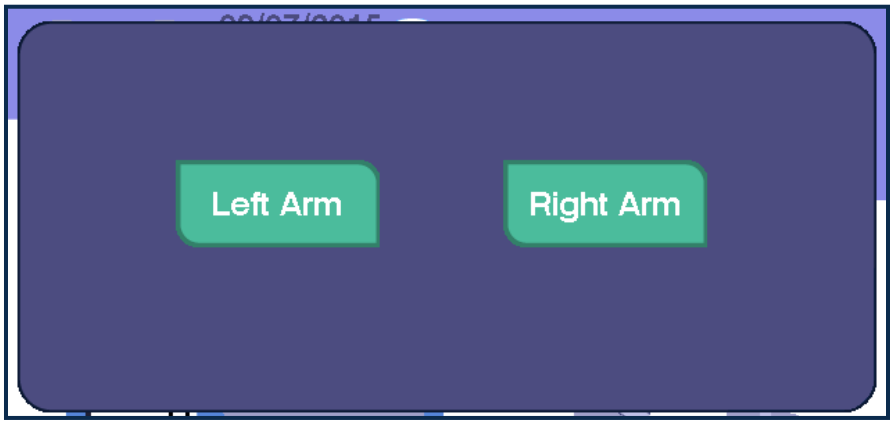
4. Prepare the venipuncture site per the center's SOPs.

5. Use a hemostat to clamp the apheresis needle tubing near the Luer end.

6. Perform the venipuncture per the center's SOPs. To determine the arm used for venipuncture, tap **Left Arm** or **Right Arm**.

   Tapping either button indicates that venipuncture has already been done.

Figure 93: Typical Arm Entry Overlay



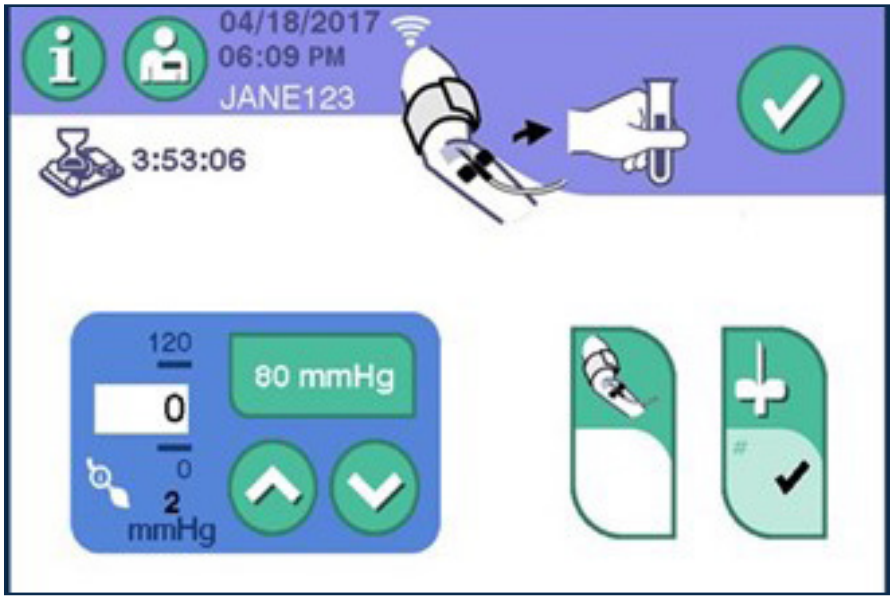
7. Enter the needle set details as per the center's SOP. Note that this might be done during Data Entry.

CAUTION

- Do not exceed the configured sample volume when taking donor blood samples, as this may lead to excessive blood loss.
- Do not take samples from the disposable set unless the disposable set includes a sampling pouch near the needle set. The remainder of the disposable set contains AC, which may dilute the sample.

8. If prompted, perform sampling per the center's SOPs.

Figure 94: Typical Sampling Screen



9. Aseptically connect the apheresis needle set to the needle connector at the end of the donor line on the disposable set.

CAUTION

- ➞ Ensure the needle set to disposable set connection is tight to prevent air infusion and leaks.
- ➞ The operator should monitor the venipuncture site for any adverse effects (e.g., hematoma formation).

NOTE

- ➞ Do not hang hemostats on any of the weigh scale hangers. Unexpected weight on any of the weigh scales may cause alerts/alarms.

10. Remove the hemostats from both the apheresis needle tubing and the short donor line tubing.

11. After venipuncture and (if required) sampling are completed and the hemostats removed, tap the **Check** button on the **Venipuncture** screen.

    - If the **Arm Entry** button is disabled, use the **Check** button to confirm that venipuncture was performed. The system starts the procedure. The cuff inflates to the configured pressure setting for collection.

Section 4.8: Monitoring the Procedure

CAUTION

- Although the system is automated, plasmapheresis procedures must be monitored.
- End the procedure without fluid return if set integrity is compromised. Do not reinfuse reservoir contents.
- To avoid inaccurate pressure sensor readings, end the procedure without fluid return if blood has touched or entered into the pressure sensor ports (P1 or P2).
- Do not push open any clamp at any time during the procedure, unless directed by troubleshooting instructions.
- End the procedure without fluid return if there is unexpected noise from the separation device.
- If there is a leak from the plasma collection container, end the procedure with optional fluid return. Estimate and record the collection volume according to the center's SOPs in order to ensure proper reporting of plasma loss.
- Failure to monitor the AC container and end the procedure if air enters the AC line after a 3004 alert may lead to air infusion or blood clots.

NOTE

- Alerts resulting from interference with the reservoir scale may require procedure termination.
- Do not open any pump handle at any time between disposable set Install Check and disposable set removal, except when directed by troubleshooting instructions.
- Do not open the Hb detector assembly door at any time between disposable set Install Check and disposable set removal, except when directed by troubleshooting instructions.
- Do not open the lower separator support, adjust the alignment of the separator, or squeeze the separator at any time between disposable set Install Check and disposable set removal, except when directed by troubleshooting instructions.

During the procedure, blood from the donor is withdrawn and reinfused in several short cycles; each cycle includes a Collection Phase and a Reinfusion Phase. An icon displays on the touchscreen to indicate the current phase.

- **Collection Phase** icon

- **Reinfusion Phase** icon

Plasma is separated and collected into the plasma collection container during each Collection Phase. Concentrated cells are stored in the reservoir during each Collection Phase and reinfused to the donor during each Reinfusion Phase.

Collection and Reinfusion Phases alternate until the target collection volume is reached. The device then advances to the Final Reinfusion Phase.

Some donors (e.g., low-weight, high-hematocrit donors) may not be able to donate the nomogram value due to Aurora Xi's calculations and tolerance. See "Plasma Collection Ends Automatically Prior to Reaching Target Collection Volume (Unit Under Nomogram)".

NOTE

→ Tapping the disposable tubing Y-connectors above and below the blood pump during Collection Phases may remove air bubbles, which may help reduce air detection alerts/alarms during Reinfusion Phases.

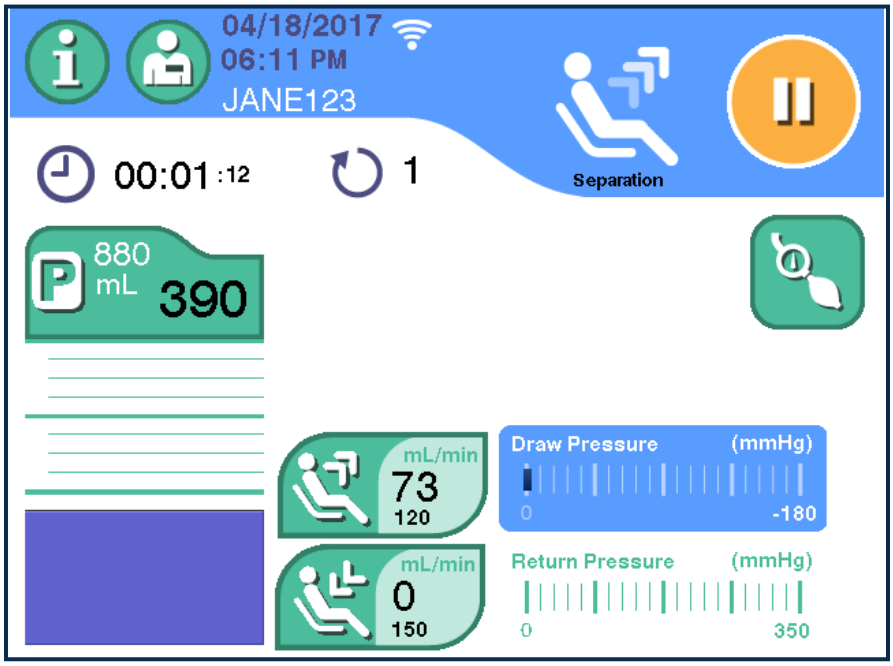
Intelligent flow control (IFC) monitors and automatically responds to donor blood flow issues that may occur during the procedure. Flow rate and cuff pressure are automatically adjusted to attain maximum flow rates. Flow stops when occlusions are detected.

On the **Main Collection** screen, the draw and return rates are indicated in the **Draw Rate** button and the **Return Rate** button (the larger number represents the current rate and the smaller number represents the target rate).

The draw pressure and return pressure status bars on the **Main Collection** screen displays colors to indicate the status of fluid flow during the Collection and Reinfusion Phases. The pressure status bars also appear on the **Pause** screen to aid in changing an apheresis needle set during the procedure.

- **Dark Blue:** Optimal flow
- **Yellow:** Possible flow restriction during the Collection Phase. The donor is prompted to increase squeeze.
- **Orange:** Occlusion is imminent or has already been detected. The system attempts to automatically decrease draw or return rate(s).

Figure 95: Typical Main Collection Screen – Collection Phase



Collection Phase

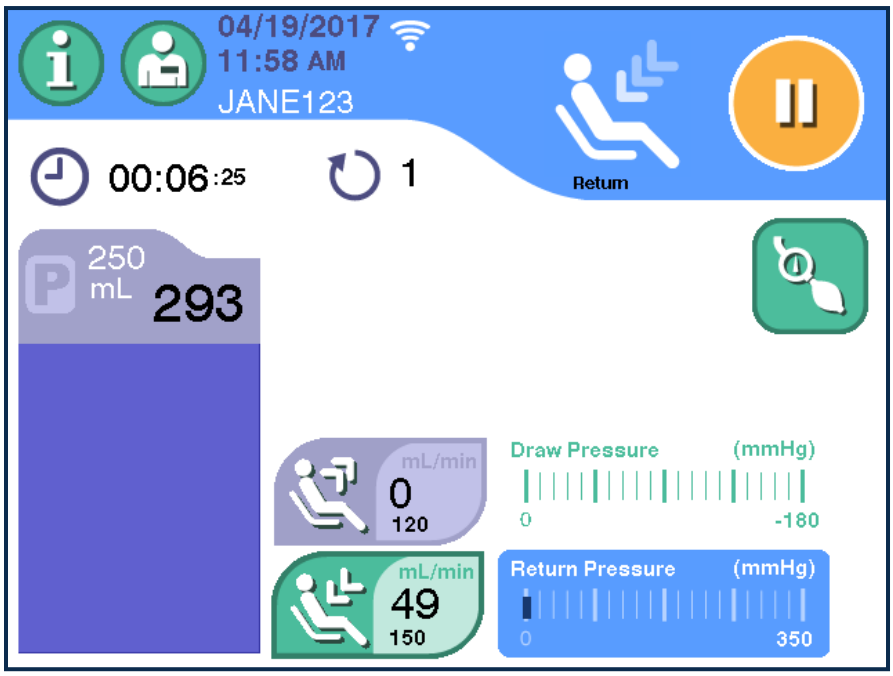
At the start of collection, the device primes the disposable set with anticoagulated blood, displacing the other fluids already in the set. As whole blood (WB) is drawn from the donor, AC is added.

- The **Squeeze** icon is displayed on the Donor Display at the beginning of each Collection Phase.

- The donor should squeeze and release their fist to aid blood flow. For detailed information about the donor display, see **"Donor Display" on page 2-10**.
- The **Draw Rate** button displays the draw rate during the Collection Phase. The larger number represents the current rate and the smaller number represents the target rate.

When the reservoir contents reach the configured amount, all pumps stop, the pressure cuff deflates, the separator slows, and the system transitions to the Reinfusion Phase.

Figure 96: Typical Main Collection Screen – Reinfusion Phase



Reinfusion Phase

At the beginning of each Reinfusion Phase, the **Squeeze** icon disappears from the donor display, and the donor should stop squeezing.

During each Reinfusion Phase:

- The blood clamp and plasma clamp close, and the reinfusion clamp opens.
- The blood pump reverses direction and pumps the contents of the reservoir back to the donor.
- The return rate appears in the **Return Rate** button. The larger number represents the current rate and the smaller number represents the target rate.

After the reservoir contents are reinfused to the donor, the device begins another Collection Phase, if necessary.

Air Purge During Reinfusion

The device manufacturer provides three air detection recovery methods during reinfusion. The center's administrative settings determine which method below is used.

- **Operator-initiated air purge:** When air is detected, the air in line alert/alarm condition is generated. The operator must tap the **Clear Air In Line** button on the alert/alarm screen. The operator must then tap the **Check** button on the alert/alarm screen to resume the procedure.

- **Automatic air purge:** When air is detected, the air in line alert/alarm condition is generated. The system automatically performs air purge. The operator must tap the **Check** button on the alert/alarm screen to resume the procedure.
- **Automatic air purge and resumption:** When air is detected, the system displays the **Air Purge** icon and automatically performs air purge. The system resumes automatically, without operator intervention.

IFC During Collection Phase

During the Collection Phase, if blood flow from the vein causes P1 pressure to approach the occlusion detection threshold, the device prompts the donor to increase squeezing on the donor display and the Draw Pressure status bar indicates yellow.

If flow problems continue and the pressure reaches the occlusion detection threshold, the following actions occur:

- Draw Pressure status bar turns orange,
- **Main Collection** screen displays an **Auto Occlusion Restart** icon,

- Donor display prompts the donor to increase squeezing, and
- Device briefly pauses fluid flow from the donor.

After a brief time to allow the vein to rest, the system attempts to restart Fluid Flow. To help prevent more occlusions, the system alternates between increasing the cuff pressure and temporarily reducing the draw rate.

When the system restarts fluid flow and the pressure remains below the occlusion detection threshold and/or the draw rate decreases, an alert/alarm is generated. After resuming collection, if the flow is maintained with good vein pressure, the fluid flow is gradually increased back to the operator-set target draw rate.

When the operator adjusts the target draw rate setting and the system increases fluid flow from the donor, the device adjusts the flow to match the new setting within the currently set limits.

IFC During Reinfusion Phase

During the Reinfusion Phase, if P1 pressure approaches the maximum return pressure limit, the return pressure status bar turns orange and the system temporarily decreases the flow rate. If the pressure reaches the maximum return pressure limit, an alert/alarm is generated, stopping fluid flow until the operator responds to the alert/alarm.

If flow is maintained with a good vein pressure, with a dark-blue return pressure status bar, flow is slowly increased back to the operator-set target return rate. When the operator adjusts the target return rate setting and the system is increasing fluid flow to the donor, the device adjusts the flow to match the new setting within the currently set limits.

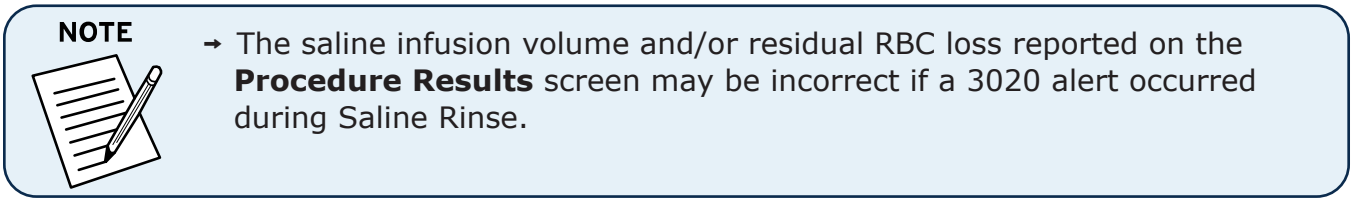
Final Reinfusion Phase

After the target collection volume is reached, the device advances to the Final Reinfusion Phase.

For a Saline Protocol, the device returns the reservoir contents, rinses the separator with saline, infuses the preset volume of saline, and then the remaining reservoir contents are reinfused to the donor. The system monitors the infusion of saline in the following ways:

- **Pump Volume:** If the pump-tracked volume of saline used has reached the target saline volume, then saline infusion is complete. In this case, the volume of Saline Used presented on the **Procedure Results** screen equals the target saline volume.
- **Air Detection:** Repeated air detection causes the system to complete saline infusion, irrespective of the target saline infusion volume. In this case, the volume of Saline Used presented on the **Procedure Results** screen may be less than the target saline volume. See "Low Saline Delivery (for Saline Protocol)" for more information.

In the No Saline Protocol, the device returns the reservoir contents. The remaining blood in the separator is pumped to the reservoir, a small amount of donor's blood is pumped into the reinfusion line, and the remaining reservoir contents are reinfused to the donor.



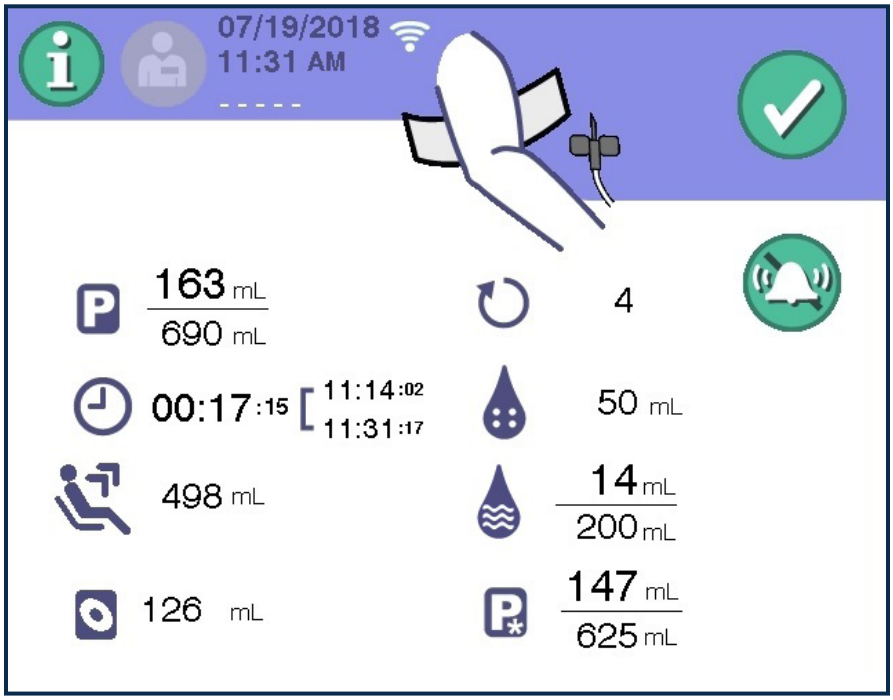
→ The saline infusion volume and/or residual RBC loss reported on the **Procedure Results** screen may be incorrect if a 3020 alert occurred during Saline Rinse.

Disconnecting the Donor

When the final reservoir contents are reinfused into the donor, an audible tone sounds, the green signal light flashes, and the **Procedure Results** screen is displays the **Disconnect Donor** prompt. A tone sounds periodically as a reminder to disconnect the donor.

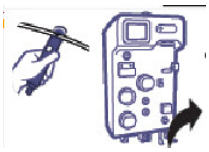
If desired, tap the **Mute** button to silence the tone.

Figure 97: Typical Procedure Results Screen – Disconnect Donor Prompt



To disconnect the donor:

1. Clamp the short donor line or needle set.
2. Remove the pressure cuff from the donor arm.
3. Follow the center's SOPs for removing the needle from the donor and for venipuncture site care.
4. Tap the **Check** button to indicate that the donor is disconnected.
5. If an undercollection or overcollection occurred and the operator is required to enter a reason per the configured administrative settings, follow the instructions in "Undercollection and Overcollection".
6. The **Remove Plasma Collection Container and Seal Tubing** prompt displays.



Undercollection and Overcollection

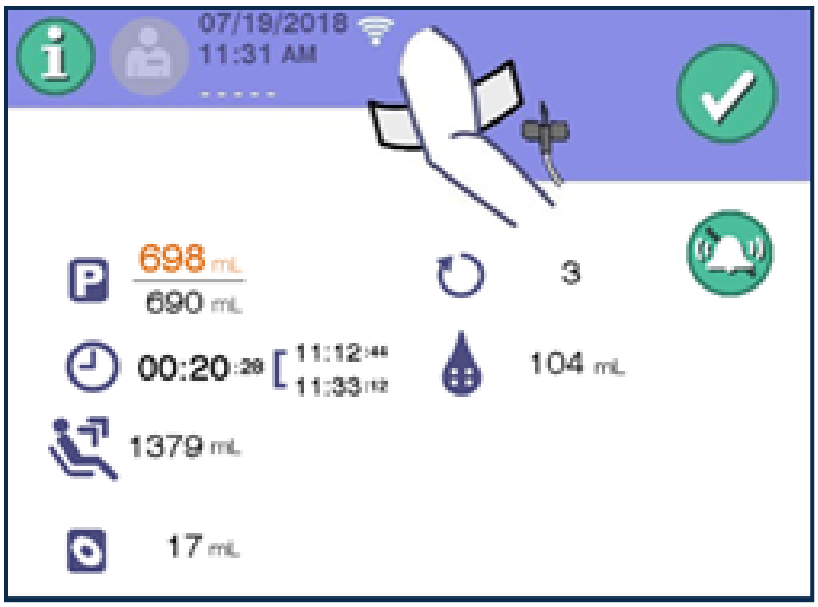
NOTE

→ The screenshots below are for an overcollection. If an undercollection occurs, similar screens are used but are specific to undercollection.

This section applies when an undercollection or overcollection occurs and the operator is required to enter a reason per the configured admininstrative settings.

When the **Check** button is selected from the **Disconnect Donor** prompt on the **Procedure Results** screen, the system will prompt the operator to enter information based on whether an undercollection or overcollection occurred.

Figure 98: Example Procedure Results Screen with an Overcollection



When the **Check** button is selected, a screen similar to the **Overcollection** screen appears.

Figure 99: Overcollection Screen

This screen can be used to select the **Category** and **Reason** from the list generated by the administrator in the administrator settings. If the keypad option is enabled in the administrator settings, the reason may be entered by typing on the keypad or through barcode scanning (if enabled).

Figure 100: Overcollection Screen – Select Reason and Category

When the **ABC** button is pressed to enter a reason, a keypad appears.

The operator can manually enter a reason or scan a barcode with the reason (if enabled and the barcode is in the correct format.) Refer to **"Section 7.12: Barcode Symbologies"** for more information.

When the reason is successfully saved, the system will advance to the **Sealing the Disposable Set and Removing the Collection Container** state.

Figure 101: Overcollection Keypad

Sealing the Disposable Set and Removing the Collection Container

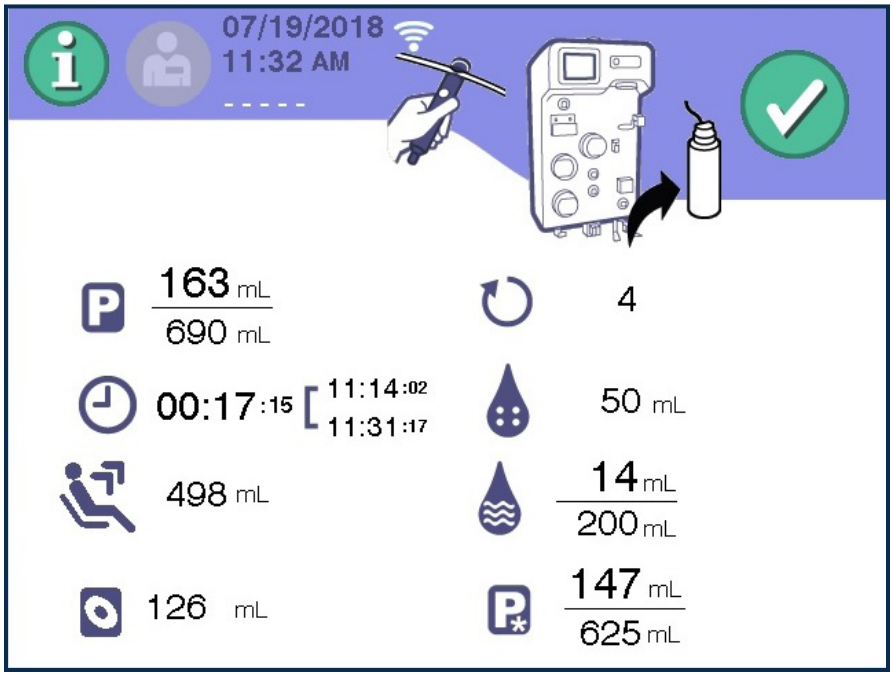
NOTE

→ Tube sealing equipment should be validated by the center for use with the disposable set.

To remove air from the collected product, if required by the center's SOPs.

1. Place a hemostat on the plasma line.
2. Remove the tubing from the plasma clamp.
3. Open the separator lower support.
4. Open the cell pump.
5. While squeezing the plasma collection container, remove the hemostat.
6. Continue squeezing until all of the air is emptied from the plasma collection container.

Figure 102: Typical Procedure Results Screen – Remove Plasma Collection Container and Seal Tubing Prompt



7. When air is removed from the plasma collection container, place the hemostat back on the plasma line to prevent free flow back into the plasma collection container.
8. Seal the disposable set in the following locations:
   - Plasma line below the plasma clamp
   - P1 line and P2 line below the filters
   - The donor short line between the Y1-connector and the Luer
   - The saline line and AC line below the connectors
9. Disconnect the plasma collection container from the disposable set and remove it.

CAUTION

➞ Plasma samples for testing are to be taken from the mixed collection container, not the plasma line, to prevent false negative infectious disease test results.

10. Tap the **Check** button. The **Procedure Results** screen displays the **Unload Set** prompt.

If the device is configured for remote communication, the Procedure Record is transmitted to the data management system after the plasma container is removed.

Removing the Disposable Set

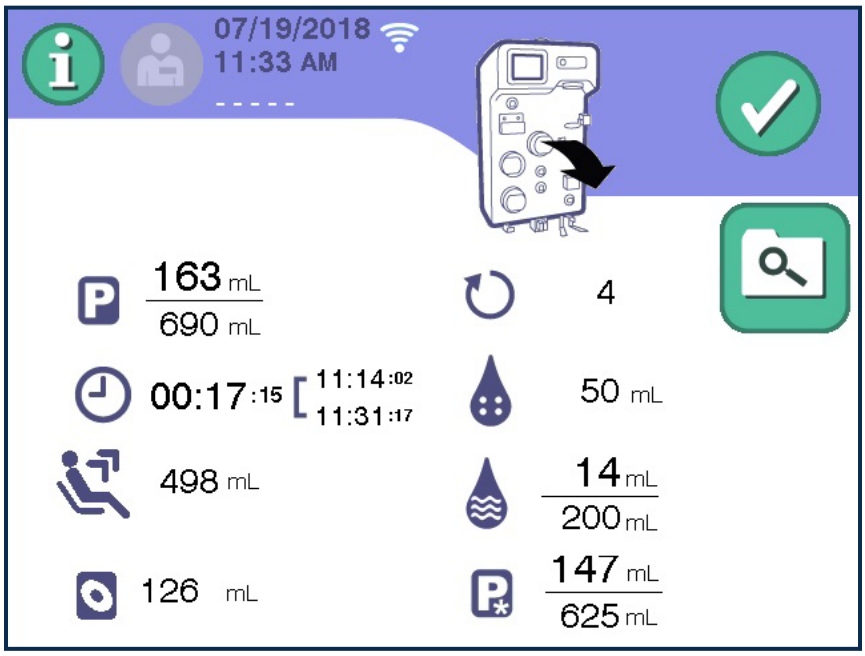
CAUTION

- Clean and disinfect blood spills immediately. Treat all spills and potentially contaminated surfaces as potential biohazards.
- If any solution containers have been exposed to blood, treat the containers as potentially biohazardous.

When the **Unload Set** prompt is displayed on the **Procedure Results** screen, remove the disposable set as follows:

1. Turn the P1 connector counterclockwise while pulling the P1 connector straight away from the P1 Luer.
2. Turn the P2 connector counterclockwise while pulling the P2 connector straight away from the P2 Luer.
3. Open the pressure transducer cover.

Figure 103: Typical Procedure Results Screen – Unload Set Prompt



4. Grasp the P1 tubing above and below the transducer cover and move tubing toward the front of the device. Then, move the P1 tubing out from behind the transducer door to the left.
5. Grasp the P2 tubing above and below transducer cover and move tubing toward the front of the device. Then, move the P2 tubing out from behind the transducer door to the right.
6. Open the pumps and Hb detector assembly door. All clamps open automatically.
7. Remove the remainder of the disposable set and solutions from the device and discard per the center's SOPs.

Recording Procedure Information

Record procedure information per the center's SOPs. This section provides information on where to obtain procedure results on the **Procedure Results** screen.

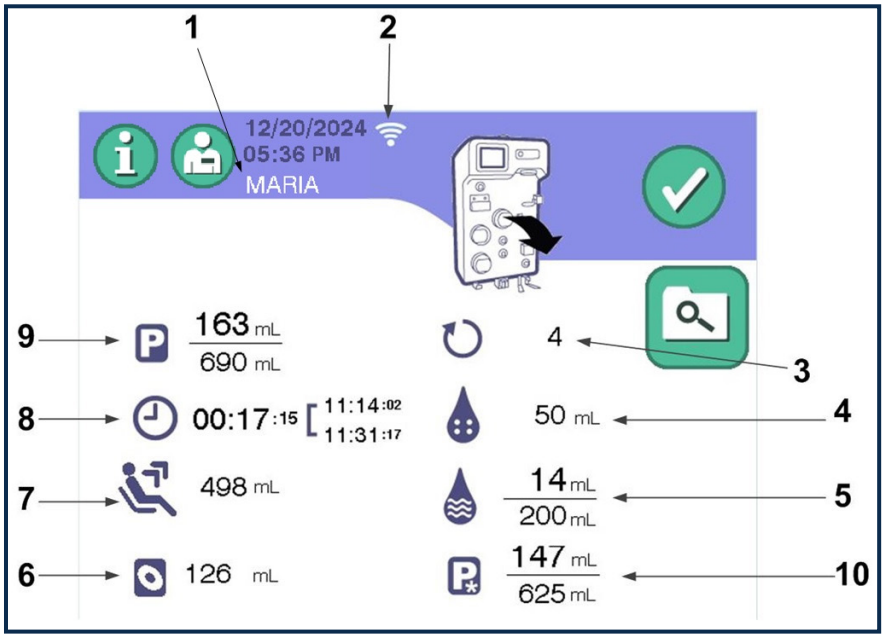
CAUTION

- If configured for use with a data management system and the Procedure Record is not transmitted to the data management system, the operator shall record appropriate procedural information (according to the center's SOPs) from the **Procedure Results** screen manually.

1. **Operator ID:** The last operator ID entered.

2. **Network Status Indicator:** Displays the device network connection status with the data management system. If the device is connected to the data management system, the **Network Connected** icon is displayed. If the device is not connected to the data management system (status is **Disconnected** or **Limited**), the **Network Not Connected** icon is displayed. See the "Glossary of Graphics" for **Network Connected** and **Network Not Connected** icons.

Figure 104: Typical Procedure Results Screen Elements



3. **Number of Cycles:** The total number of cycles completed.

4. **AC Used (mL):** The total amount of AC used by the system during the procedure.

5. **Saline Used (mL):** The estimated total amount of saline used by the system during the procedure (top number) and the target saline used volume (bottom number). This information is only displayed for a Saline Protocol.

6. **Red Blood Cell (RBC) Loss:** The estimated residual volume of red cells remaining in the disposable set (± 15% or 10 mL, whichever is greater). This may or may not be displayed on the **Results** screen for normally completed procedures per administrative settings.

NOTE

- If the total collection volume displays as "--- mL" in orange text, estimate the RBC loss using information provided in Appendix A.

7. **Whole Blood Processed:** The estimated amount of donor whole blood that was drawn by the device, expressed in mL. This value includes all the whole blood drawn from the donor, not just the volume processed through the separator.

8. **Total Procedure Time:** Depending on the administrative settings selected, this is the start and stop with elapsed time as the operator acknowledges venipuncture to when operator is prompted to disconnect the donor, or identifies the donor is disconnected.

9. **Collection Volume:** The total collection volume (top number) and the target collection volume (bottom number), where both volumes include AC, expressed in mL. Accuracy is within ± 10 mL, based on manufacturer's default plasma density configuration.

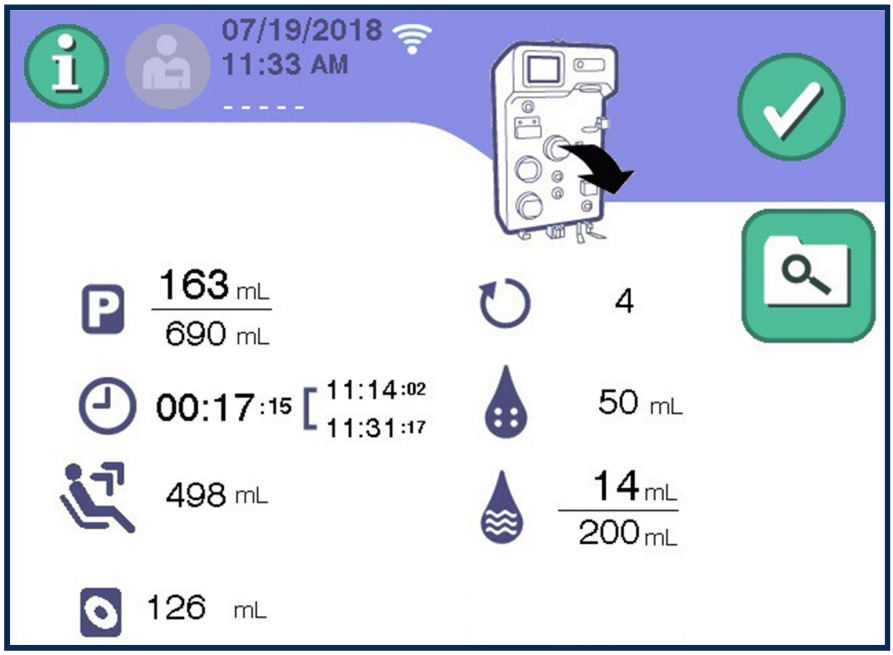
NOTE

- If the target collection volume has not been set, it is displayed as "--- mL" in orange text. It will be shown as 0 mL when viewed through DXT.
- If the total collection volume is displayed as "--- mL" in orange text, the operator shall determine the collection volume using the **Weigh Product** button in the **Instrument Settings** tab using the **Information** button (see "Weigh Product").

- If this volume is accompanied by an orange banner, see "Plasma Collection Ends Automatically Prior to Reaching Target Collection Volume (Unit Under Nomogram)" for more information.
- If this volume is displayed in orange text, an overcollection or undercollection occurred per administrative settings.

10. **Plasma Volume:** The total plasma volume (top number) and the target plasma volume (bottom number), where both volumes exclude AC, expressed in mL. This may or may not be displayed on the **Results** screen per administrative settings.

Figure 105: Typical Results Screen



NOTE

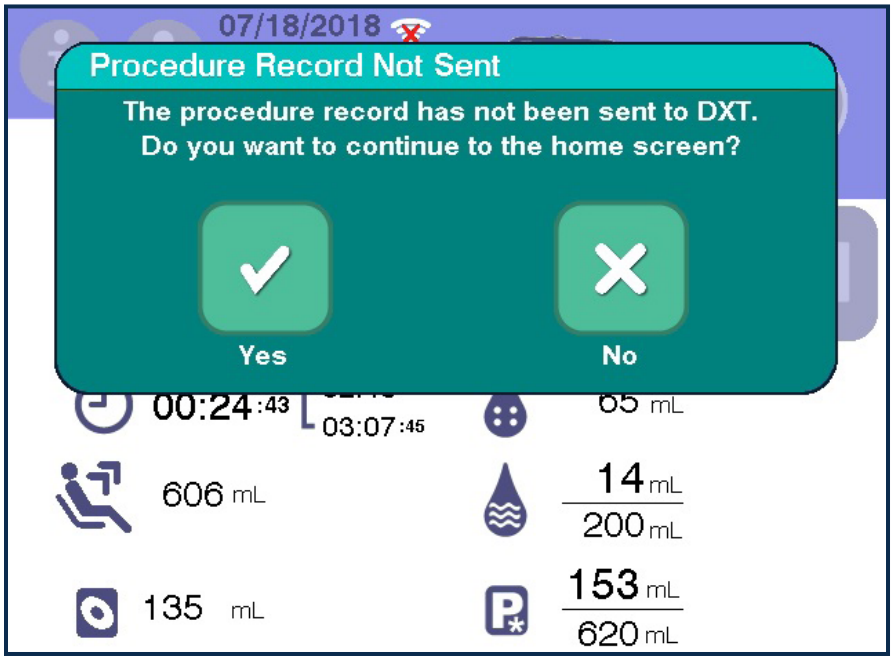
→ For procedures performed with the Adaptive Nomogram, the **Procedure Results** screen only displays the total plasma volume.

After recording the necessary information, tap the **Check** button to return to the **Home** screen or press the **STOP** button to power OFF the device.

If the device is configured for remote communication and Record Upload Confirmation is enabled (see "Data Management Settings" in the Administrator's Guide), the Procedure Record will be sent to the data management system.

If the device loses network connection, the **Record Upload Confirmation** overlay indicates the Procedure Record could not be sent.

Figure 106: Typical Record Upload Confirmation Failure Overlay



1. Tap **Yes** to return to the **Home** screen.

2. Tap **No** to remain on the **Procedure Results** screen. Record the procedure information per institutional SOPs.

Once network connection is restored between the device and the data management system, the Procedure Record is sent to the data management system.

NOTE

→ Non-donation, demo, and QC records are also sent to a data management system. However, if these records fail to be sent to the data management system, the operator is not notified.

Procedure View Button

The **Procedure View** button allows for review of disposables data, donor information, procedure summary, and procedure events review.

Find **Procedure View** button details in **"Procedure Record Overlay" on page 4-80**.

Section 4.9: Making Adjustments

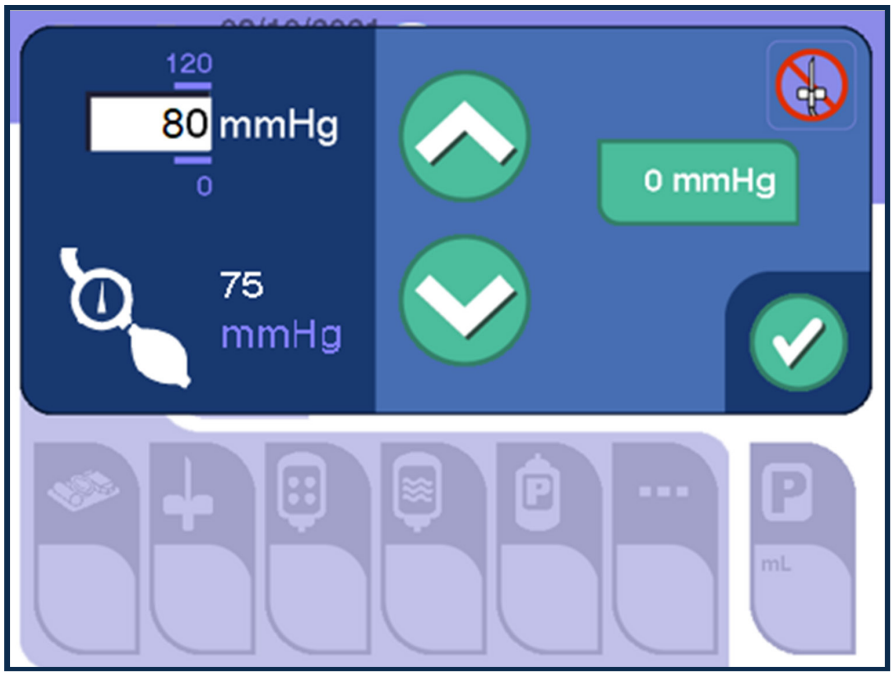
Cuff Adjustment

The **Cuff Pressure** button is accessible during procedure setup and performing the procedure.

During procedure setup, the **Cuff Pressure** button can be used to adjust the inflation pressure to perform vein examinations.

Do not perform venipuncture until prompted, as shown in the **Do Not Stick** icon displayed in the **Cuff Pressure** overlay. Once venipuncture is permitted, the icon is replaced with P1 pressure.

Figure 107: Typical Cuff Pressure Overlay



During the procedure set-up, to adjust the inflation pressure and performance, except when paused, tap the **Cuff Pressure** button and use the overlay's **Up** and **Down** buttons when blood is drawn from the donor. Changes take effect after tapping the **Check** button. The actual cuff pressure is shown to the right of the **Cuff** icon.

Draw Rate Adjustment

During the procedure, the **Draw Rate** button can be used to adjust the draw rate.

Tap **Draw Rate** and use the **Up** and **Down** buttons on the overlay to adjust the rate by 5 mL/min increments. Changes take effect after tapping the **Check** button.

Return Rate Adjustment

During the procedure, the **Return Rate** button can be used to adjust the return rate. Tap **Return Rate** and use the **Up** and **Down** buttons to adjust the rate by 5 mL/min increments.

Changes take effect after tapping the **Check** button.

Changing the Target Collection Volume During a Procedure

During the procedure, adjust the target collection volume by tapping the **Collection Volume** button (increase or decrease) in the displayed overlay.

The target collection volume is set via the configured nomogram per administrative settings (the nomogram must be cleared by the appropriate regulatory body). The operator cannot change the collection volume to a value greater than the maximum collection volume determined by the nomogram.

Pausing the Procedure

During the Collection and Reinfusion Phases, tap the **Pause** button to pause the procedure.

When paused, the screen banner turns orange and the pause timer shows how long blood flow has stopped.

NOTE

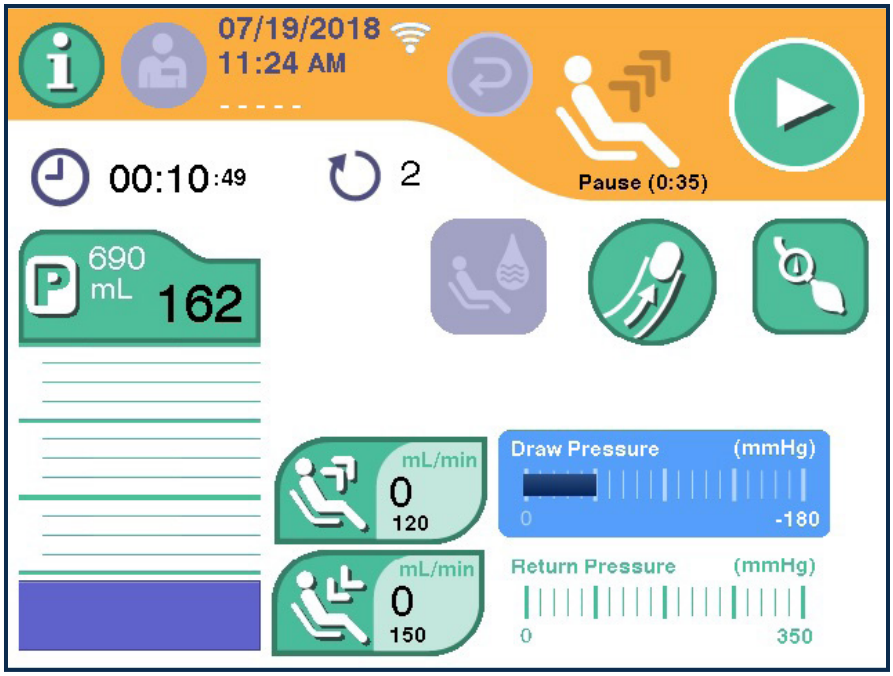
- It is recommended not to tap the **Pause** button to ensure a complete prime of the separator.

The **Pause** icon indicates the direction of blood flow when the procedure resumes.

The **Collection Pause** icon indicates blood will be drawn from the donor.

The **Reinfusion Pause** icon indicates reinfusion will occur.

Figure 108: Typical Pause Screen



If no action is taken by the operator within two minutes, an audible tone sounds.

When the procedure is paused, the operator can resume the procedure, infuse saline, clear air in the line, or adjust current cuff pressure.

Resuming the Procedure

To resume the procedure, tap the **Start** button.

NOTE

- An automatic air purge occurs when resuming from Pause if the system suspects that the needle set was changed.
- Auto-purging occurs after the cuff is inflated, followed by a long period of inactivity, when the system suspects that the needle set was changed.

Reverse Flow

To change the direction of flow on resumption from Pause (i.e., to change from the Collection to the Reinfusion Phase or from the Reinfusion Phase to the Collection Phase when resuming the procedure), tap **Reverse Flow**.

The **Reverse Flow** button is enabled once separation begins. It is disabled near the end of the Collection and Reinfusion Phases and after the target collection volume is reached.

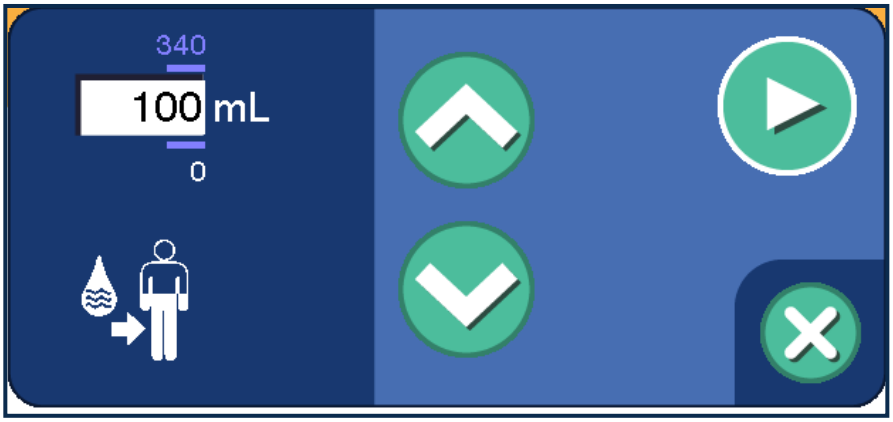
NOTE

- If the operator taps the **Reverse Flow** button during the first Collection Phase, it is recommended to allow the first Reinfusion Phase to complete, in order to ensure that the procedure is not slowed.

Infuse Saline

To infuse saline to the donor, tap **Infuse Saline** to display the **Mid-Procedure Saline Infusion** overlay.

Figure 109: Typical Mid-Procedure Saline Infusion Overlay



The overlay automatically shows the administrator-configured default target saline volume. On the overlay, tap **Up** and **Down** to adjust the target amount of saline for infusion.

NOTE

- The maximum saline volume allowed will always be less than the current saline volume as the saline is reserved for the end of the procedure rinse.

Once the target is set, tap **Start** to begin the infusion.

The **Start** button switches to a **Pause** button on the overlay. The displayed saline volume rises as saline begins infusion. Infusion automatically stops after reaching the target, or you can stop by tapping **Pause**. Tap **Cancel** to return to the **Pause** screen after saline is administered.

Clear Air in Line

To purge air from the donor line, tap **Clear Air In Line**. The button is animated while air is being purged and stops when the line is cleared. To cancel this action, you must press the **STOP** button.

Cuff Adjustment When Paused

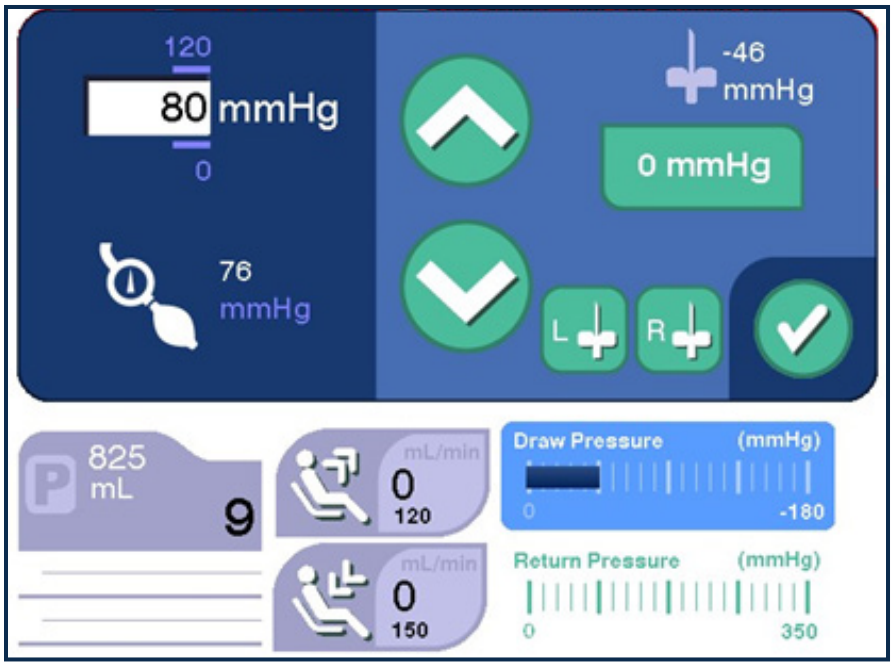
NOTE

→ Adjusting the cuff pressure when paused does not affect the cuff pressure setting during the Collection Phase.

When paused, tap **Cuff Pressure** to adjust the cuff pressure for venipuncture adjustment. To adjust the cuff pressure, tap **Up/ Down** or the **Pressure Preset** button on the associated overlay. The actual cuff pressure and P1 pressure are displayed on the overlay.

See **"Change Apheresis Needle Set During the Procedure" on page 5-158** for additional information about this overlay.

Figure 110: Typical Cuff Pressure Pause Screen



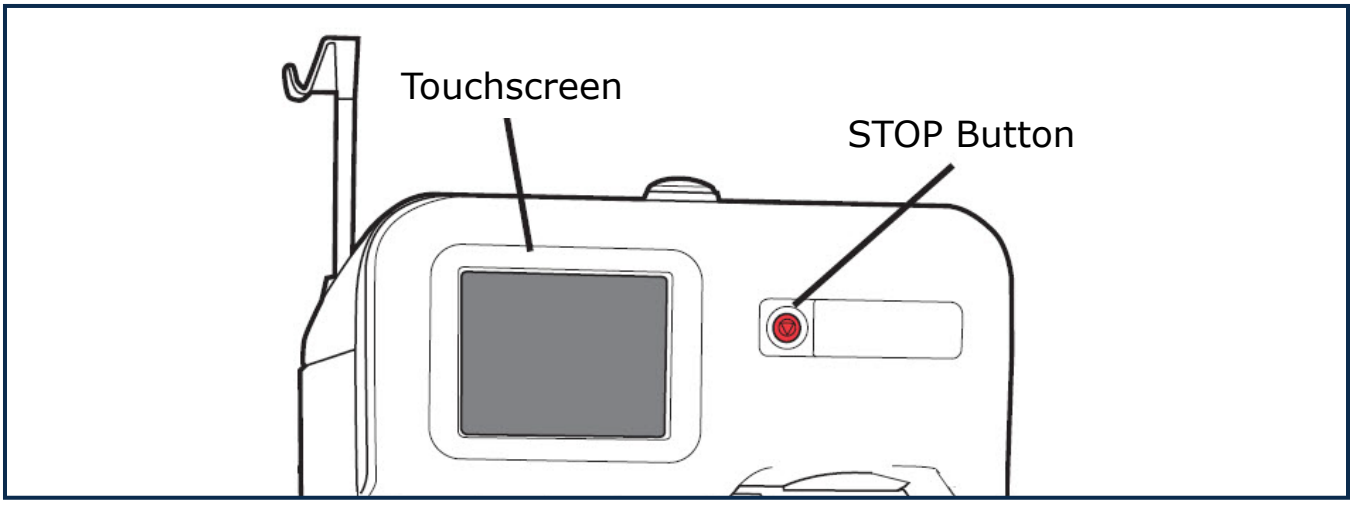
Section 4.10: Using the STOP Button

CAUTION

→ Failure to use the **STOP** button when powering OFF the device may cause the device to become non-functional.

The **STOP** button is located to the right of the touchscreen and is used to end a procedure. Pressing the **STOP** button while a donor is connected automatically stops all pumps and closes all clamps.

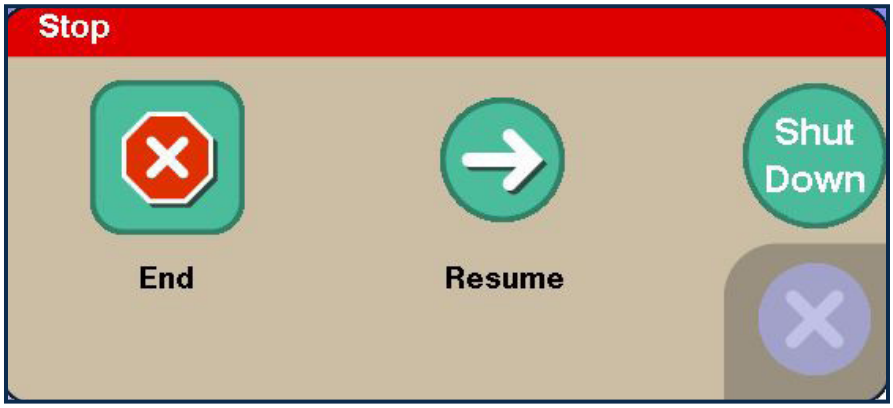
Figure 111: STOP Button Location



After the **STOP** button is pressed, the system displays an overlay with options based on the current status of the procedure.

Resume and **Shut Down** buttons are always enabled.

Figure 112: Typical STOP Button Overlay

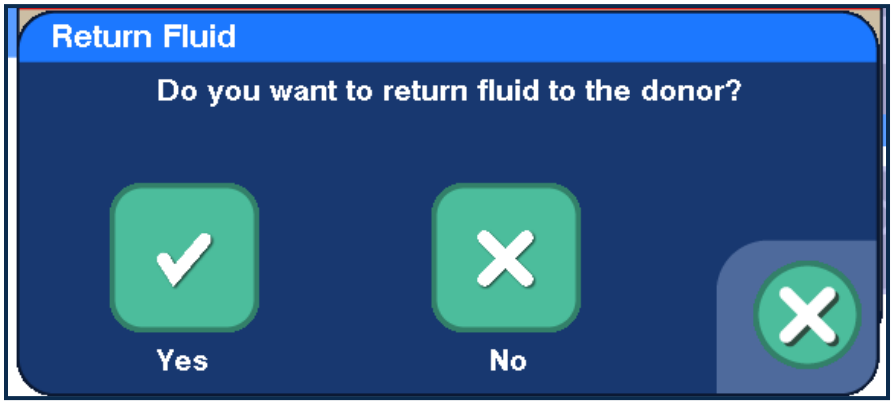


End the Procedure

The **End Procedure** button may or may not be enabled depending on the overlays that appear (e.g., status of the procedure).

When **End Procedure** is tapped, the **Confirm No Fluid Return** overlay or the **Fluid Return Optional** overlay appears based on the current status of the procedure.

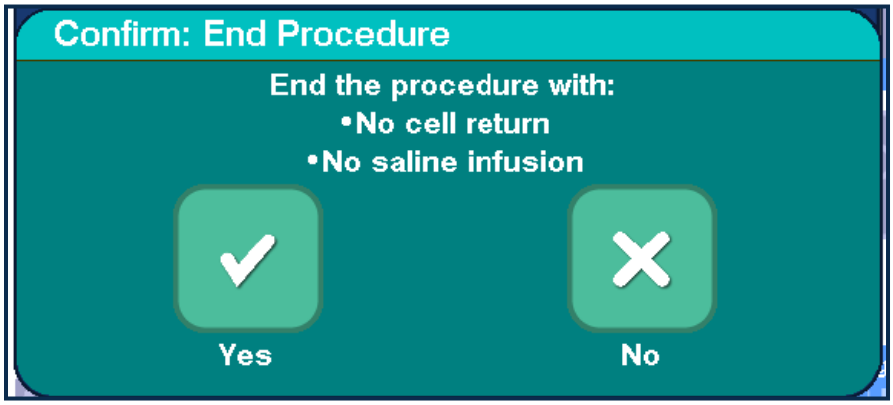
Figure 113: Typical Confirm No Fluid Overlay



If Yes is selected on the **Confirm No Fluid Return** overlay, the system goes to the **Post Collection** screen without returning fluids to the donor.

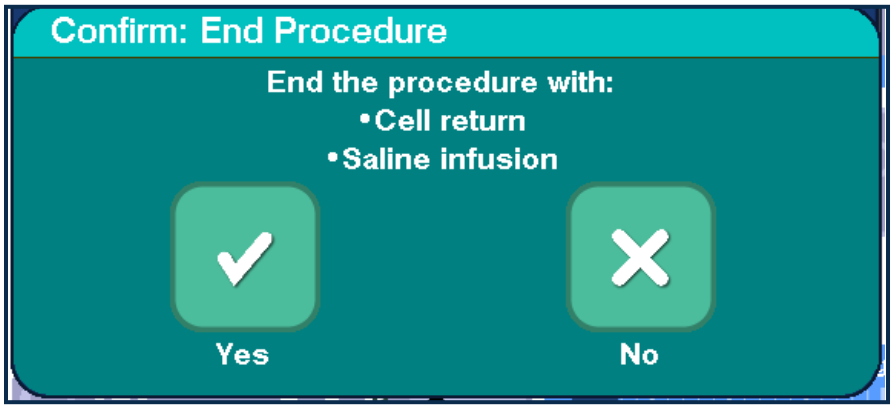
If No is selected on the **Confirm No Fluid Return** overlay, the system returns to the **STOP** overlay.

Figure 114: Typical Return Optional Fluid Overlay



If Yes is selected on the **Fluid Return Optional** overlay, the system prompts the operator to confirm the return of fluids to the donor.

Figure 115: Typical Fluid Requested Confirmation Overlay for Saline Procedure



If Yes is selected on the **Fluid Return Requested Confirmation** overlay for Saline Procedure, the system automatically returns fluids (i.e., reservoir contents and saline, when applicable). The touchscreen displays the **Post Collection** screen.

If No is selected on the **Fluid Return Optional** overlay, the **Confirm No Fluid Return** overlay displays.

Resume

The **Resume** button will always be enabled. Tap **Resume** to close the **STOP Options** overlay. The system resumes where the procedure was previously paused.

Shut Down

This button will always be enabled. For detailed information on how to power OFF the device, see **"Section 3.3: Powering OFF the Device"**.

Section 4.11: Changing or Reentering the Operator ID During the Procedure

Tap **Operator ID** and use the keypad to change or reenter operator identification. The **Operator ID** button can be accessed through the **Information** overlay.

Section 4.12: Advanced Options

Advanced options may be performed during a procedure. This section provides information on how to access advanced options and a detailed description of each option.

Tap the **Information** button to access the **Procedure Information** page or the **Information Settings** page. For detailed information about either page, see the relevant entry in this section.

Procedure Information

Tap the **Procedure Information** tab to display the **Procedure Information** page.

The **Procedure Information** page provides access to view or change information during the procedure using page elements. This section identifies and describes each element.

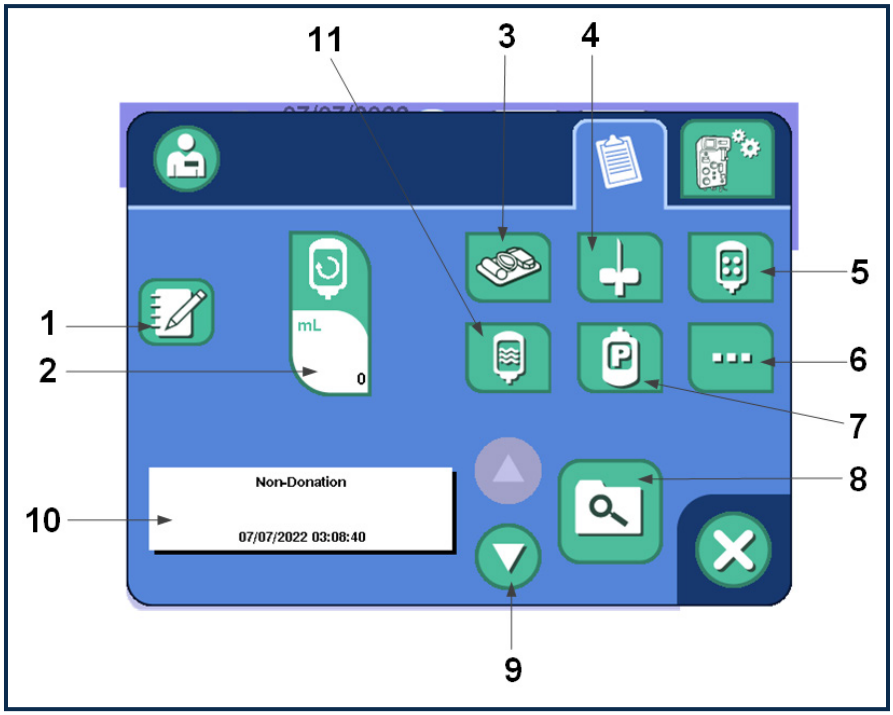
NOTE

➞ Tapping the **Cancel** button displays the previous overlay/screen.

1. **Notepad:** Provides ability to enter notes to the electronic record. To enter a note, tap the **Notepad** button. Type in the desired note or scan the desired note using the barcode scanner, then tap the **Check** button to return to the previous screen.

   - The note is logged into the Procedure Record, along with the operator ID and the date and time that the note was recorded.

Figure 116: Typical Procedure Information Page



2. **ECV (Extracorporeal Volume) Limit Button:** Provides access to set extracorporeal red blood cell volume limit in mL. This setting is the maximum amount of red cells to be drawn by the device at any point during the procedure. The maximum limit is an administrative setting. The operator may decrease this setting for donor comfort and/or to reduce donor reactions, per the center's SOPs. When using the Adaptive Nomogram, the ECV Limit must be set to 200 mL for new and lapsed donors.

3. **Disposable Set Data Button:** Provides access to change or add disposable set information.

4. **Needle Set Data Button:** Provides access to change or add needle set information.

5. **AC Container Button:** Provides access to change or add AC container information.

6. **User-Defined Soft Goods Button:** Provides access to change or add user-defined disposables information.

7. **Plasma Container Data Button:** Provides access to change or add plasma collection container disposable information.

8. **Procedure View Button:** Displays additional information for the selected electronic record.

9. **Up/Down Buttons:** Tap the **Up** or **Down** button to scroll and change the selected electronic record.

10. **Procedure Record Data:** Displays record type (i.e., non-donation, donation, demo, and QC), procedure ID (if used), date, and time for the selected electronic record.

11. **Saline Container Data Button:** Provides access to change or add saline container information.

Accessing Procedure Records

Information from previous procedures can be accessed while on the **Procedure Information** tab or at the end of a procedure. To access Procedure Records, do the following:

1. Tap the **Up** or **Down** button to find the Procedure Record.

2. Tap the **Procedure View** button. The **Procedure Record** overlay displays.

3. To return to the previous screen, tap the **Cancel** button.

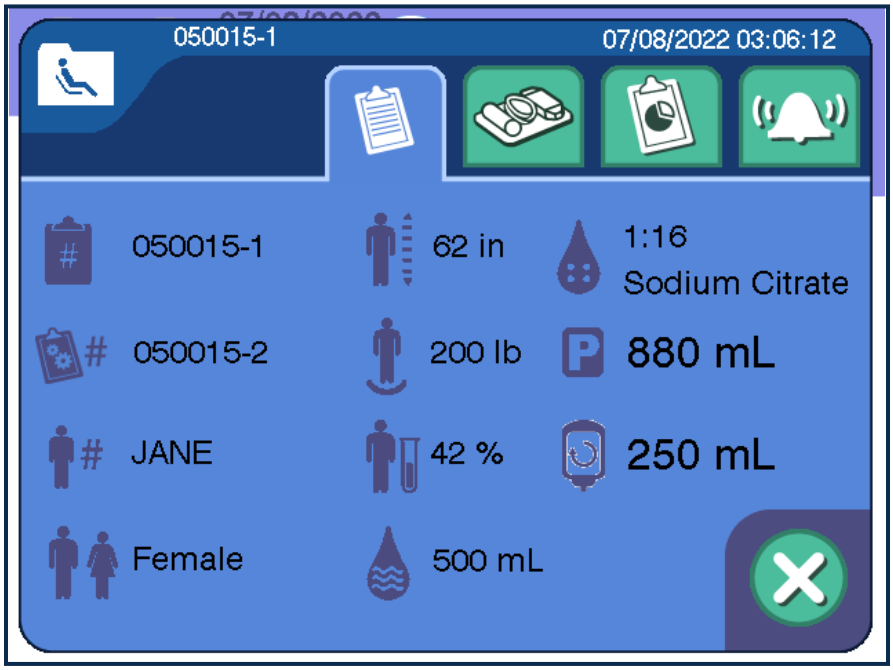
Procedure Record Overlay

Donor Parameters Tab

The **Donor Parameters** tab on the **Procedure Record** overlay displays information entered about the donor during the selected procedure.

This section identifies and describes each element. Note that certain features may not be activated due to the administrative settings set on the device.

Figure 117: Typical Procedure Record Overlay – Donor Parameters



1. **Procedure ID:** The procedure ID for the selected procedure.

2. **Donation Setup ID:** The donation ID for the selected procedure.

3. **Donor ID:** The donor ID number entered for the selected procedure.

4. **Donor Gender:** The donor's gender.

5. **Donor Height:** The entered height for the donor. This can be in inches (in) or centimeters (cm), depending on the administrative settings.

6. **Donor Weight:** The entered weight for the donor. This can be in kilograms (kg) or pounds (lb), depending on the administrative settings.

7. **Donor Hematocrit/Hemoglobin:** The entered hematocrit or hemoglobin value for the donor. Note that this is the hematocrit or hemoglobin, depending on the administrative settings.

8. **Procedure Protocol Information:** Describes if the procedure was a saline or non-saline procedure.

9. **Anticoagulant Information:** Describes the type of anticoagulant used for the procedure and the AC ratio.

10. **Target Collection Volume:** The target collection volume for the procedure, which includes AC, expressed in mL.

11. **ECV Limit:** The extracorporeal red blood cell limit, expressed in mL.

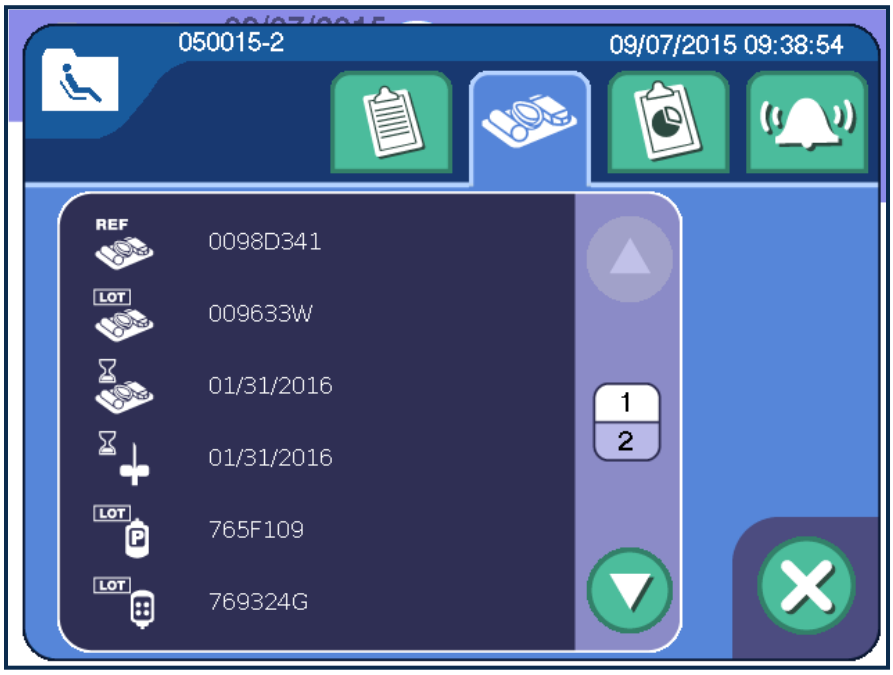
Set Summary Tab

The **Set Summary** tab on the **Procedure Record** overlay describes the entered disposables data for the selected procedure. Only information that was required by the administrator, and was entered, is shown on this device.

The following section describes the possible information that could be entered for each disposables accessory. See **"Entering Disposables Data" on page 4-5**.

1. **Code Number:** Displays the entered code number of the specific soft good.
2. **Lot Number:** Displays the entered lot number of the specific soft good.
3. **Expiration Date:** Displays the entered expiration date of the specific soft good.

Figure 118: Typical Procedure Record Overlay – Set Summary



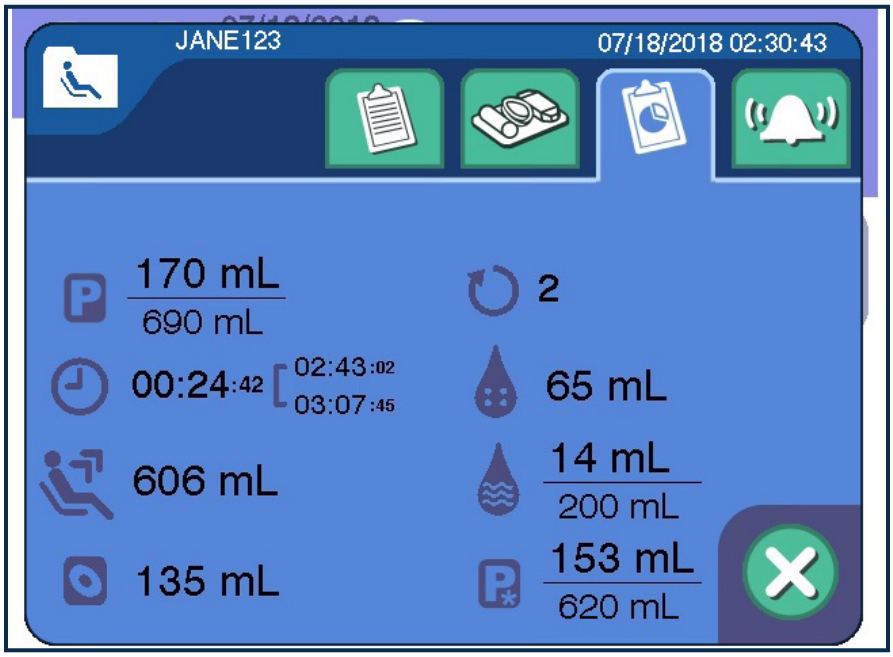
NOTE

→ Only icons that have information to display is shown. If information was not entered for a code number, a lot number, or an expiration date, then the corresponding icon will not be presented on the screen.

Procedure Summary Tab

The **Procedure Summary** tab on the **Procedure Record** overlay describes procedure information from the selected procedure. This section identifies and describes each element.

Figure 119: Typical Procedure Record Overlay – Procedure Summary



1. **Collection Volume (mL):** The total collection volume (top number) and the target collection volume (bottom number), where both volumes include AC. Accuracy is within ± 10 mL, based on the manufacturer's default plasma density configuration.

NOTE

- If this volume is displayed in orange text, the operator determines the collection volume using the **Weigh Product** button in the **Instrument Settings** tab using the **Information** button (see **"Weigh Product" on page 4-88**).
- If this volume is accompanied by an orange banner, see **"Plasma Collection Ends Automatically Prior to Reaching Target Collection Volume (Unit Under Nomogram)" on page 5-162** for more information.

2. **Procedure Time:** The start time, stop time, and elapsed time of the procedure. The start time indicates when the operator acknowledges venipuncture. Depending on the administrative settings selected, the end time may indicate when the operator is prompted to disconnect the donor or when the operator acknowledges the donor is disconnected. The elapsed time is the difference between the start and stop time.

3. **Whole Blood Processed (mL):** The estimated donor whole blood amount drawn by the device. This value includes all the whole blood drawn from the donor, not just the volume processed through the separator.

4. **Red Blood Cell (RBC) Loss:** The estimated residual volume of red cells remaining in the disposable set (± 15% or 10 mL, whichever is greater). This may or may not be displayed on the **Results** screen for normally completed procedures, per administrative settings.

NOTE

→ If this volume is displayed in orange text, the operator estimates the RBC loss using the information provided in **Appendix A**.

5. **Number of Cycles:** The total number of cycles completed.

6. **AC Used (mL):** The total amount of AC used by the system during the procedure.

7. **Saline Used (mL):** The estimated total amount of saline used by the system during the procedure (top number) and the target saline used volume (bottom number). This information is only displayed for a Saline Protocol.

8. **Plasma Volume (mL):** The total plasma volume (top number) and the target plasma volume (bottom number), where both volumes exclude AC. This may or may not be displayed on the **Procedure Record** overlay, per administrative settings.

NOTE

→ For procedures performed with the Adaptive Nomogram, the **Procedure Summary** screen only displays the total plasma volume.

Event Summary Tab

The **Event Summary** tab on the **Procedure Record** overlay displays information on selected events throughout the procedure, such as alarms, alerts, and scale checks. This section identifies and describes each element.

Figure 120: Typical Event Summary Tab

1. **Alarm Check Box:** Displays the alarms that occurred during the selected procedure.
2. **Alert Check Box:** Displays the alerts that occurred during the selected procedure.
3. **Other Check Box:** Displays other procedure parameters occurred during the selected procedure.
4. **Up and Down Buttons:** Allows the operator to tap the **Up** or **Down** button to scroll through the events that occurred during the procedure.

Section 4.13: Barcodes

Barcodes contain information which a center can use to collect and track information about the donor, operator, procedure, disposable sets, and accessory items used during a procedure. These items need to be barcode enabled.

NOTE

→ If using GS1-128 (1D and 2D DataMatrix) or ISBT-128 barcode symbology, entry fields may not need to be selected prior to data entry. The device recognizes those barcodes and may automatically populate the appropriate field(s).

Using A Barcode Scanner

To scan a barcode:

1. Hold the scanner 2 – 3 inches (5 – 7.5 cm) from the selected barcode.
2. Point the scanner's light beam over the center of the barcode, perpendicular to the lines of the barcode. When the scanner accepts the barcode, an audible beep(s) sounds.

Figure 121: Typical Barcode

   - If the scanner fails to emit a light beam, an audible beep(s) does not sound, or a barcode does not appear in the entry field, contact your qualified service representative.
3. Check the entry field on the touchscreen. If a disposable set is expired, a tone sounds, the set timer flashes, and a new disposable set must be installed.
4. Verify all entered information is correct, then tap the **Check** button.

NOTE

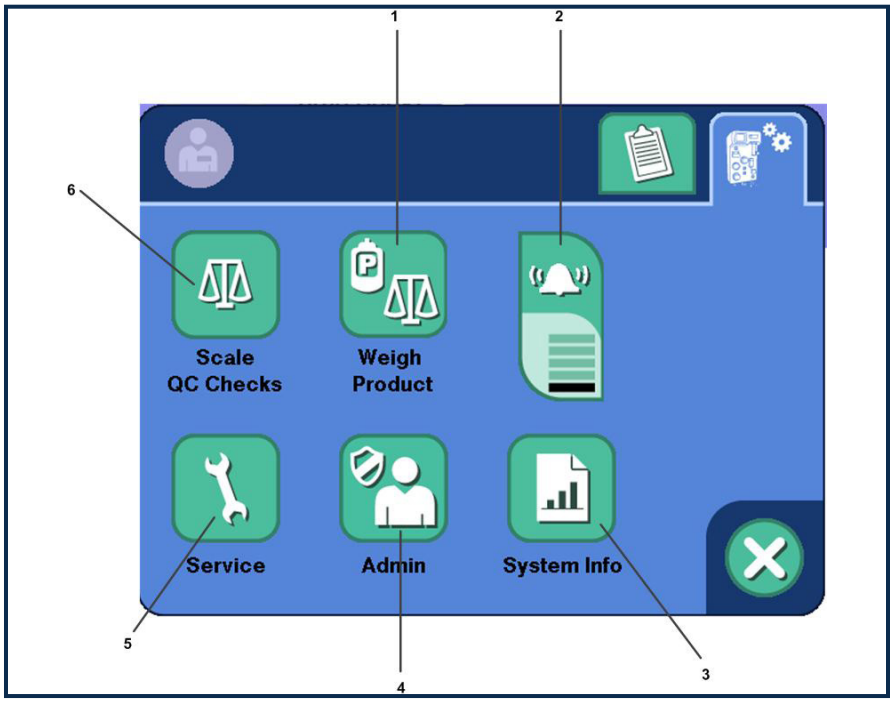
→ If the barcode scanner fails to read properly, the keypad is always available for manual entry. Enter all the numbers and letters displayed under the barcode, disregarding any special characters, using the alphanumeric keypad.

Section 4.14: Instrument Settings

Tap the **Instrument Settings** tab to view the **Instrument Settings** page. This page provides access to various options using buttons.

To view the previous overlay/screen, tap the **Cancel** button.

Figure 122: Typical Instrument Settings Page



1. **Weigh Product Button:** This button weighs the collected product on the plasma collection scale. For detailed information, see **"Weigh Product" on page 4-88**.

2. **Sound Level Button:** This button adjusts the sound level of audible tones while a procedure is in progress.

3. **System Info Button:** This button allows the operator to view additional system information such as device usage, software configuration, network configuration, and changing the screen date and time. For detailed information about each feature, see **"System Information" on page 4-90**.

4. **Admin Button:** This button provides access to the administrative settings. This button is password protected. For additional information about administrative settings, see the Aurora Xi Administrator's Guide.

5. **Service Button:** This button accesses Service Mode. This button is password protected. Contact your local service representative or authorized service personnel for additional information.

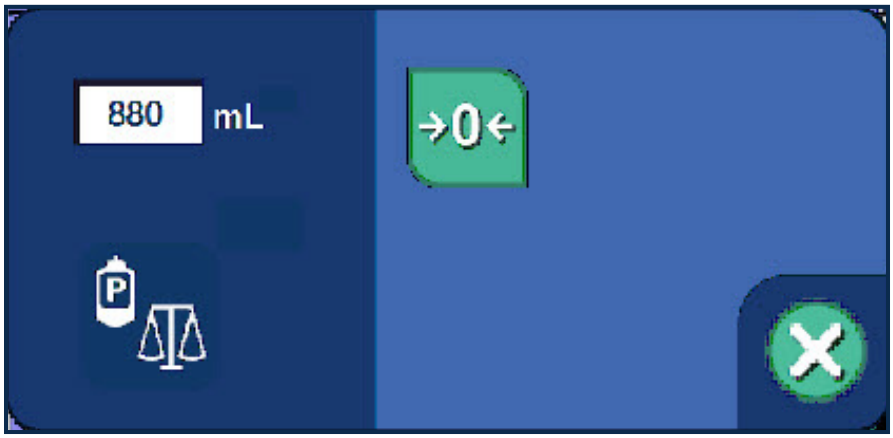
6. **Scale Check Button:** This button allows the operator to perform weigh scale checks, verification, and calibration (if enabled). For detailed information about the weigh scale verification or calibration, see **"Verifying Weigh Scales" on page 3-4**.

Weigh Product

If a procedure is currently not in process, this option is available to determine the collection volume (plasma volume with AC) using the plasma weigh scale. Perform the following:

1. Tap the **Weigh Product** button. The **Weigh Product** overlay displays.

Figure 123: Typical Weigh Product Overlay



2. If there is a plasma collection container on the plasma weigh scale, remove the container.

3. Place an empty equivalent plasma collection container on the plasma weigh scale hanger.

NOTE

- The accuracy of this measurement depends on the equivalency of the container, including aspects such as tubing lengths, labeling, and tubing positions.
- The calculation for product volume utilizes the product density configured through administrative settings.

4. Tap the **Tare** button. Zero volume is displayed on the overlay.

5. Remove the empty container from the plasma weigh scale hanger.

6. Place the plasma collection container with product on the weigh scale hanger. The collection volume (plasma volume with AC) is displayed on the overlay.

7. To return to the previous screen, tap **Cancel**.

Adjusting the Sound Level

Use the following steps to change the volume of the audible tones made by the device. The sound level adjustment is available while a procedure is in progress.

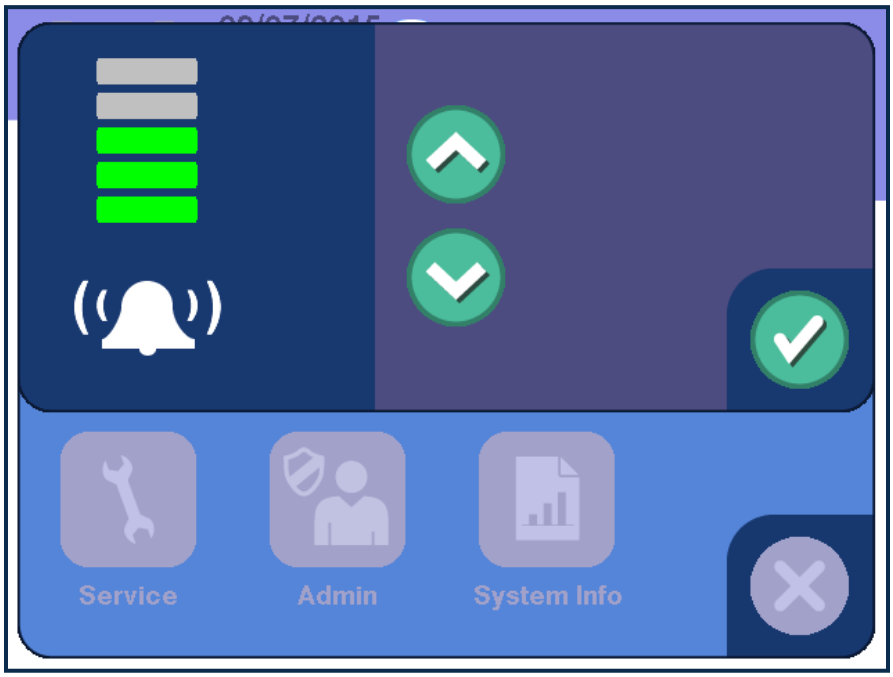
1. Tap **Sound Level**.

Figure 124: Typical Instrument Settings Tab

2. Tap **Up** or **Down** to adjust the sound level.

4. Tap the **Check** button to return to the **Information** overlay.

Figure 125: Typical Sound Adjustment Overlay



System Information

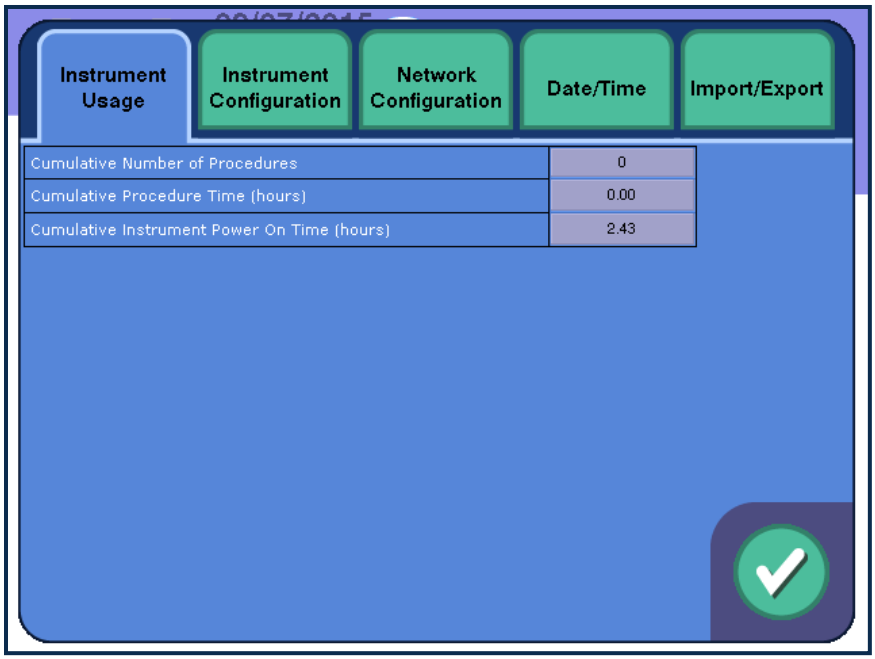
The **System Information** page provides access to device usage information, software configuration information, network configuration information, and the ability to change the device date and time display settings.

Tap the **System Information** button. To display the previous overlay/screen, tap **Cancel**.

Instrument Usage

The **Instrument Usage** page displays the cumulative number of procedures, cumulative procedure time (hours), and cumulative power ON time (hours).

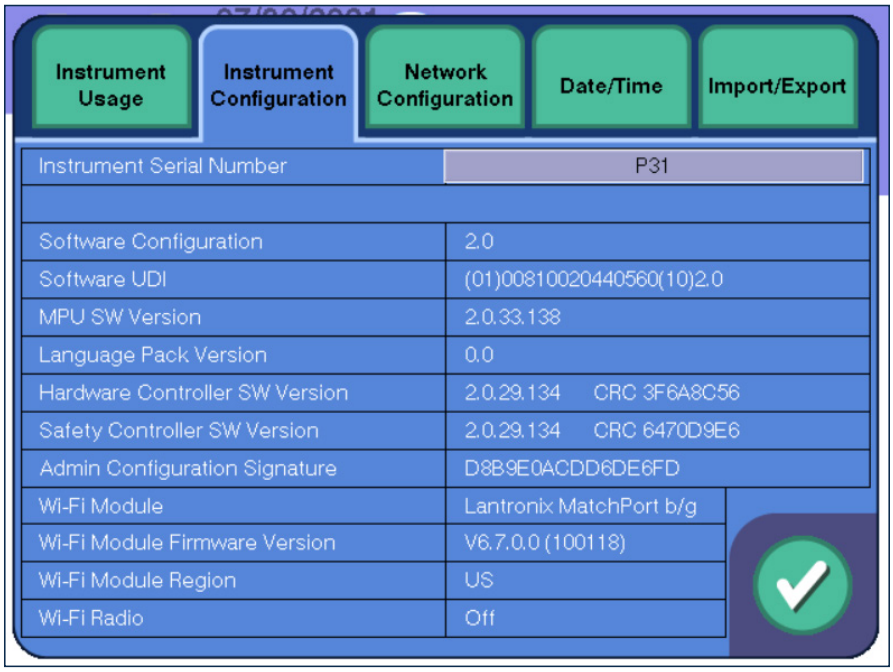
Figure 126: Typical Instrument Usage Page



Instrument Configuration

The **Instrument Configuration** page displays the serial number, Unique Device Identification (UDI), software versions for the MPU, language pack, hardware, safety controllers, and Wi-Fi module parameters such as module type, firmware version, region, and radio status (applicable if device is configured to connect to a Wi-Fi network; or Wi-Fi module parameters will not show).

Figure 127: Typical Instrument Configuration Page

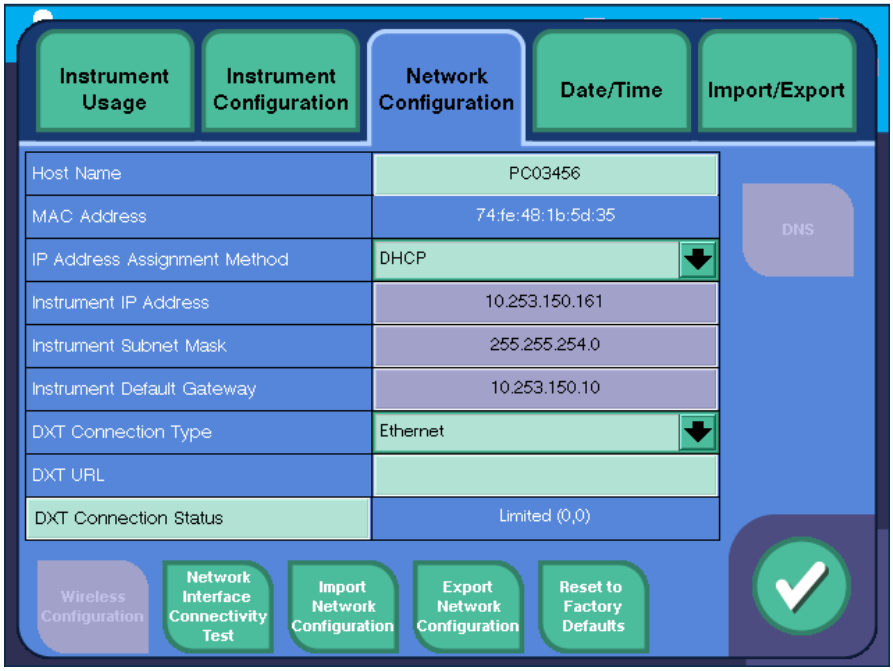


Network Configuration

The **Network Configuration** page displays the current device network configuration and the manufacturer's data management system information.

Instructions for how to set-up network configurations and import/export network configuration files can be found in the Aurora Xi Service Manual.

Figure 128: Typical Network Configuration Page



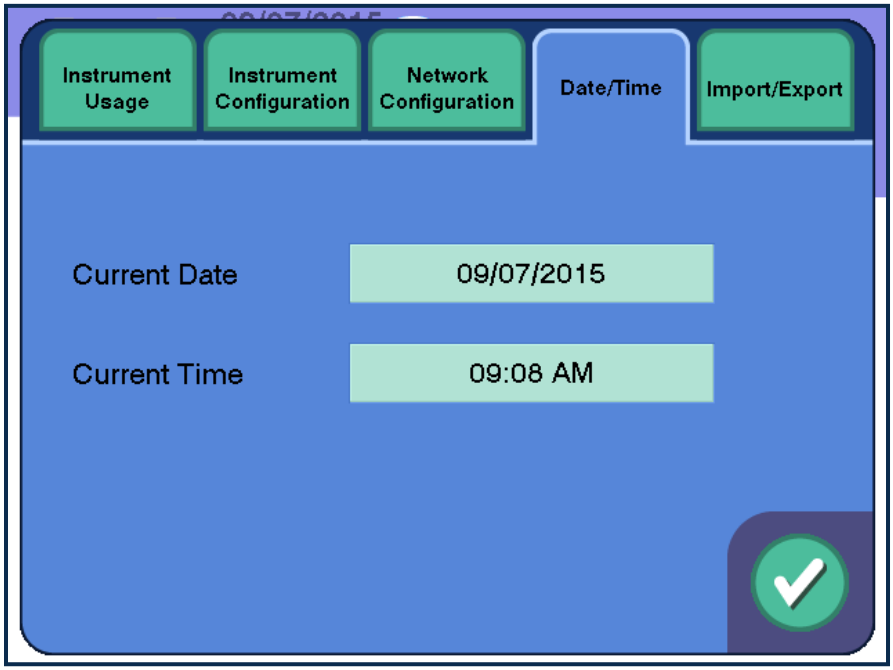
Date/Time

The **Date and Time Settings** page allows the operator to change the screen date and time. This information cannot be edited during a procedure. If needed, tap the desired field on the **Date and Time Settings** page. An associated overlay is displayed. Enter the appropriate information. Tap the overlay **Check** button to confirm and return to the **Date and Time Settings** page. Tap **Cancel** to confirm the displayed entry and return to the previous overlay/screen.

When the device is configured for remote communication, the device is able to synchronize its system clock to the data management system. This ensures accuracy in time stamps in Procedure Records. The time and date on the device displays the time and date set for the data management system server.

Manually changing the date and time on the device triggers re-synchronization of the system clock with the server of the data management system.

Figure 129: Typical Date and Time Settings Page

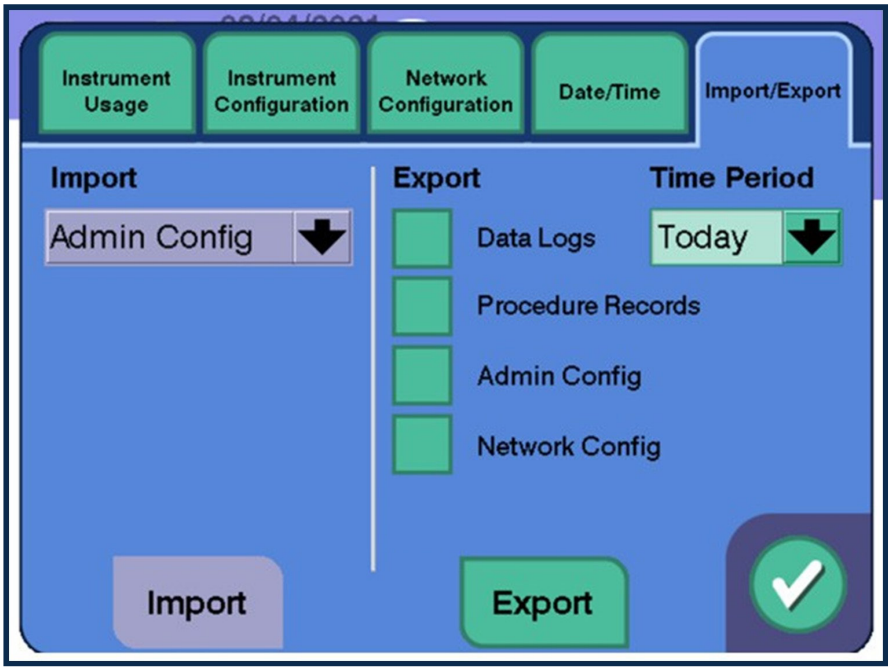


Import/Export

The **Import/Export** page allows the operator to export records, logs, and configuration files from the device.

Instructions for how to export log files, perform a software update, import and export administrative settings, import language packs, and import and export network configurations can be found in the Aurora Xi Service Manual.

Figure 130: Typical Import/Export Page



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Chapter 5
Troubleshooting

This chapter provides a description of the device's alert/alarm system and how to troubleshoot the system.

- For troubleshooting conditions with alert/alarm codes, see **"Section 5.2: Alerts/Alarms in Numeric Order"**.
- For troubleshooting conditions with no alert/alarm codes, see **"Section 5.3: Non-Alert/Alarm Troubleshooting"**.
- When troubleshooting any condition, refer to your center's SOPs.

Section 5.1: Alert/Alarm Overview

Alerts/alarms may occur any time the device is powered ON. If a donor is connected when an alert/alarm occurs, all pumps stop, all clamps close, and the cuff deflates. If the device loses power, the unpowered safe state stops all pumps, closes all clamps except the blood clamp, and deflates the cuff.

When an alert/alarm condition occurs, the system displays an alert/alarm screen. For detailed information about the elements on the alert/alarm screen, see**"Alert/Alarm Screen Elements" on page 5-2**.

Each alert/alarm is assigned a unique numeric code. To troubleshoot alerts/alarms, see **"Section 5.2: Alerts/Alarms in Numeric Order"**.

NOTE

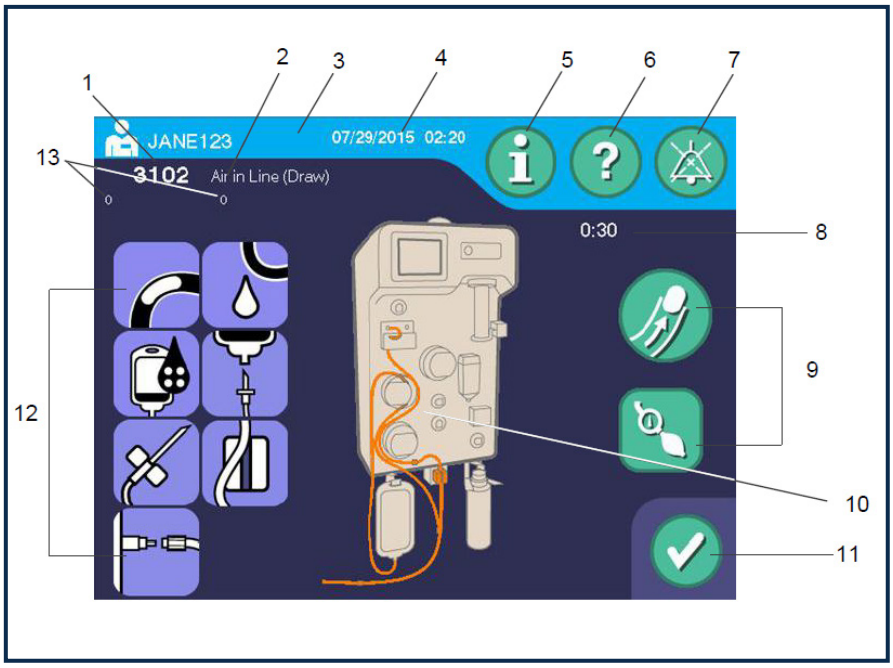
- Alert/alarm messages should be documented per local regulatory requirements
- The section on alert/alarm terminology also covers any advisories that occur.
- An audible tone will not sound for a power loss alert.
- Alert/alarm logs are saved in the electronic Procedure Record when the device is powered OFF or power is lost.
- When the system has run out of space to save more alert/alarm log files, it overwrites the oldest log file.
- The system can store up to 1000 events in each Procedure Record.
- The system can store up to 600 Procedure Records and 600 system event logs.

In addition, the system provides an audio sound tone and illuminates the device signal light. Depending on the priority of the alert/alarm, the signal light changes color and/or flashes. For detailed information about the signal light and audio tones, see **"System Status" on page 5-4**.

Alert/Alarm Screen Elements

This section identifies and provides detailed information about alert/alarm screen elements.

Figure 131: Typical Alert/Alarm Screen



1. **Alert/Alarm Code:** Displays the alert/alarm code.

2. **Alert/Alarm Title:** Displays the alert/alarm title.

3. **Alert/Alarm Header:** The alert/alarm header is across the top of the screen. The header color is dependent on the alert/alarm priority. For detailed information about the alert/alarm header color priority, see **"System Status" on page 5-4**.

4. **Date/Time:** Displays the current date and time.

5. **Information Button:** Tap to view or change information during the procedure, access the notepad, and change the operator ID.

   - For detailed information about the **Information** button, see **"Advanced Options" on page 4-78**.
   - For detailed information about the notepad, see **"Accessing the Notepad" on page 5-3**.

6. **Help Button:** Tap to access **Help** screens. **Help** screens provide additional information about a particular alert/alarm. For detailed information about the **Help** screens, see **"Accessing Help Screens" on page 5-3**.

7. **Audio Pause Button:** Tap to silence the audible alert/alarm tone for two minutes. Tap it again to unmute the alert/alarm tone.

8. **Pause Timer:** Displays the total time blood flow has been stopped.

9. **Action Buttons:** Tap to access actions required for alert/alarm resolution.

10. **Device Map:** Diagram that illustrates the alert/alarm condition location and where to check the disposable set or device for possible condition source.

11. **Check Button:** Tap to save entries and close the displayed touchscreen or overlay.

12. **Troubleshooting Icon(s):** Displayed to identify the possible causes of the alert/alarm condition. For a detailed list of alert/alarm icons, see the **"Glossary of Graphics"**.

13. **Data 1 and Data 2 Code:** Codes for service purposes only. When calling service, provide these codes to assist service.

Accessing Help Screens

If more information is desired about the alert/alarm, tap the **Help** button.

To return to the original alert/alarm screen, tap the **Check** button**.**

Accessing the Notepad

To access the notepad, tap the **Information** button. To enter a note, tap the **Notepad** button to display a keypad overlay. Type in the desired note or scan the desired note using the barcode scanner, then tap the **Check** button to return to the previous screen. The note is logged in the Procedure Record, along with the operator ID and the date and time that the note was recorded.

System Status

System status for the device signal light and audio tones are described in the following table:

Table 1: System Status

System Status		Screen Header Color	Signal Light Color	Audible Tone (Set 1)	Audible Tone (Set 2)
Normal operating conditions	Procedure not in progress	Lavender	N/A	N/A	N/A
	Procedure in progress	Blue	Green (continuous)		
Procedure paused		Orange	Green (flashing)	N/A	N/A
Advisory		Blue		Two-tone chime	Two-tone chime
Low priority alarm		Yellow	Yellow (continuous)	Two beeps in a row	Single beep
Medium priority alarm		Orange	Yellow (flashing)	Three beeps in a row	Three beeps in a row
High priority alarm		Red	Red (flashing)	Three beeps in a row, then two beeps in a row	Three beeps in a row, then two beeps in a row

NOTE

- Currently, there are no medium priority or high priority alarms.
- If Alert/Alarm Presentation is set to All Alarms, then the system uses Audible Tone (Set 2). Otherwise, the system uses Audible Tone (Set 1).

Auto-Recovery

The system may attempt to automatically resolve certain alert/alarm conditions and resume the procedure without operator intervention (auto-recovery). When this happens, an **Auto-Recovery** icon is displayed and buttons on the screen are disabled.

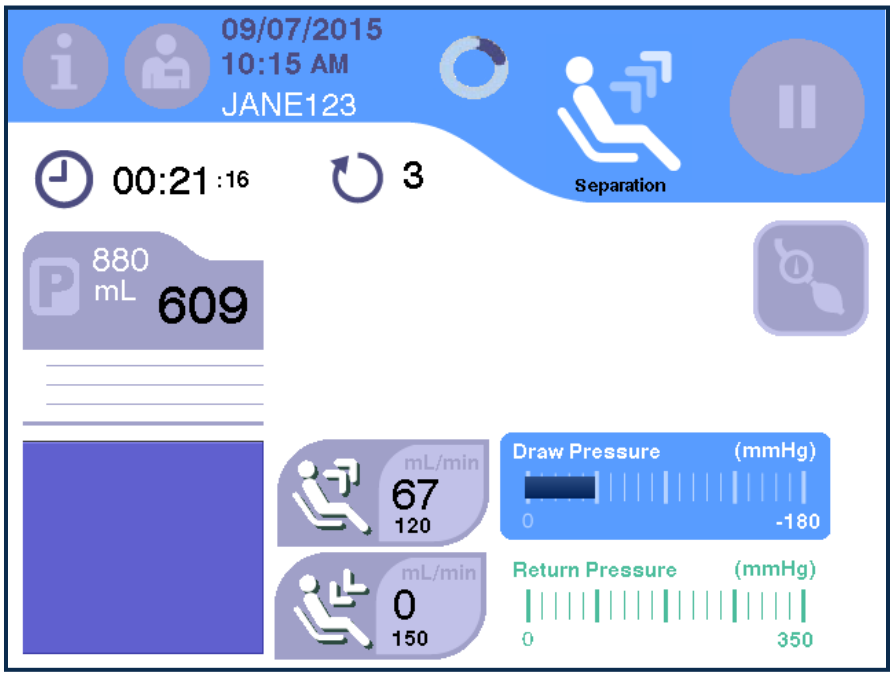
If the auto-recovery is successful, the icon is no longer displayed and buttons are re-enabled. If the auto-recovery is unsuccessful, the system generates an alert/alarm requiring operator intervention.

NOTE

- Clearing Air Auto-Recovery alert (3110) does not result in another alert if not corrected. This alert prompts the operator to perform an air purge prior to returning fluids to the donor.

Auto-recovery is documented in the Procedure Record as an alert.

Figure 132: Typical Example Screen During Auto-Recovery



A summary of auto-recovering alerts is listed in the following table:

Table 2: Auto-Recovery Codes

Auto-Recovery Code	Icon Displayed	Auto-Recovery Name
2062	Auto-Recovery	Blood Pump Fast Stop Error
2064	Auto-Recovery	Hardware Brake Error
3100	Auto-Recovery – Purging	Clearing Air...
3110	Auto-Recovery	Clearing Air...
3630	Auto-Recovery	Cuff Left Inflated
10021	Auto-Recovery – Collection Scale Disturbed	Scale Disturbed
10022	Auto-Recovery – Reservoir Scale Disturbed	Scale Disturbed
10023	Auto-Recovery – AC Scale Disturbed	Scale Disturbed
10050	Auto-Recovery	Pressure Out of Range
10101	Auto-Recovery	AC Pump Rate Error
10102	Auto-Recovery	Blood Pump Rate Error
10103	Auto-Recovery	Cell Pump Rate Error
10104	Auto-Recovery	AC Pump Rate Error
10105	Auto-Recovery	Blood Pump Rate Error
10106	Auto-Recovery	Cell Pump Rate Error
10107	Auto-Recovery	Pump Overspeed

Auto-Recovery Code	Icon Displayed	Auto-Recovery Name
10108	Auto-Recovery	Reverse Direction
10111	Auto-Recovery	Separator Communication Error
10112	Auto-Recovery	Separator Rate Error
14037	Auto-Recovery	Sensor Read Failure

NOTE

➞ When the auto-recovering 3100 alert occurs, the system may purge one or more times before resuming the procedure, in order to fully clear air.

Recoverable Alerts/Alarms

Recoverable alerts/alarms may indicate conditions that affect donor safety if not resolved. These alerts/alarms may occur while the procedure is in progress. Operator intervention is required.

Use the touchscreen to resolve alerts/alarms. Tap the **Check** button on the screen to continue the procedure after resolving an alert/alarm.

After clearing an alert/alarm, do not tap any buttons if previous screen flashes before re-displaying the alert/alarm screen. Persistent recoverable alerts/alarms may require that the procedure be ended.

CAUTION

➞ Repeatedly clearing a persistent alert/alarm by tapping the **Check** button without resolving the underlying condition may lead to inaccuracies in the blood and AC monitoring safety systems.

If the device has a persistent alert/alarm condition, press the **STOP** button to end the procedure. For detailed information about using the **STOP** button, see **"Section 4.10: Using the STOP Button"**.

Non-Recoverable Alerts/Alarms

Non-recoverable alerts/alarms require the operator to immediately disconnect the donor and end the procedure.

Some non-recoverable alerts/alarms may also allow the operator to perform optional manual reinfusion prior to disconnecting the donor. See **"Section 5.3: Non-Alert/Alarm Troubleshooting"**. The following table provides actions for displayed icons:

Icon	Action
	Disconnect the donor.
	Press the **STOP** button and shut down the device.
	Switch to power OFF.

NOTE

➔ After positioning the power switch to OFF, wait at least 10 seconds before attempting to position the power switch back to ON.

Alert/Alarm System Delays

Scale and Pump Mismatch alerts/alarms (3008, 3020, 3021, and 10014) may take up to 25 mL of pumped volume before a leak is detected.

In a No Saline Protocol, the system may pump up to 60 mL before a leak in the reservoir is detected by a Fluid Not Seen in Reservoir alert/alarm (3001).

Section 5.2: Alerts/Alarms in Numeric Order

The alerts/alarms are listed in numeric order. The system displays the higher priority alarms over the lower priority alarms. Within the alerts and advisories, those that have fewer recovery options are assigned a higher priority.

- The priority listed in the flowchart only applies to the "All Alerts" setting under the Alert/Alarm Presentation menu in the administrative settings. Refer to **"Table 1: System Status"** to see the priority for other settings.
- For a complete list of alert/alarm codes, see **"Table 3: Alert/Alarm Codes"**.

The flowcharts in this section provide operator instructions for resolving Aurora Xi alerts/alarms. Each flowchart contains the following information:

- **Code:** Numeric code of the alert/alarm. The codes are categorized below:

Code	Alert/Alarm Category
0xxx	General
1xxx	Initialization
2xxx	Set-Up
3xxx	Collection
4xxx	Post-Collection
5xxx	Rinse/Infusion
8xxx	Communications
9xxx	Data Management
10xxx	Platform Functions
11xxx	Safety Monitor
12xxx	System Utility
13xxx	User Interface
14xxx	Operating System
15xxx	Software

- **Title and Help Text:** Name of the alert/alarm.
- **Priority:** Classification of condition.
- **Meaning:** Description of alert/alarm.
- **Flowchart:** Steps to follow for alert/alarm condition.

If an alert/alarm persists and you are unable to solve the issue after following the flowchart, contact service. For detailed information on how to contact service, see **"Section 6.7: Service"**.

The following warnings and cautions should be considered when resolving alerts/alarms.

WARNING

- The system cannot prevent or detect all blood loss. Failure of the operator to perform alert recovery actions can increase the hazard for blood loss and increase the extracorporeal blood volume.
- If particulate matter is observed in the disposable set, end the procedure without returning fluids or reservoir contents.
- If the donor line is removed from the air detector, ensure that the correct line is re-installed to maintain effective air detection.
- If an Air In Line alert (3102) is present and the procedure is going to be ended, inspect the donor line for air. If air is present in the donor line, end the procedure without fluid return, to mitigate the risk of air infusion.

CAUTION

- End the procedure without fluid return if set integrity is compromised. Do not manually reinfuse reservoir contents.
- Clean and disinfect blood spills immediately. Treat all spills and potentially contaminated surfaces as potential biohazards.
- If there is a leak from the plasma collection container, end the procedure with optional fluid return. Estimate and record the collection volume according to the center's SOPs in order to ensure proper reporting of plasma loss.
- Do not attempt to clear the donor line, blood line, or needle, or resolve a venipuncture problem by infusing saline to the donor.
- Do not replace a depleted AC container because it will impact the system's ability to manage the citrate infusion rate.
- Air infusion or blood clots may develop if you fail to monitor the AC container and end the procedure if air enters the AC line after a 3004 alert.
- Do not push open any clamp at any time during the procedure, unless directed by troubleshooting instructions.
- Be sure to not kink the P1 or P2 lines when recovering from blood detection alerts.
- If there is blood on the saline container outside of the saline clamp, end the procedure with optional fluid return.
- If blood has moved to the AC container side of the AC pump, end the procedure without fluid return.
- End the procedure without fluid return if there is unexpected noise from the separation device.
- If a 3302 alert/alarm occurs, do not return fluids or reservoir contents.

CAUTION

- If red blood cells become visible in the plasma line or collection container, end the procedure with optional fluid return.
- To avoid inaccurate pressure sensor readings, end the procedure without fluid return if blood has touched or entered into the pressure sensor ports (P1 or P2).
- If two 3025 alerts occur in a saline procedure, the plasma product should be discarded due to possible dilution with saline.
- Do not open any pump handle at any time between disposable set Install Check and disposable set removal, except when directed by troubleshooting instructions.
- Do not open the Hb detector assembly door at any time between disposable set Install Check and disposable set removal, except when directed by troubleshooting instructions.
- Do not open the lower separator support, adjust the alignment of the separator, or squeeze the separator at any time between disposable set Install Check and disposable set removal, except when directed by troubleshooting instructions.

Table 3: Alert/Alarm Codes

Alert/ Alarm Code	Title	Alert/Alarm Presentation			
		All Alerts	Select Alerts	All Alarms	
				Outside of Collection	During Collection
1003	Incorrect Date/Time	Advisory	Advisory	Advisory	N/A
1030	Stop Button Error	Advisory	Advisory	Advisory	N/A
2001	P1 and P2 Vent Failure	Advisory	Advisory	Advisory	N/A
2002	Low P2 Pressure	Advisory	Advisory	Advisory	N/A
2003	High P1, Low P2 Pressures	Advisory	Advisory	Advisory	N/A
2004	P1, P2 Reversed	Advisory	Advisory	Advisory	N/A
2005	High P1 Pressure	Advisory	Advisory	Advisory	N/A
2006	AC Line Revered	Advisory	Advisory	Advisory	N/A
2007	High P1 Pressure	Advisory	Advisory	Advisory	N/A
2009	Low P2 Pressure	Advisory	Advisory	Advisory	N/A
2011	Low P1 Pressure	Advisory	Advisory	Advisory	N/A
2013	P1 Pressure Loss	Advisory	Advisory	Advisory	N/A
2014	P2 Pressure Loss	Advisory	Advisory	Advisory	N/A
2015	P2 Vent Failure	Advisory	Advisory	Advisory	N/A
2016	P2 Vent Failure	Advisory	Advisory	Advisory	N/A
2017	P2 Vent Failure	Advisory	Advisory	Advisory	N/A

Alert/ Alarm Code	Title	Alert/Alarm Presentation			
		All Alerts	Select Alerts	All Alarms	
				Outside of Collection	During Collection
2020	Reservoir Scale Out of Range	Advisory	Advisory	Advisory	N/A
2021	Tubing Not Detected	Advisory	Advisory	Advisory	N/A
2022	Transducer Cover Open	Advisory	Advisory	Advisory	N/A
2030	Plasma Scale Out of Range	Advisory	Advisory	Advisory	N/A
2040	Fluid Detected	Advisory	Advisory	Advisory	N/A
2053	Hb Detector Out of Range	Advisory	Advisory	Advisory	N/A
2062	Blood Pump Fast Stop Error	Advisory	Advisory	Advisory	N/A
2064	Hardware Brake Error	Advisory	Advisory	Advisory	N/A
2101	P2 Pressure Out of Range	Advisory	Advisory	Advisory	N/A
2102	No Saline Detected	Advisory	Advisory	Advisory	N/A
2103	No AC Weight Detected	Advisory	Advisory	Advisory	N/A
2110	Solutions Prime has been Attempted Too Many Times Without Completion	Advisory	Advisory	Advisory	N/A
2111	AC Line in Air Detector	Advisory	Advisory	Advisory	N/A
2112	No Fluid at Air Detector	Advisory	Advisory	Advisory	N/A
2113	AC Not Flowing	Advisory	Advisory	Advisory	N/A
2114	No Change on AC Scale	Advisory	Advisory	Advisory	N/A
2120	No Saline Added to Reservoir	Advisory	Advisory	Advisory	N/A
2130	Reverse Prime Failed	Advisory	Advisory	Advisory	N/A
2131	Reverse Prime Failed	Advisory	Advisory	Advisory	N/A
2140	P1 Pressure Out of Range	Advisory	Advisory	Advisory	N/A
2141	No Fluid at Air Detector	Advisory	Advisory	Advisory	N/A
2150	Plasma Scale Out of Range	Advisory	Advisory	Advisory	N/A
2160	Missing Data	Advisory	Advisory	Advisory	N/A
2301	Pressure Out of Range	Advisory	Advisory	Advisory	N/A
2302	Motor Test Error	Advisory	Advisory	Advisory	N/A
2304	Cuff Pressure Out of Range	Advisory	Advisory	Advisory	N/A
2305	Tubing Detected	Advisory	Advisory	Advisory	N/A
2307	Set Timeout	Advisory	Advisory	Advisory	N/A
2310	Fault Detection System Error	Advisory	Advisory	Advisory	N/A

Alert/ Alarm Code	Title	Alert/Alarm Presentation			
		All Alerts	Select Alerts	All Alarms	
				Outside of Collection	During Collection
2311	Fluid Detected	Advisory	Advisory	Advisory	N/A
2320	Weight on Scale	Advisory	Advisory	Advisory	N/A
2321	Weight on Scale	Advisory	Advisory	Advisory	N/A
2322	Weight on Scale	Advisory	Advisory	Advisory	N/A
2325	Scale QC Expired	Advisory	Advisory	Advisory	N/A
2326	Scale QC Expired	Advisory	Advisory	Advisory	N/A
2327	Scale QC Expired	Advisory	Advisory	Advisory	N/A
2338	Hb Detector Out of Range	Advisory	Advisory	Advisory	N/A
2354	Hb Detector Needs Calibration	Advisory	Advisory	Advisory	N/A
2400	Weight on Scale	Advisory	Advisory	Advisory	N/A
2401	Calibration Required	Advisory	Advisory	Advisory	N/A
2402	Weight on Scale	Advisory	Advisory	Advisory	N/A
2403	Calibration Required	Advisory	Advisory	Advisory	N/A
2404	Weight on Scale	Advisory	Advisory	Advisory	N/A
2405	Calibration Required	Advisory	Advisory	Advisory	N/A
2409	Gain Outside of Tolerance Limit	Advisory	Advisory	Advisory	N/A
2410	Gain Outside of Tolerance Limit	Advisory	Advisory	Advisory	N/A
2411	Gain Outside of Tolerance Limit	Advisory	Advisory	Advisory	N/A
3001	Fluid Not Seen in Reservoir	Advisory	Low Priority Alarm	N/A	Low Priority Alarm
3002	High P2 Pressure	Advisory	Advisory	N/A	Low Priority Alarm
3003	Low P2 Pressure	Advisory	Advisory	N/A	Low Priority Alarm
3004	Low AC	Advisory	Advisory	N/A	Low Priority Alarm
3005	Slow Plasma Collection	Advisory	Advisory	N/A	Low Priority Alarm
3008	Scale and Pump Mismatch	Advisory	Low Priority Alarm	N/A	Low Priority Alarm
3015	No Plasma Collected	Advisory	Low Priority Alarm	N/A	Low Priority Alarm

Alert/ Alarm Code	Title	Alert/Alarm Presentation			
		All Alerts	Select Alerts	All Alarms	
				Outside of Collection	During Collection
3020	Scale and Pump Mismatch	Advisory	Low Priority Alarm	N/A	Low Priority Alarm
3021	Scale and Pump Mismatch	Advisory	Low Priority Alarm	N/A	Low Priority Alarm
3022	Scale and Pump Mismatch	Advisory	Low Priority Alarm	N/A	Low Priority Alarm
3024	Collection Volume Loss	Advisory	Low Priority Alarm	N/A	Low Priority Alarm
3025	Collection Volume Increase	Advisory	Advisory	N/A	Low Priority Alarm
3100	Clearing Air…	Advisory	Advisory	N/A	Advisory
3101	Air in Line (Return)	Advisory	Advisory	N/A	Low Priority Alarm
3102	Air in Line (Draw)	Advisory	Advisory	N/A	Low Priority Alarm
3103	Air in Line (Rinse)	Advisory	Advisory	N/A	Low Priority Alarm
3110	Clearing Air…	Advisory	Advisory	N/A	Advisory
3200	Air Purge Unsuccessful	Advisory	Low Priority Alarm	N/A	Low Priority Alarm
3301	Redness Detected	Advisory	Low Priority Alarm	N/A	Low Priority Alarm
3302	Redness Limit Reached	Advisory	Low Priority Alarm	N/A	Low Priority Alarm
3303	RBCs or Redness Detected	Advisory	Low Priority Alarm	N/A	Low Priority Alarm
3304	High Redness Detected	Advisory	Low Priority Alarm	N/A	Low Priority Alarm
3508	No Blood Flow	Advisory	Advisory	N/A	Low Priority Alarm
3520	Cuff Not Inflated	Advisory	Advisory	N/A	Low Priority Alarm

Alert/ Alarm Code	Title	Alert/Alarm Presentation			
		All Alerts	Select Alerts	All Alarms	
				Outside of Collection	During Collection
3601	High Return Pressure	Advisory	Advisory	N/A	Low Priority Alarm
3603	High Return Pressure	Advisory	Advisory	N/A	Low Priority Alarm
3610	P1 Pressure Did Not Change	Advisory	Advisory	N/A	Low Priority Alarm
3620	Cuff Not Deflated	Advisory	Advisory	N/A	Low Priority Alarm
3630	Cuff Left Inflated	Advisory	Advisory	N/A	Advisory
4001	Weight on Scale	Advisory	Advisory	Advisory	Advisory
8001	Invalid USB Accessory Connected	Advisory	Advisory	Advisory	Low Priority Alarm
10001	Hb Detector Hardware Failed	Advisory	Advisory	Advisory	Low Priority Alarm
10004	Air Detector Fault	Advisory	Advisory	Advisory	Advisory
10011	Scale Disturbed	Advisory	Advisory	Advisory	Low Priority Alarm
10012	Scale Disturbed	Advisory	Advisory	Advisory	Low Priority Alarm
10013	Scale Disturbed	Advisory	Advisory	Advisory	Low Priority Alarm
10014	Scale and Pump Mismatch	Advisory	Advisory	Advisory	Low Priority Alarm
10015	AC Volume Loss	Advisory	Advisory	Advisory	Low Priority Alarm
10016	AC Volume Gain	Advisory	Advisory	Advisory	Low Priority Alarm
10017	Reservoir Volume Loss	Advisory	Advisory	Advisory	Low Priority Alarm
10018	The Reservoir Scale Detected	Advisory	Advisory	Advisory	Low Priority Alarm
10021	Scale Disturbed	Advisory	Advisory	Advisory	Advisory
10022	Scale Disturbed	Advisory	Advisory	Advisory	Advisory
10023	Scale Disturbed	Advisory	Advisory	Advisory	Advisory
10031	Scale Overload	Advisory	Advisory	Advisory	Low Priority Alarm
10032	Scale Overload	Advisory	Advisory	Advisory	Low Priority Alarm
10033	Scale Overload	Advisory	Advisory	Advisory	Low Priority Alarm

Alert/ Alarm Code	Title	Alert/Alarm Presentation			
		All Alerts	Select Alerts	All Alarms	
				Outside of Collection	During Collection
10050	Pressure Out of Range	Advisory	Advisory	Advisory	Advisory
10099	Pump Auto Recovery Failed	Advisory	Advisory	Advisory	Low Priority Alarm
10100	Auto Recovery Failed	Advisory	Advisory	Advisory	Low Priority Alarm
10101	AC Pump Rate Error	Advisory	Advisory	Advisory	Advisory
10102	Blood Pump Rate Error	Advisory	Advisory	Advisory	Advisory
10103	Cell Pump Rate Error	Advisory	Advisory	Advisory	Advisory
10104	AC Pump Rate Error	Advisory	Advisory	Advisory	Advisory
10105	Blood Pump Rate Error	Advisory	Advisory	Advisory	Advisory
10106	Cell Pump Rate Error	Advisory	Advisory	Advisory	Advisory
10107	Pump Overspeed	Advisory	Advisory	Advisory	Advisory
10108	Reverse Direction	Advisory	Advisory	Advisory	Advisory
10111	Separator Communication Error	Advisory	Advisory	Advisory	Advisory
10112	Separator Rate Error	Advisory	Advisory	Advisory	Advisory
10113	AC Moving Toward Donor	Advisory	Low Priority Alarm	Advisory	Low Priority Alarm
10114	Reverse Direction	Advisory	Advisory	Advisory	Low Priority Alarm
10115	Unexpected Transition	Advisory	Advisory	Advisory	Low Priority Alarm
10116	General System Fault	Advisory	Advisory	Advisory	Low Priority Alarm
10201	Max Draw, Purge Incomplete	Advisory	Advisory	Advisory	Low Priority Alarm
10205	Max Draw, Air in Line	Advisory	Low Priority Alarm	Advisory	Low Priority Alarm
10301	P1 Pressure Not Responding	Advisory	Advisory	Advisory	Low Priority Alarm
10302	P2 Pressure Not Responding	Advisory	Advisory	Advisory	Low Priority Alarm
11001	Fluid at P1	Advisory	Advisory	Advisory	Low Priority Alarm
11002	Fluid at P2	Advisory	Advisory	Advisory	Low Priority Alarm

Alert/ Alarm Code	Title	Alert/Alarm Presentation			
		All Alerts	Select Alerts	All Alarms	
				Outside of Collection	During Collection
11003	Pump Over Current	Advisory	Low Priority Alarm	Advisory	Low Priority Alarm
11004	Pressure Loss	Advisory	Advisory	Advisory	Low Priority Alarm
11005	Transducer Cover Open	Advisory	Advisory	Advisory	Low Priority Alarm
11006	Software Error	Advisory	Advisory	Advisory	Low Priority Alarm
11015	Software Error	Advisory	Advisory	Advisory	Low Priority Alarm
11016	Stop Button Error	Advisory	Advisory	Advisory	Low Priority Alarm
11017	Software Error	Advisory	Advisory	Advisory	Low Priority Alarm
11018	General System Fault	Advisory	Advisory	Advisory	Low Priority Alarm
11021	Pressure Sensor Fault	Advisory	Advisory	Advisory	Low Priority Alarm
11029	Software Error	Advisory	Advisory	Advisory	Low Priority Alarm
11031	Software Error	Advisory	Advisory	Advisory	Low Priority Alarm
11035	Clamp Fault	Advisory	Advisory	Advisory	Low Priority Alarm
11044	Power Failure	Advisory	Advisory	Advisory	Low Priority Alarm
11070	Cuff Left Inflated	Advisory	Advisory	Advisory	Low Priority Alarm
14011	Software Error	Advisory	Advisory	Advisory	Low Priority Alarm
14037	Sensor Read Failure	Advisory	Advisory	Advisory	Advisory
15001	Software Error	Advisory	Advisory	Advisory	Low Priority Alarm
15002	Software Error	Advisory	Advisory	Advisory	Low Priority Alarm
15003	Software Error	Advisory	Advisory	Advisory	Low Priority Alarm
15004	Software Error	Advisory	Advisory	Advisory	Low Priority Alarm

Figure 133: 1003 Incorrect Date/Time

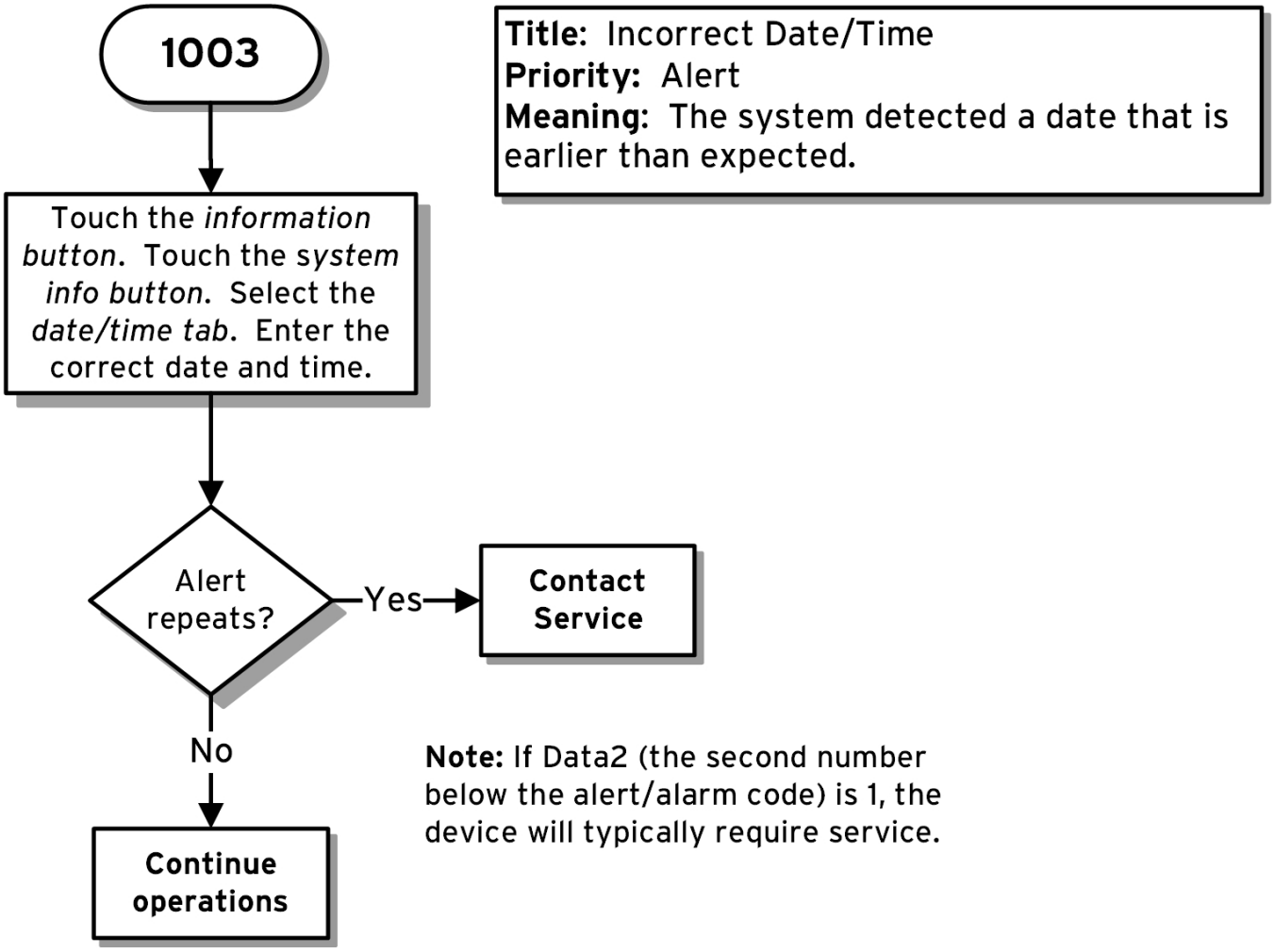


Figure 134: 1030 STOP Button Error

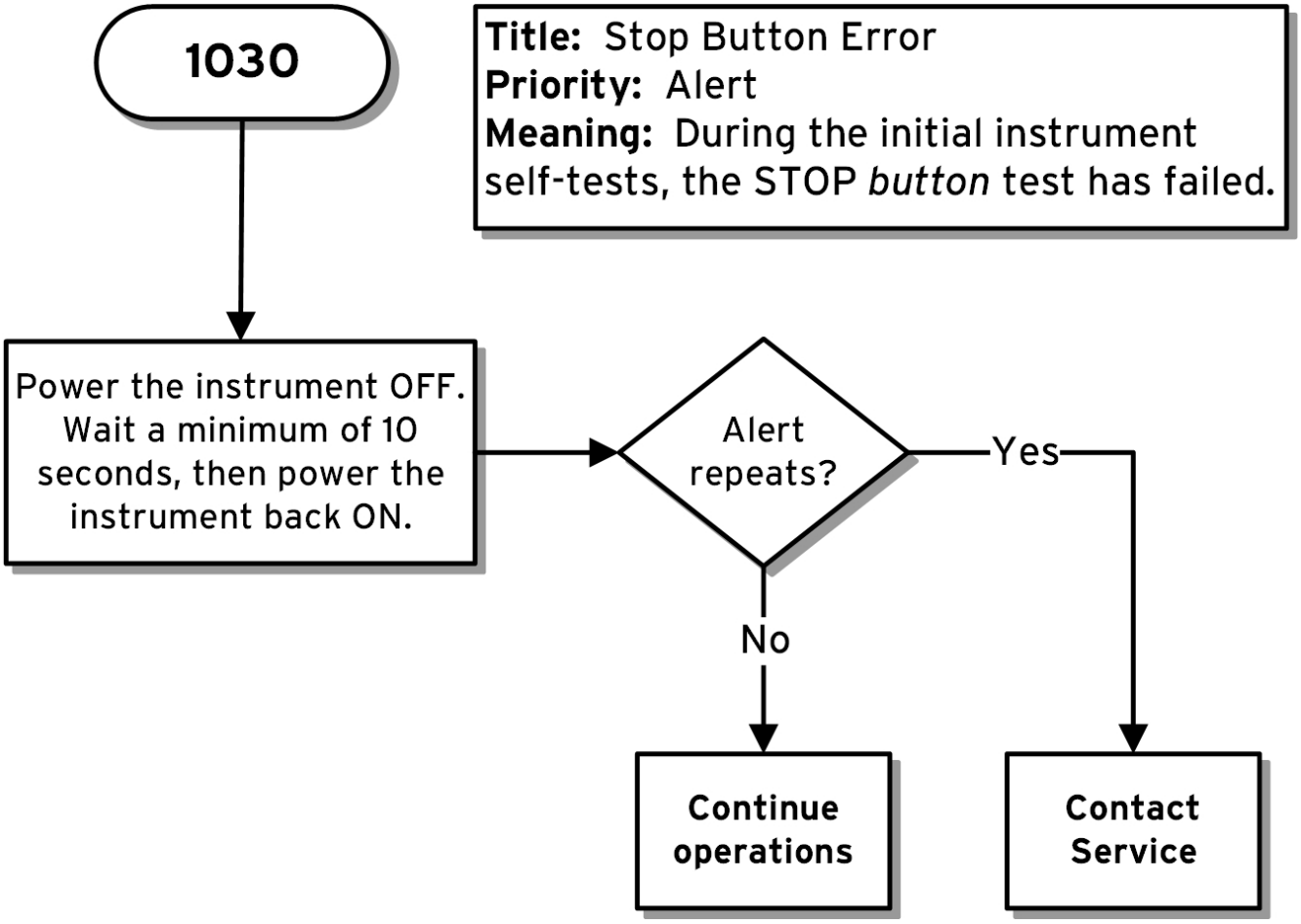


Figure 135: 2001 Initial Vent Failure

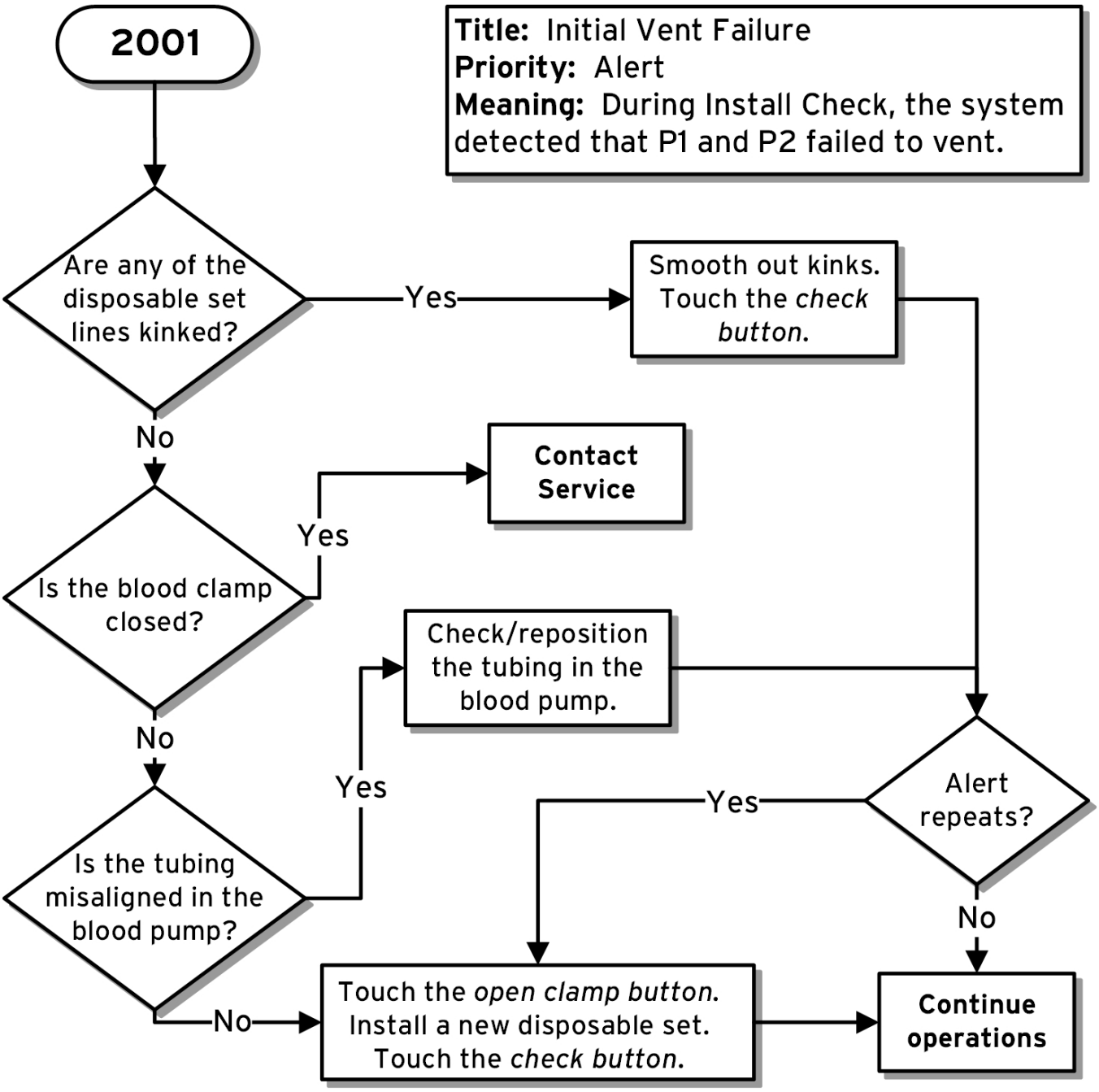


Figure 136: 2002 Low P2 Pressure

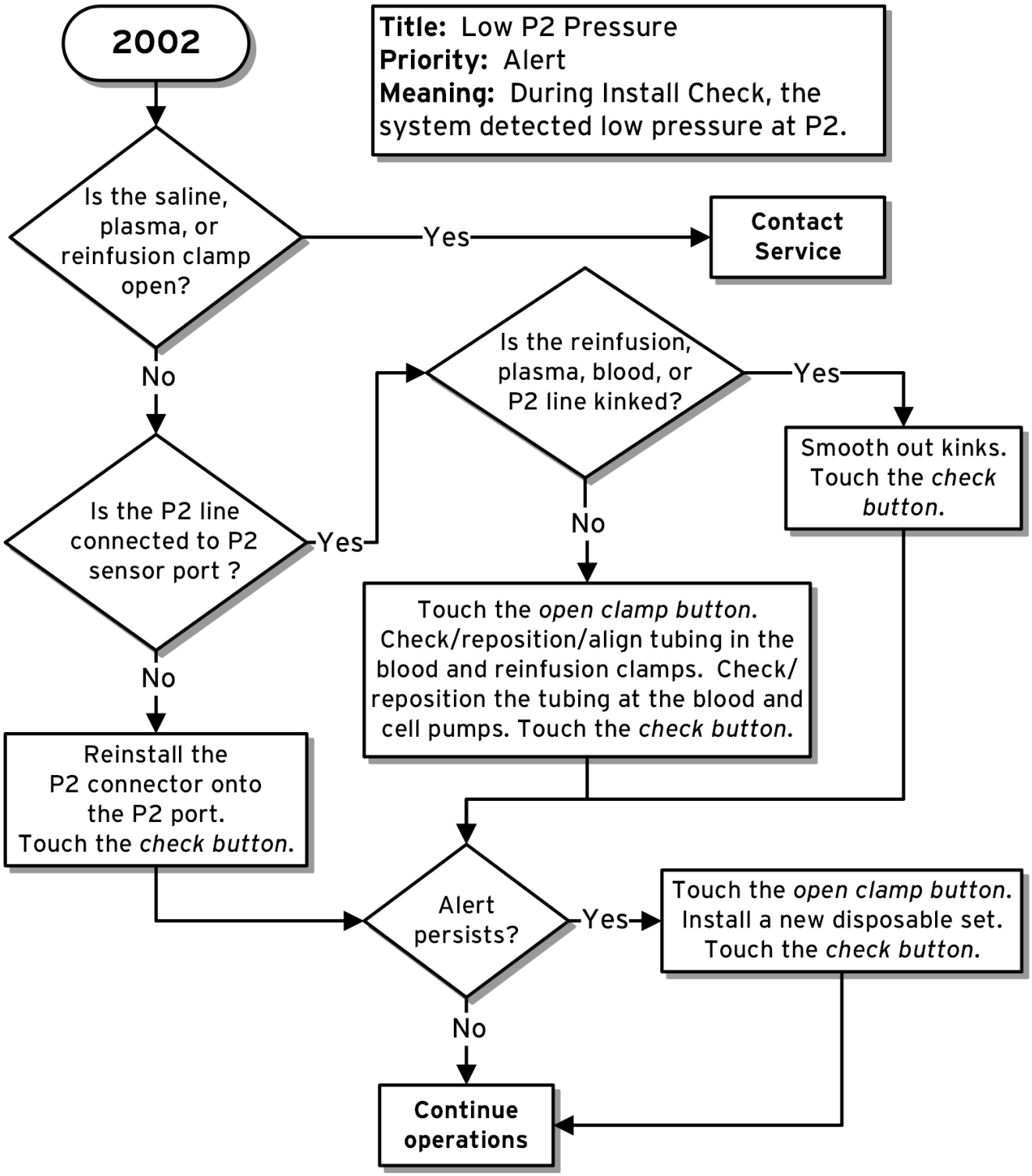


Figure 137: 2003 High P1, Low P2 Pressures

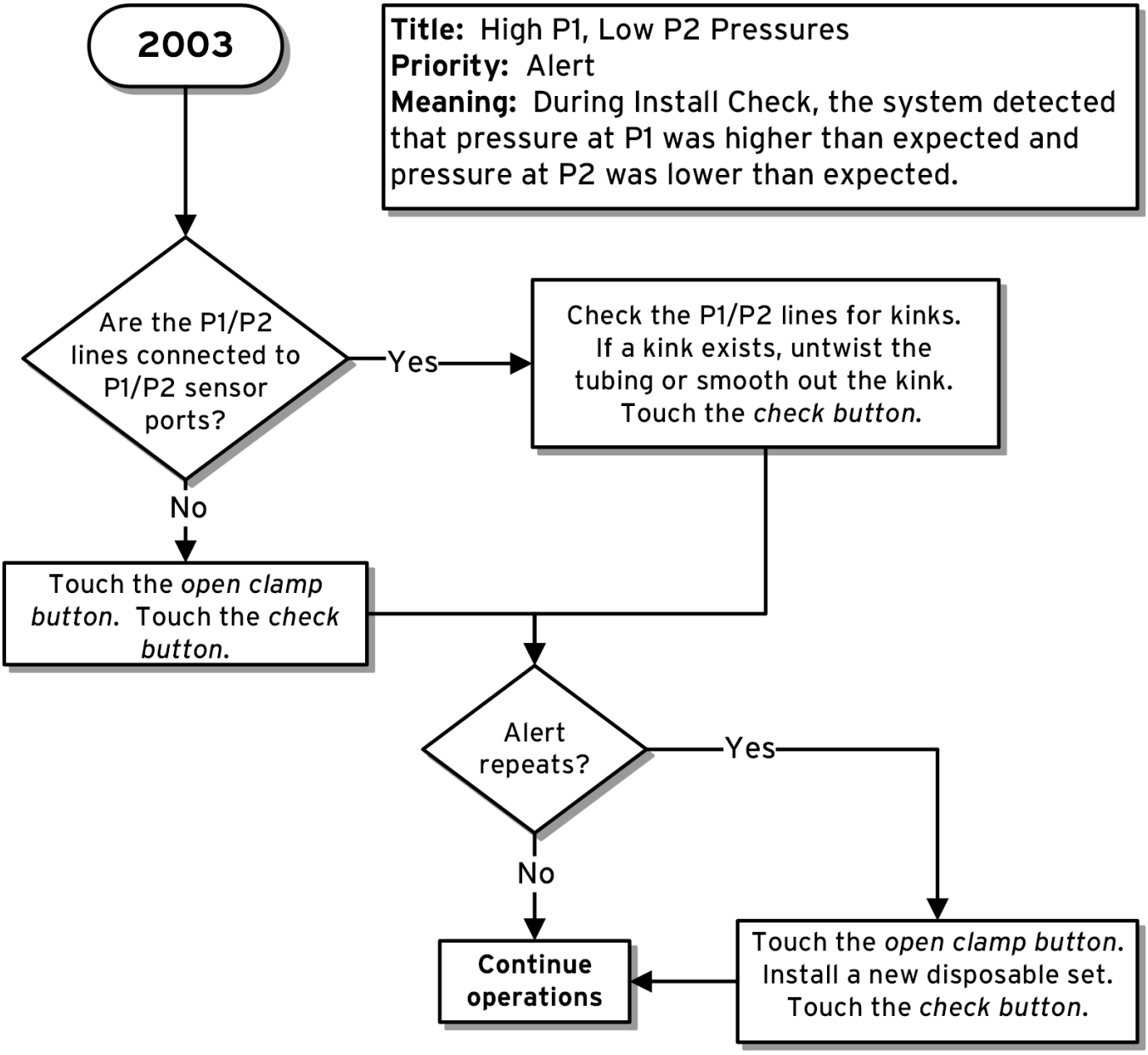


Figure 138: 2004 P1, P2 Reversed

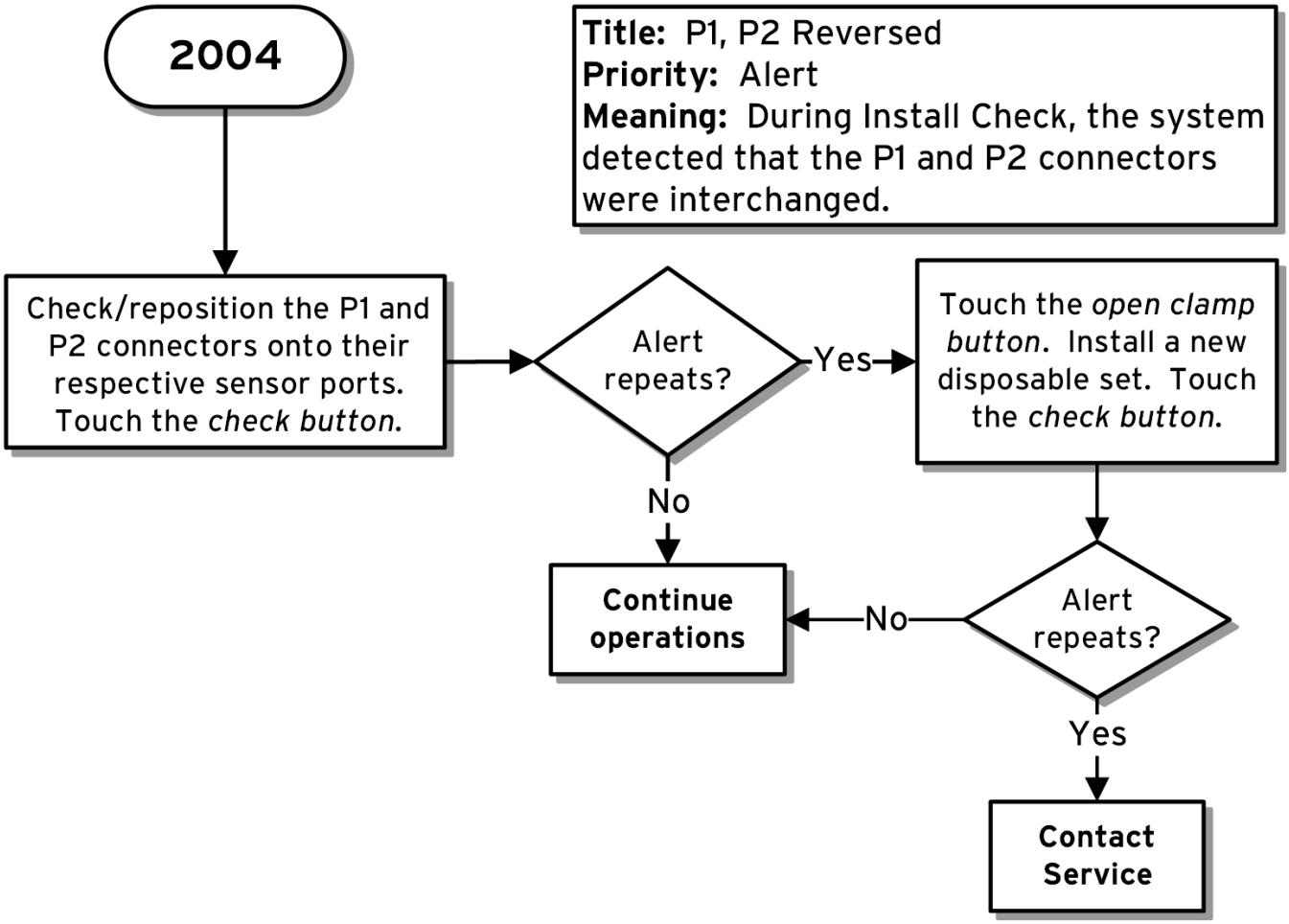


Figure 139: 2005 High P1 Pressure

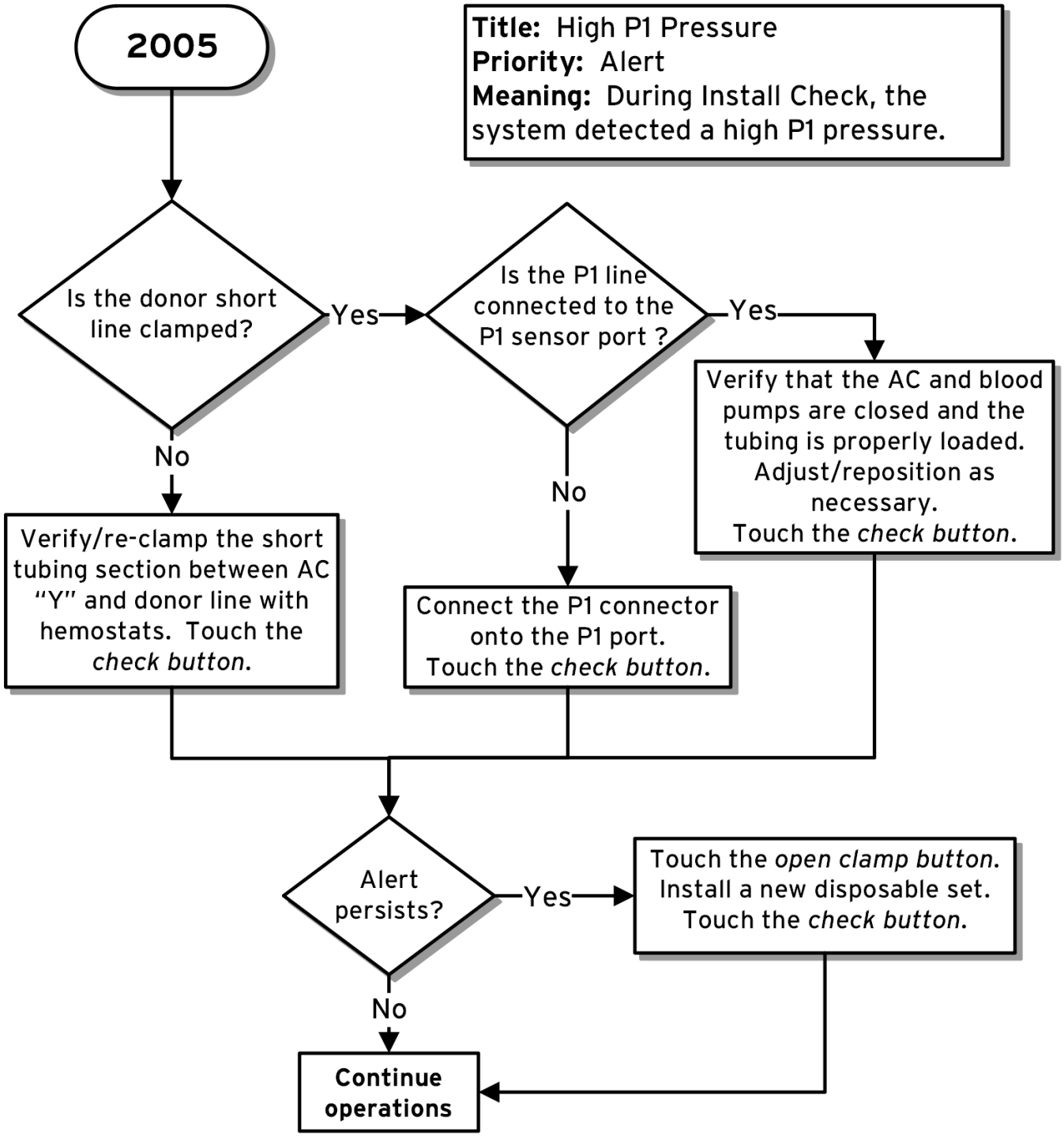


Figure 140: 2006 AC Line Reversed

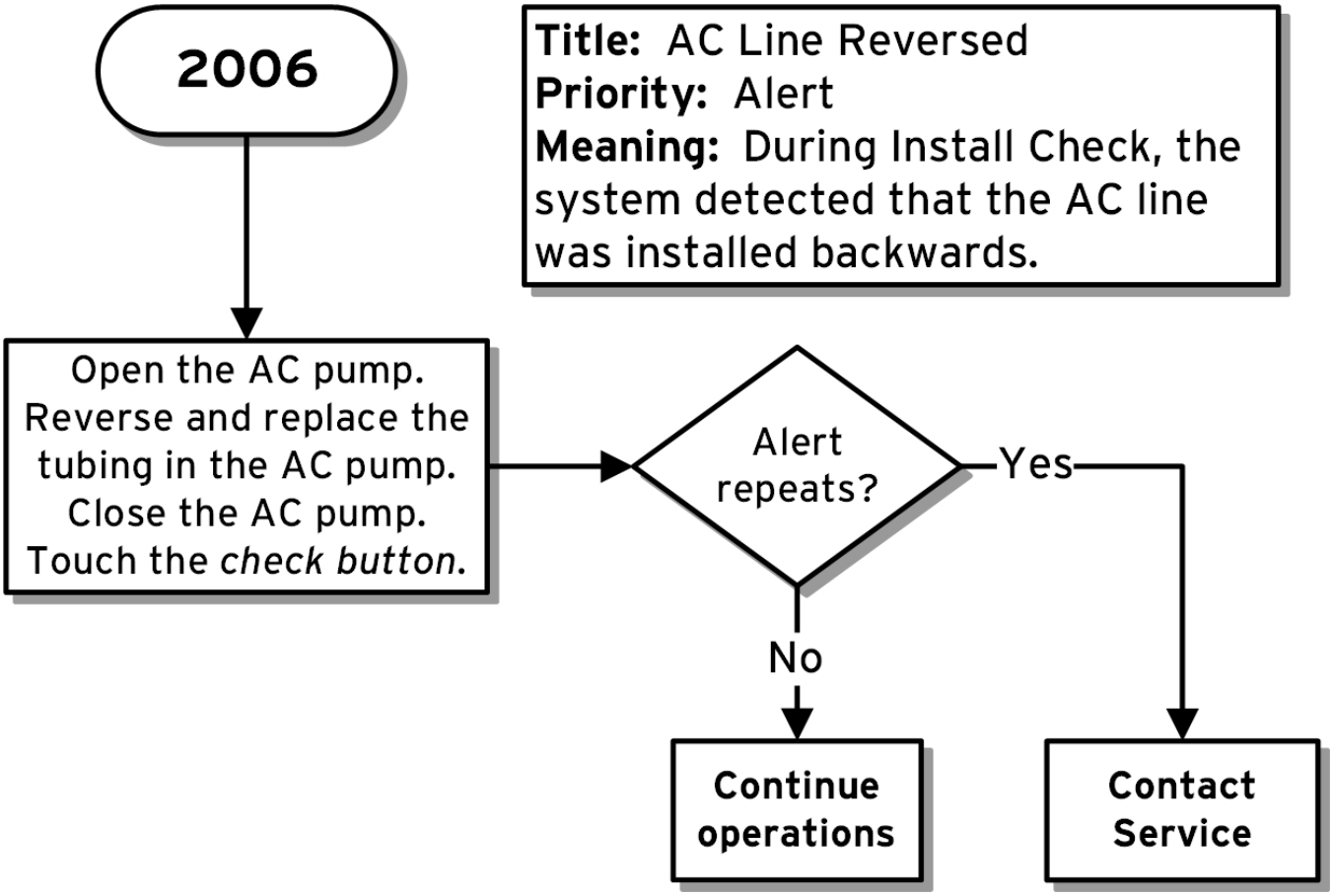


Figure 141: 2007 High P1 Pressure

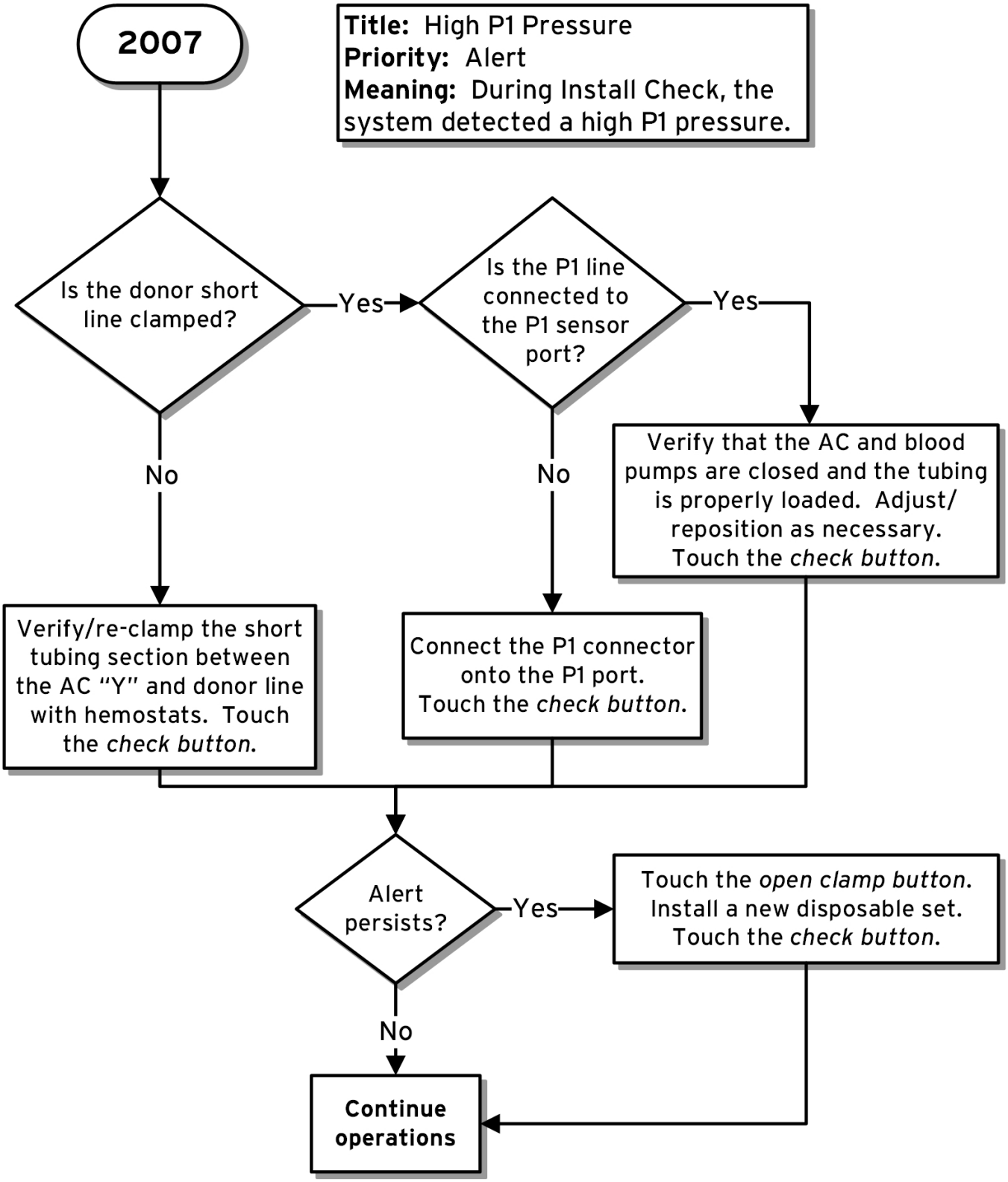


Figure 142: 2009 Low P2 Pressure

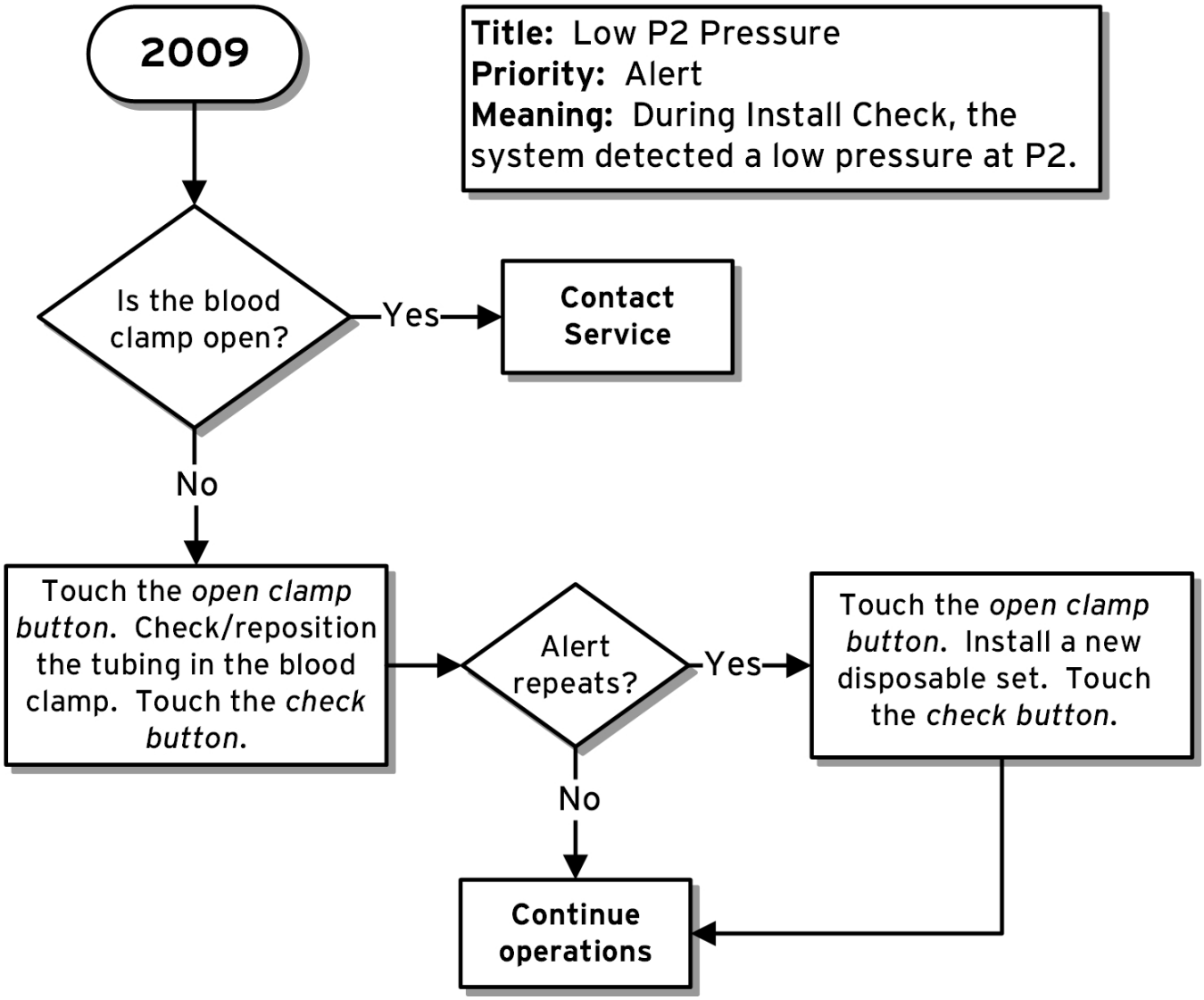


Figure 143: 2011 Low P1 Pressure

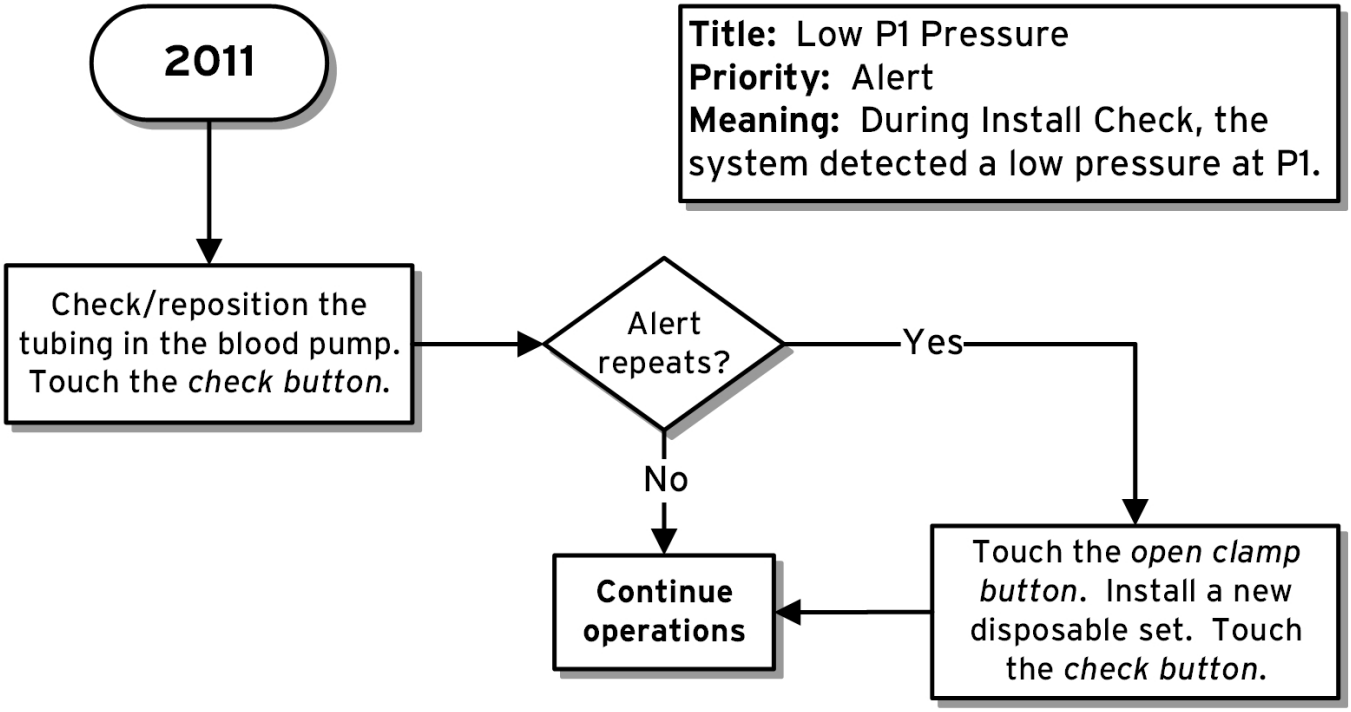


Figure 144: 2013 P1 Pressure Loss

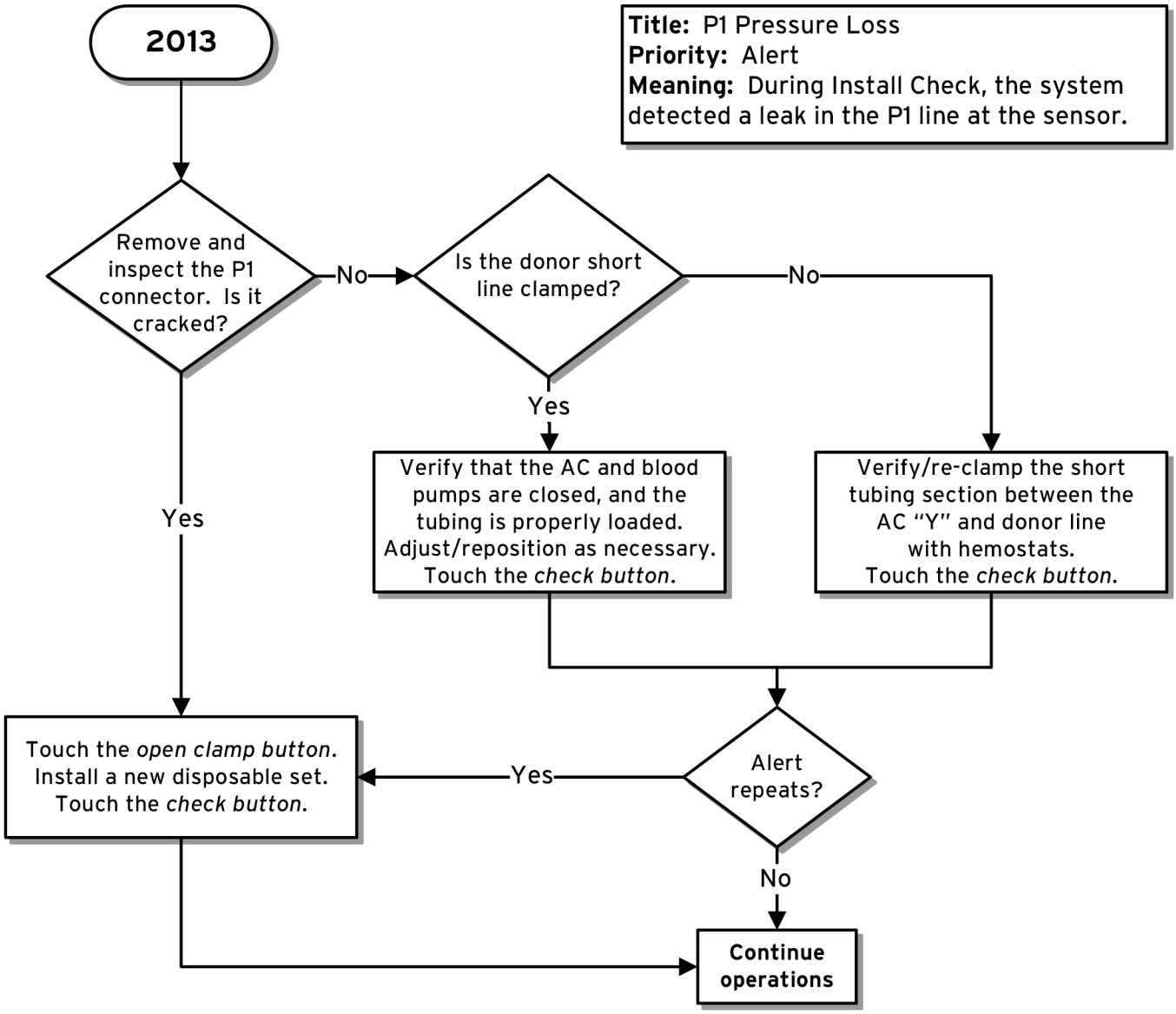


Figure 145: 2014 P2 Pressure Loss

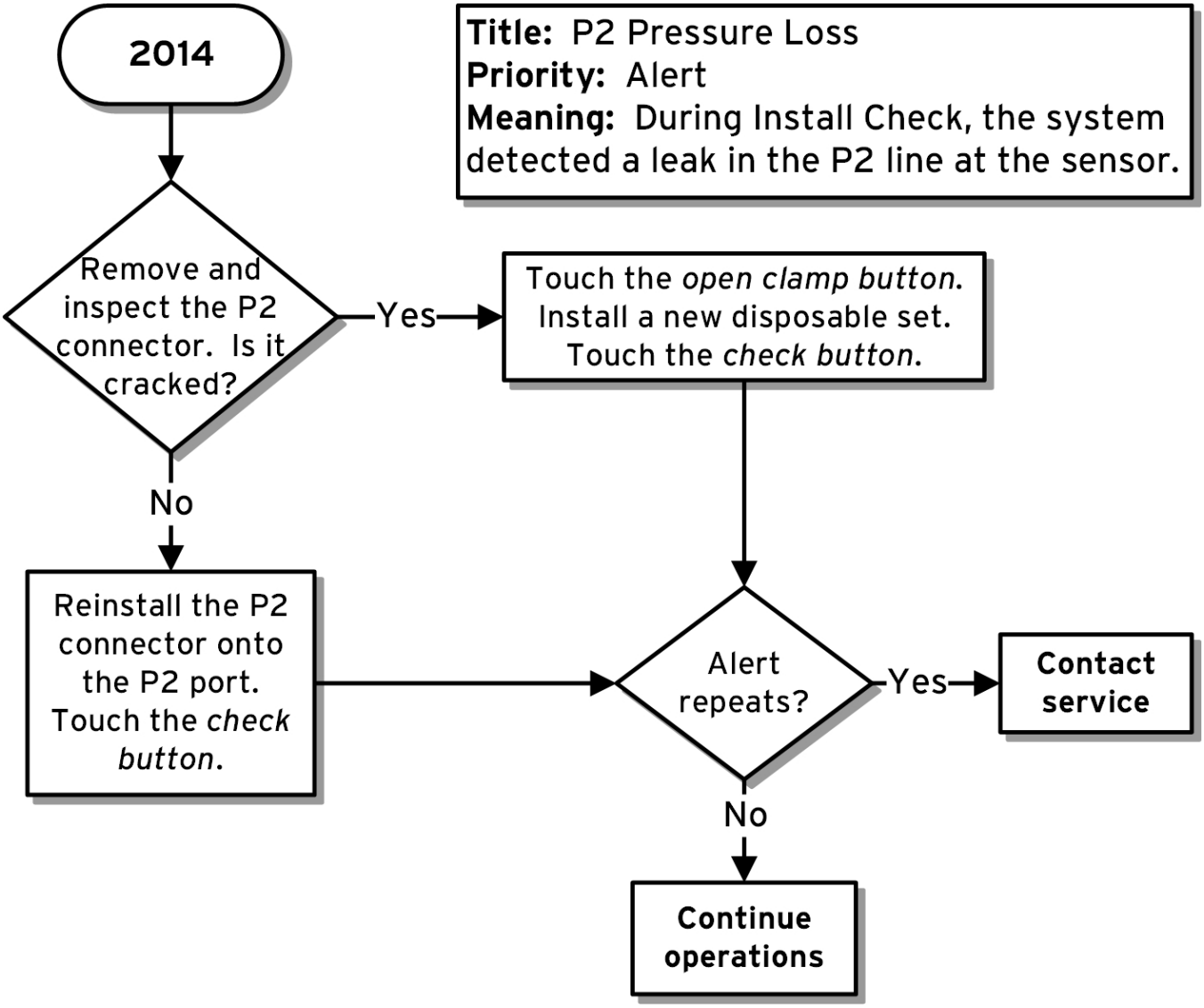


Figure 146: 2015 P2 Vent Failure

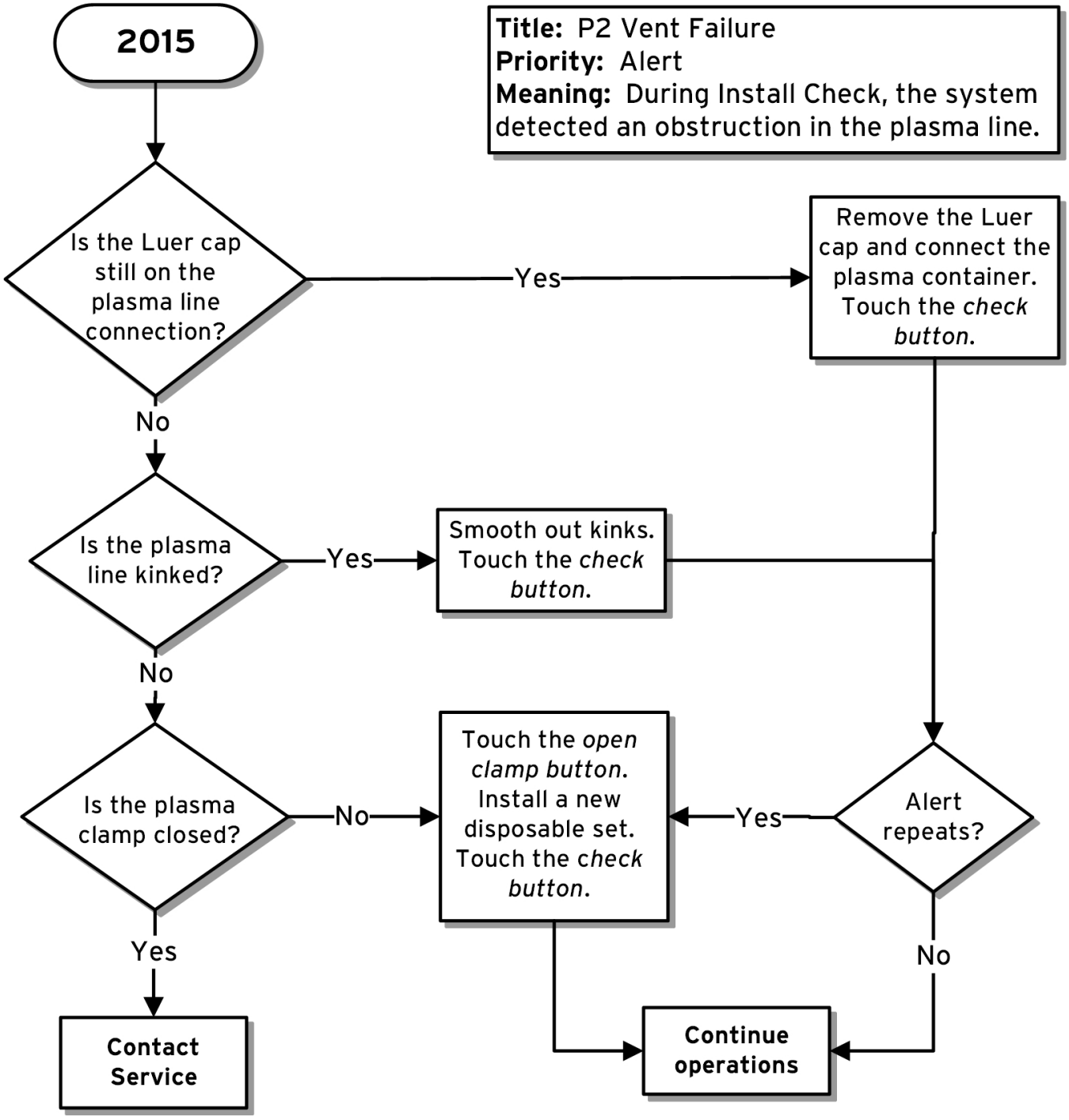


Figure 147: 2016 P2 Vent Failure

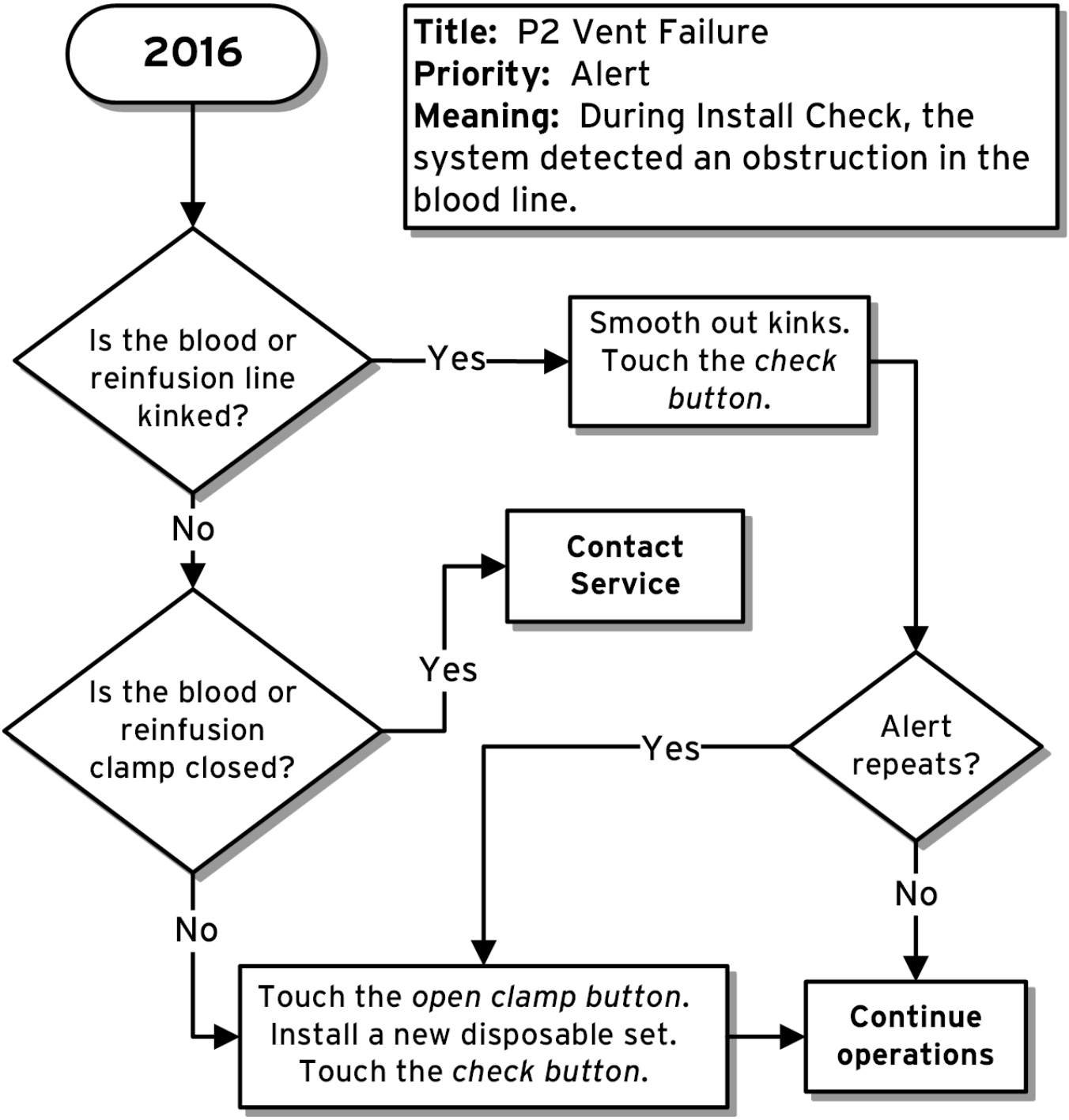


Figure 148: 2017 P2 Vent Failure

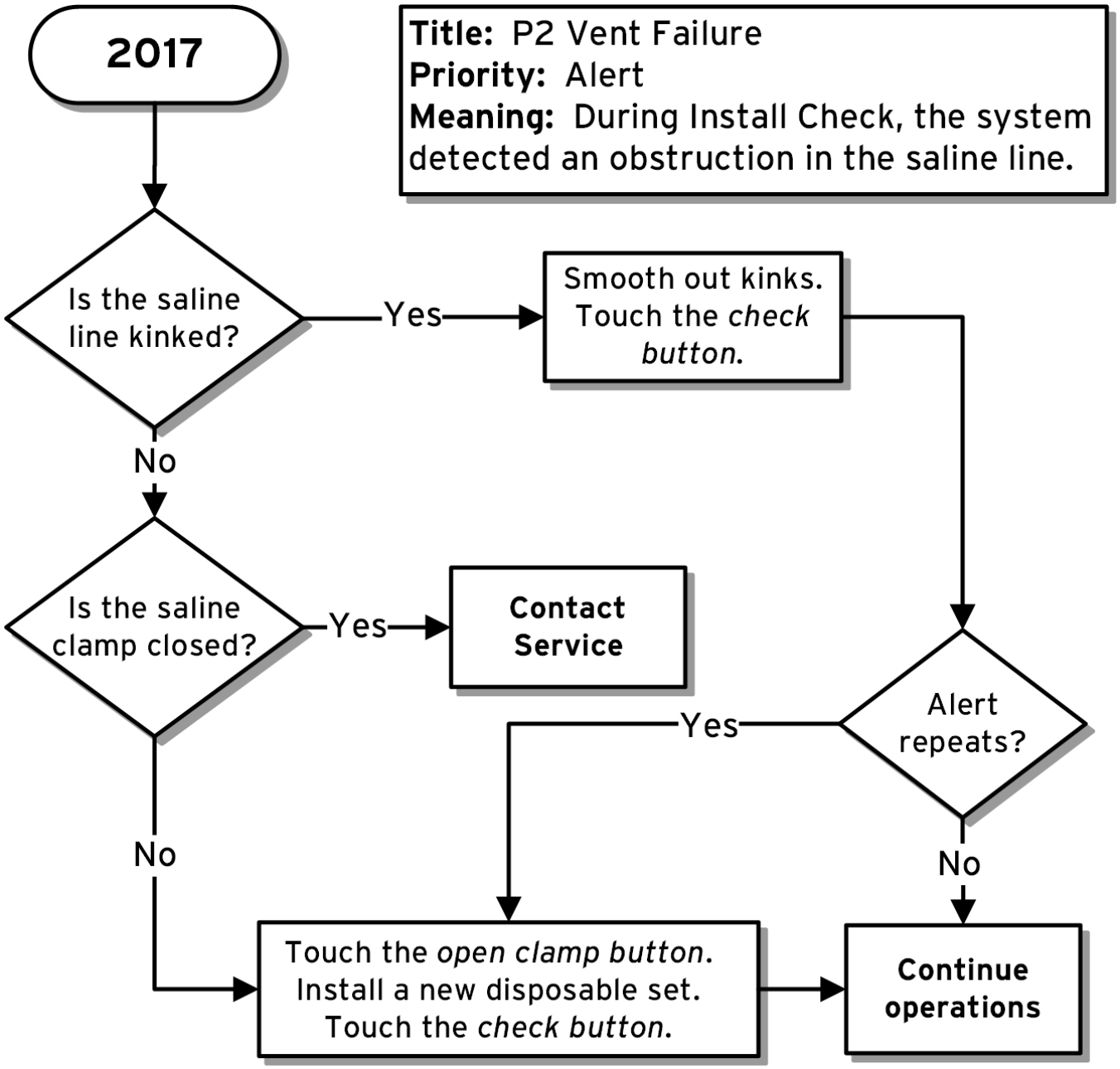


Figure 149: 2020 Reservoir Scale Out of Range

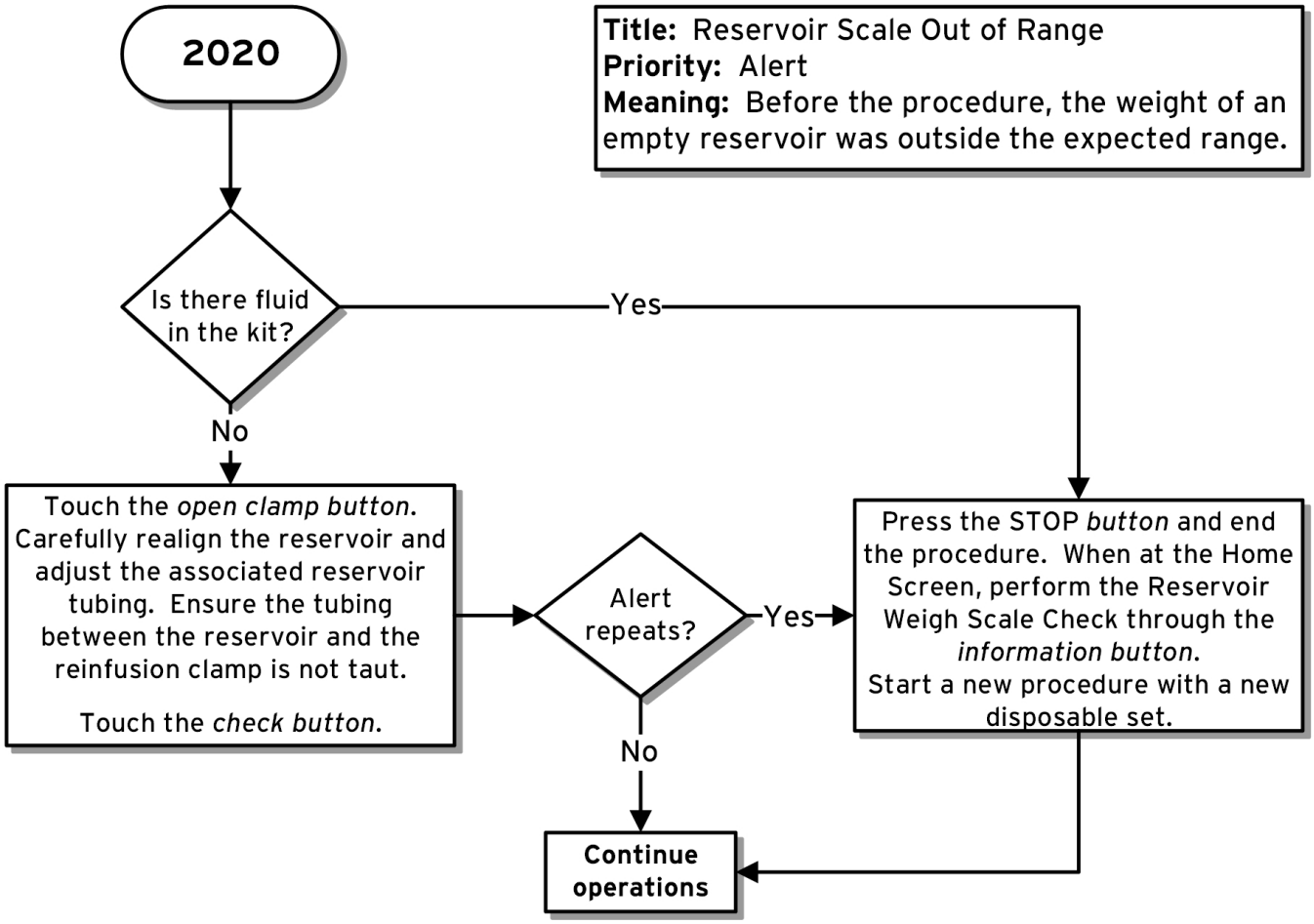


Figure 150: 2021 Tubing Not Detected

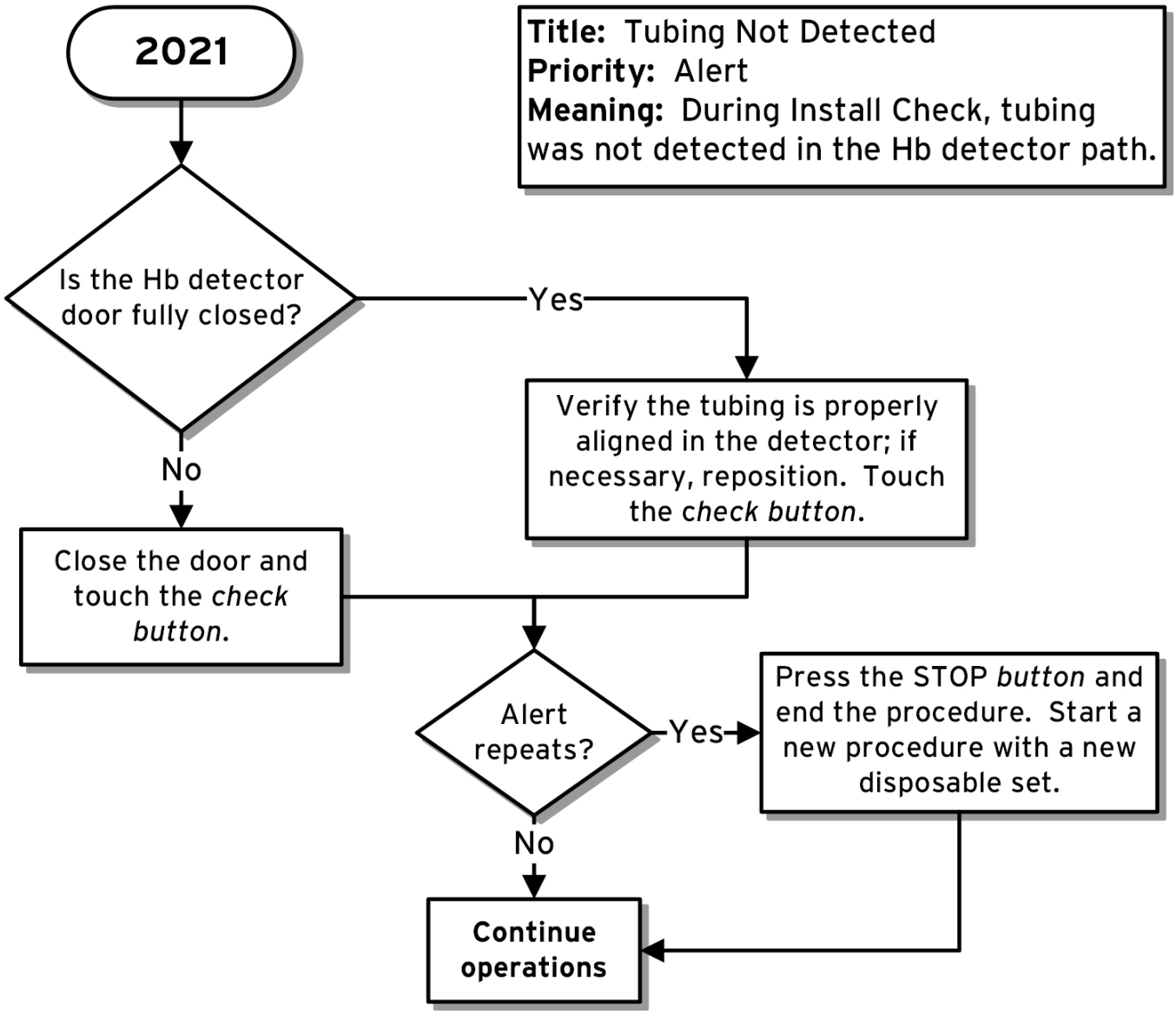


Figure 151: 2022 Transducer Cover Open

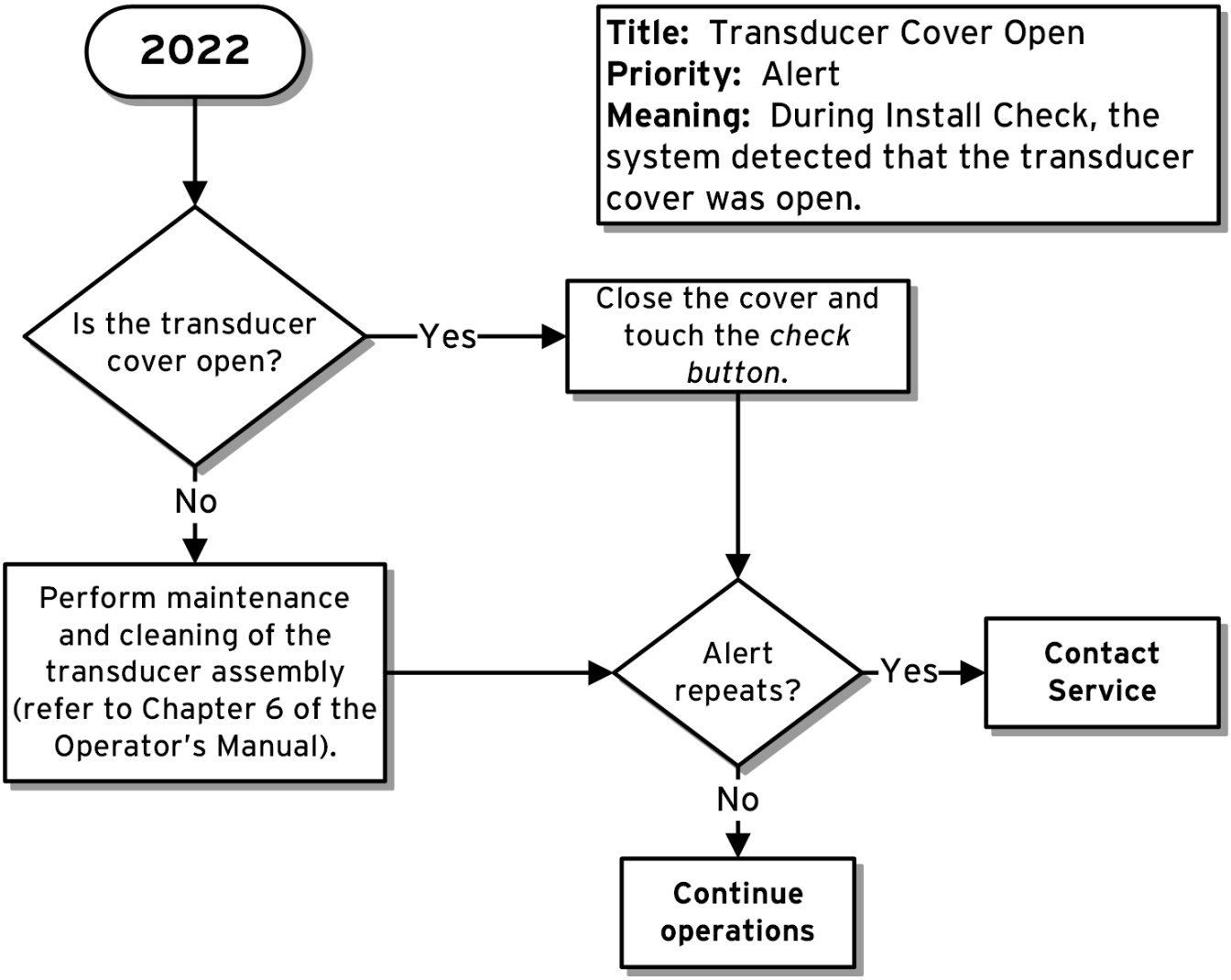


Figure 152: 2023 Tubing Not Detected

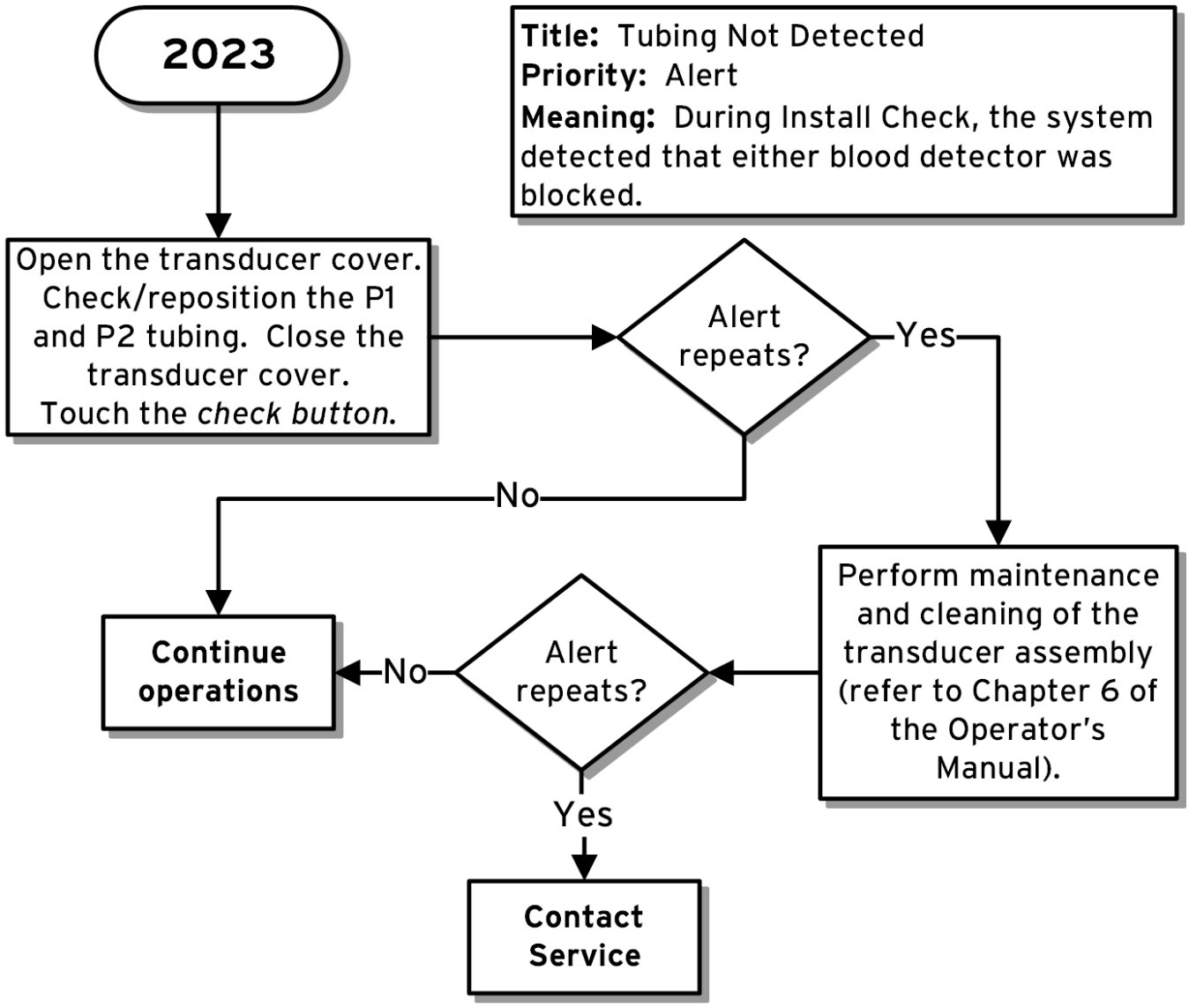


Figure 153: 2030 Plasma Weigh Scale out of Range

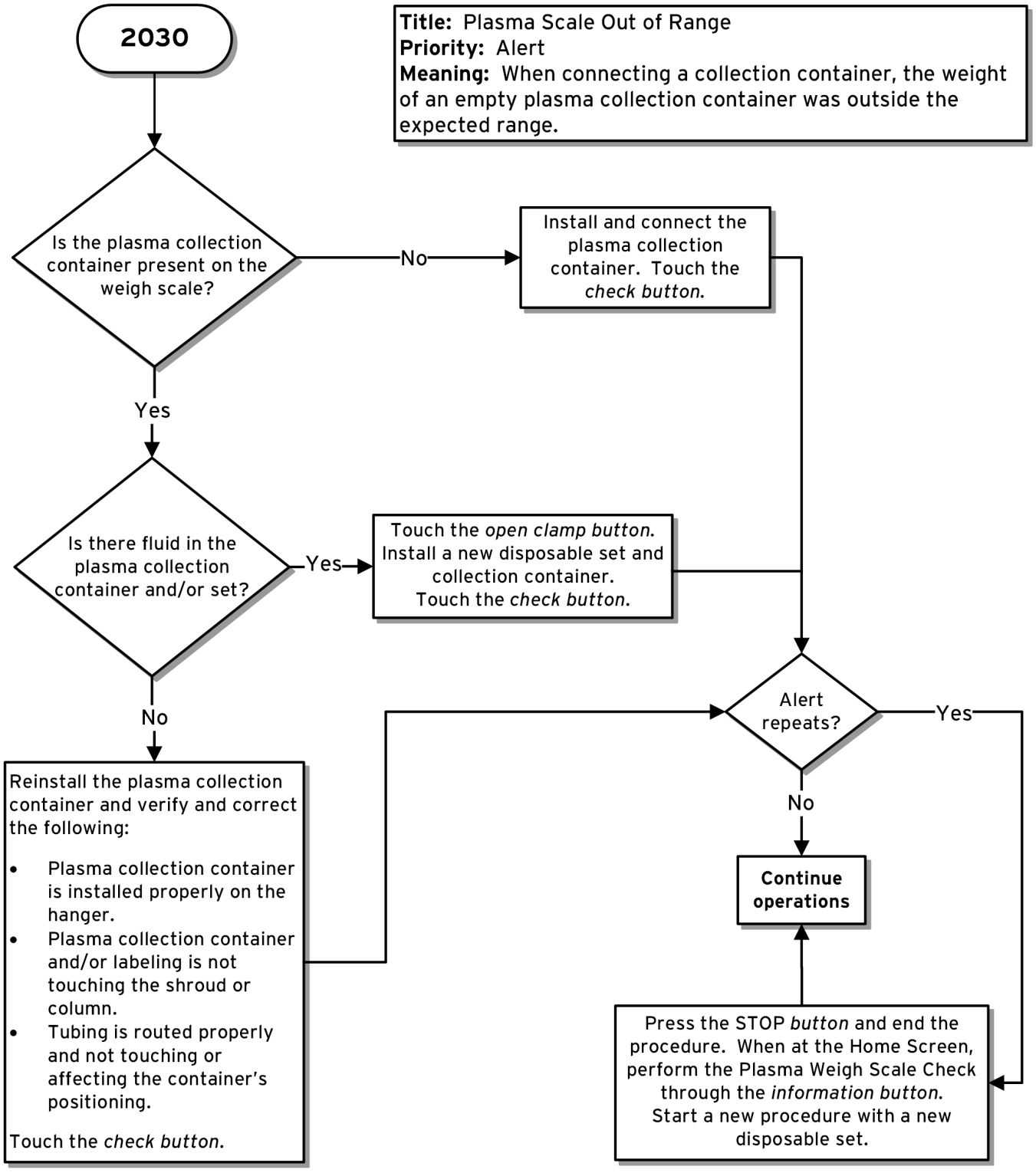


Figure 154: 2040 Fluid Detected

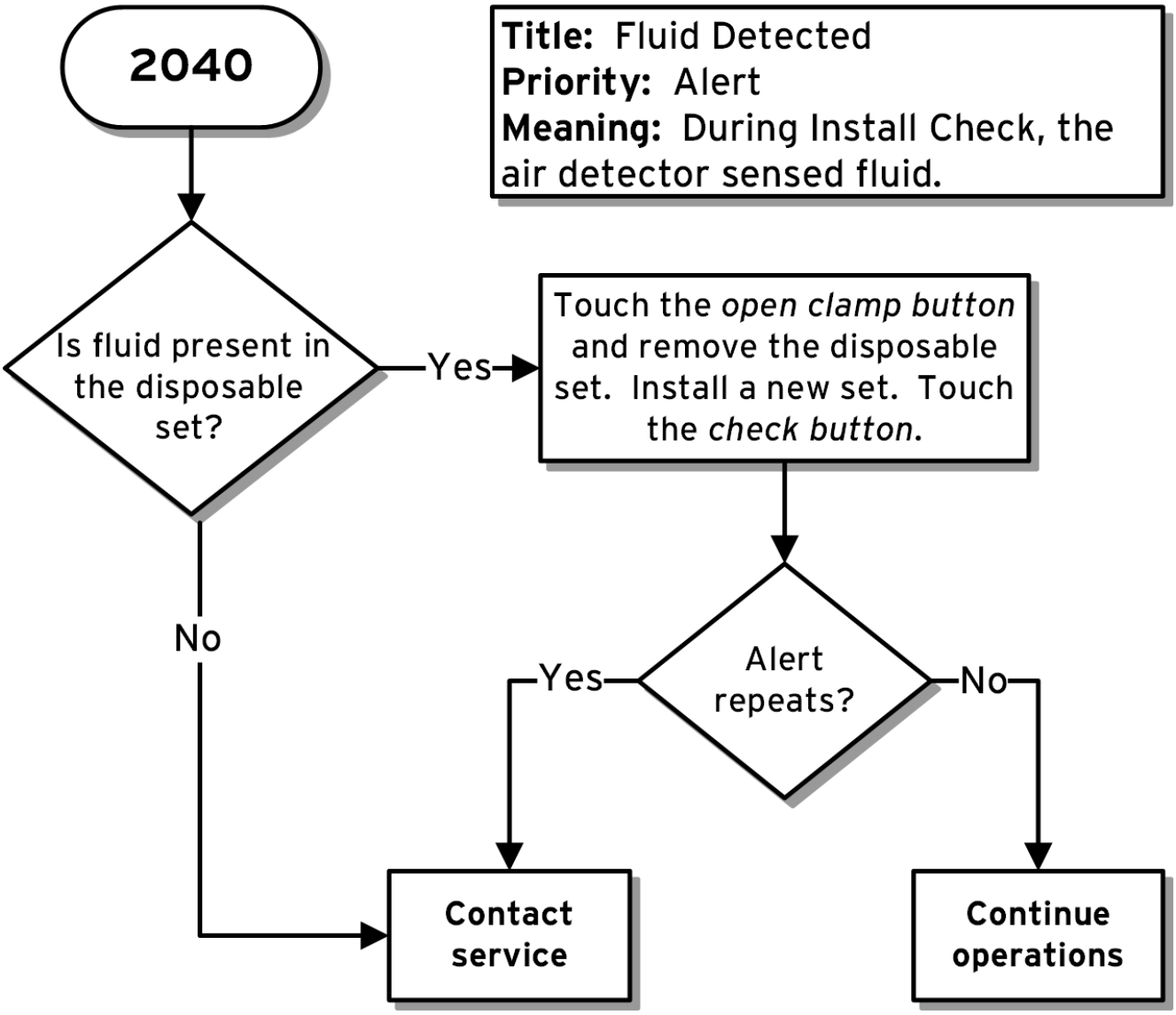


Figure 155: 2053 Hb Detector Out of Range

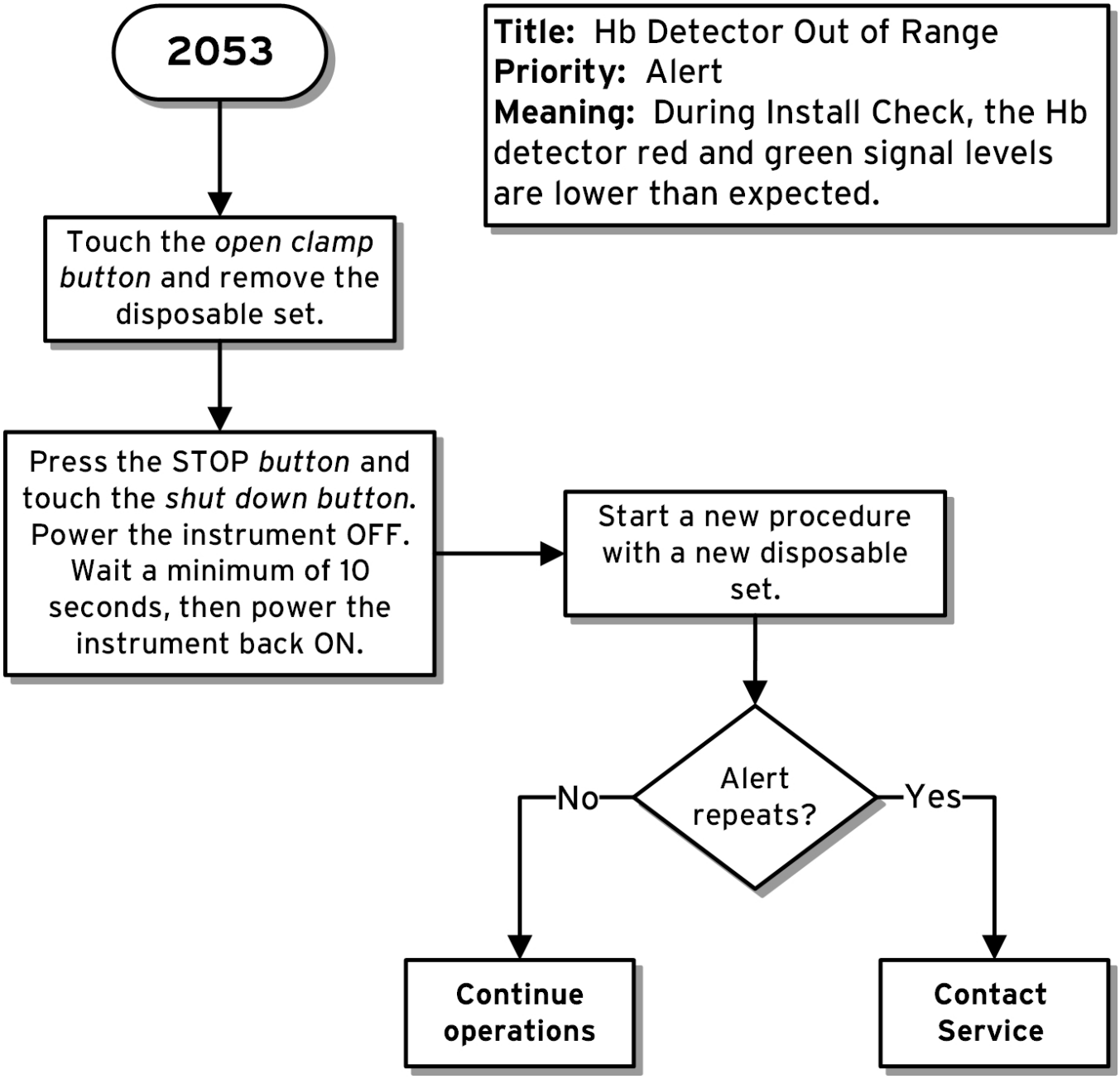


Figure 156: 2101 P2 Pressure Out of Range

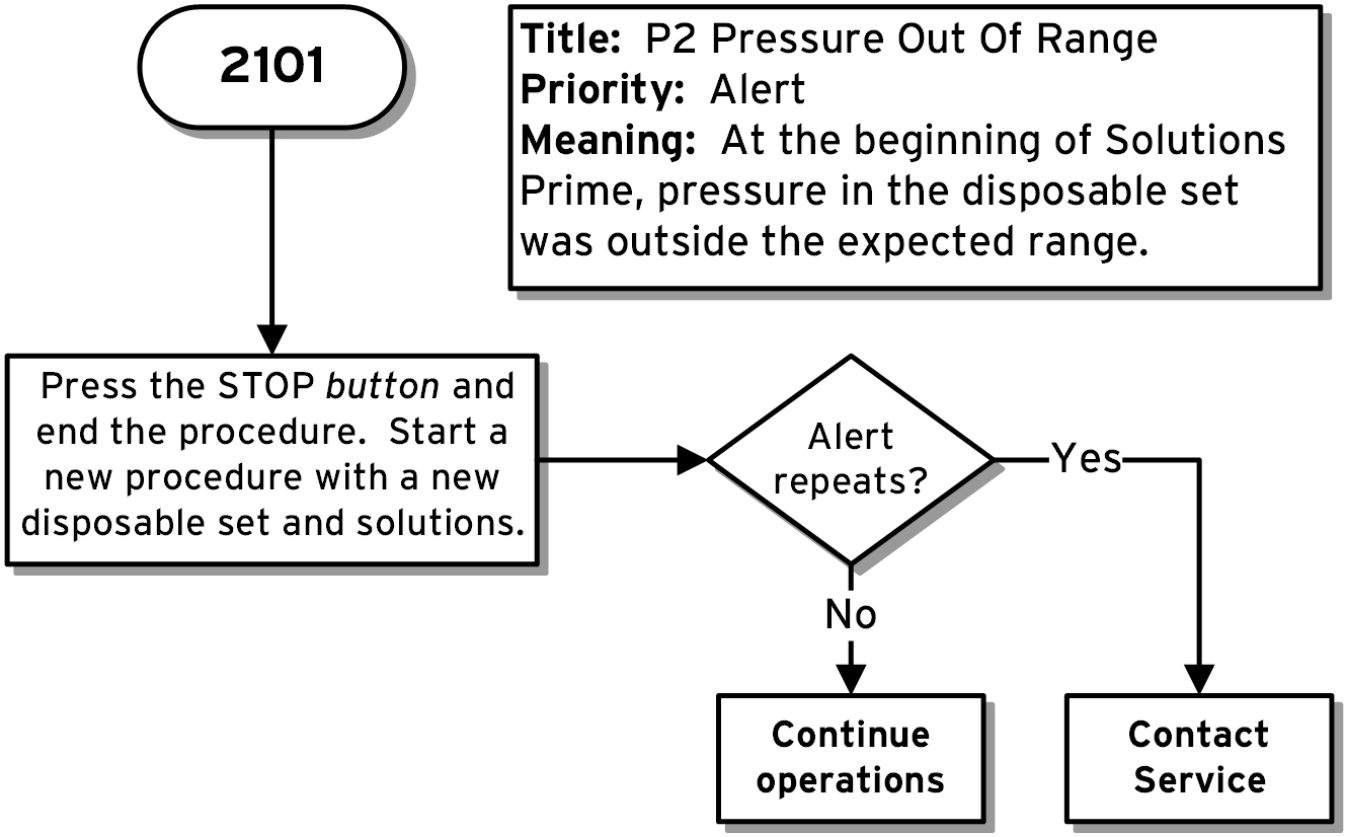


Figure 157: 2102 No Saline Detected

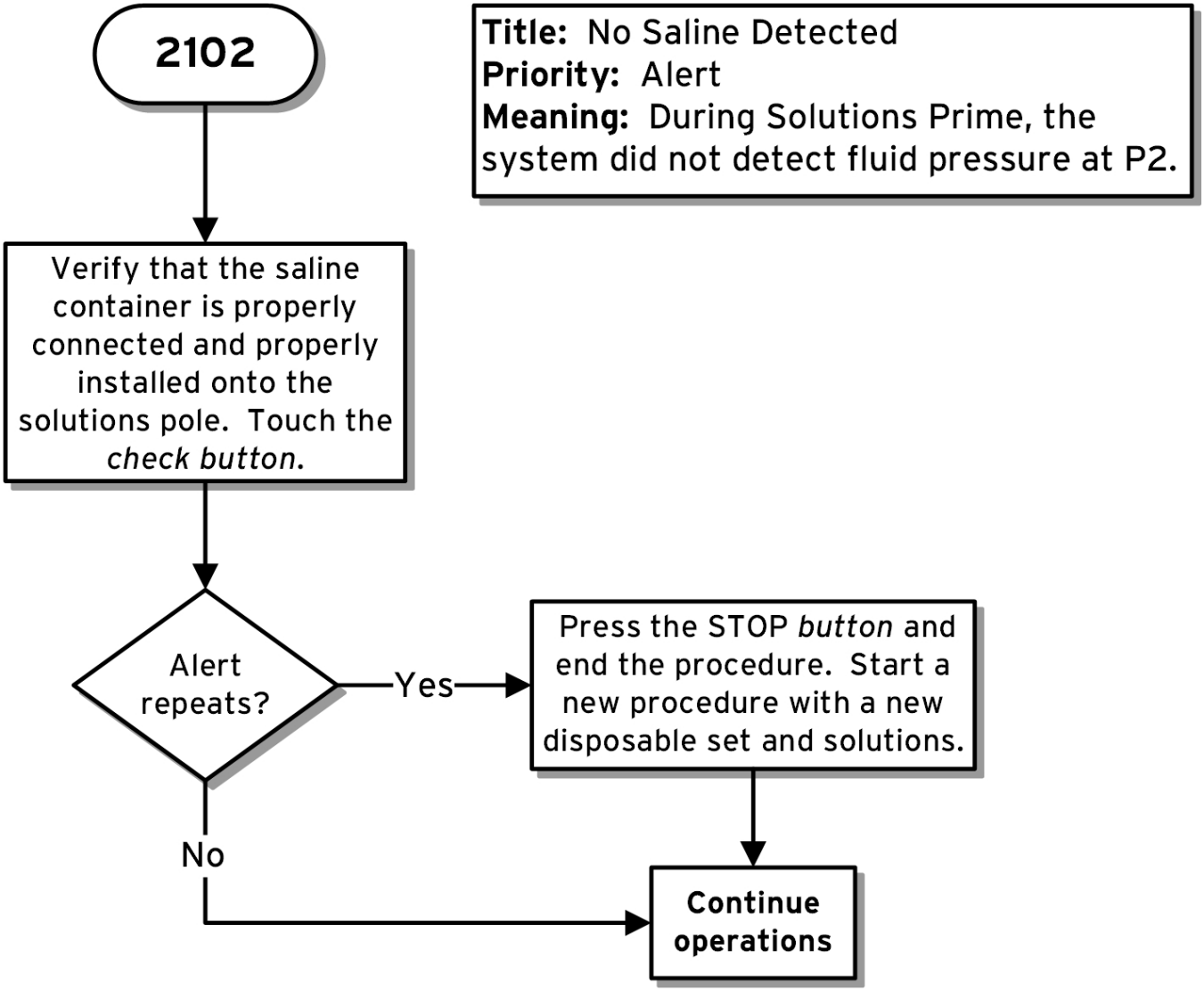


Figure 158: 2103 No AC Weight Detected

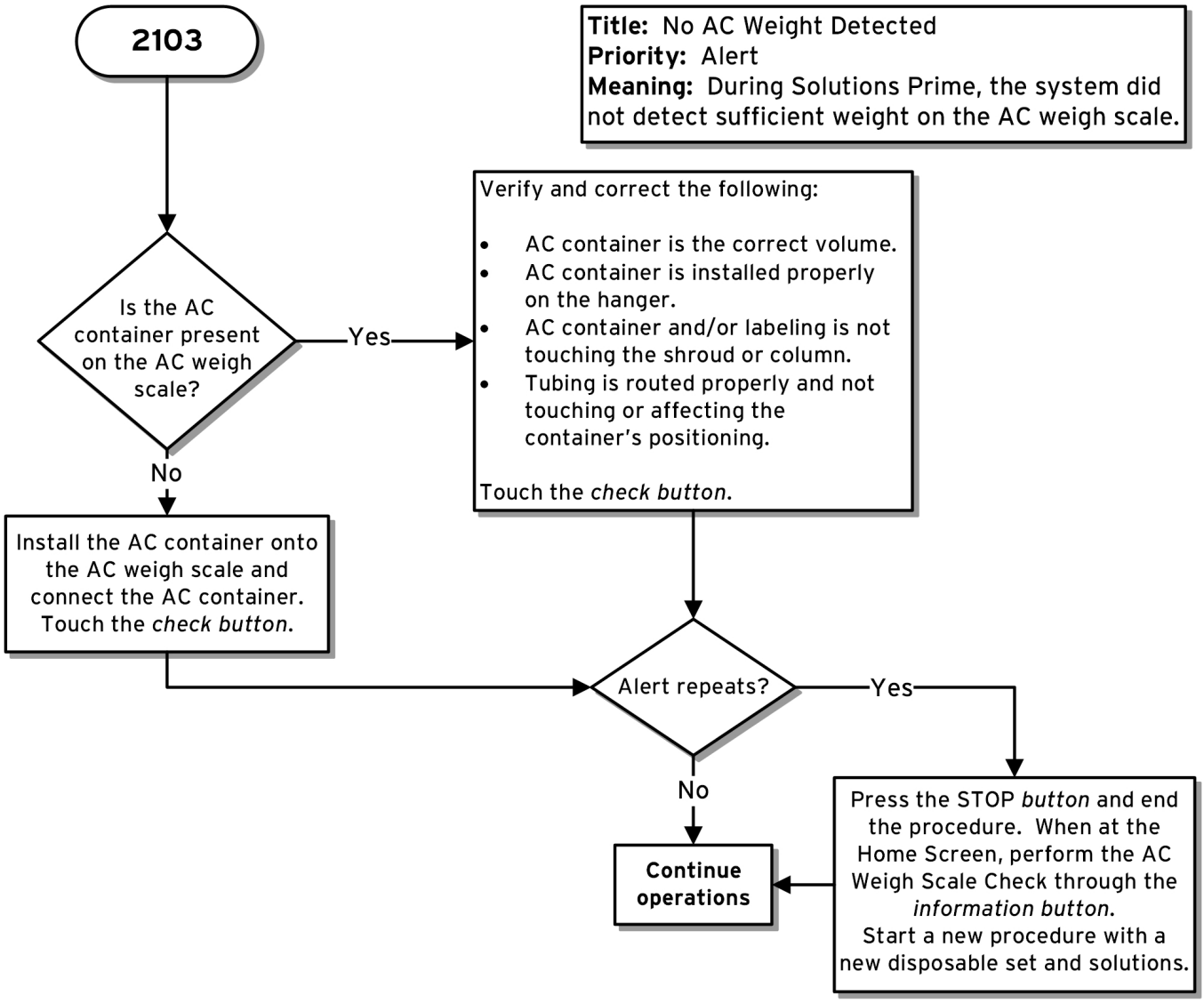


Figure 159: 2110 Prime Attempts Exceeded

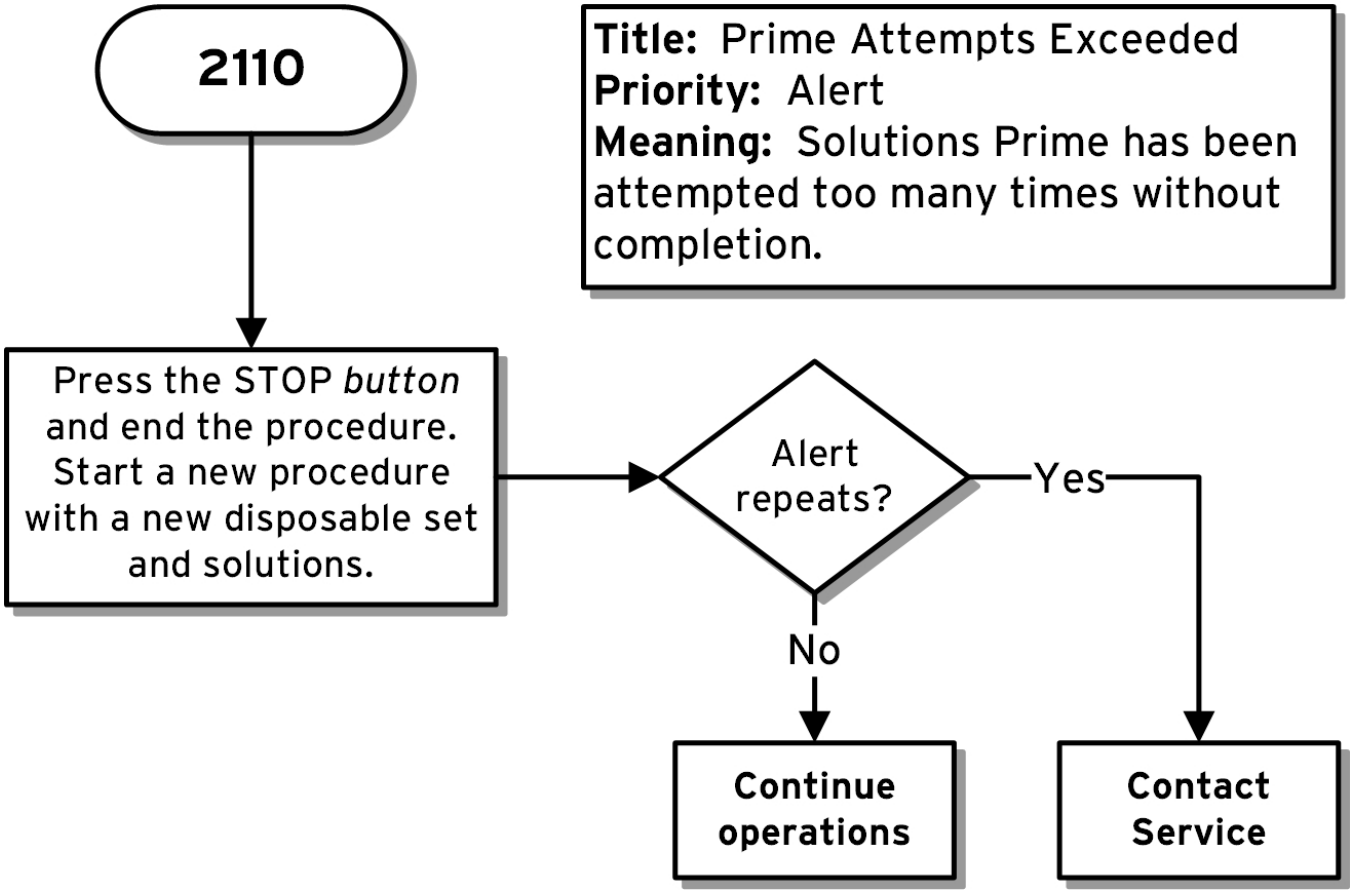


Figure 160: 2111 AC Line in Air Detector

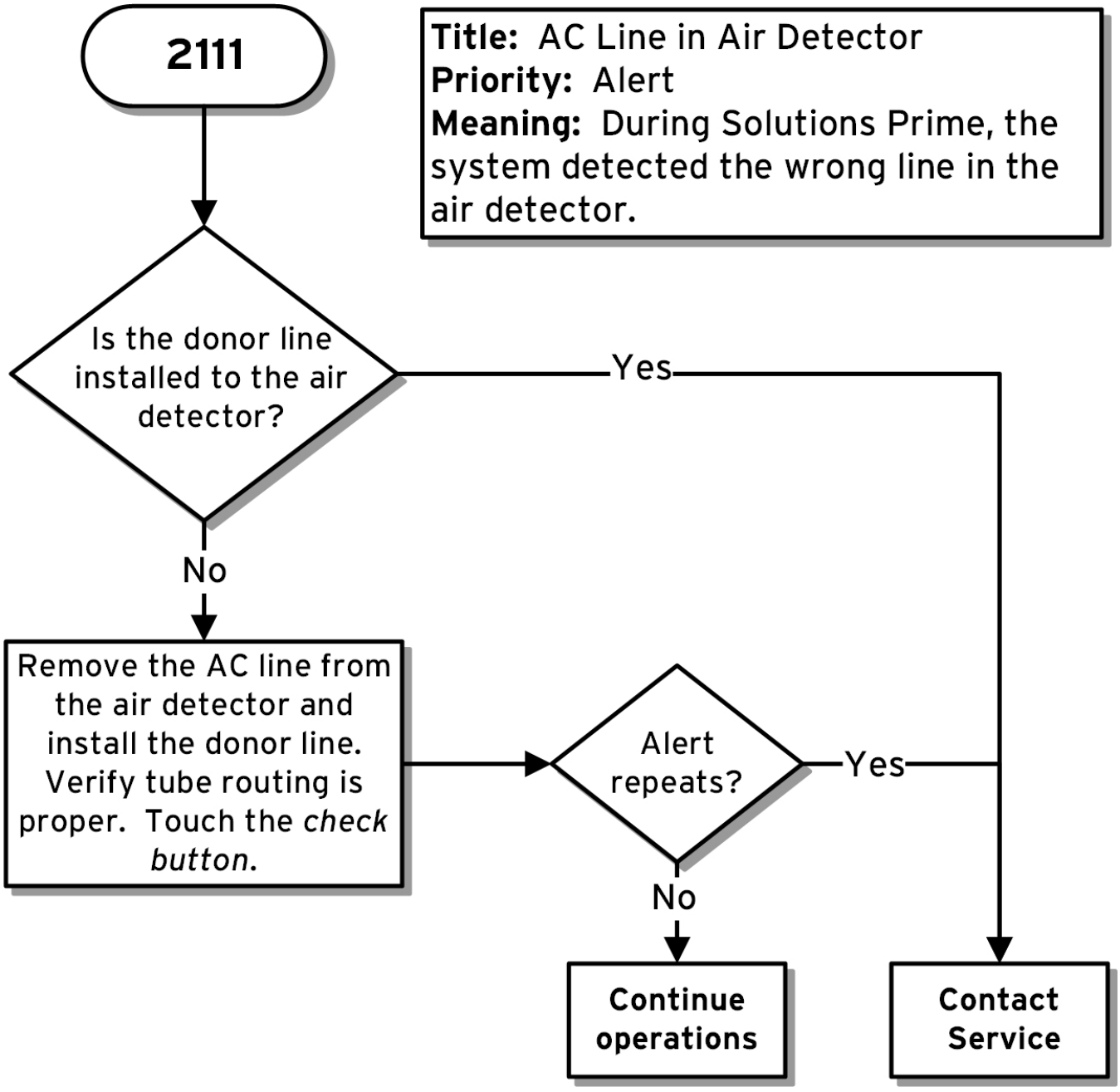


Figure 161: 2112 No Fluid at Air Detector

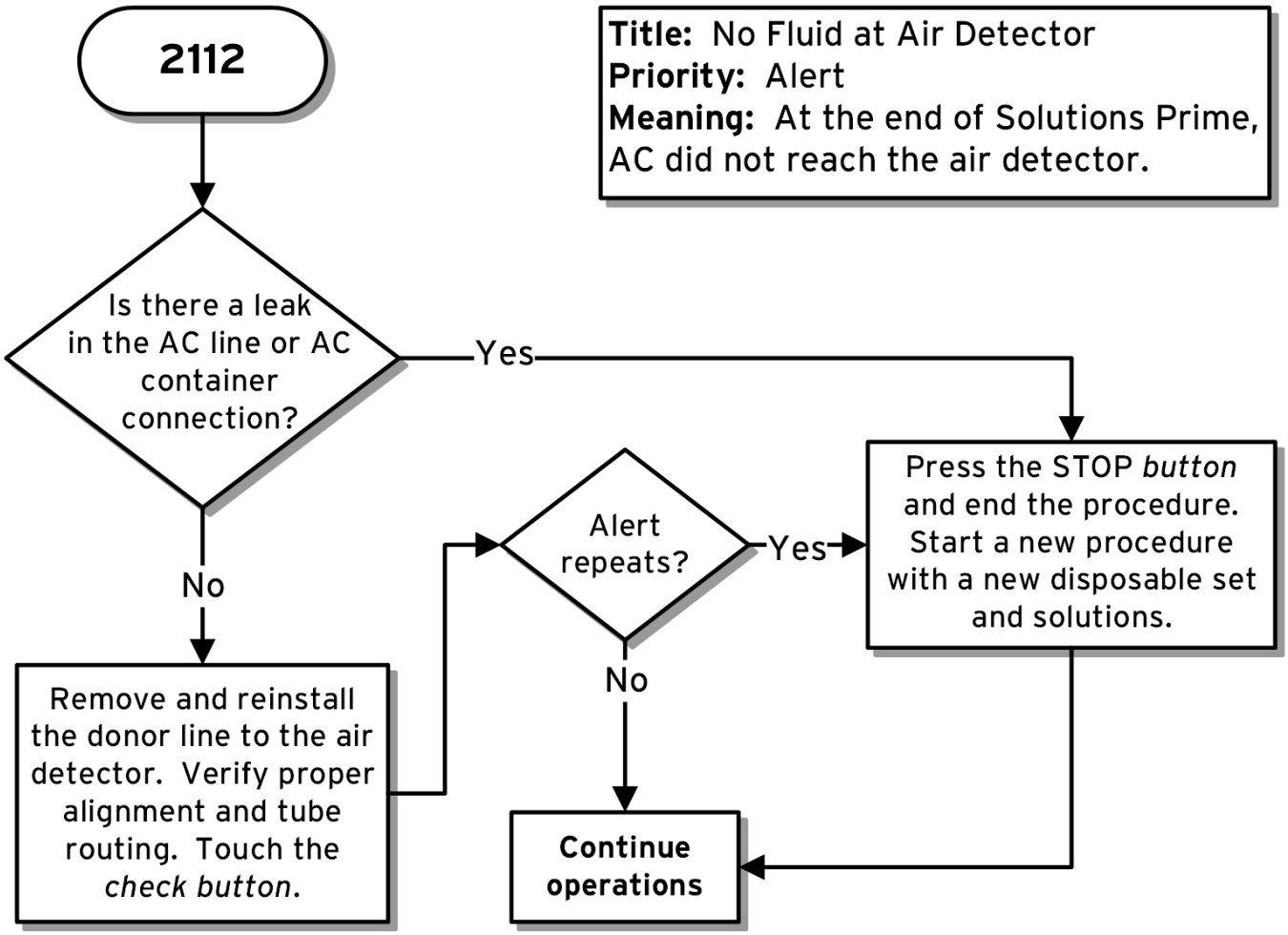


Figure 162: 2113 AC Not Flowing

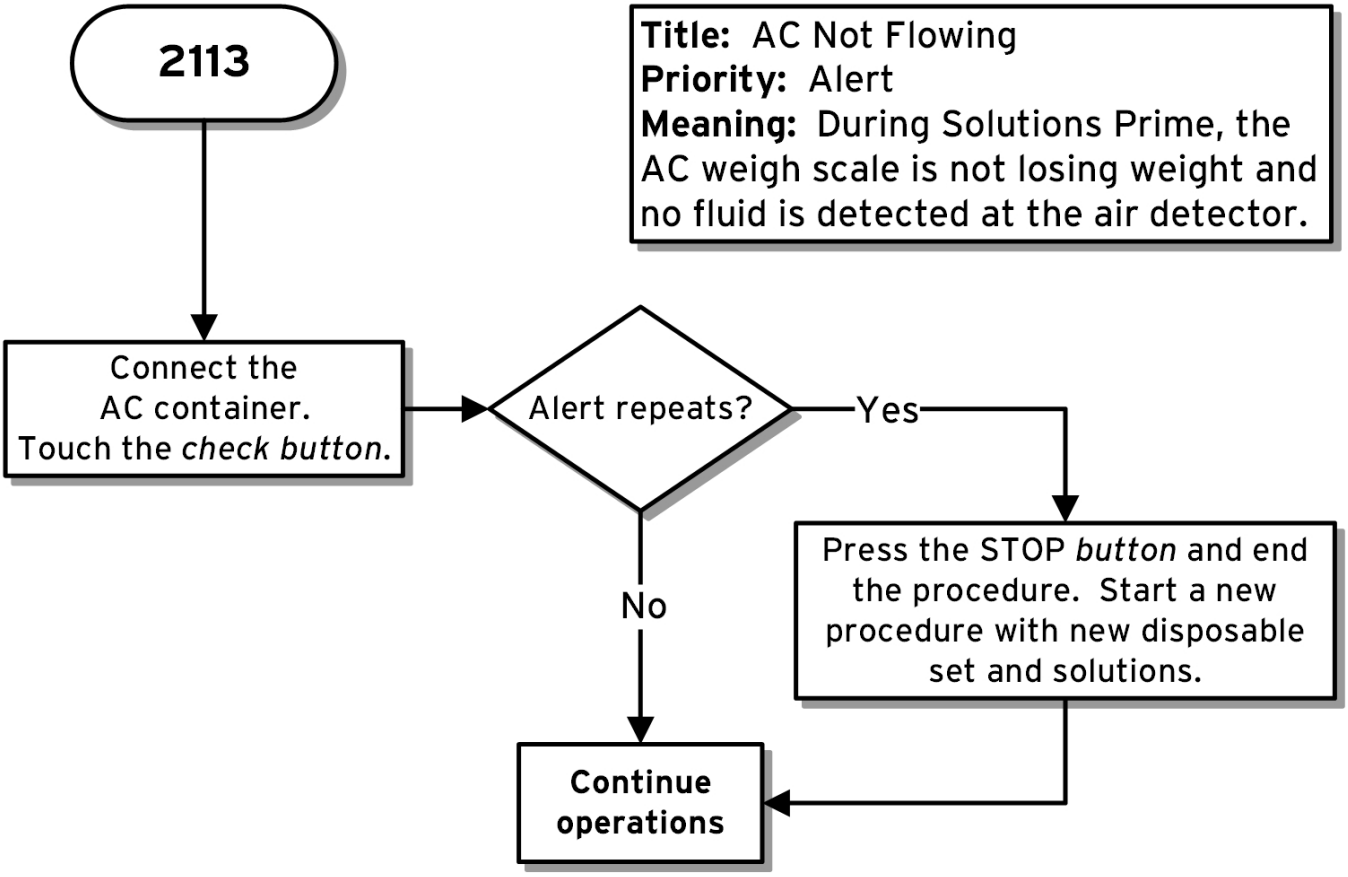


Figure 163: 2114 No Change on AC Scale

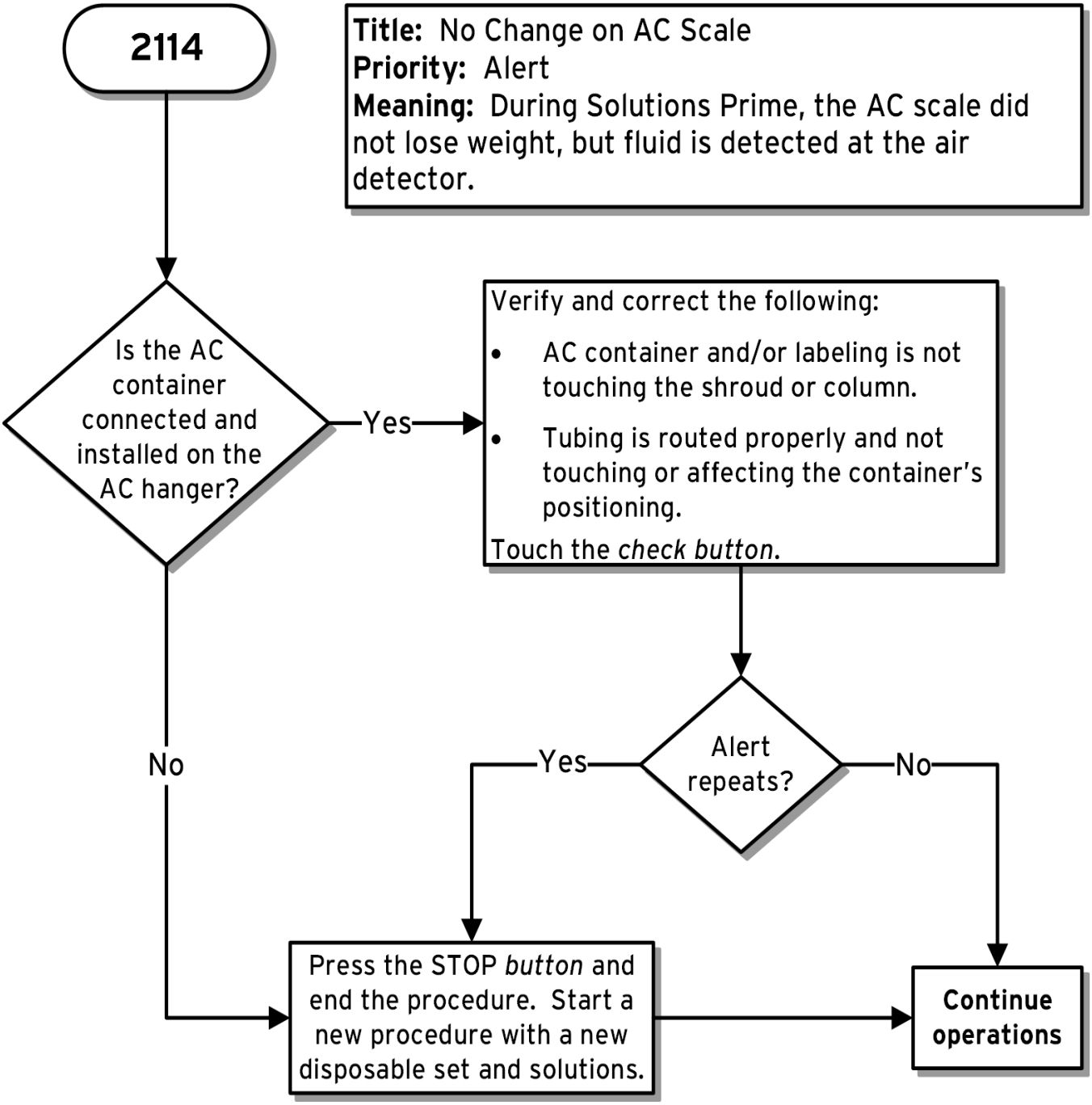


Figure 164: 2120 No Saline Added to Reservoir

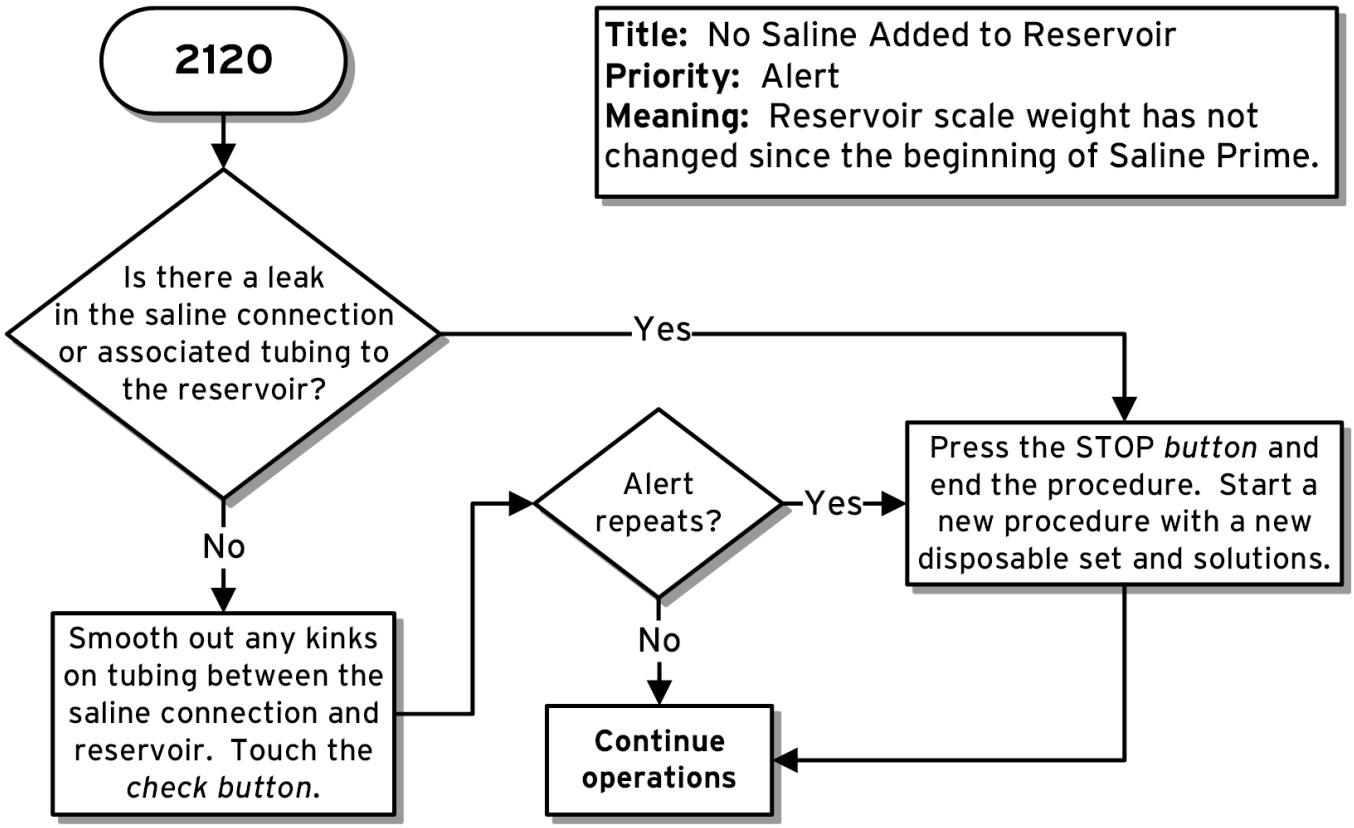


Figure 165: 2130 Reverse Prime Failed

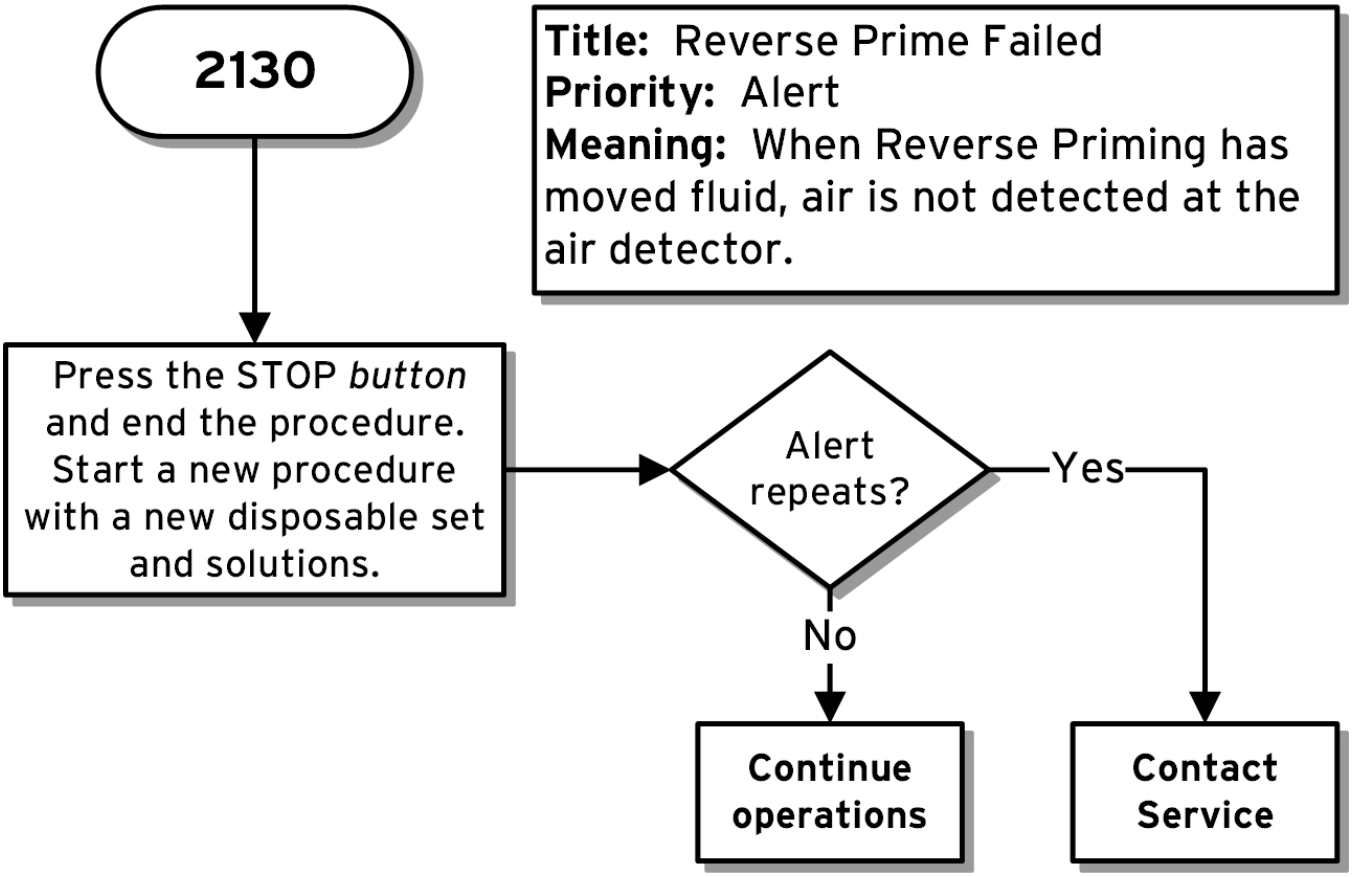


Figure 166: 2131 Reverse Prime Failed

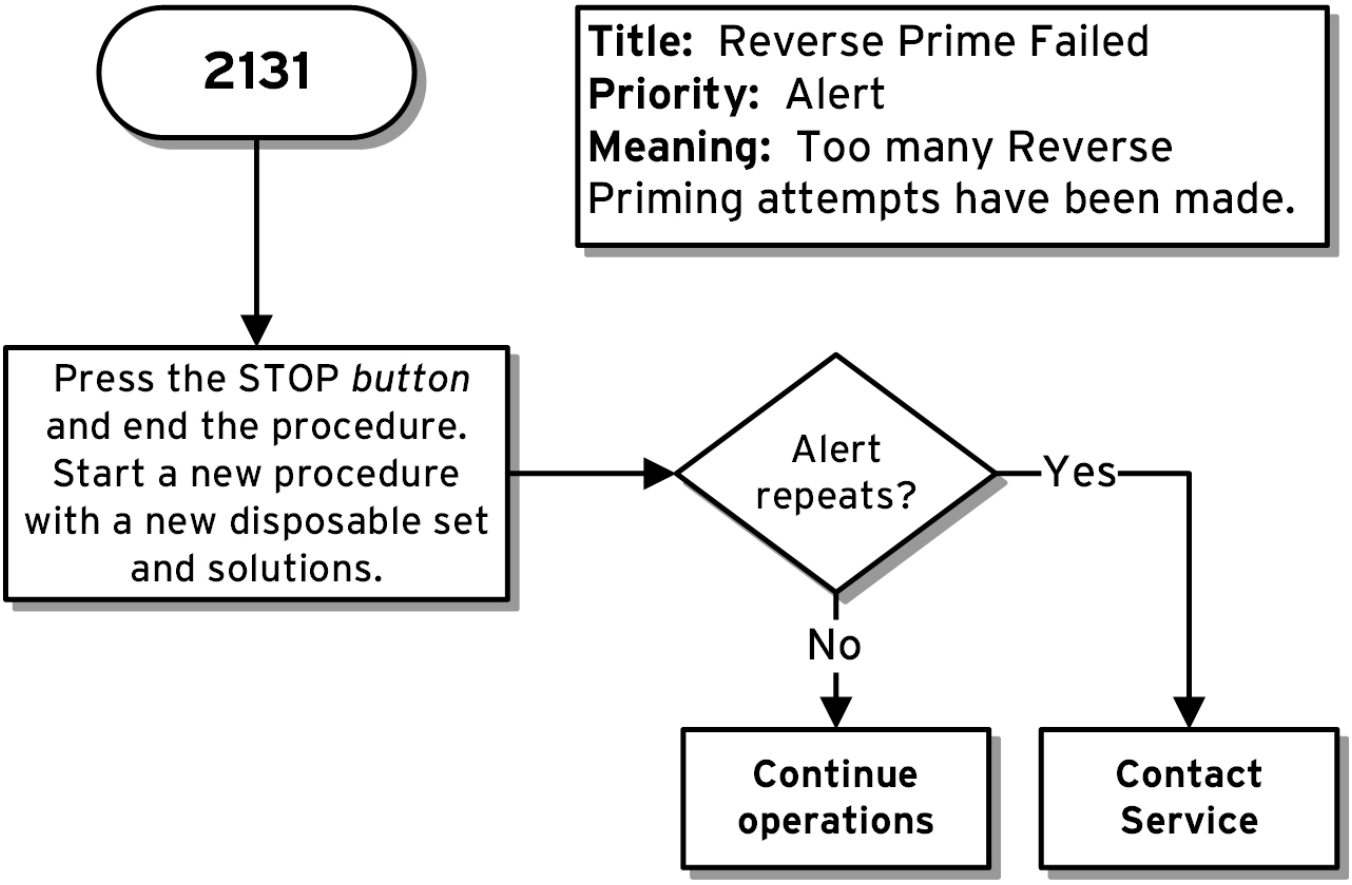


Figure 167: 2140 P1 Pressure Out of Range

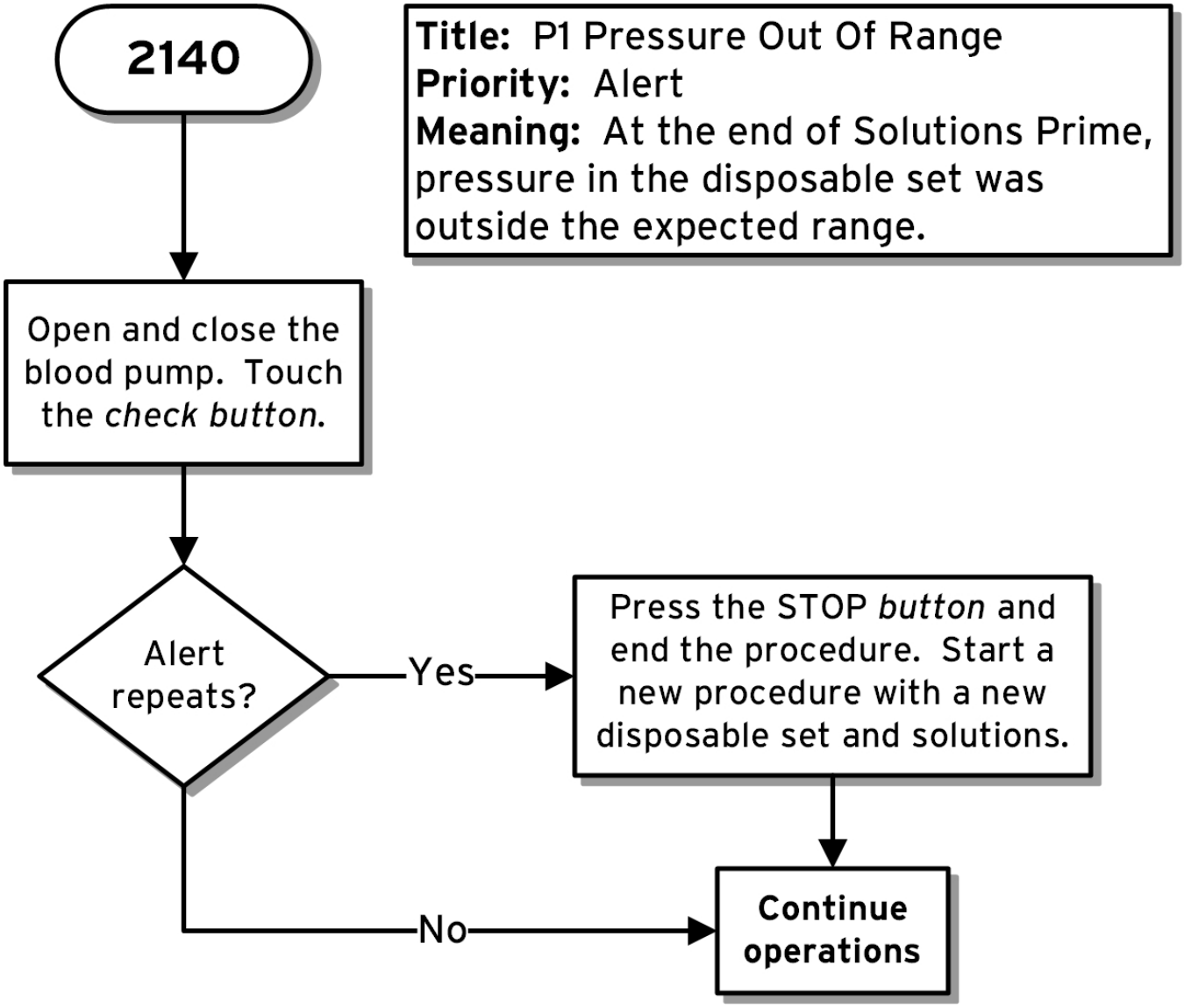


Figure 168: 2141 No Fluid at Air Detector

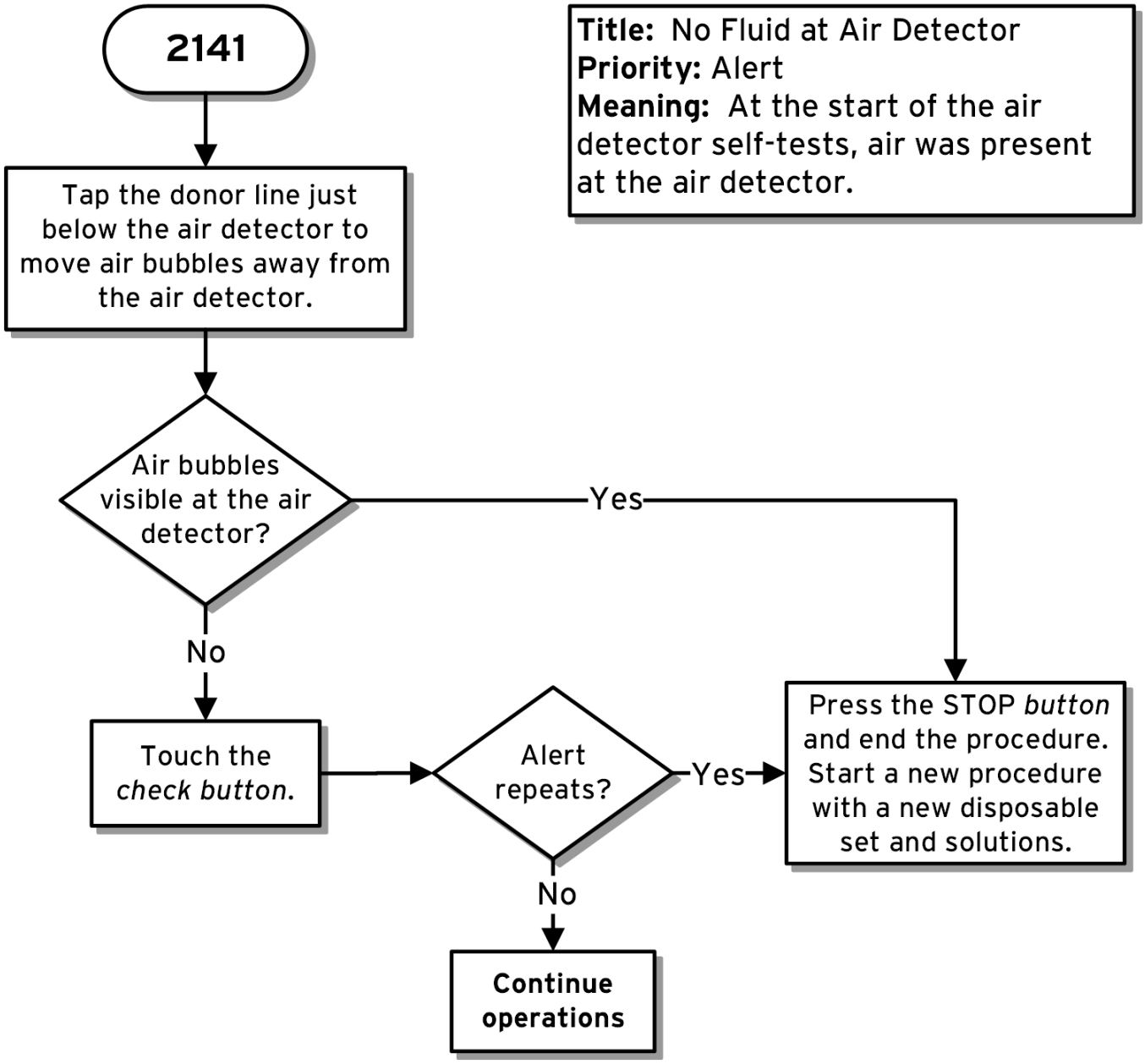


Figure 169: 2150 Plasma Scale Out of Range

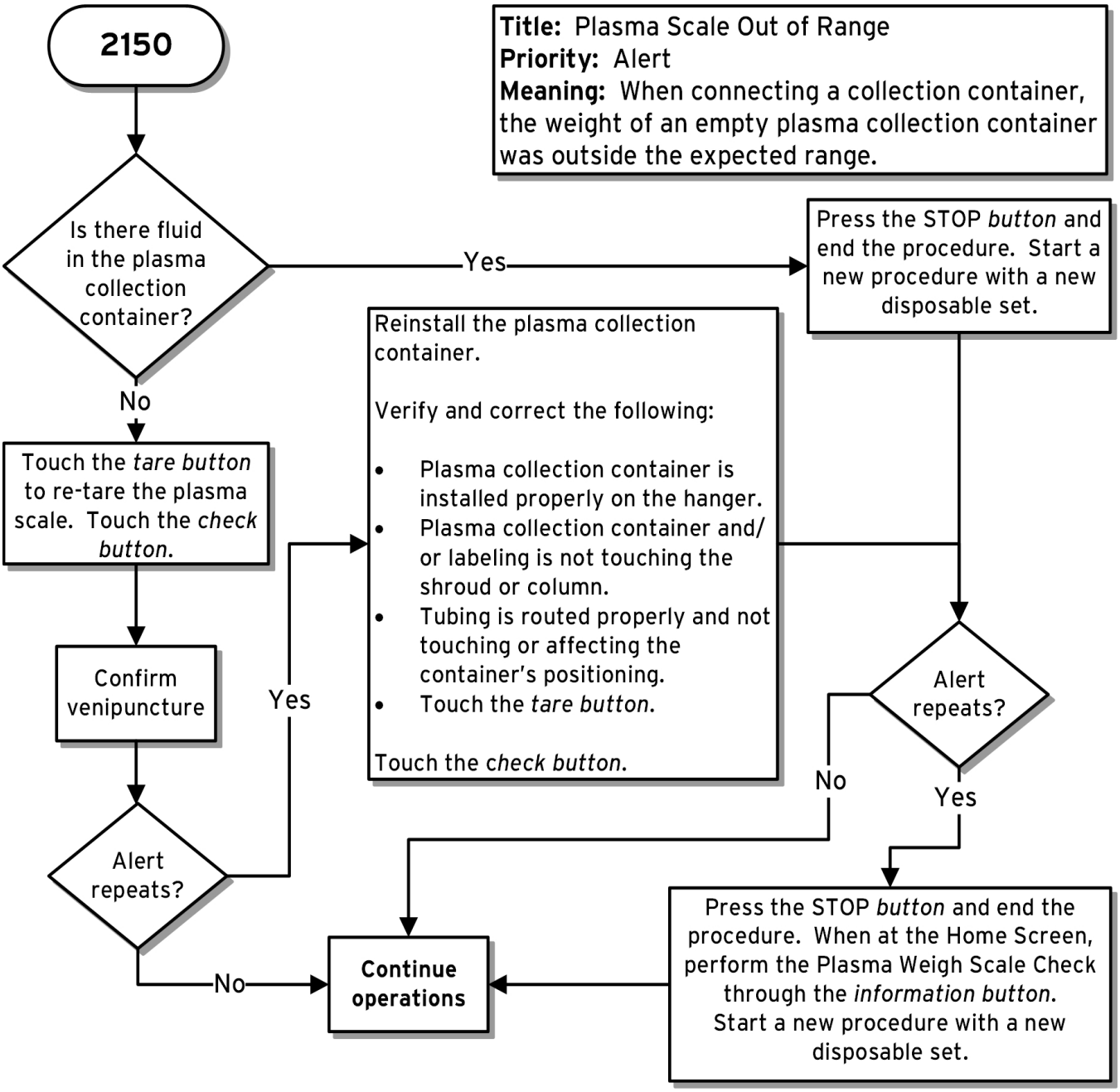


Figure 170: 2160 Missing Data

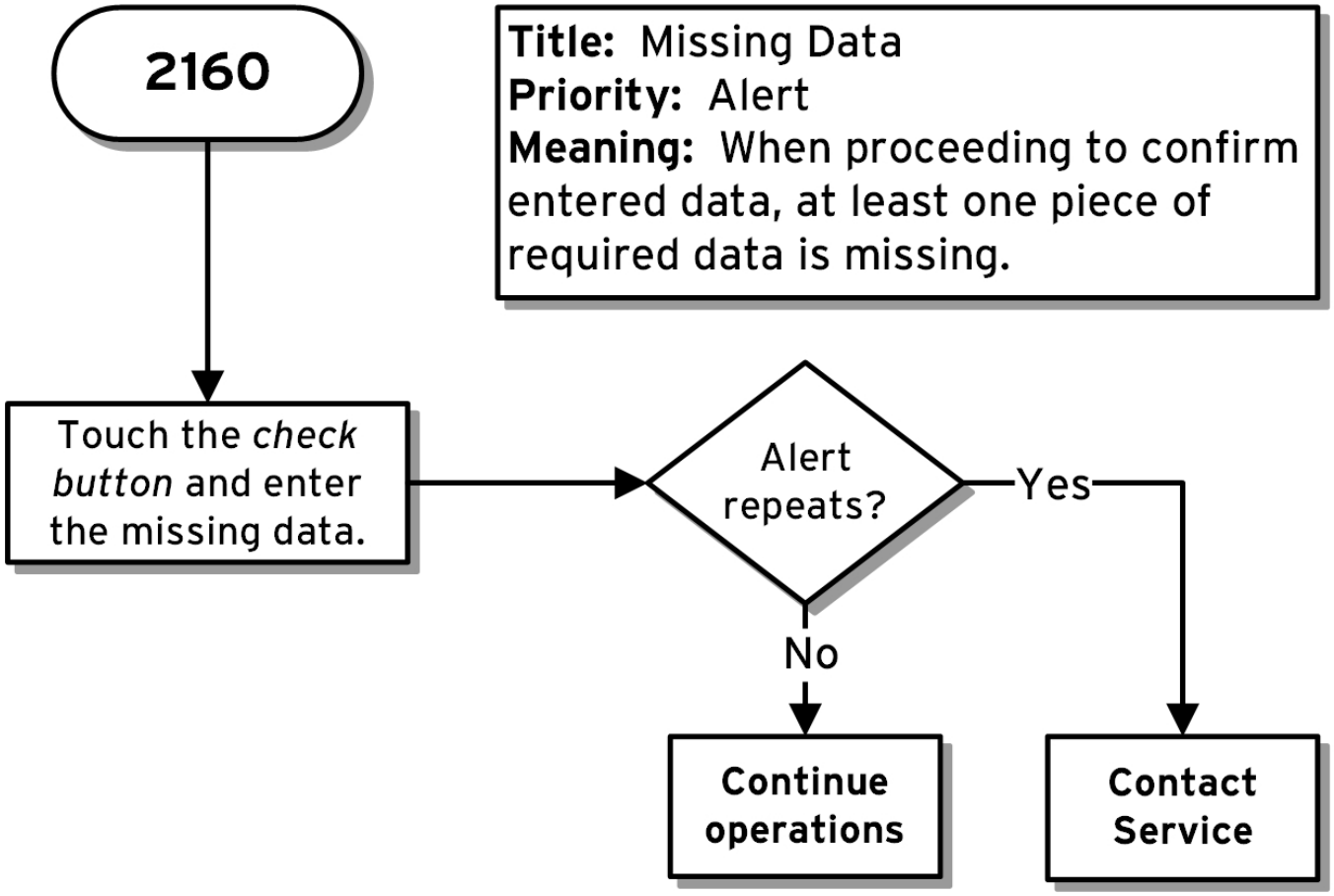


Figure 171: 2301 Pressure Out of Range

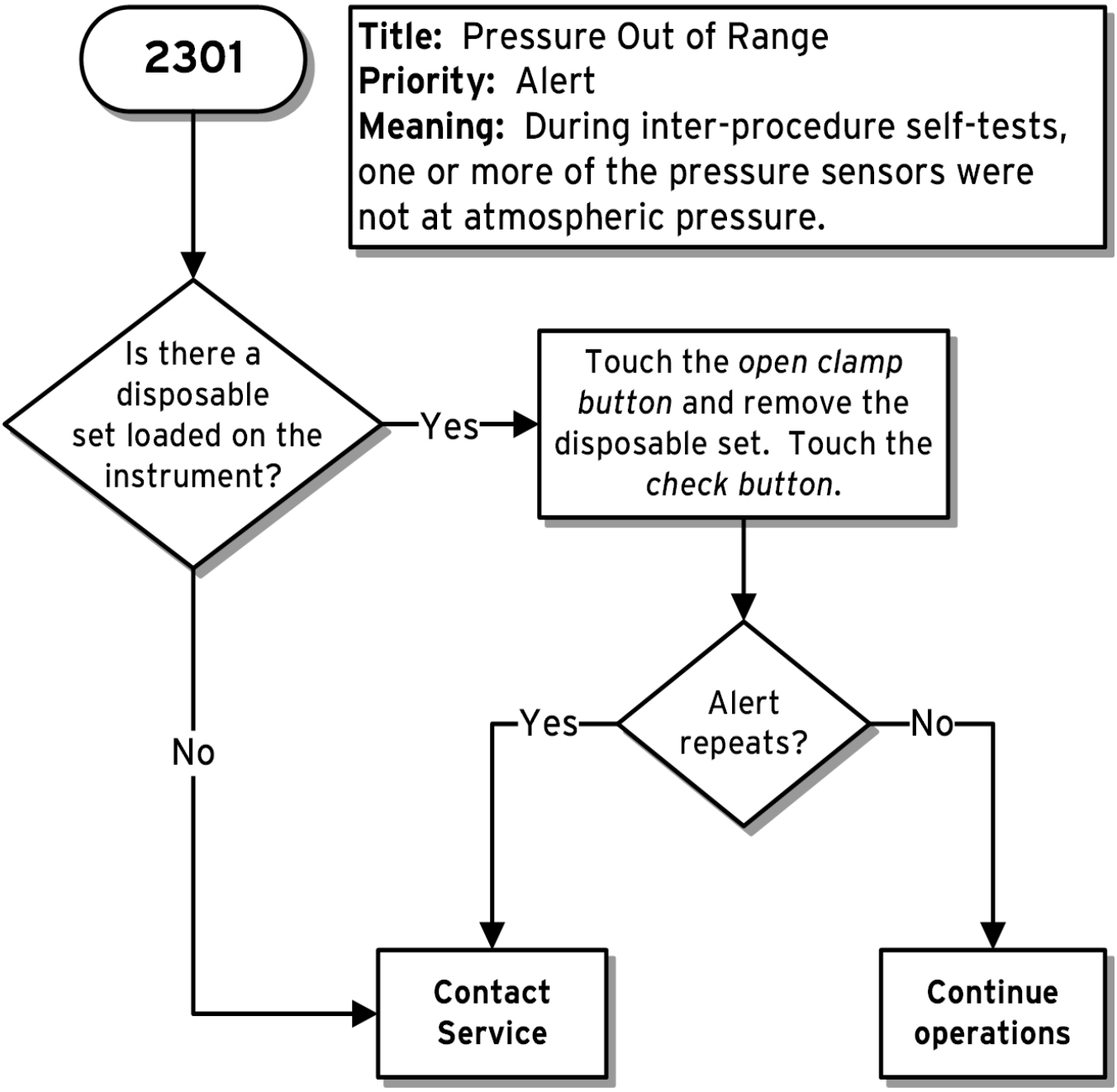


Figure 172: 2302 Motor Test Error

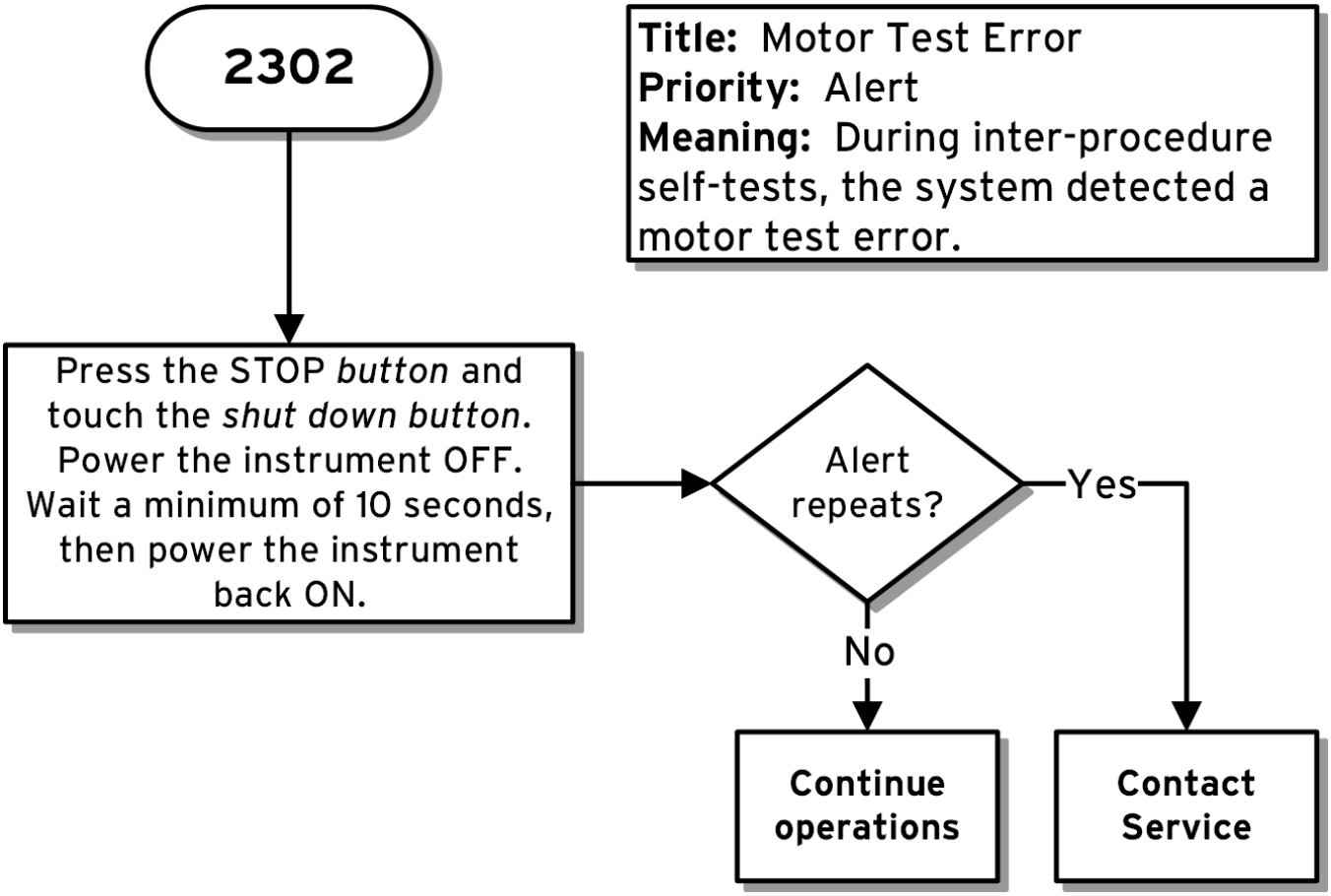


Figure 173: 2304 Cuff Pressure Out of Range

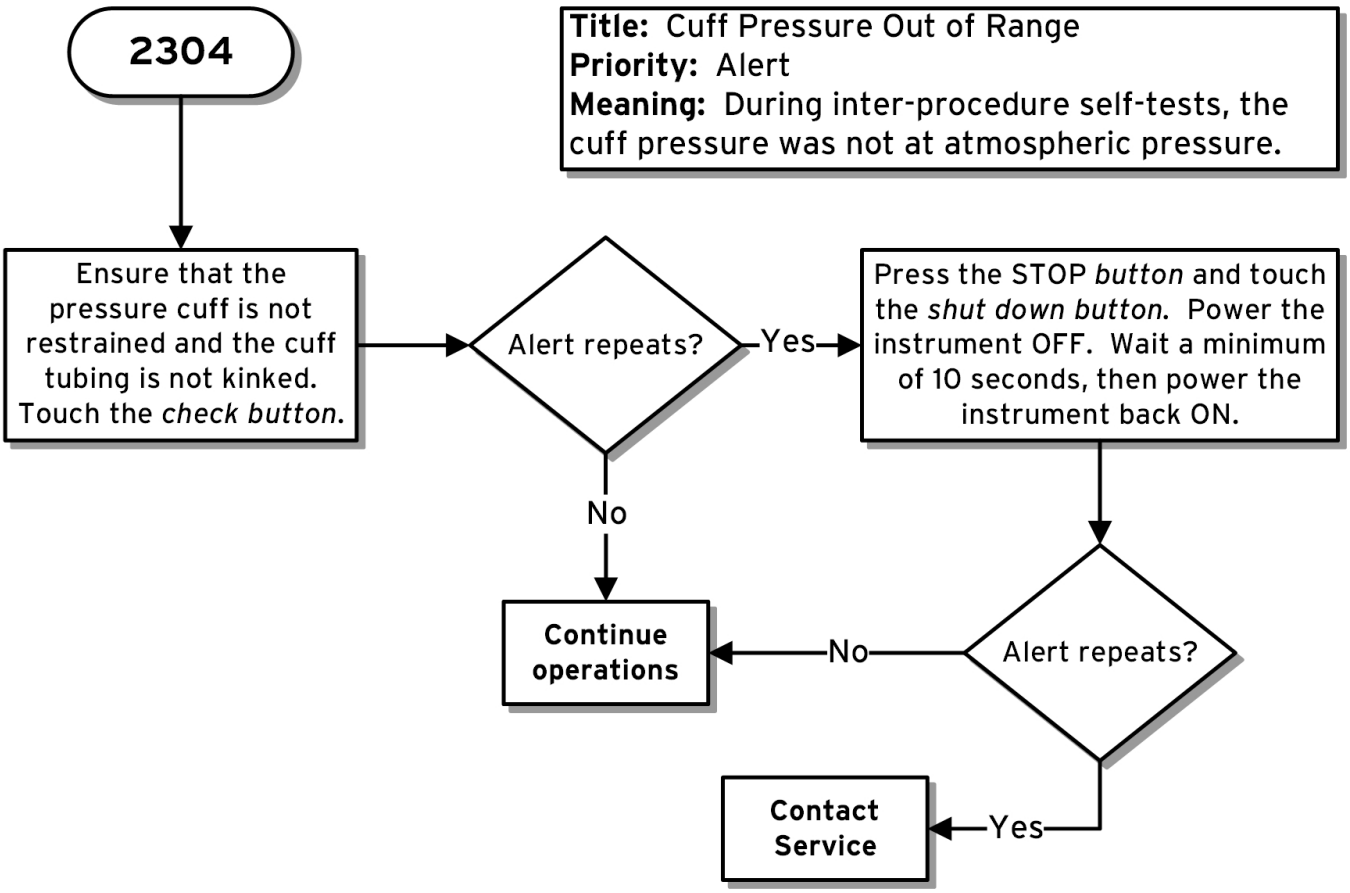


Figure 174: 2305 Tubing Detected

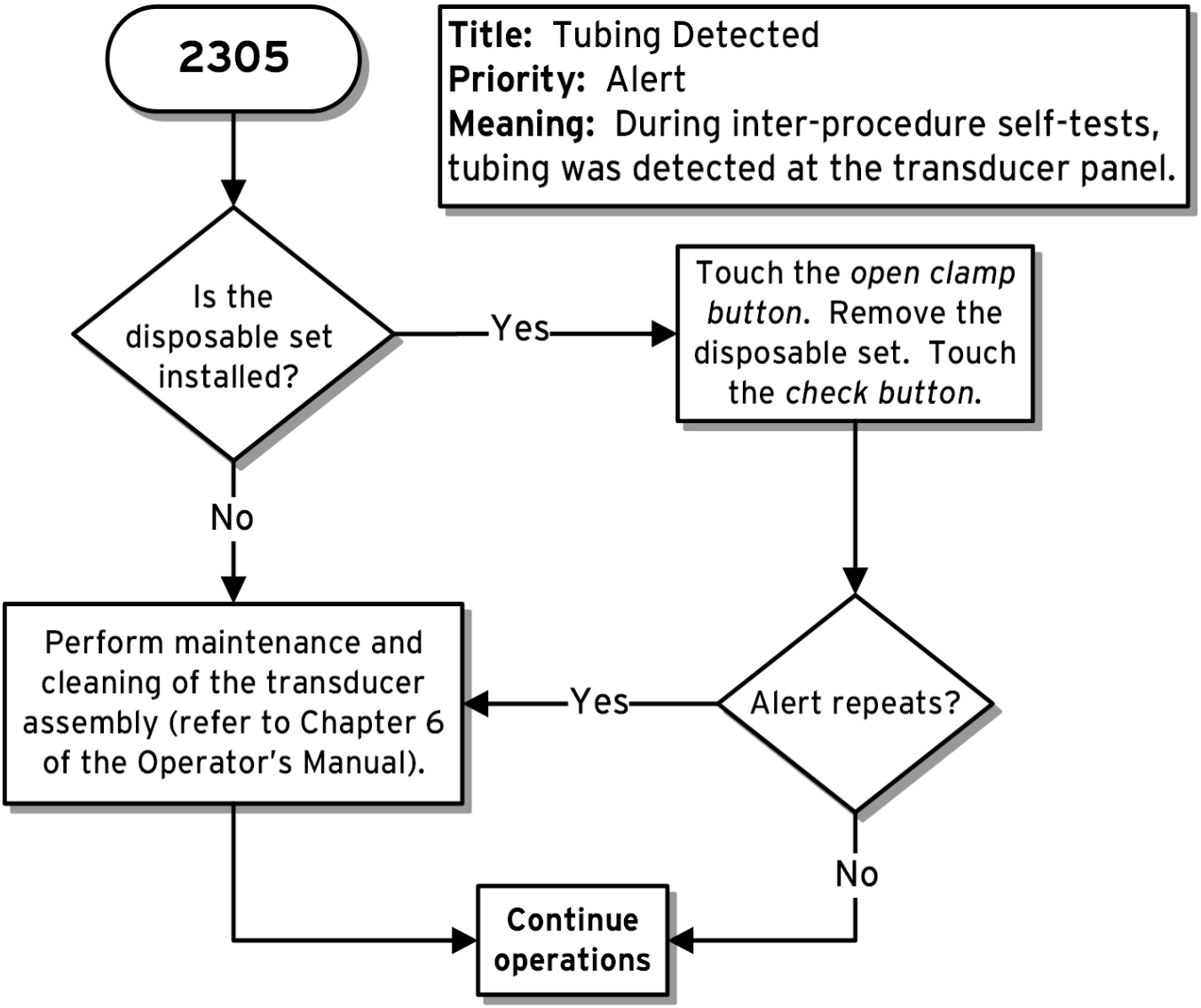


Figure 175: 2307 Set Timeout

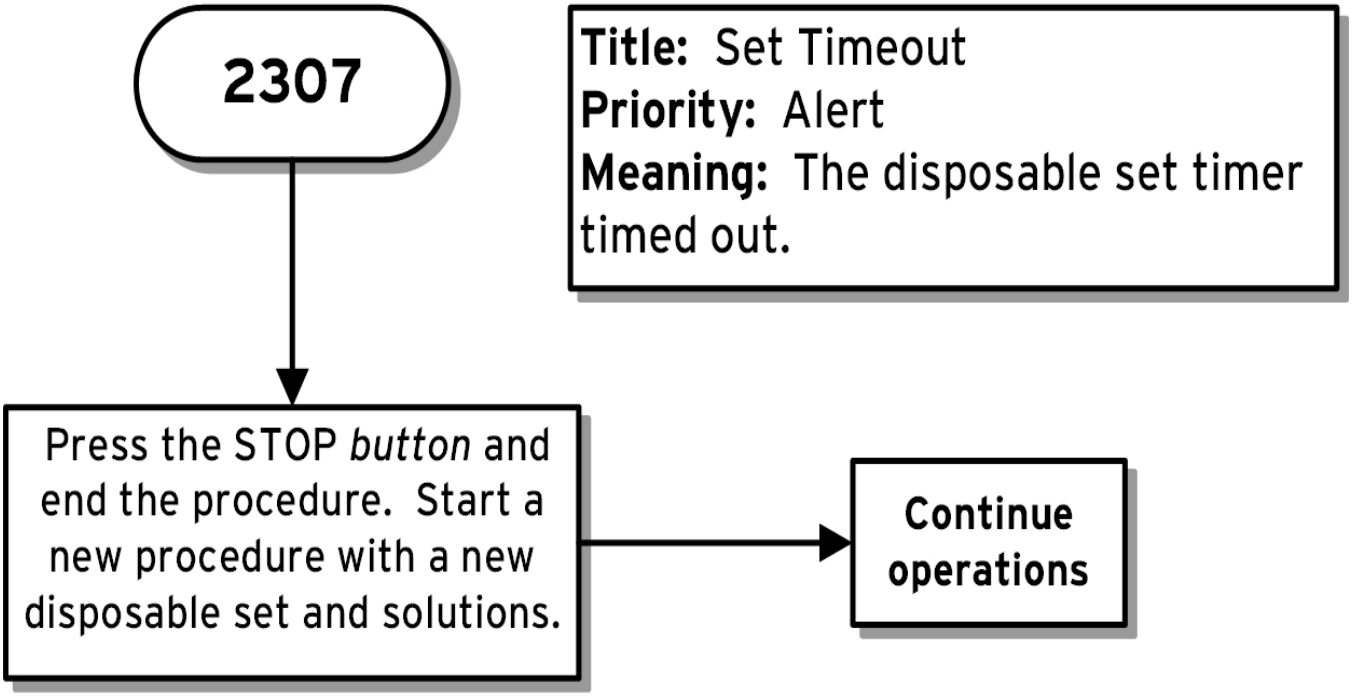


Figure 176: 2310 Fault Detection System Error

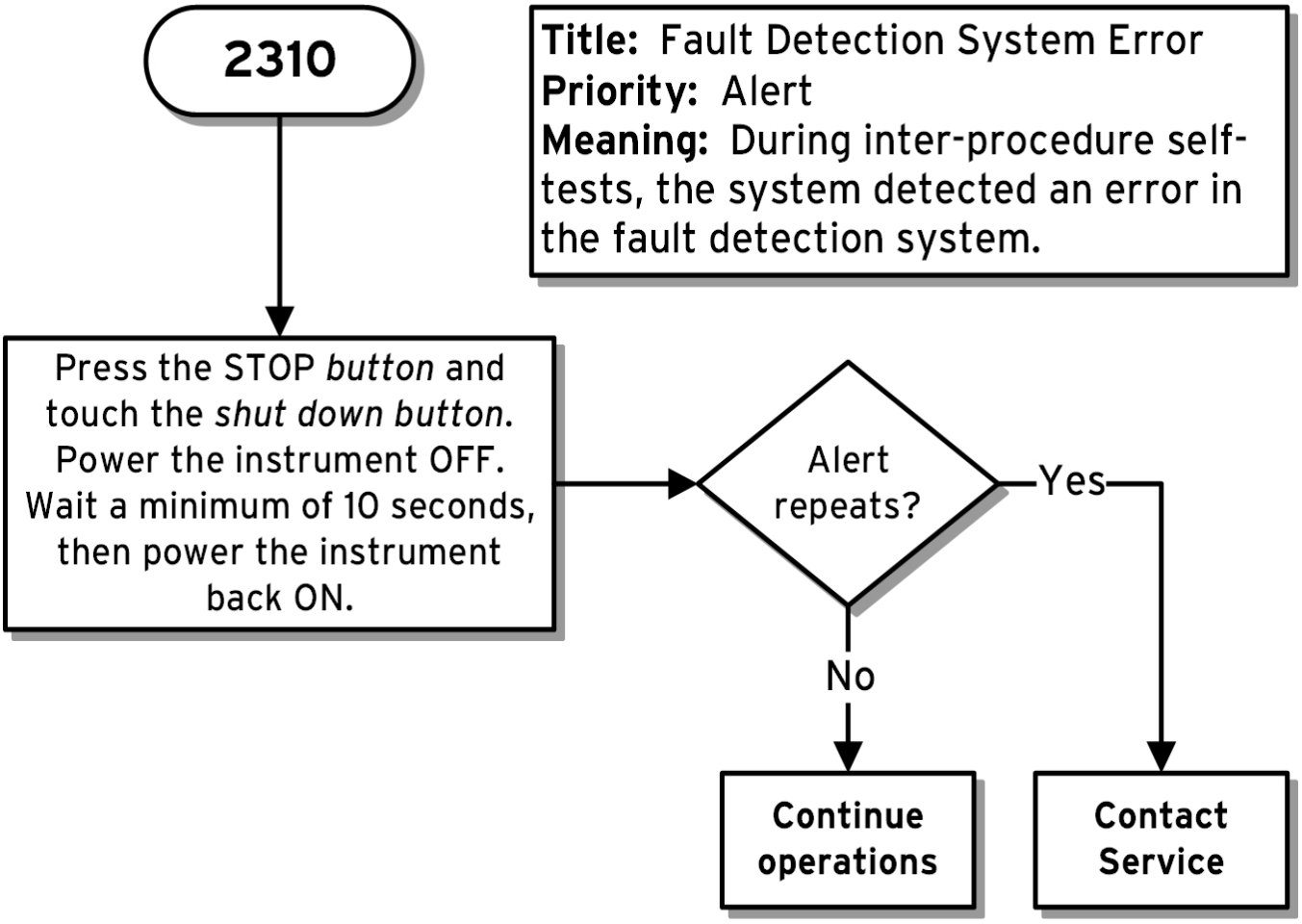


Figure 177: 2311 Fluid Detected

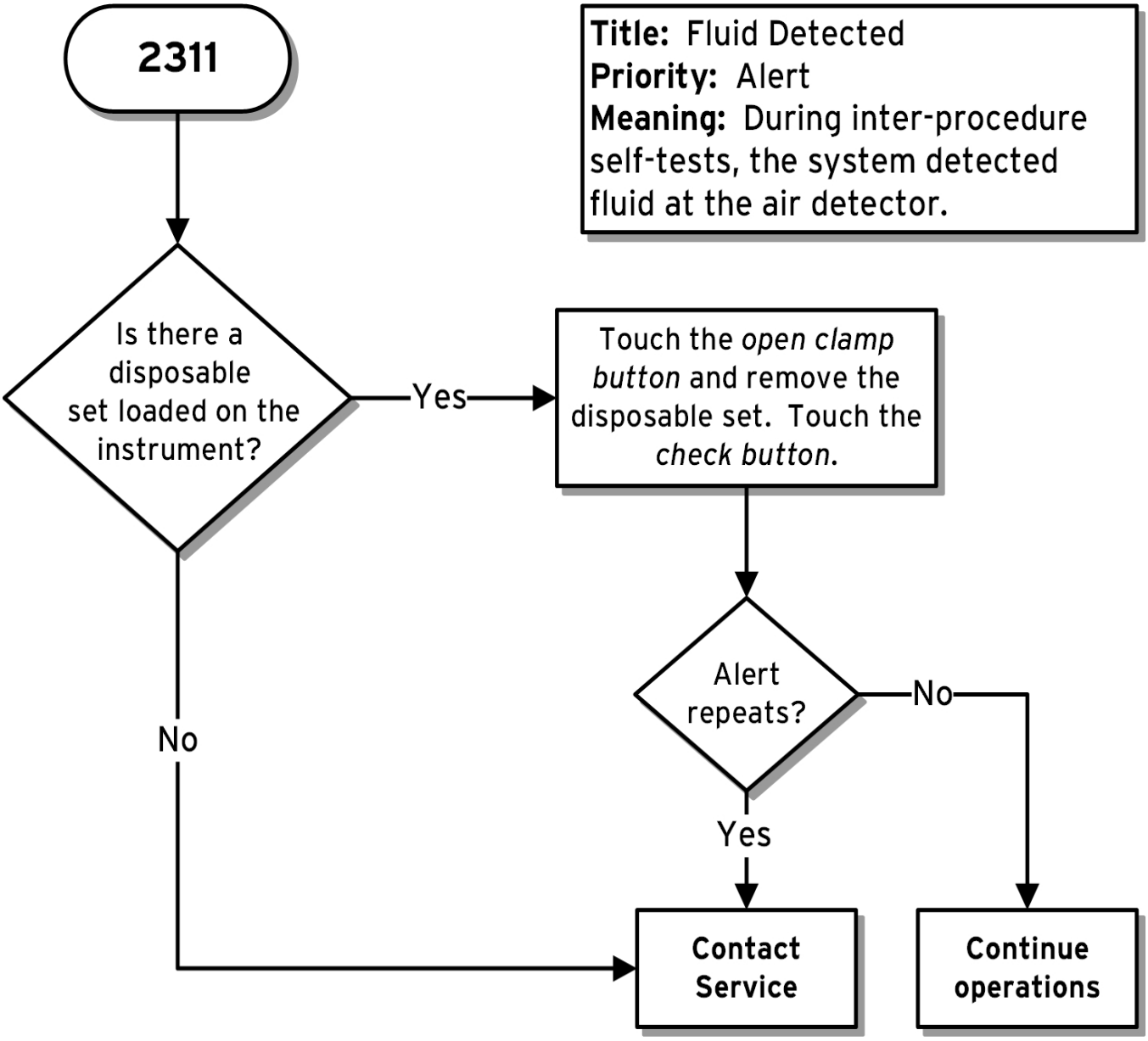


Figure 178: 2320 Weight on Scale

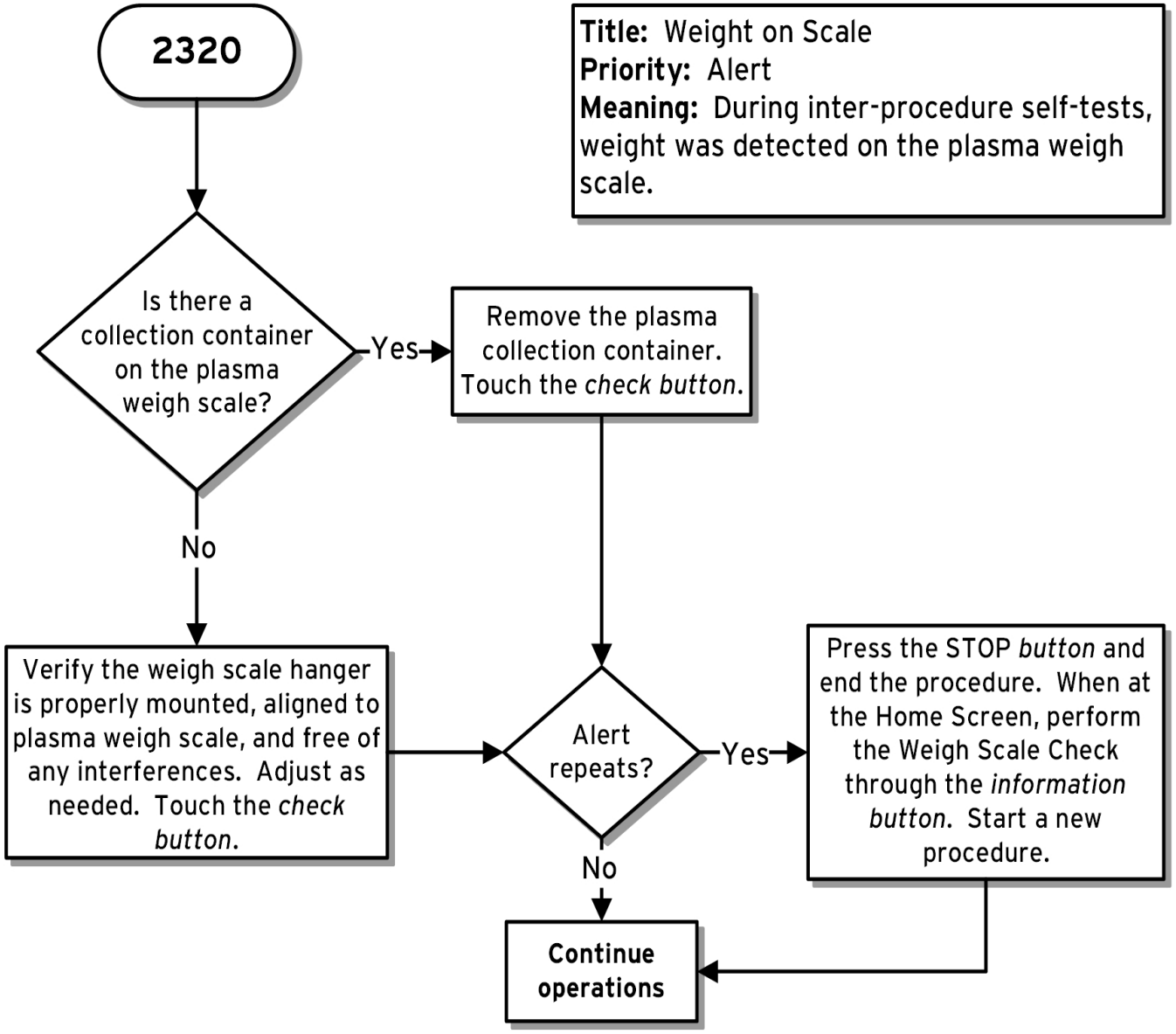


Figure 179: 2321 Weight on Scale

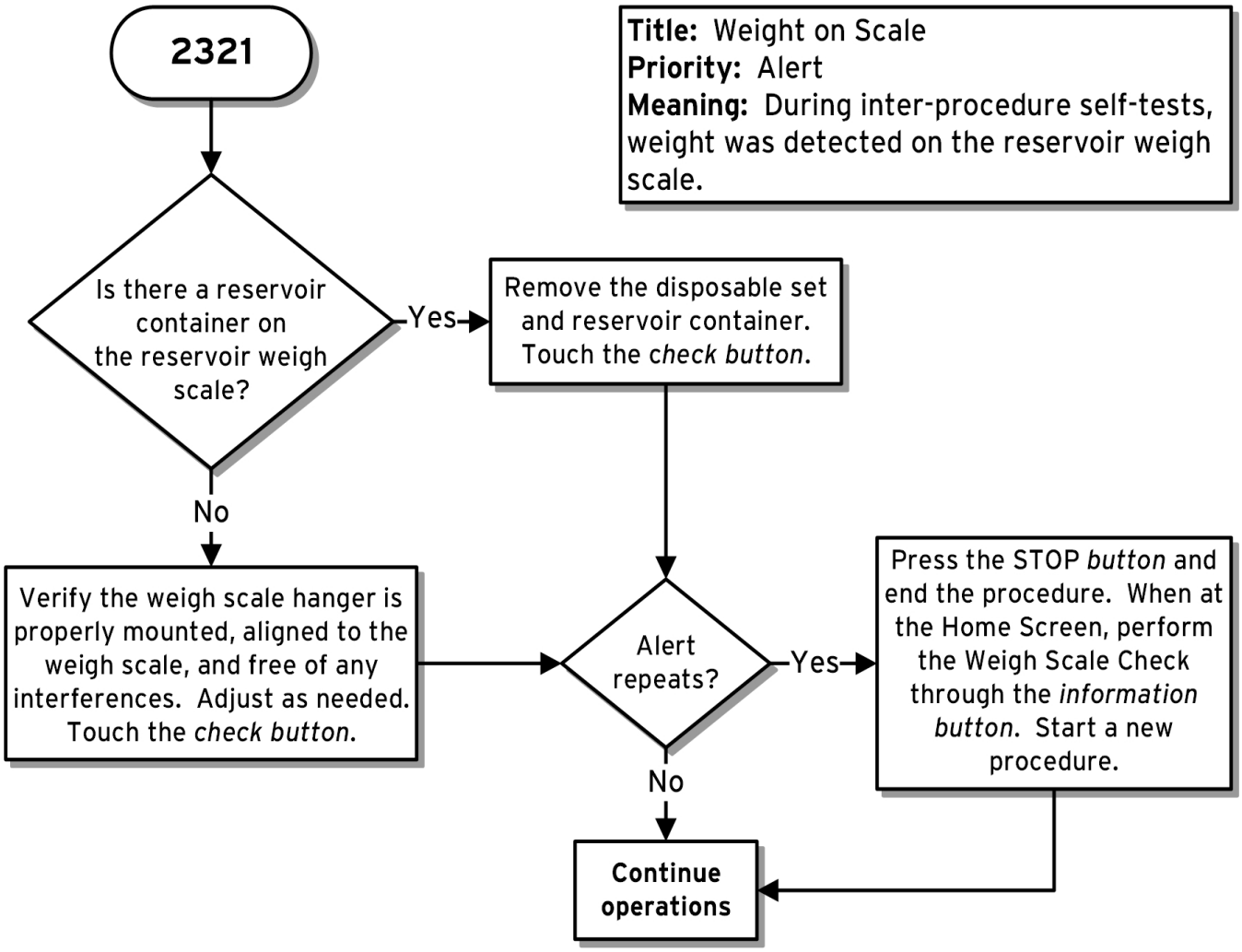


Figure 180: 2322 Weight on Scale

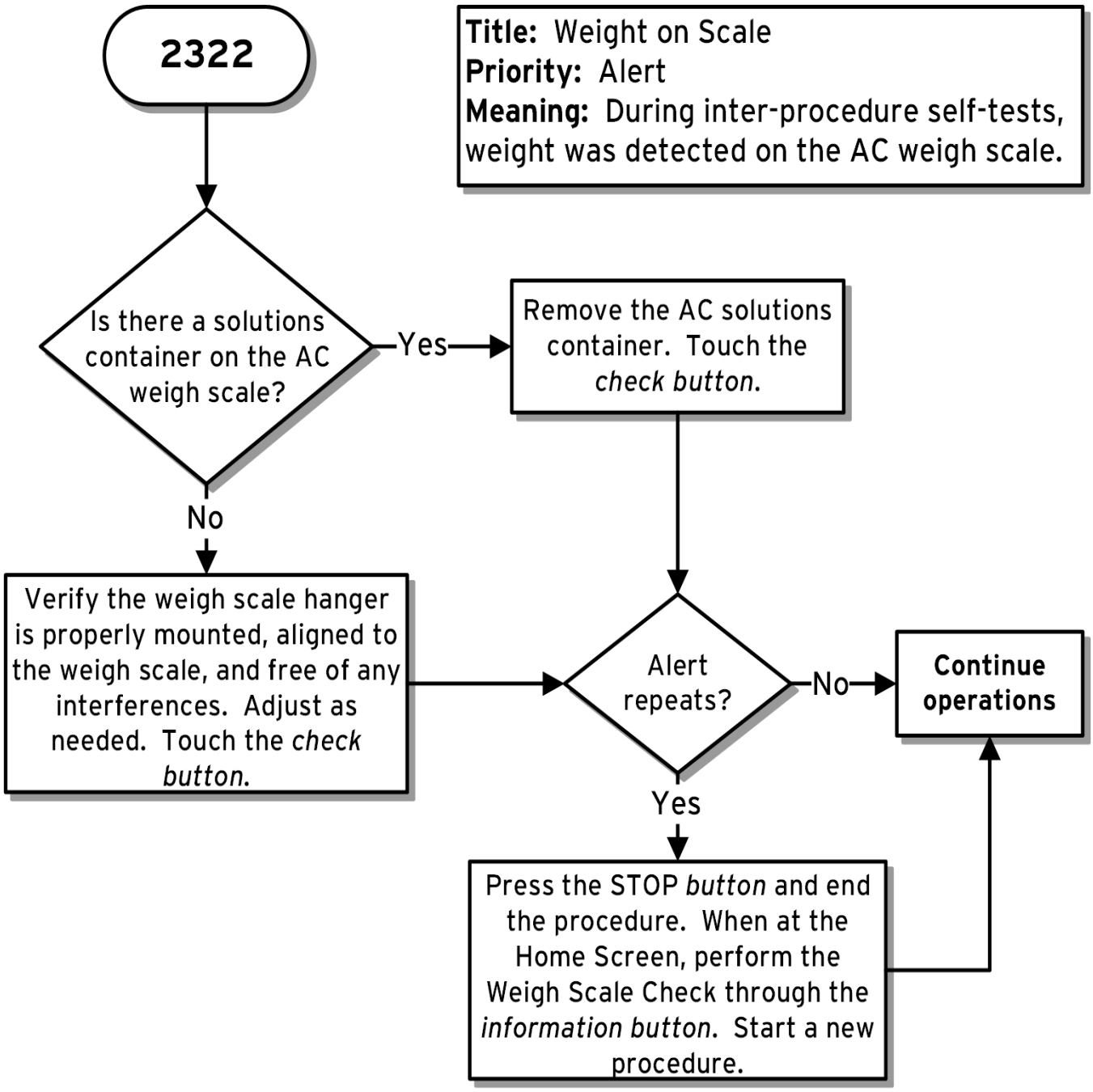


Figure 181: 2325 Scale QC Expired

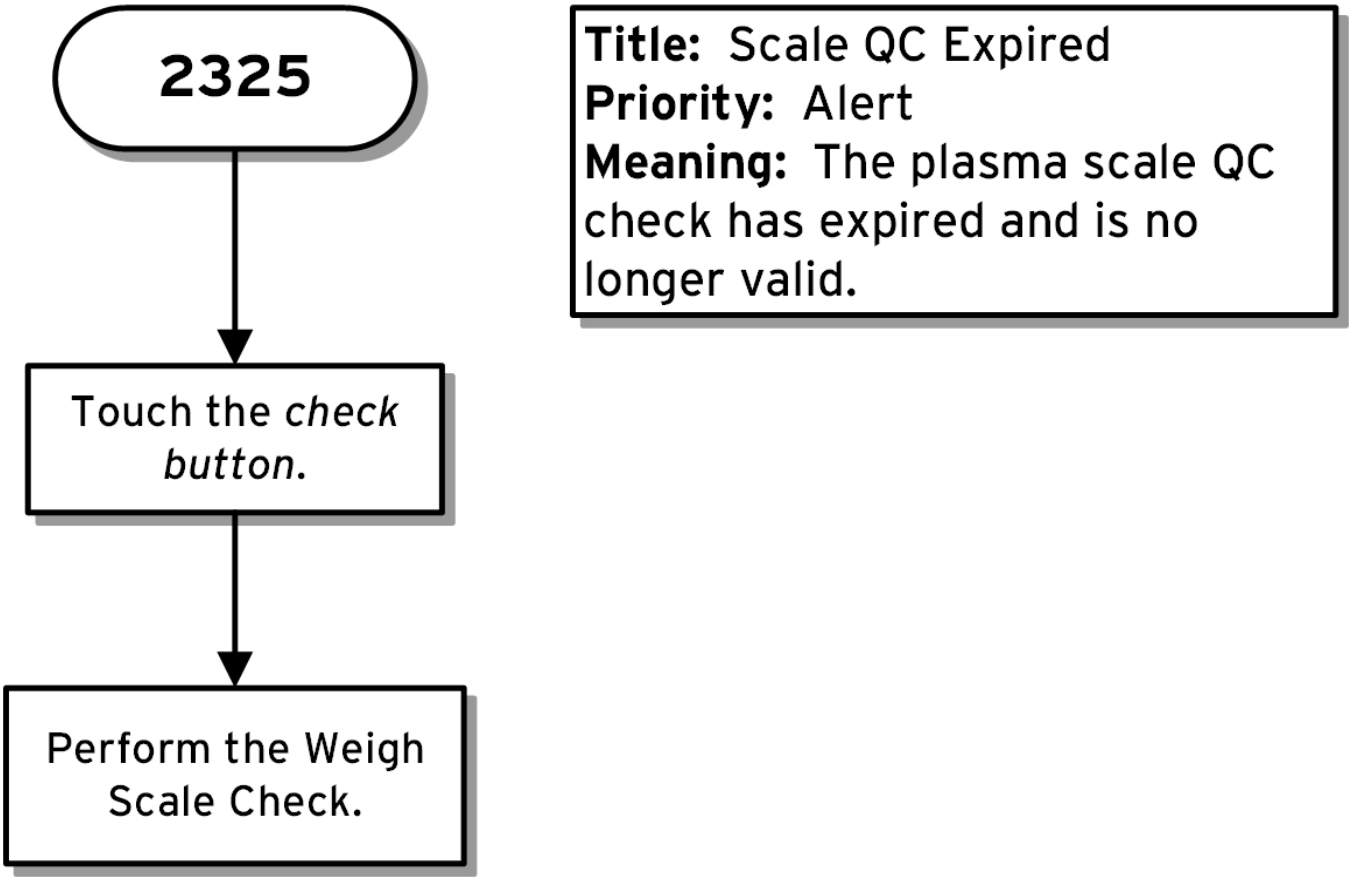


Figure 182: 2326 Scale QC Expired

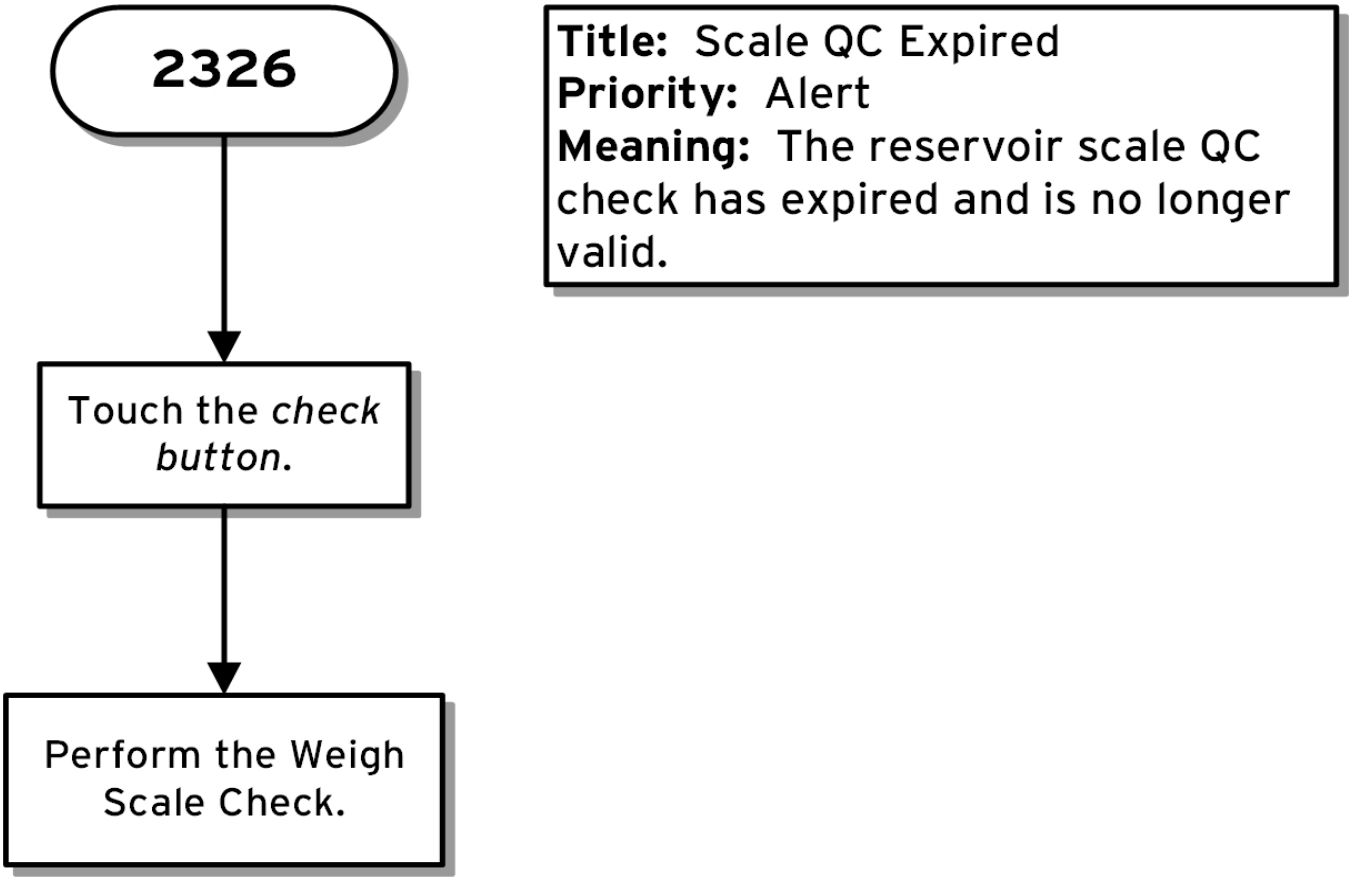


Figure 183: 2327 Scale QC Expired

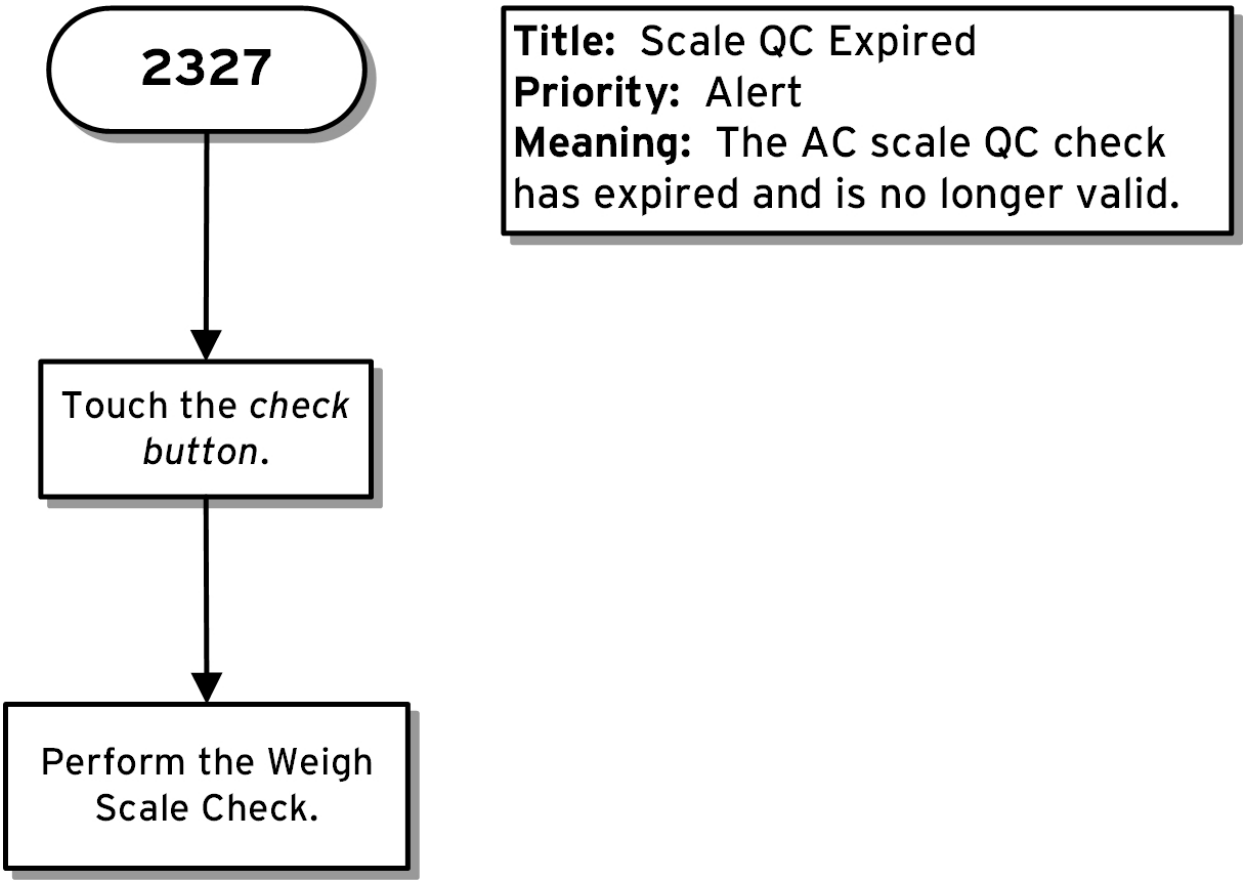


Figure 184: 2338 Hb Detector Out of Range

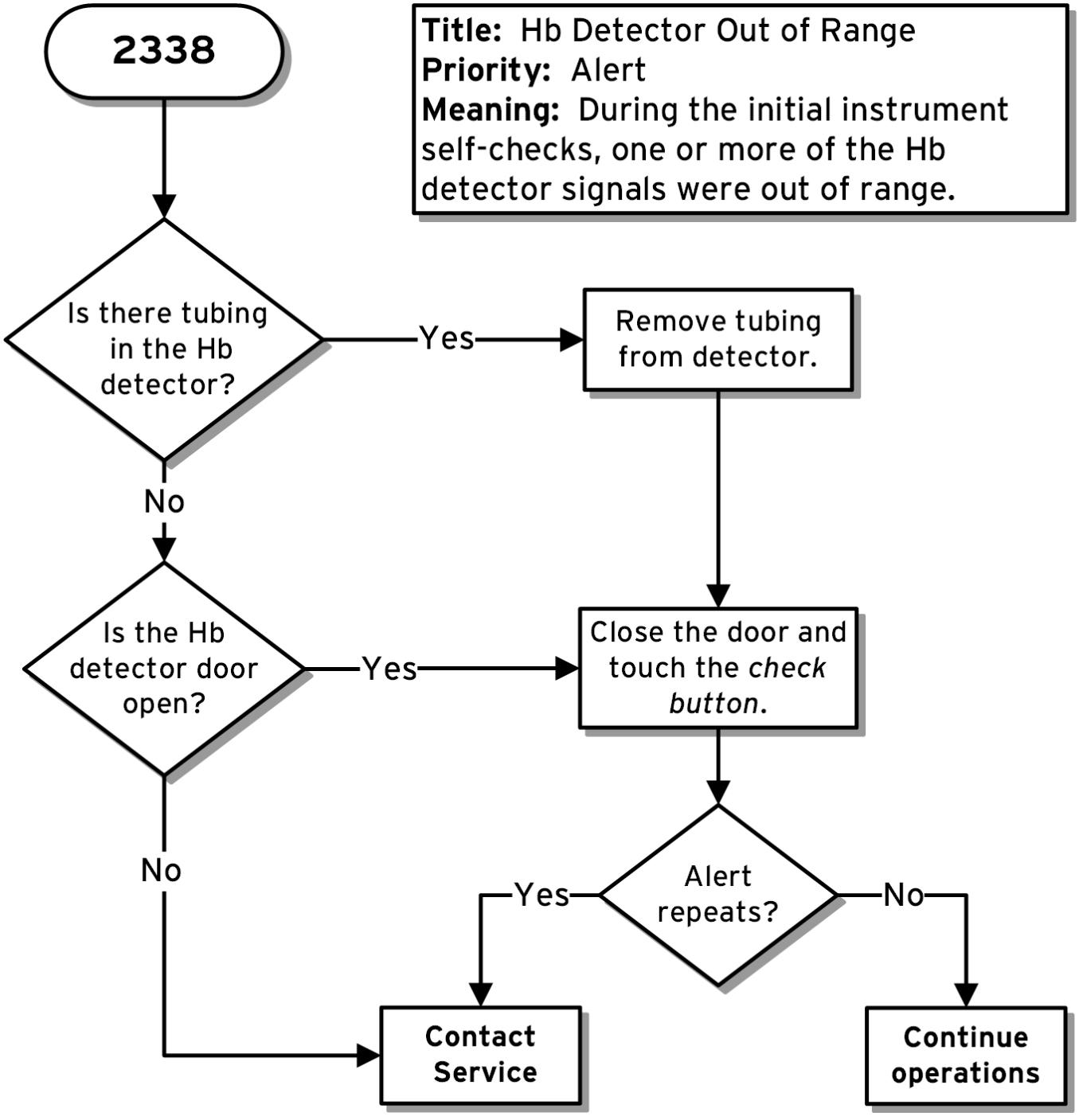


Figure 185: 2354 Hb Detector Needs Calibration

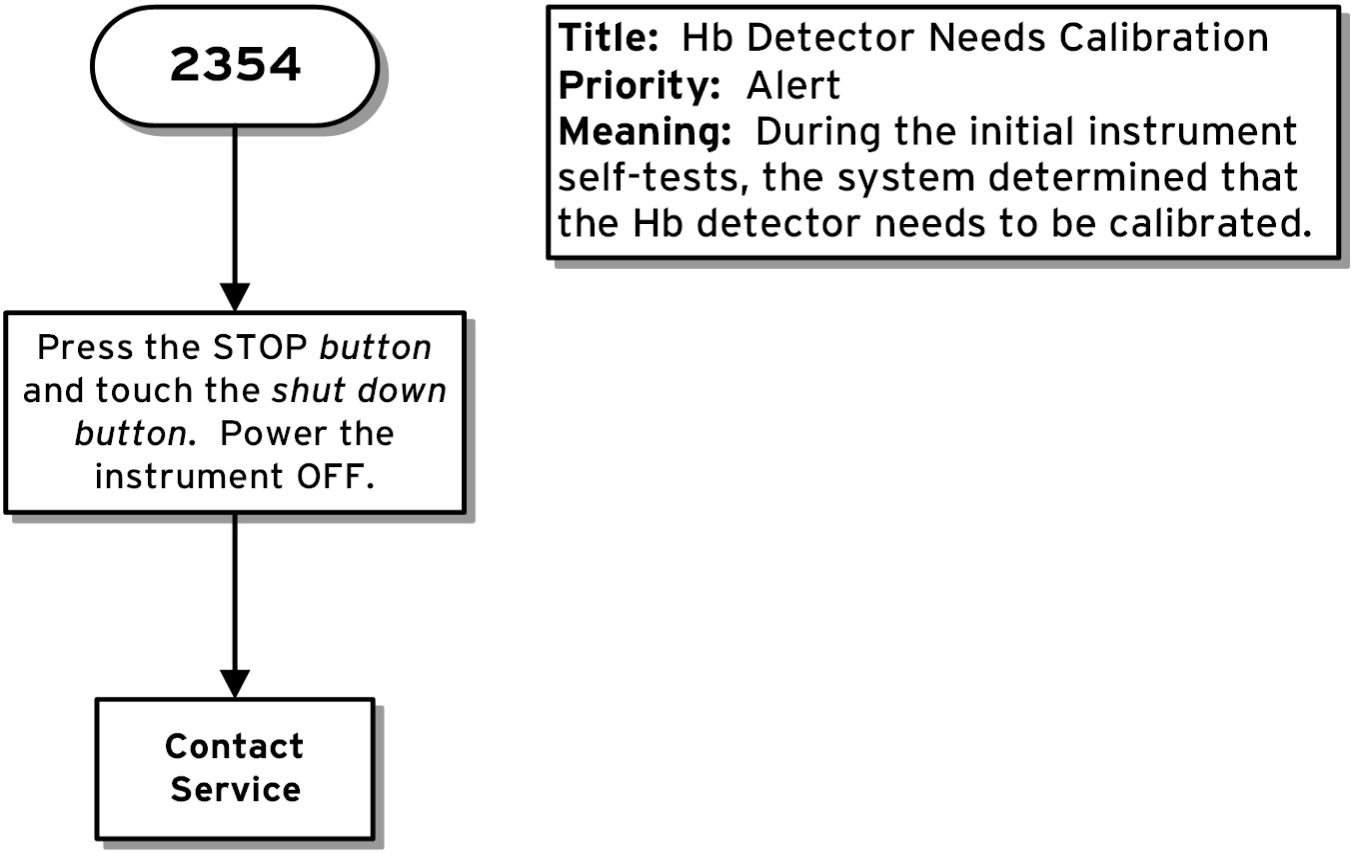


Figure 186: 2400 Weight on Scale

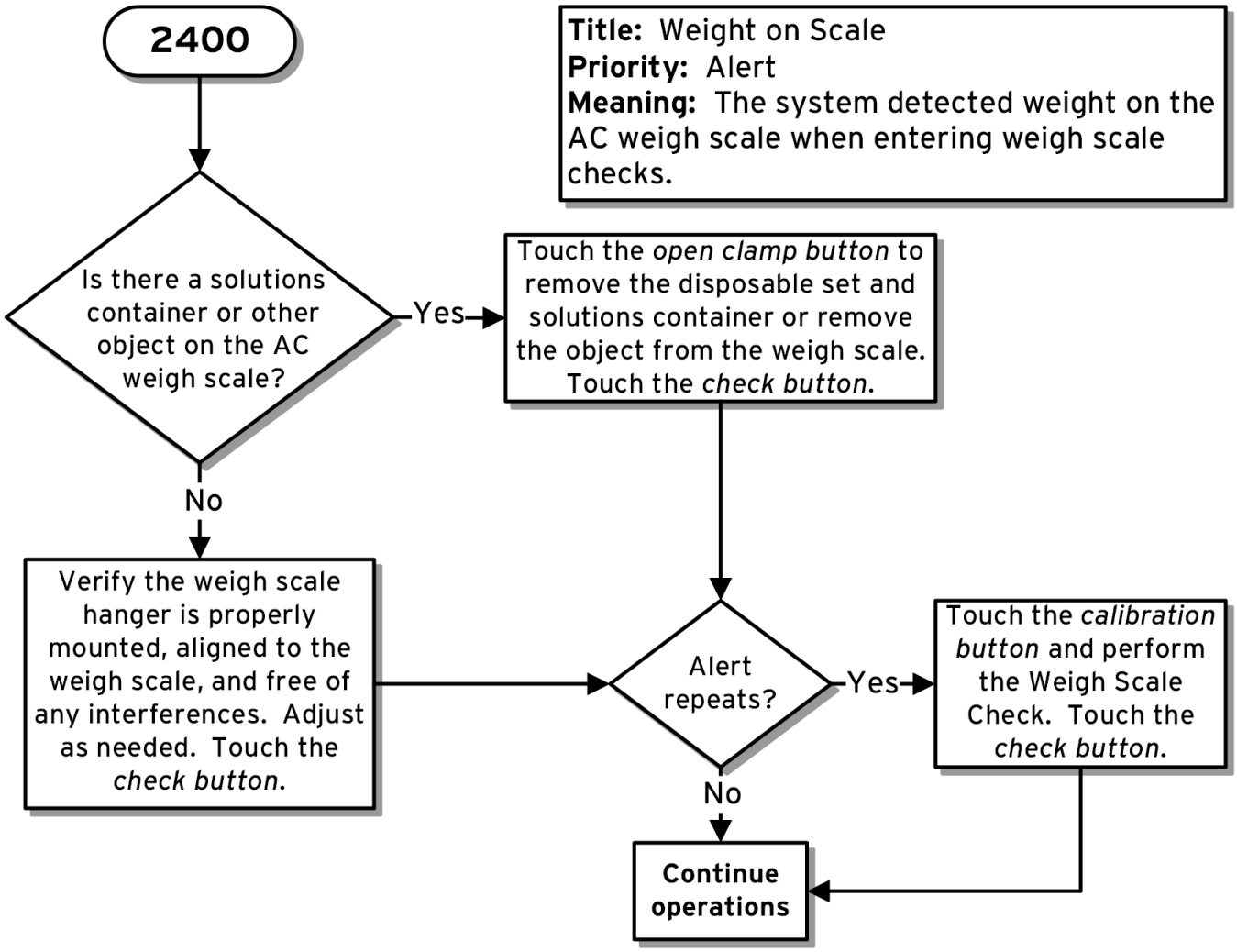


Figure 187: 2401 Calibration Required

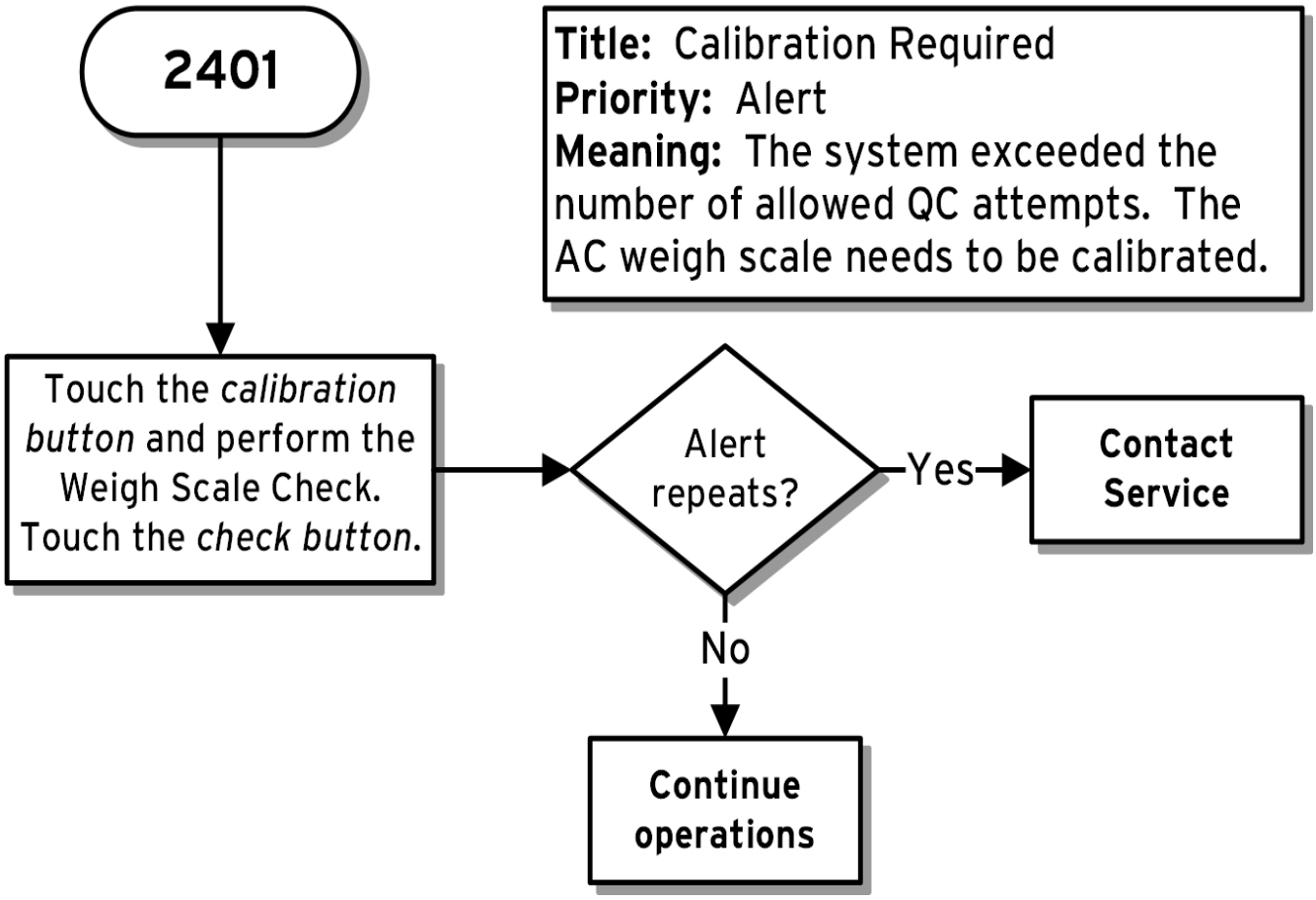


Figure 188: 2402 Weight on Scale

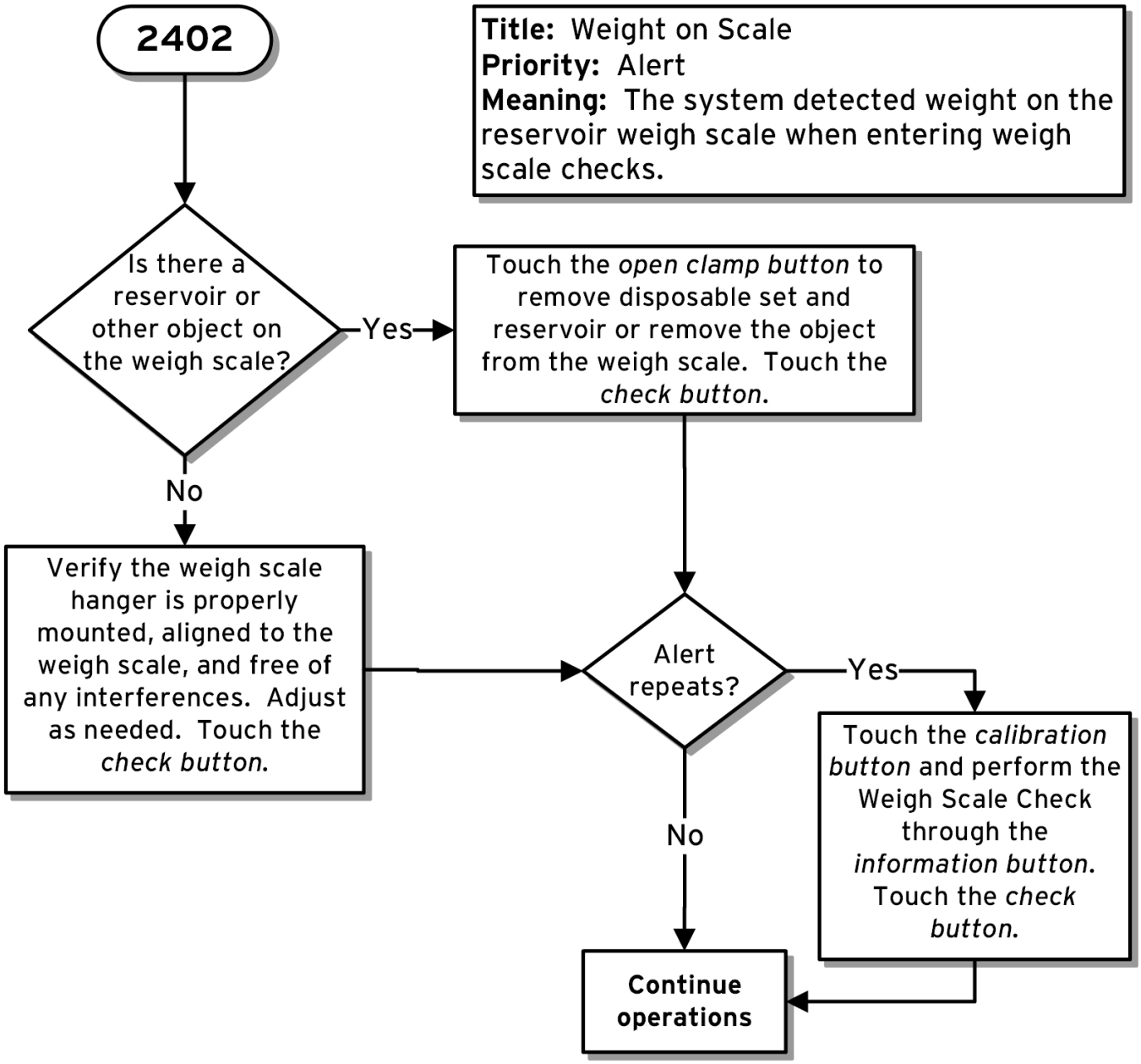


Figure 189: 2403 Calibration Required

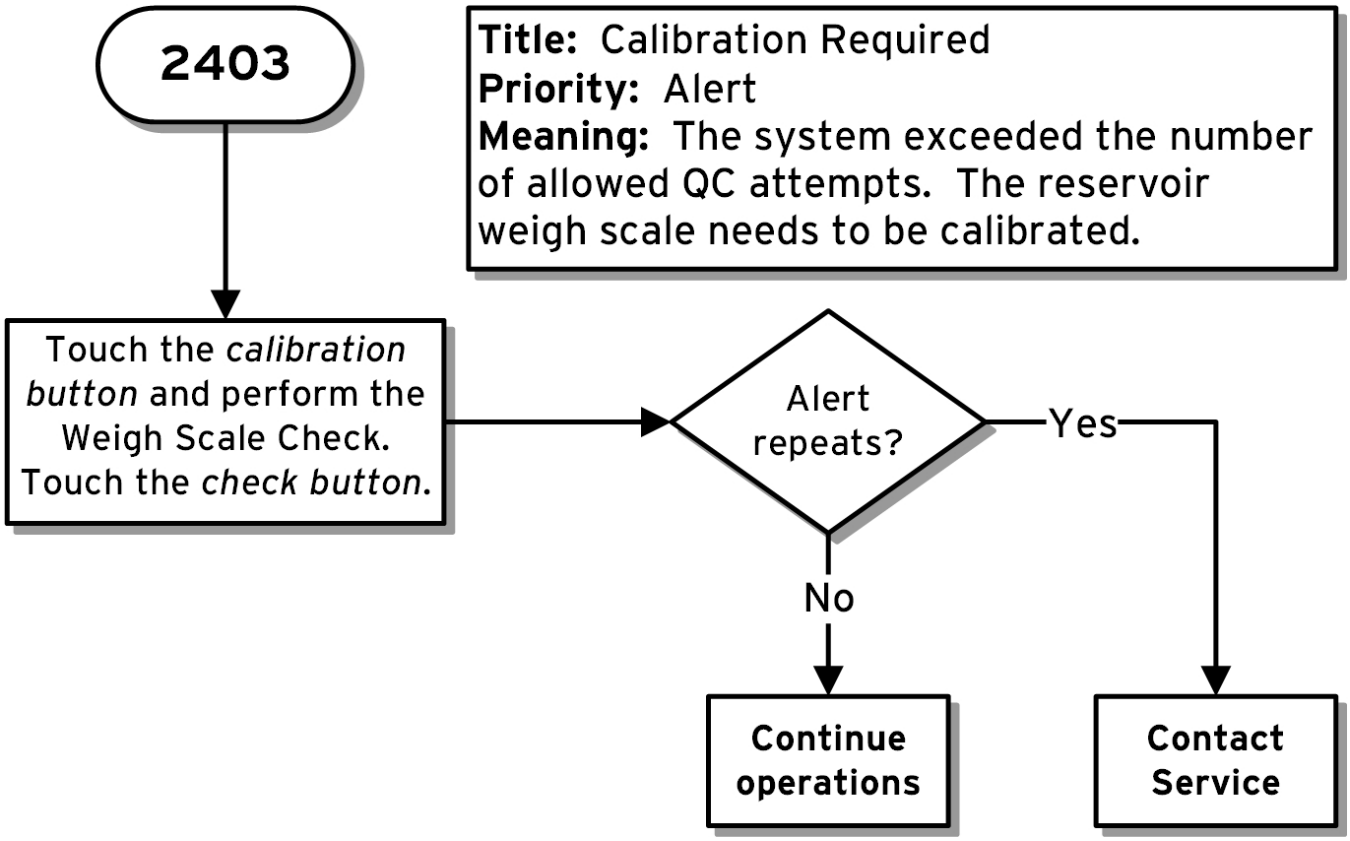


Figure 190: 2404 Weight on Scale

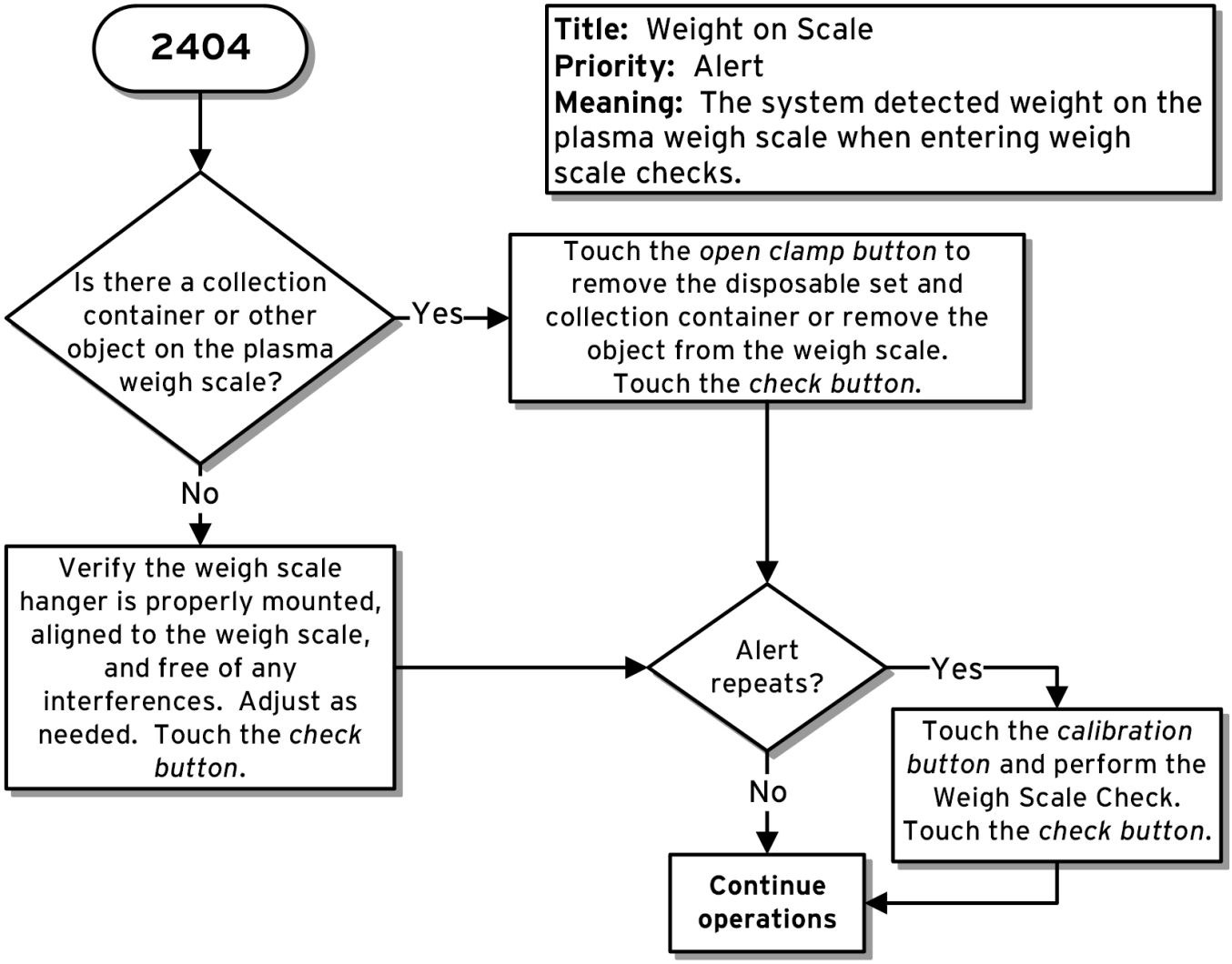


Figure 191: 2405 Calibration Required

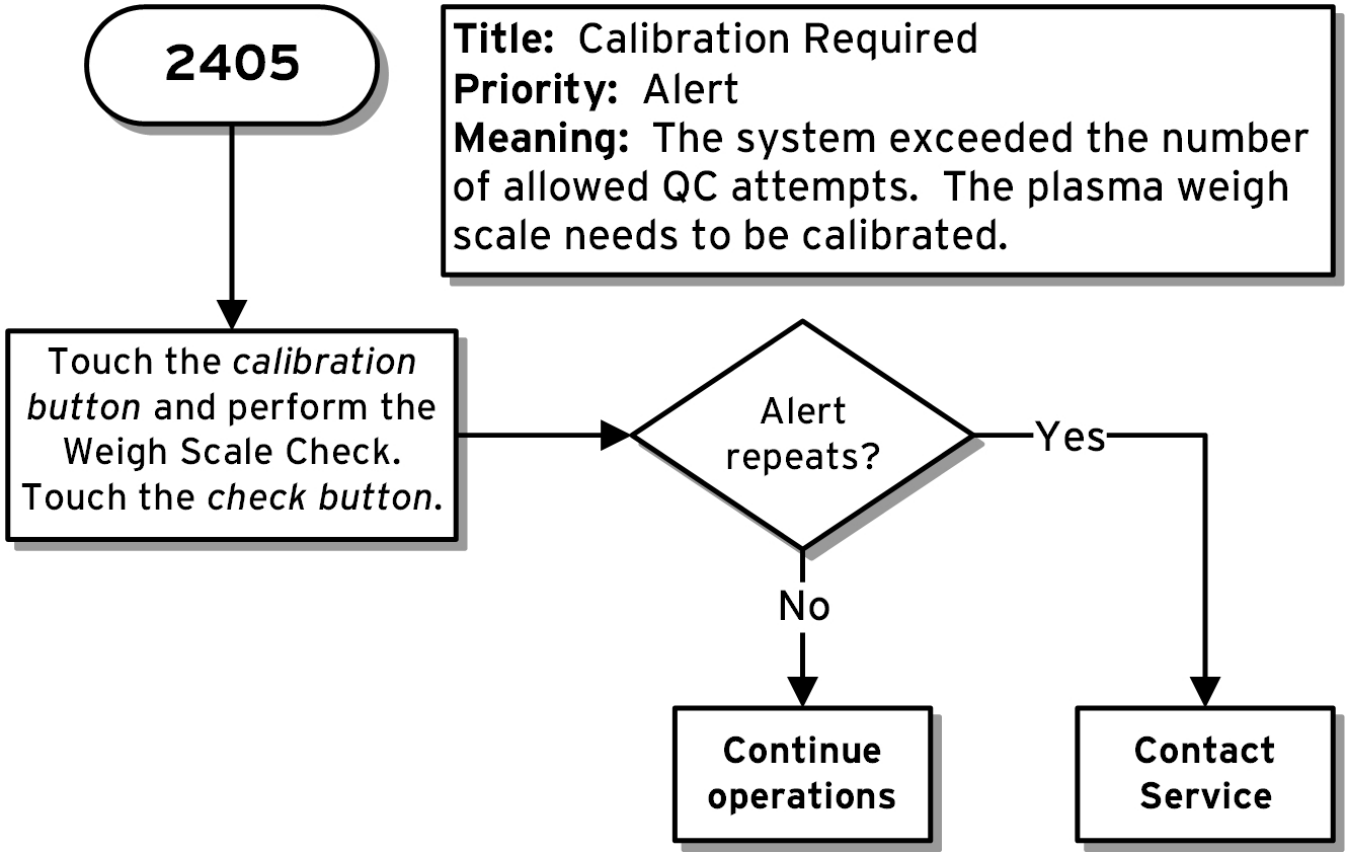


Figure 192: 2409 Gain Outside of Tolerance Limit

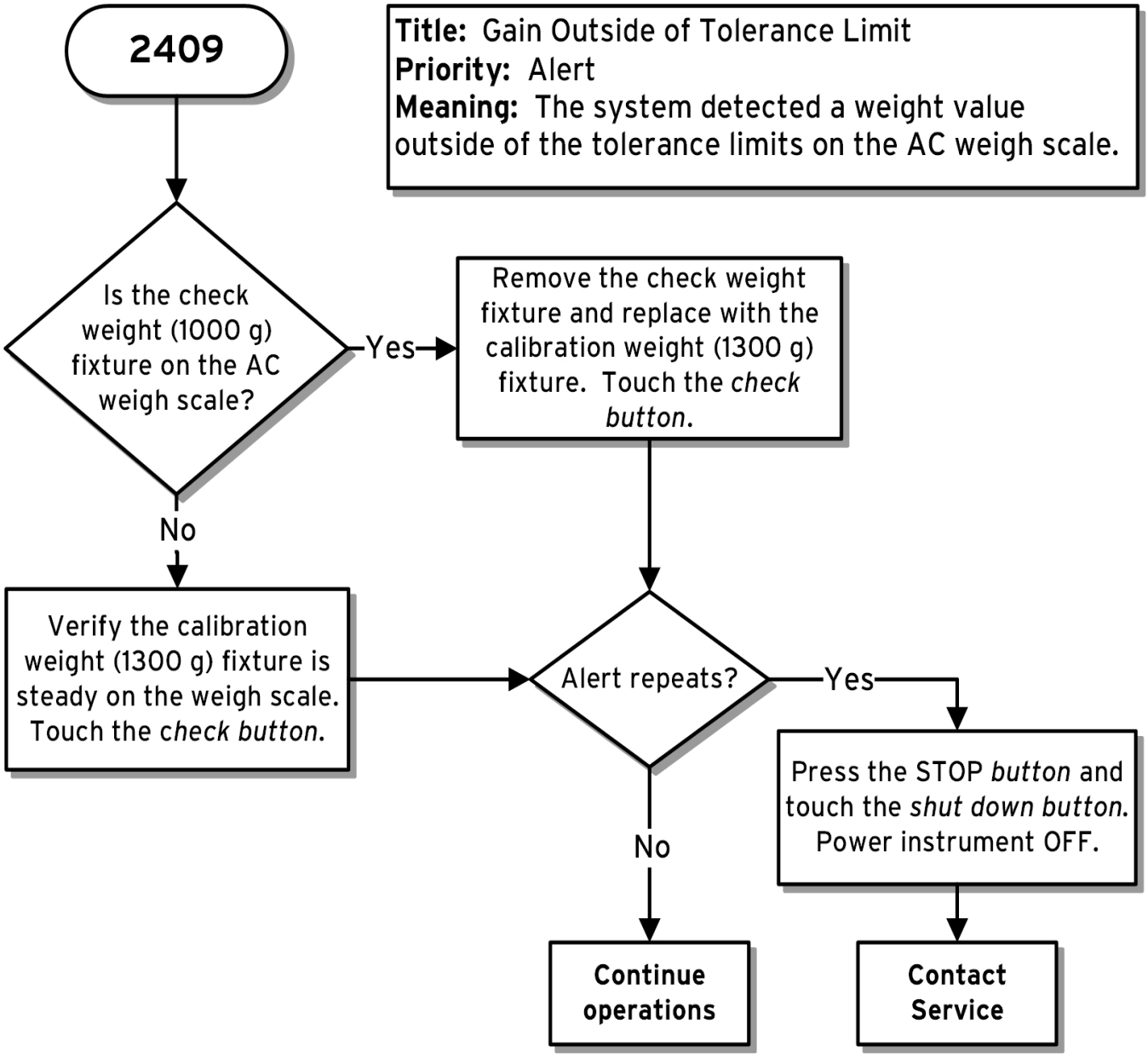


Figure 193: 2410 Gain Outside of Tolerance Limit

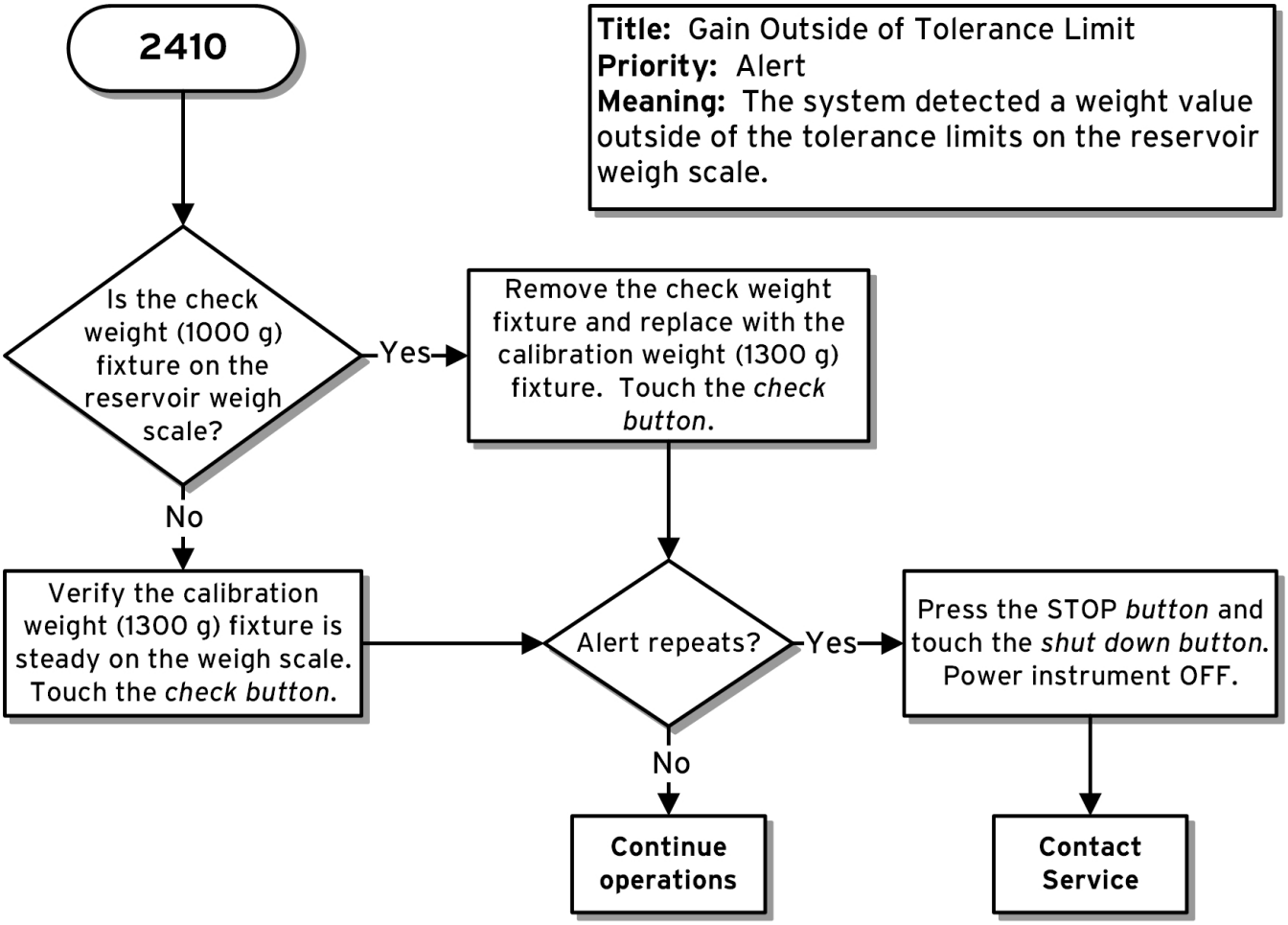


Figure 194: 2411 Gain Outside of Tolerance Limit

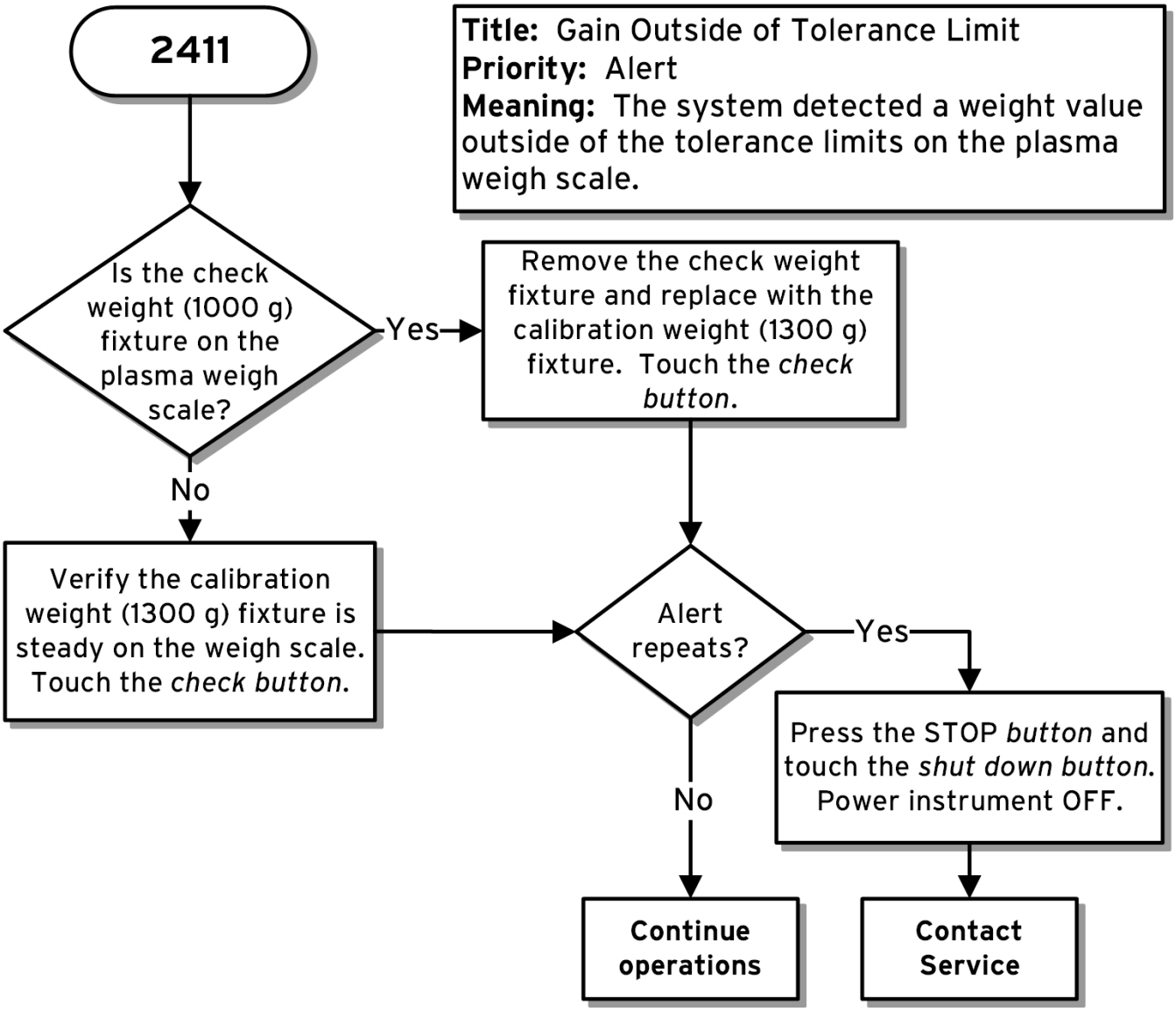


Figure 195: 3001 Fluid Not Seen in Reservoir

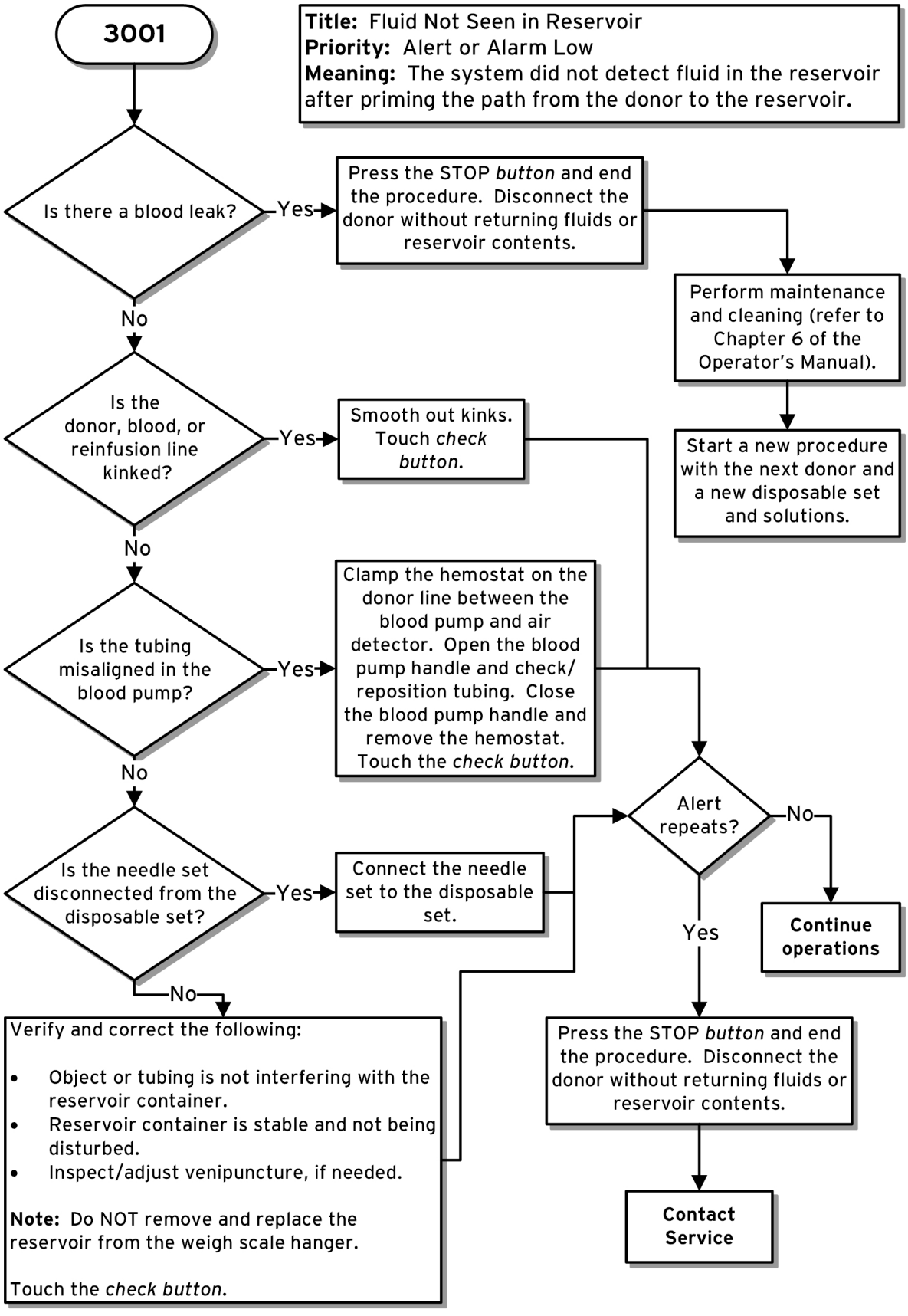


Figure 196: 3002 High P2 Pressure

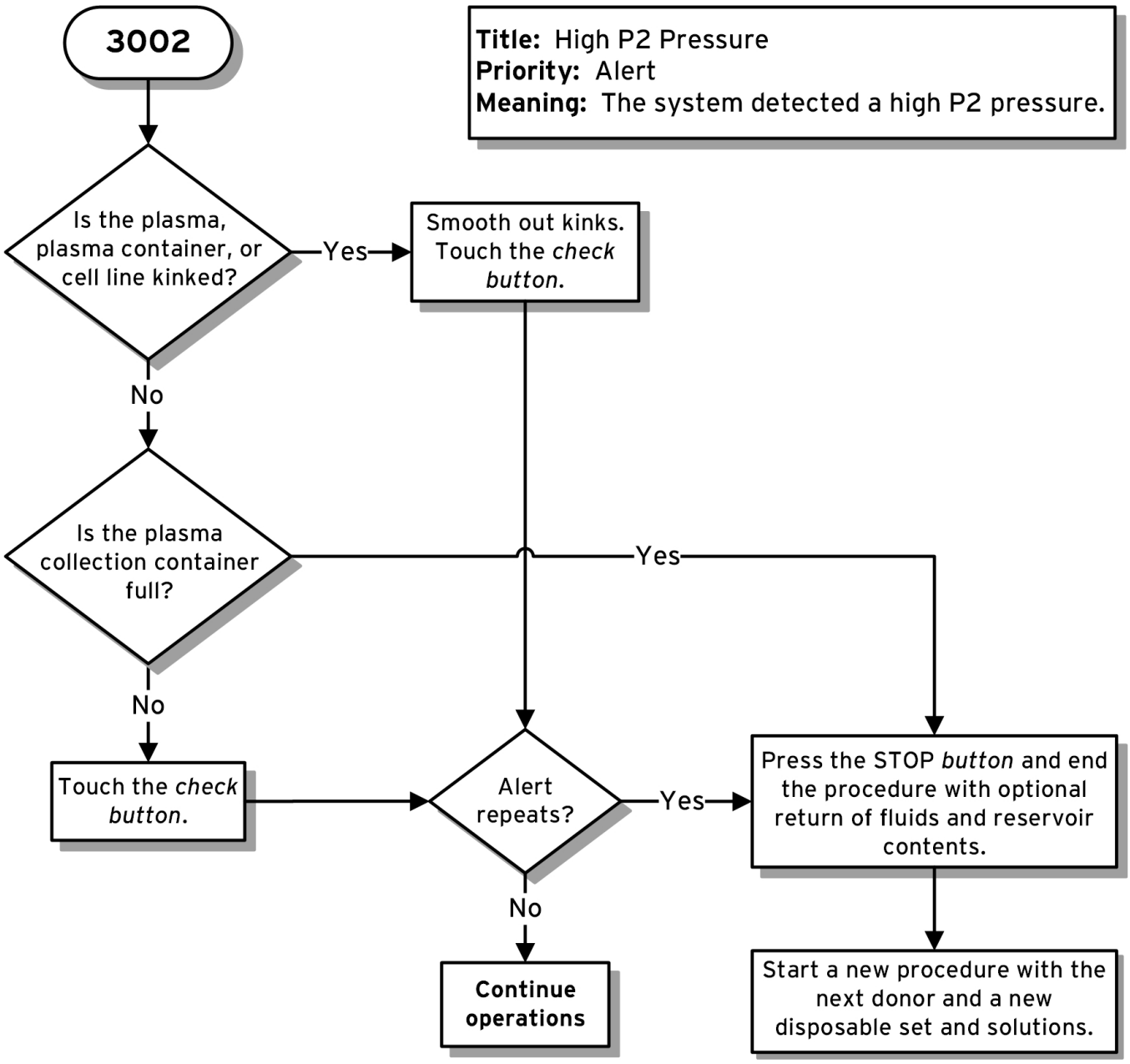


Figure 197: 3003 Low P2 Pressure

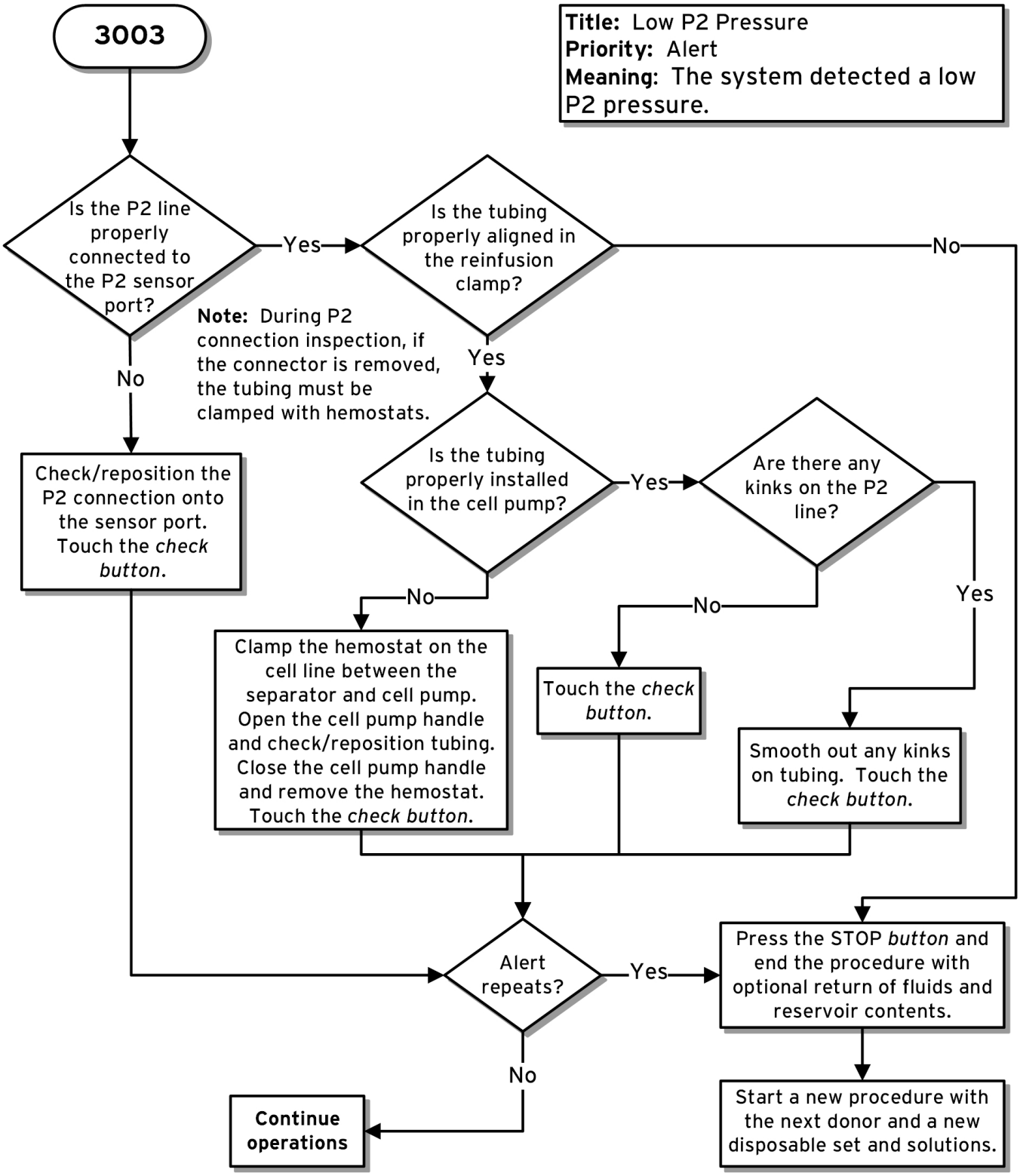
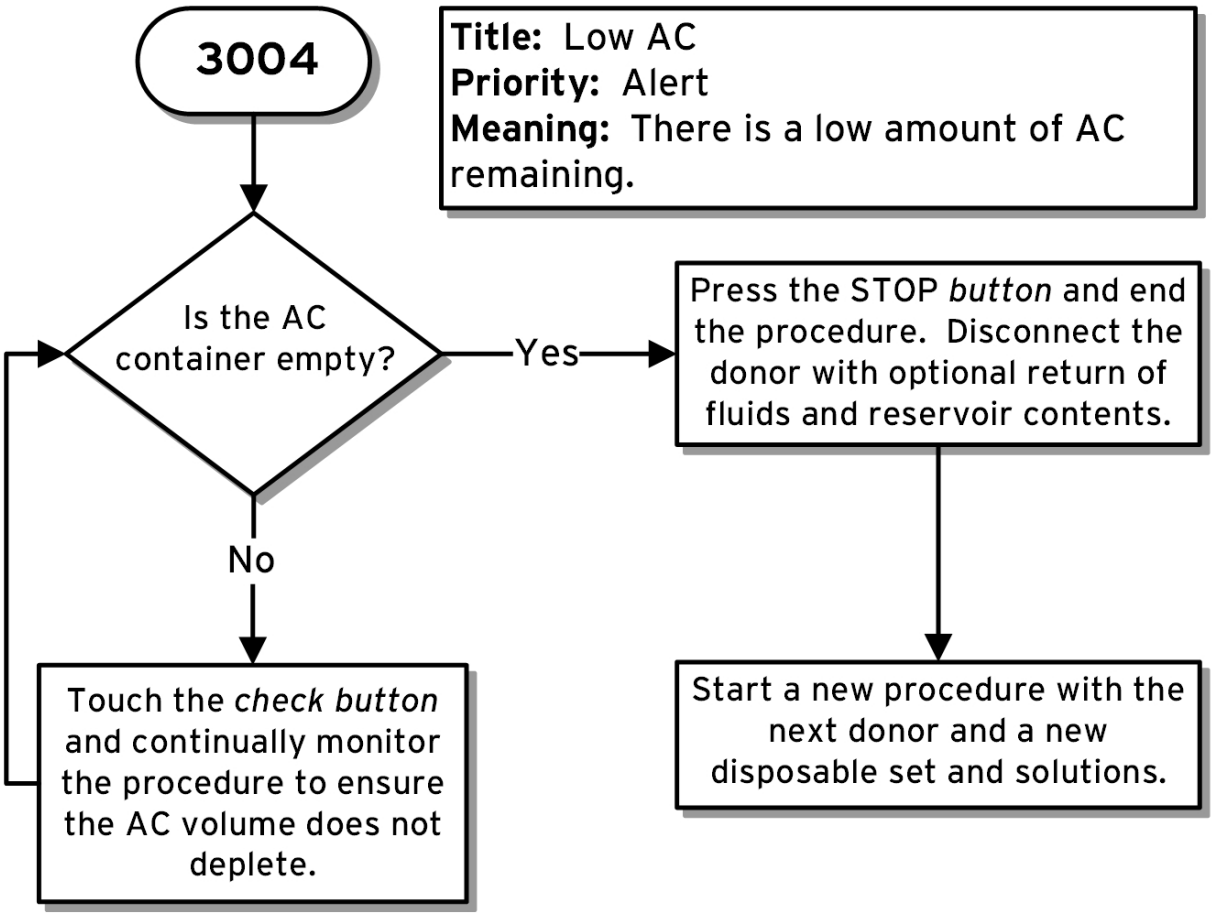


Figure 198: 3004 Low AC



CAUTION

- Failure to end or monitor the procedure after a 3004 alert may lead to air infusion or blood clots.
- Do not replace a depleted AC container to resolve a Low AC alert (3004). This will impact the system's ability to manage the citrate infusion rate.

NOTE

- The AC empty alert only occurs once in a procedure.

Figure 199: 3005 Slow Plasma Collection

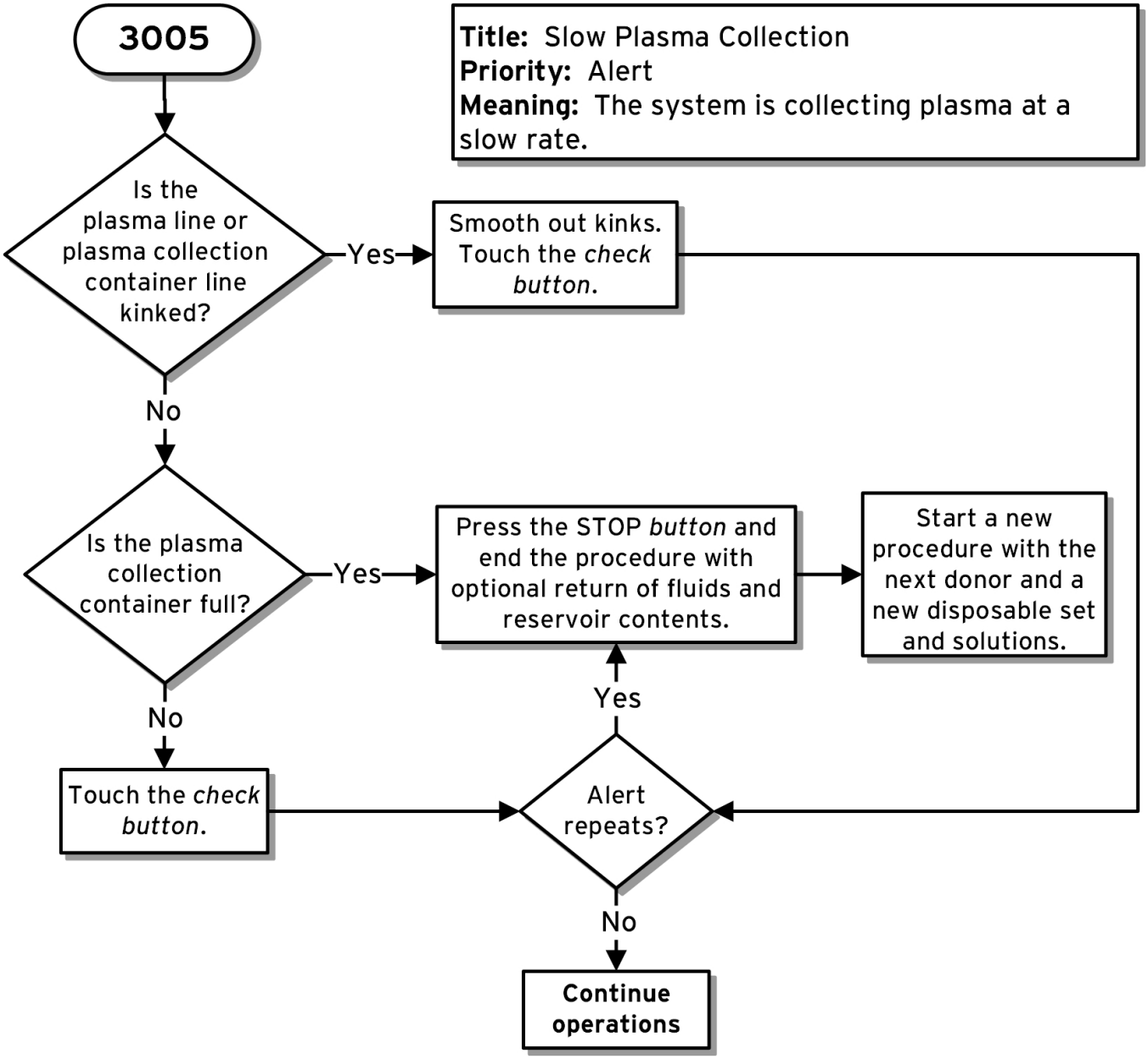
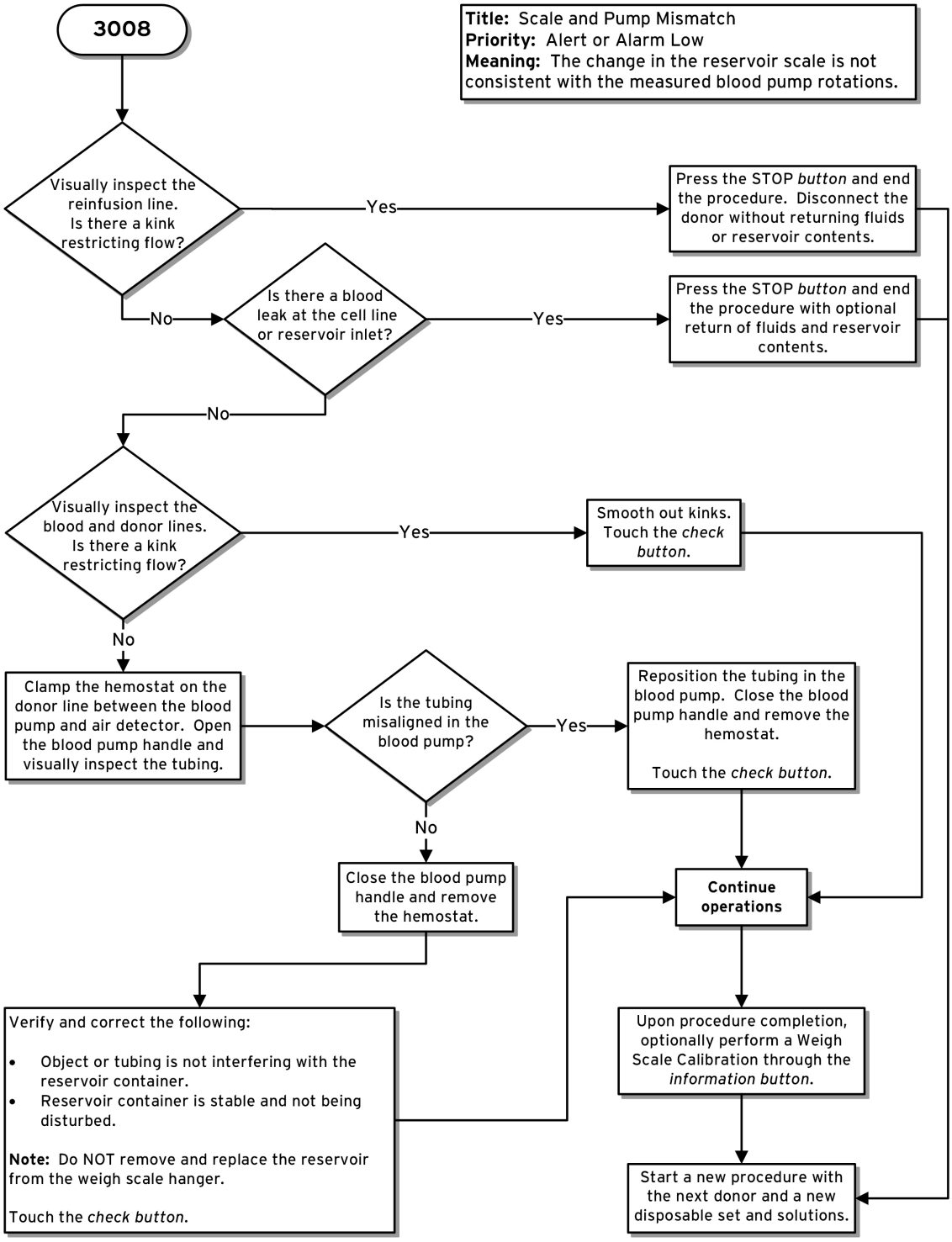


Figure 200: 3008 Scale and Pump Mismatch



CAUTION ➡ Do not push open any clamp at any time during the procedure, unless directed by troubleshooting instructions.

Figure 201: 3015 No Plasma Collected

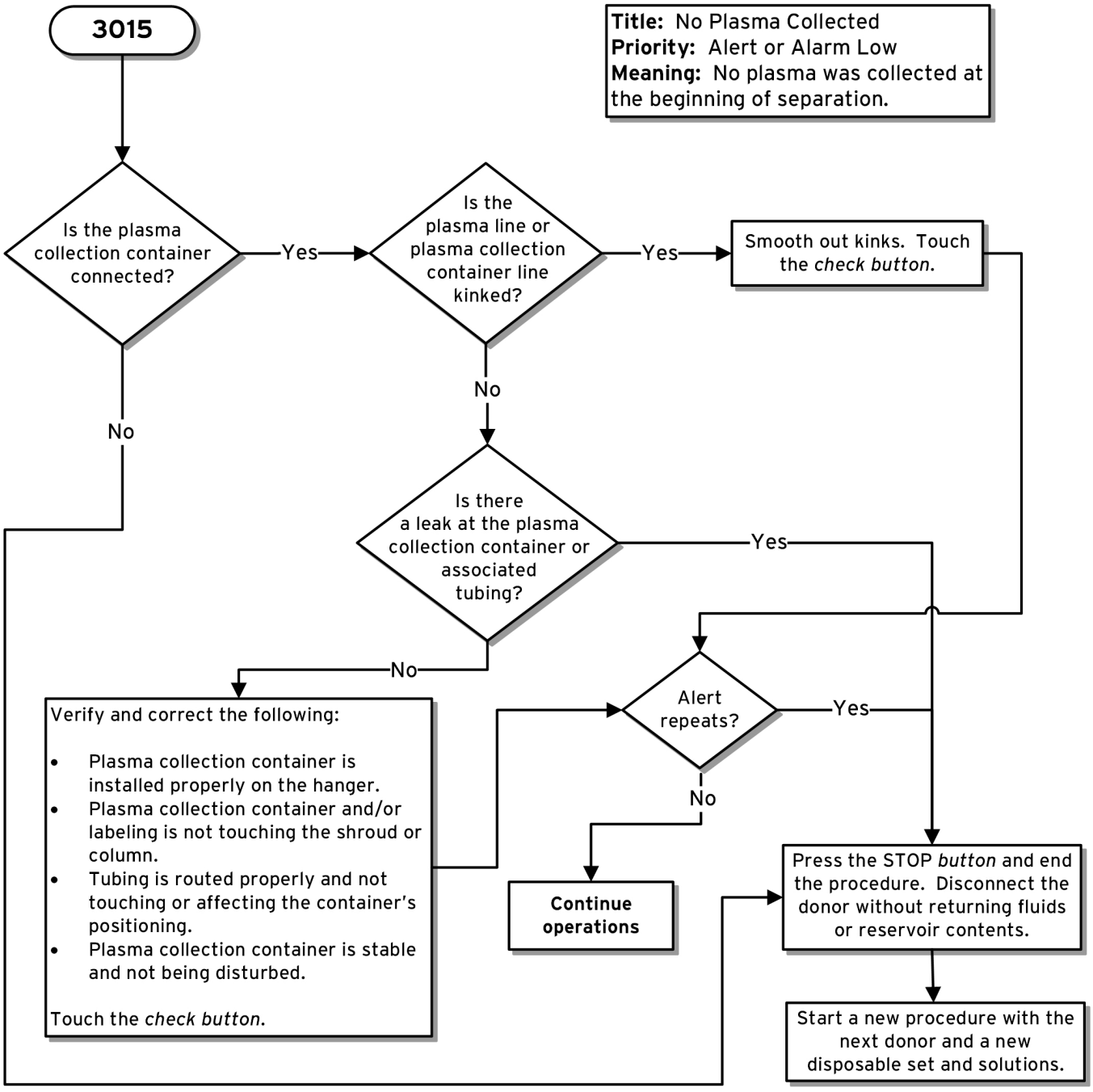
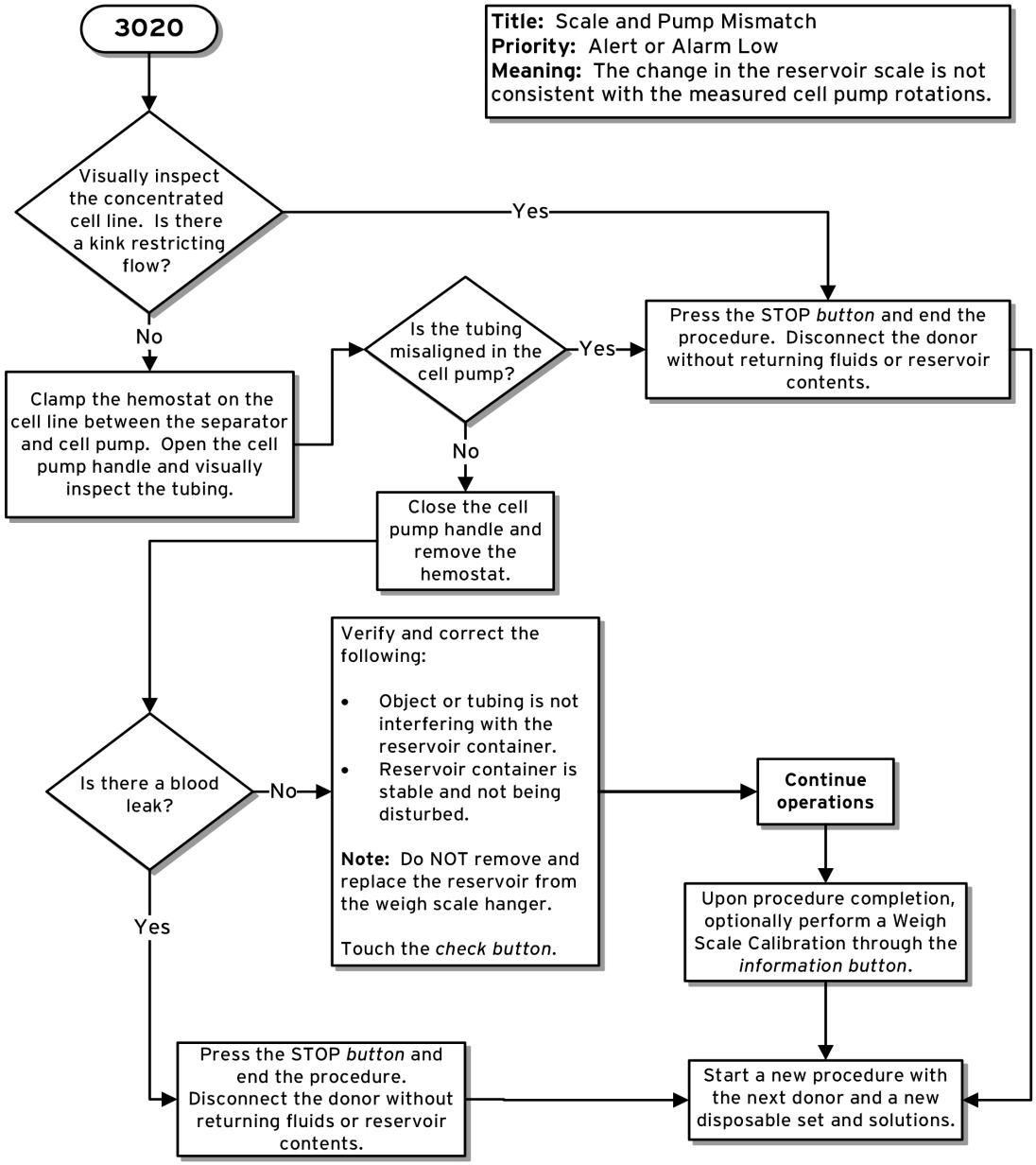


Figure 202: 3020 Scale and Pump Mismatch



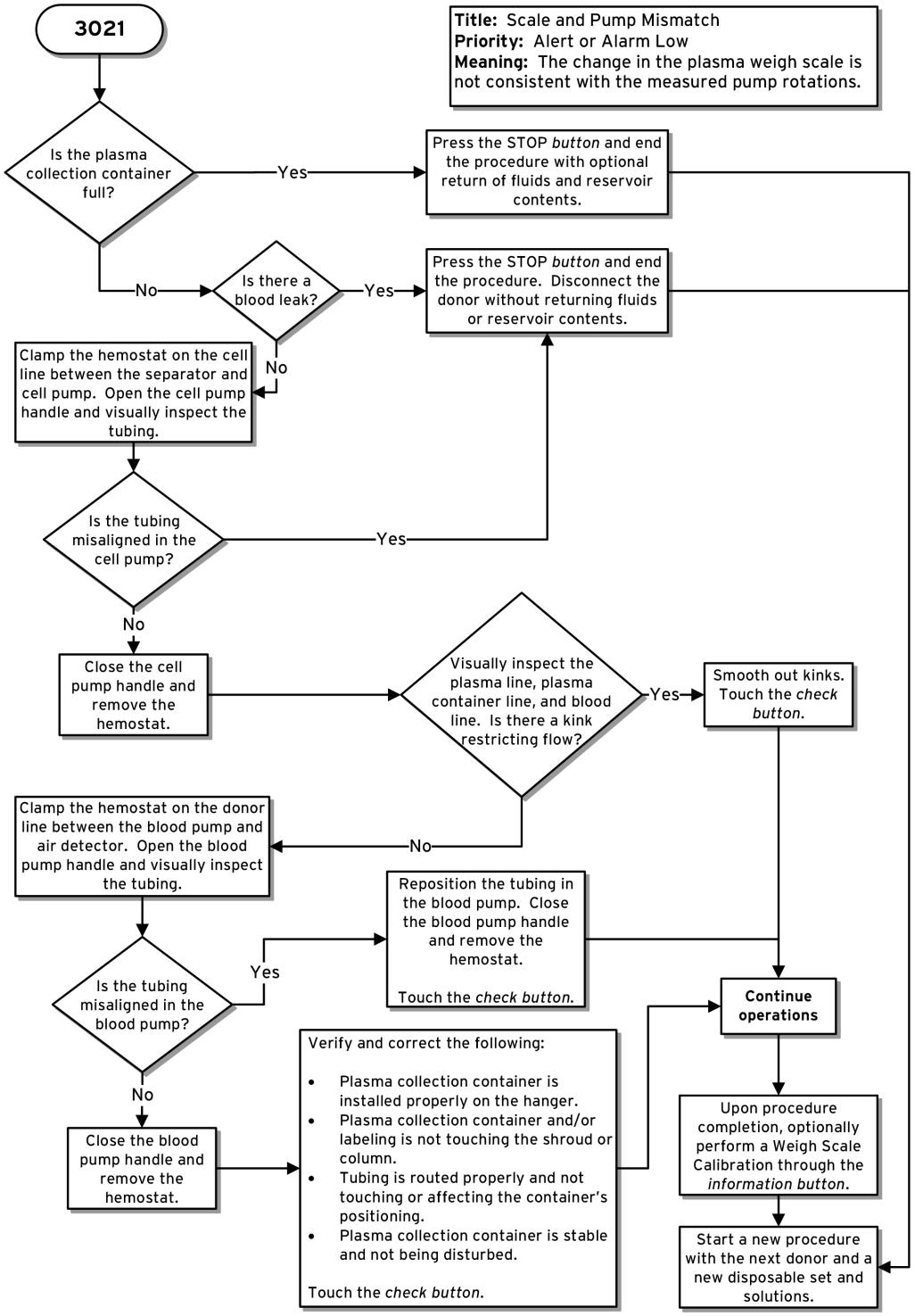
CAUTION

➔ Do not push open any clamp at any time during the procedure, unless directed by troubleshooting instructions.

NOTE

➔ The saline infusion volume and/or residual RBC loss reported on the **Procedure Results** screen may be incorrect if a 3020 alert occurred during Saline Rinse.

Figure 203: 3021 Scale and Pump Mismatch



CAUTION

→ Do not push open any clamp at any time during the procedure, unless directed by troubleshooting instructions.

Figure 204: 3022 Scale and Pump Mismatch

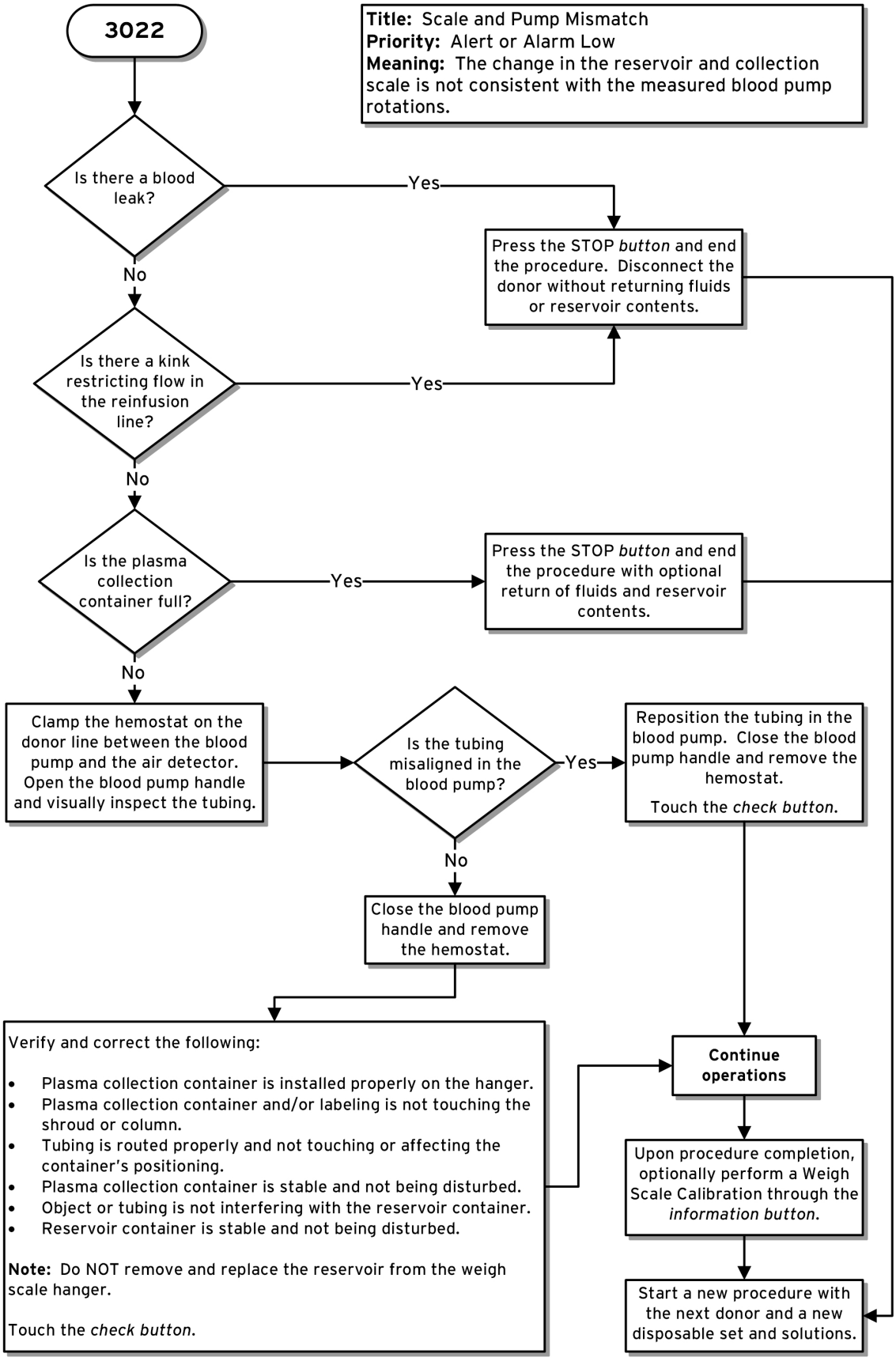


Figure 205: 3024 Collection Volume Loss

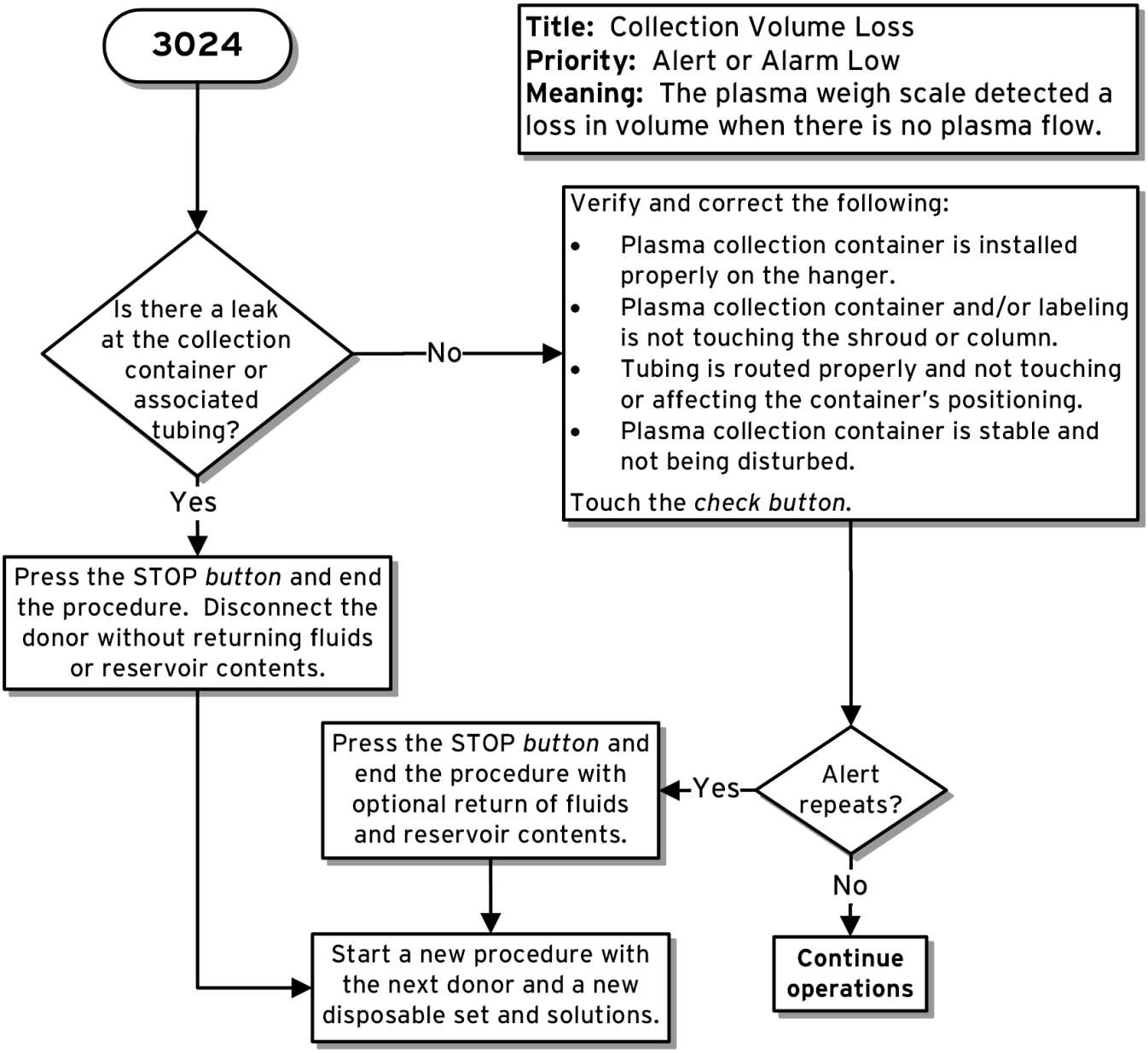
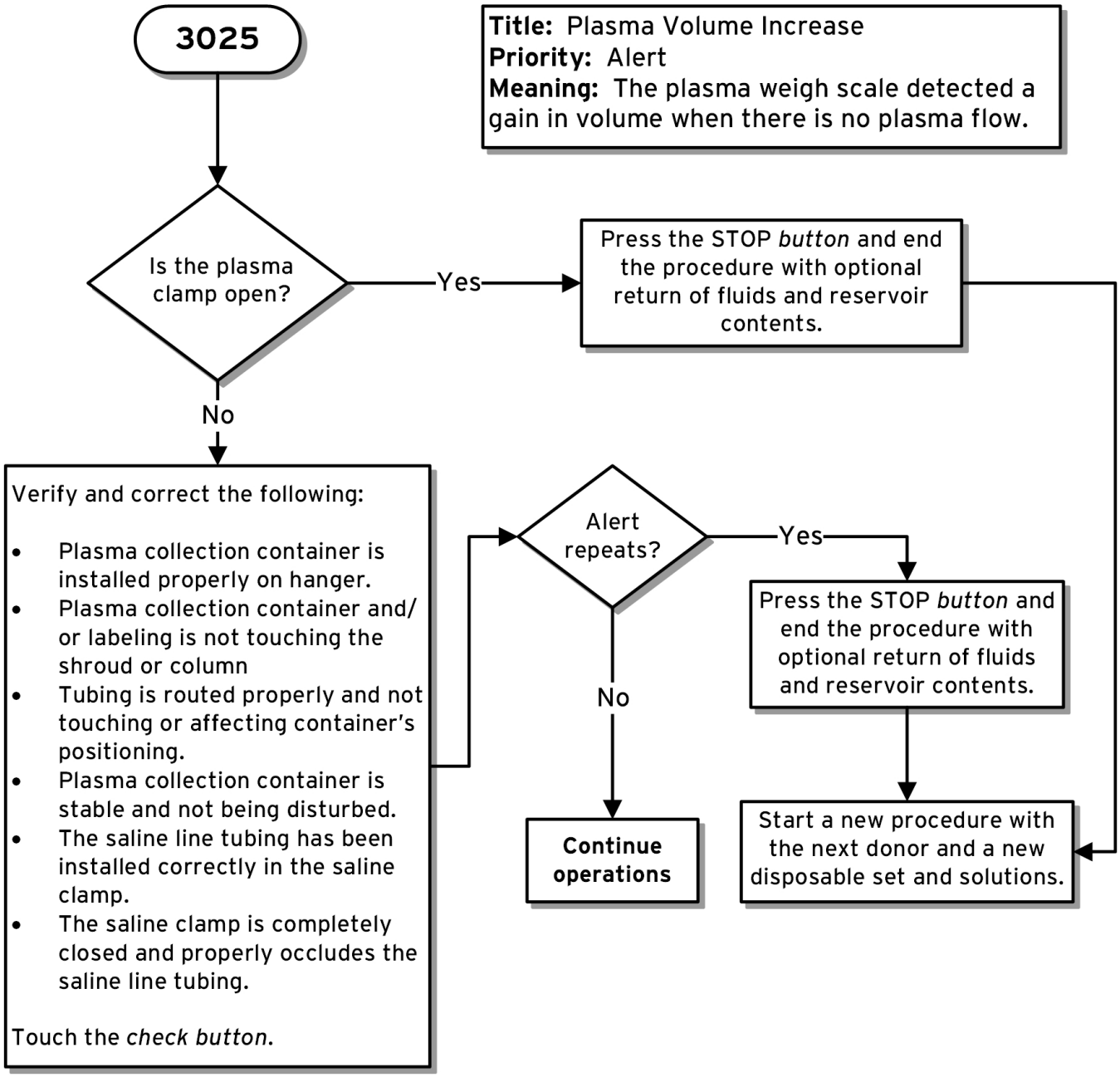


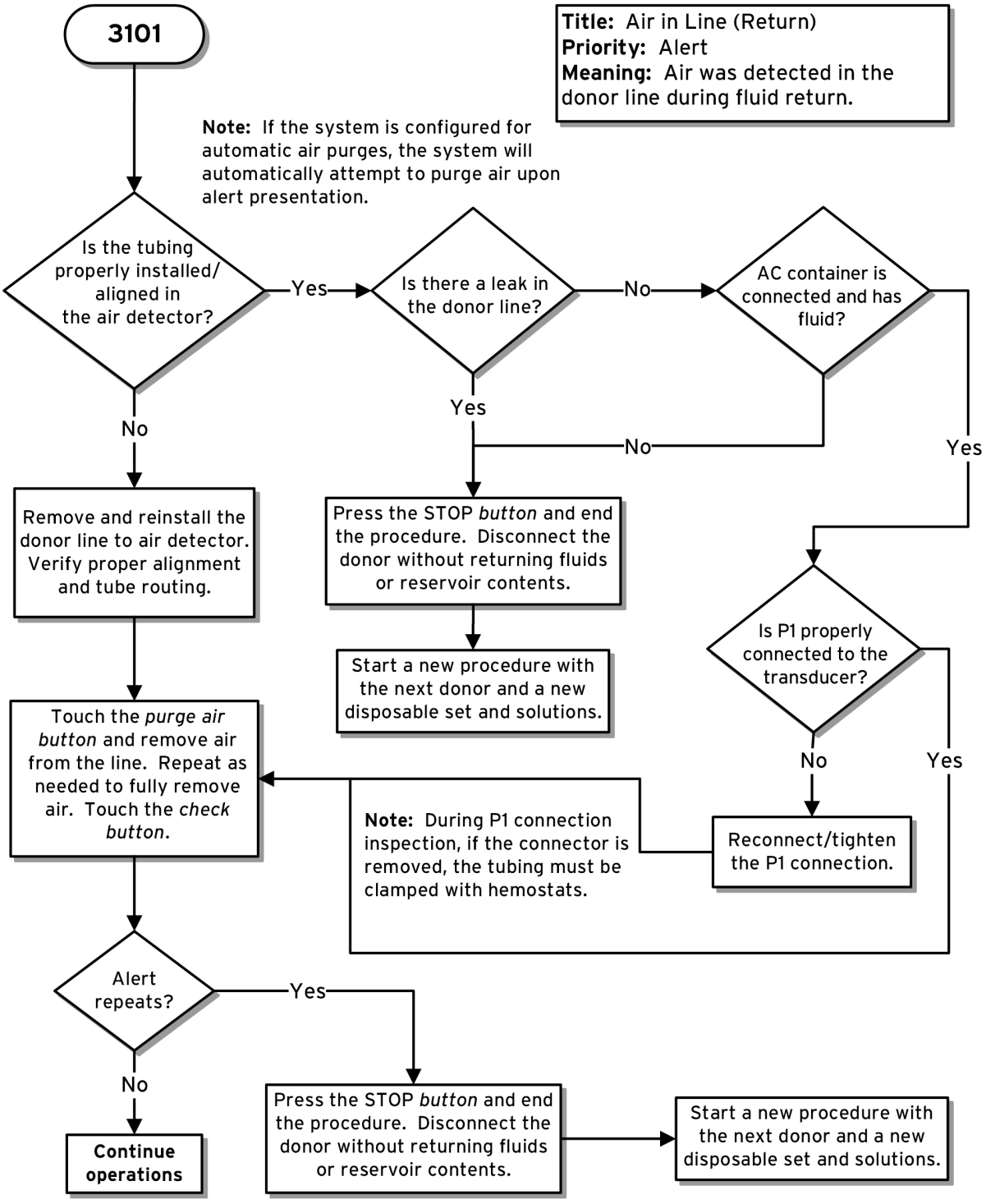
Figure 206: 3025 Collection Volume Increase



CAUTION

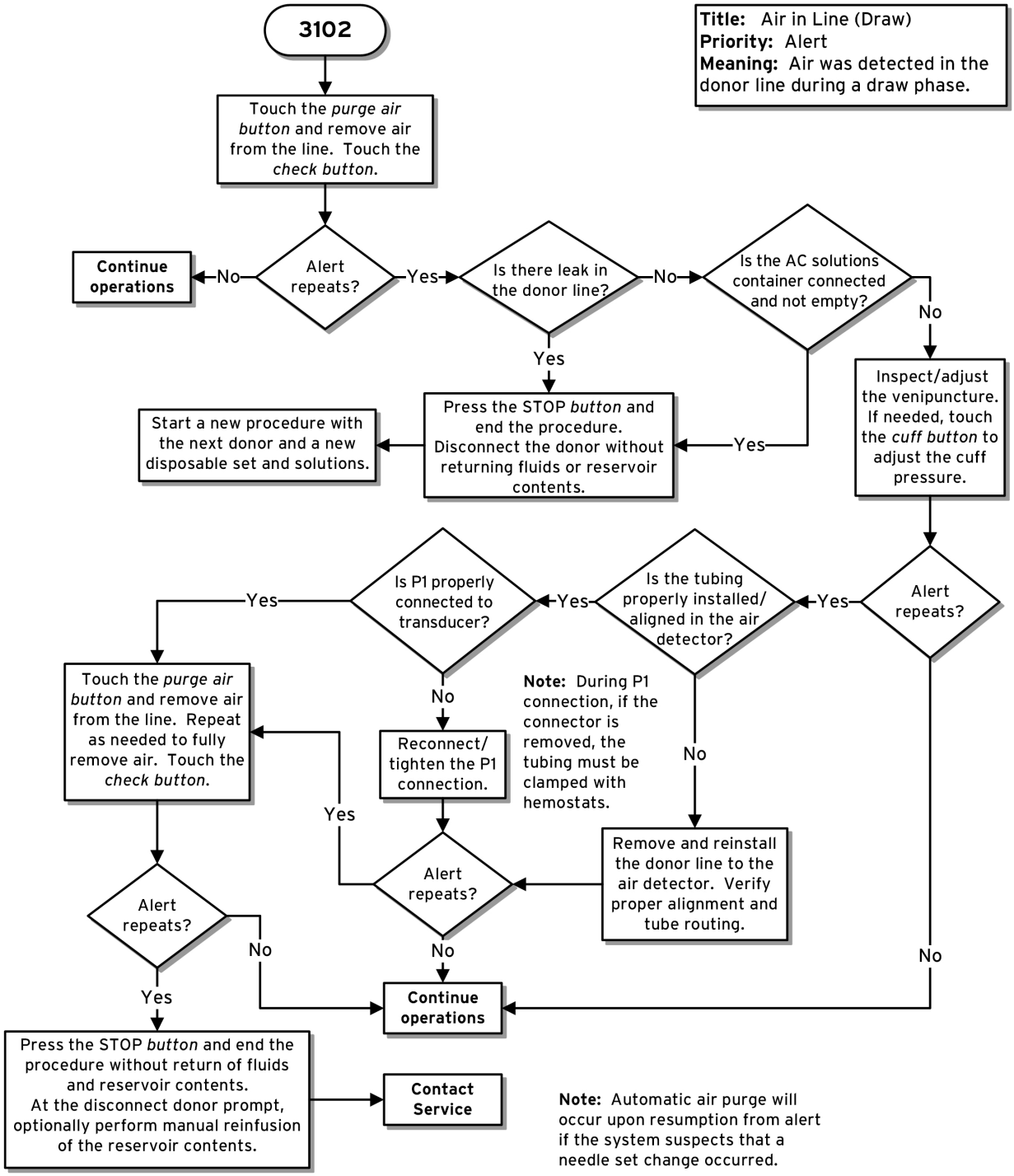
➞ If two 3025 alerts occur in a procedure, the plasma product should be discarded due to possible dilution with saline.

Figure 207: 3101 Air in Line (Return)



WARNING → If the donor line is removed from the air detector, ensure that the correct line is re-installed to maintain effective air detection.

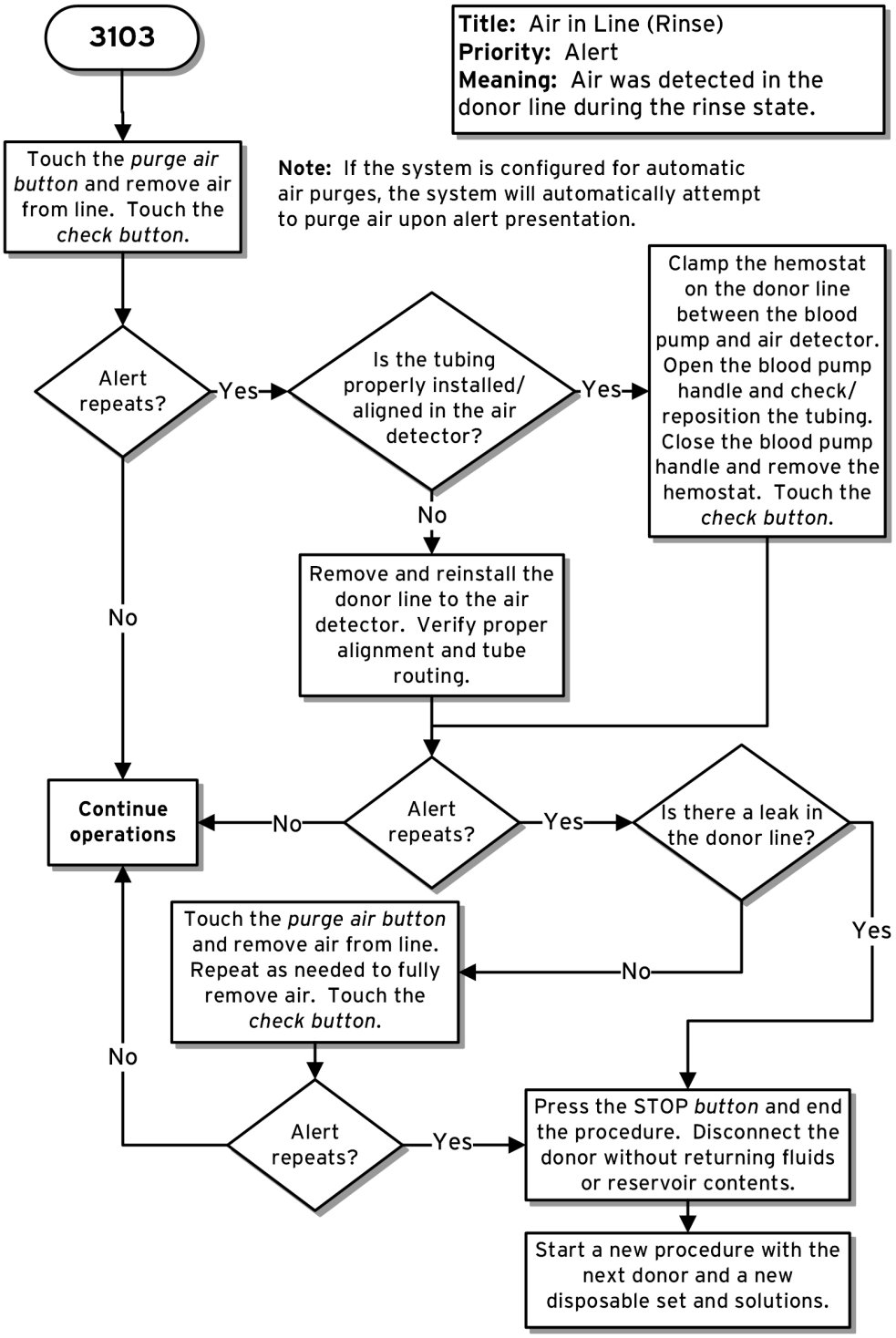
Figure 208: 3102 Air in Line (Draw)



WARNING

- If the donor line is removed from the air detector, ensure that the correct line is re-installed to maintain effective air detection.
- If an Air In Line alert (3102) is present and the procedure will be ended, inspect the donor line for air. If air is present in the donor line, end the procedure without fluid return. This will mitigate the risk of air infusion

Figure 209: 3103 Air in Line (Rinse)



WARNING

→ If the donor line is removed from the air detector, ensure that the correct line is re-installed to maintain effective air detection.

Figure 210: 3200 Air Purge Unsuccessful

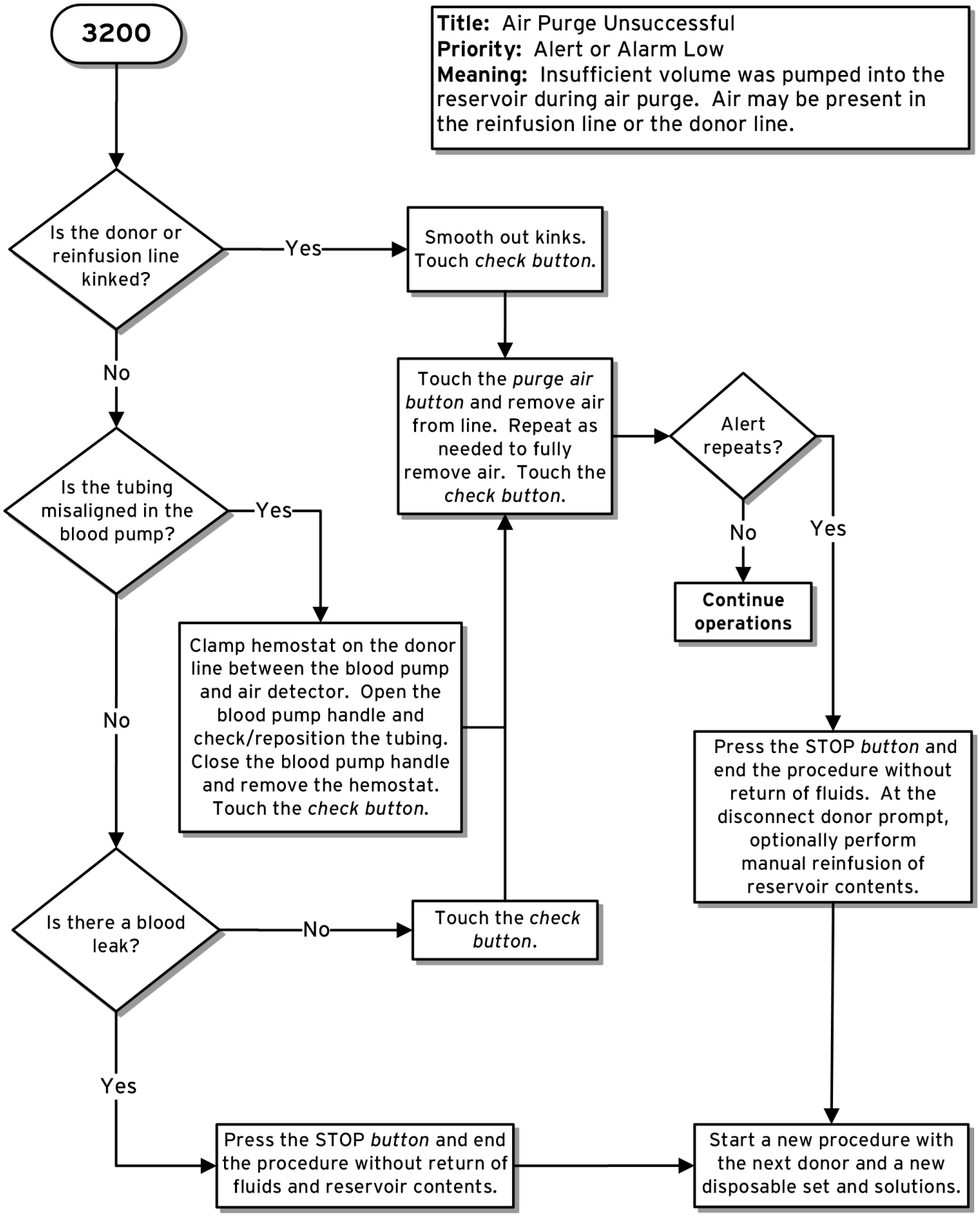


Figure 211: 3301 Redness Detected

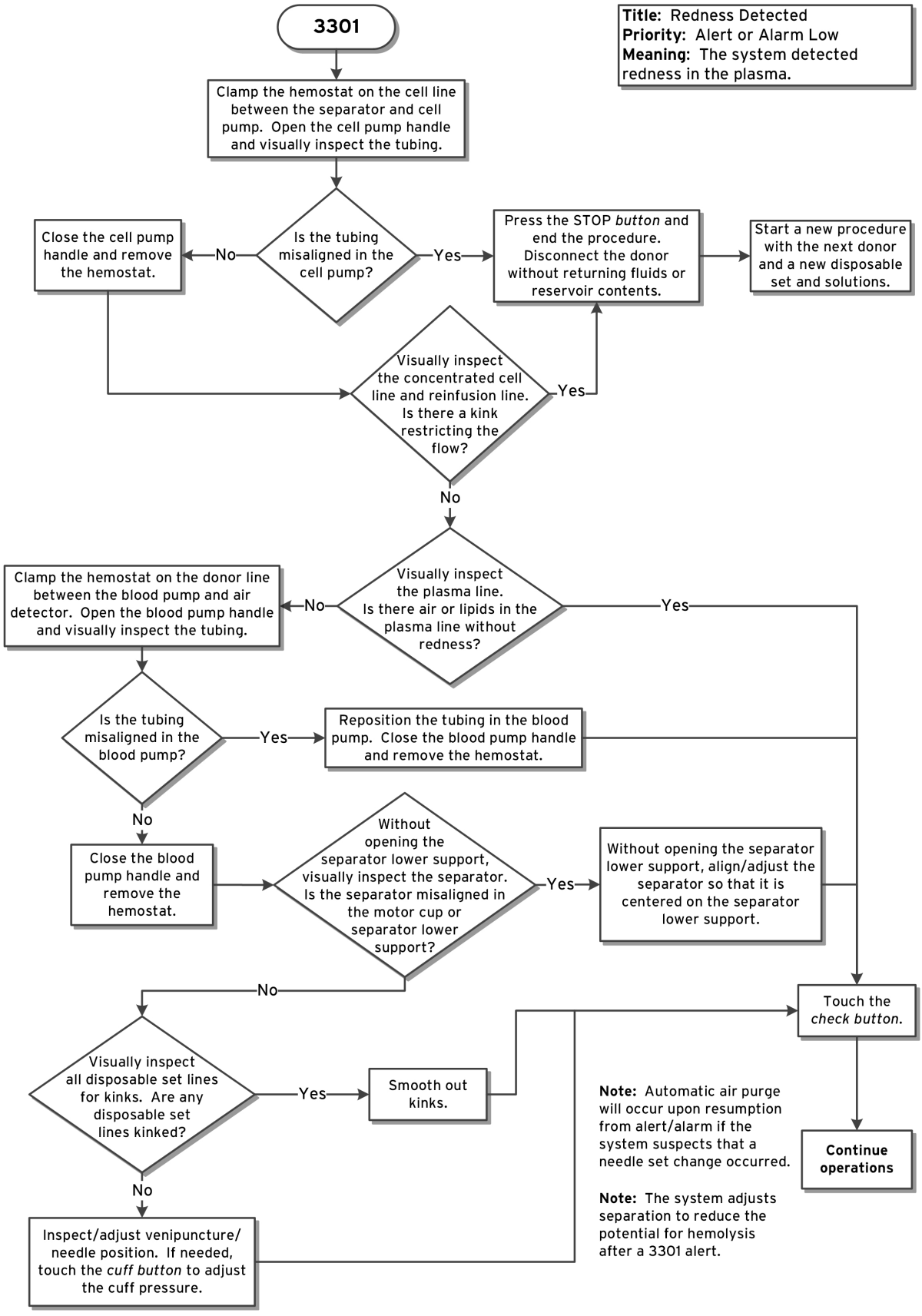
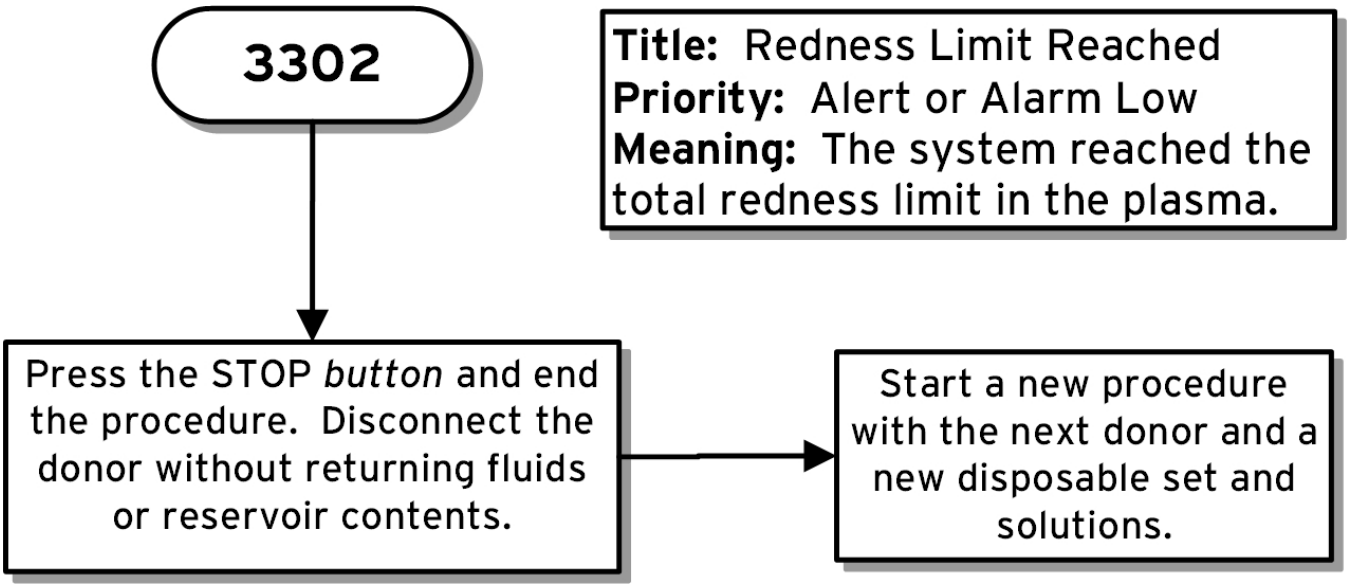


Figure 212: 3302 Redness Limit Reached



CAUTION → If a 3302 alert/alarm occurs, do not return fluids or reservoir contents.

Figure 213: 3303 RBCs or Redness Detected

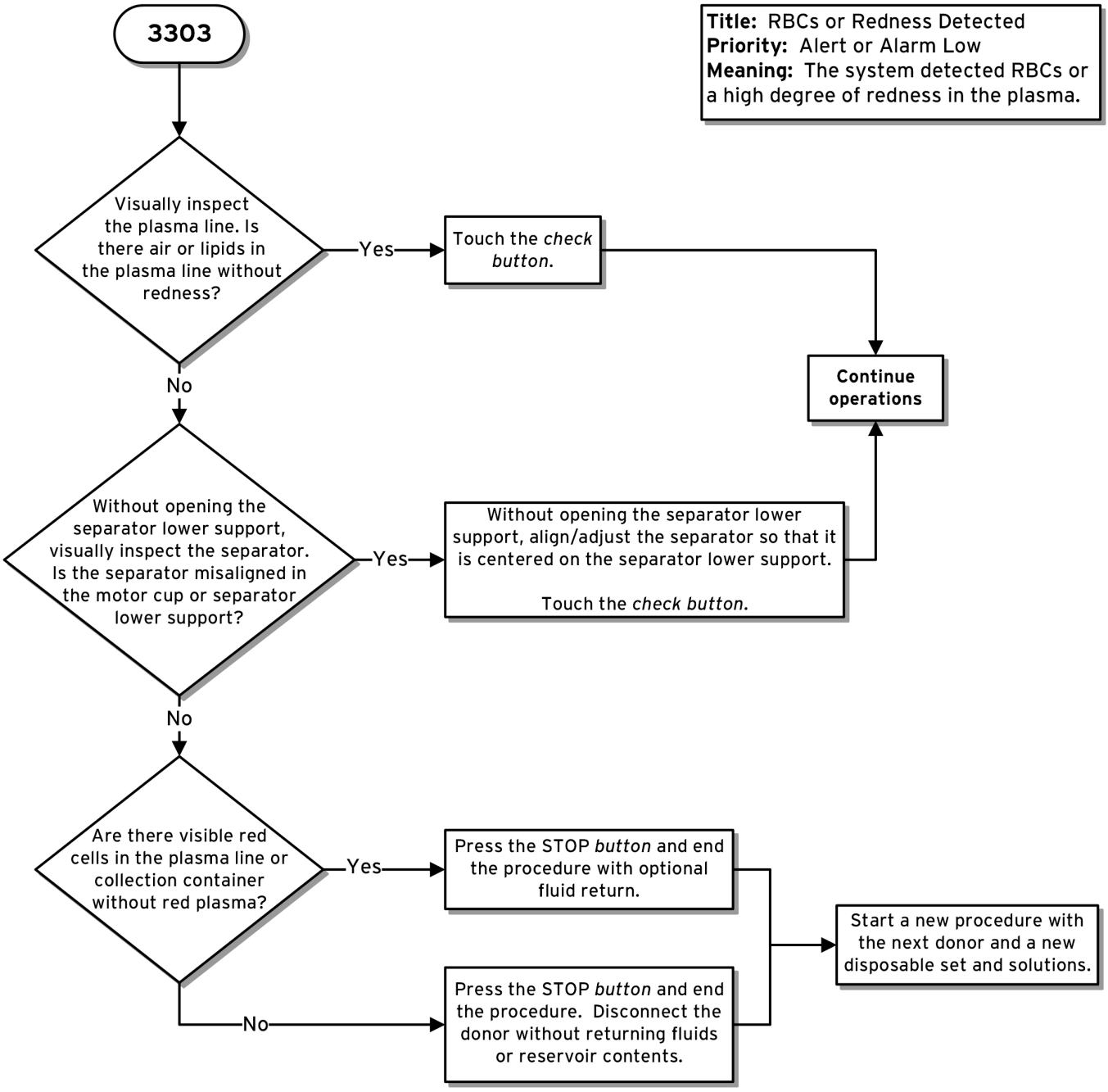


Figure 214: 3304 High Redness Detected

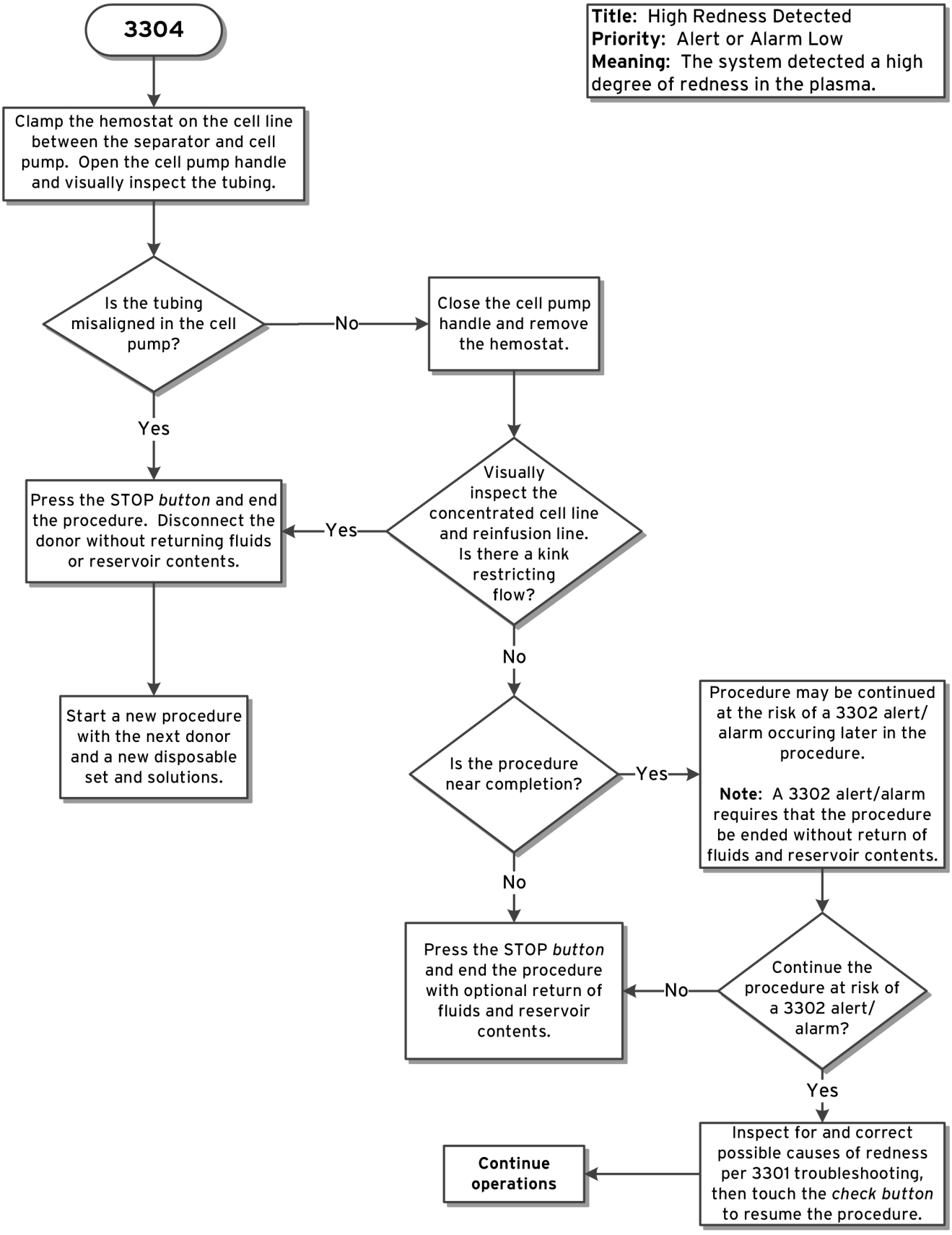


Figure 215: 3508 No Blood Flow

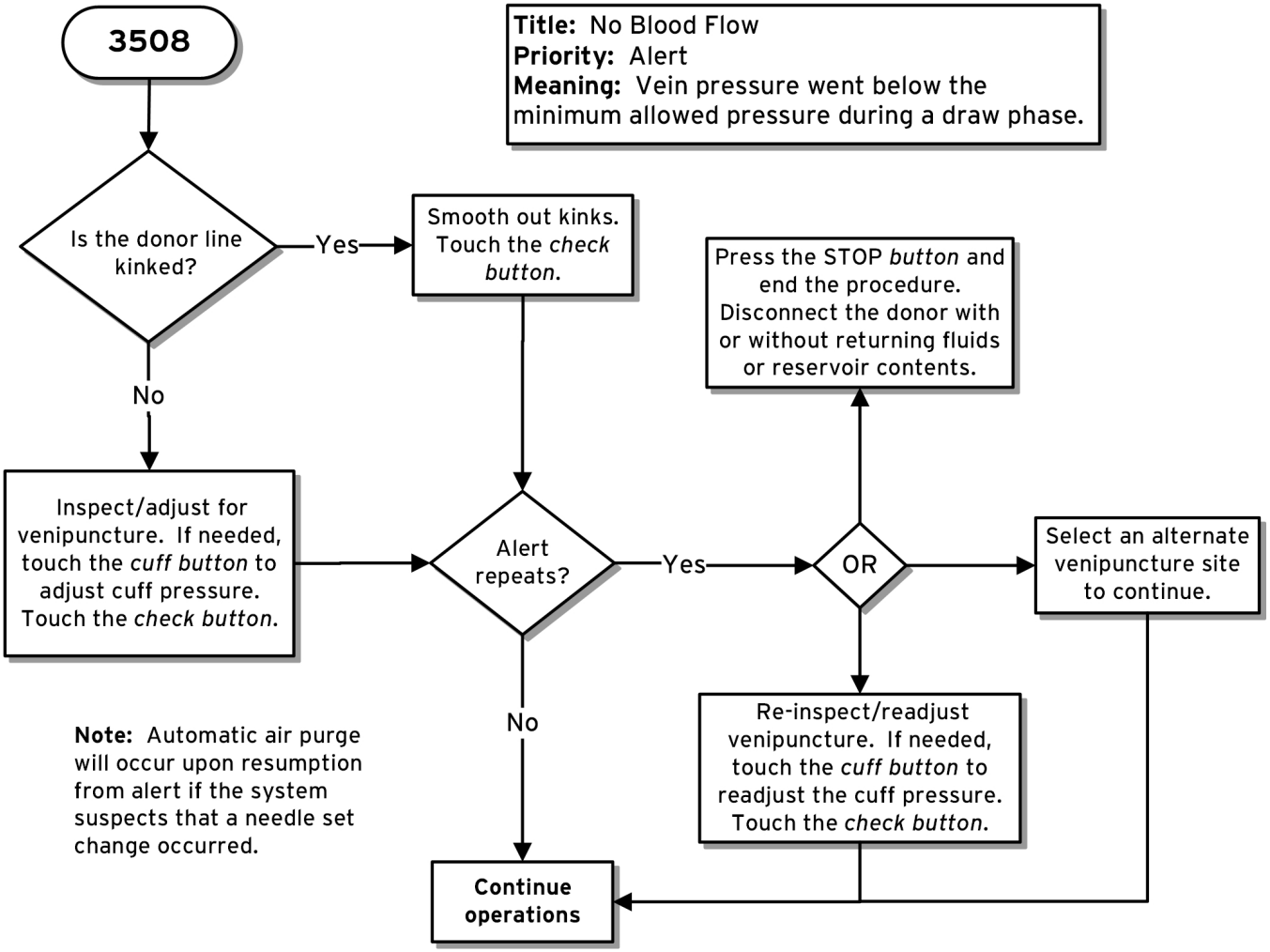


Figure 216: 3520 Cuff Not Inflated

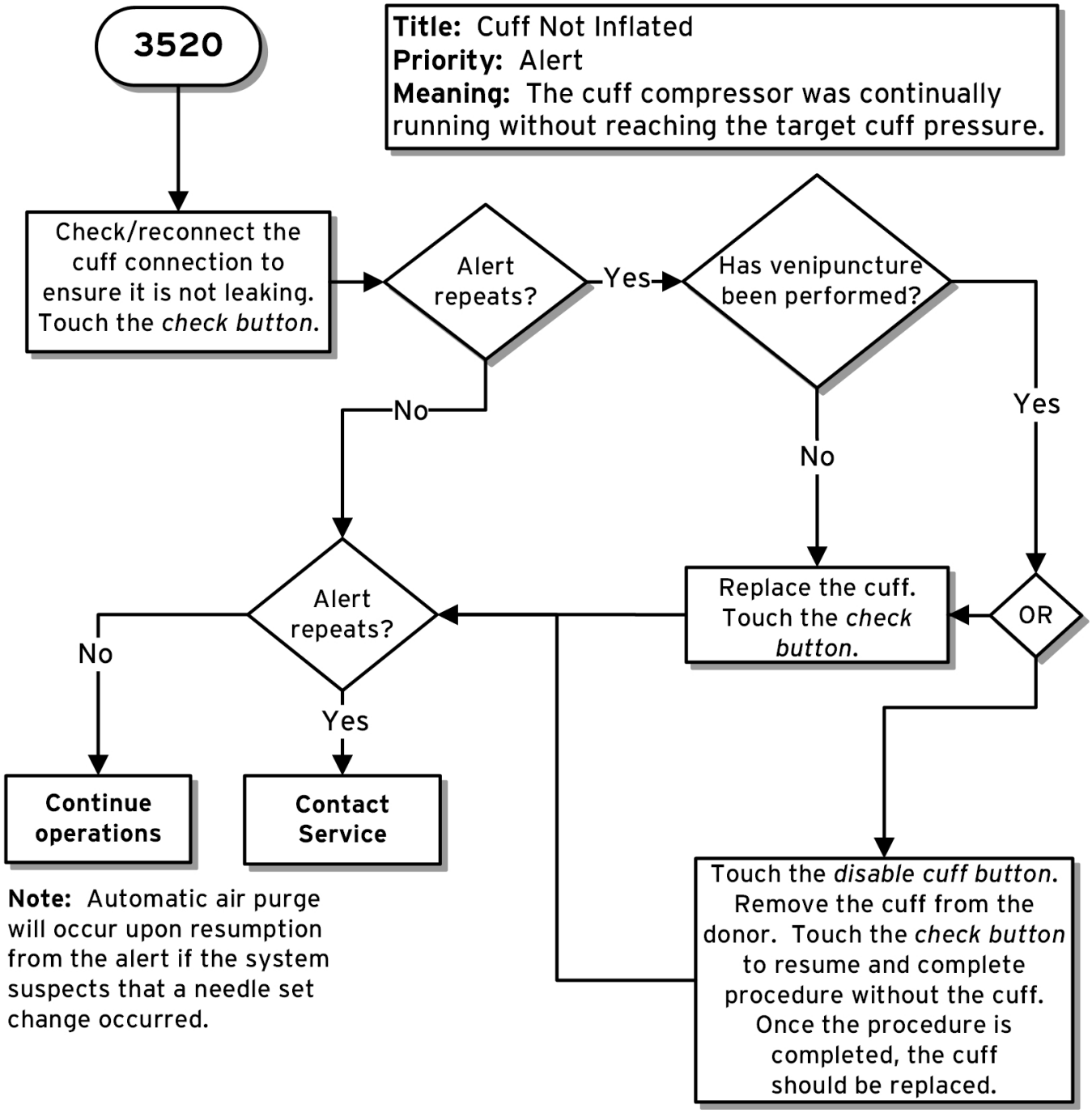


Figure 217: 3601 High Return Pressure

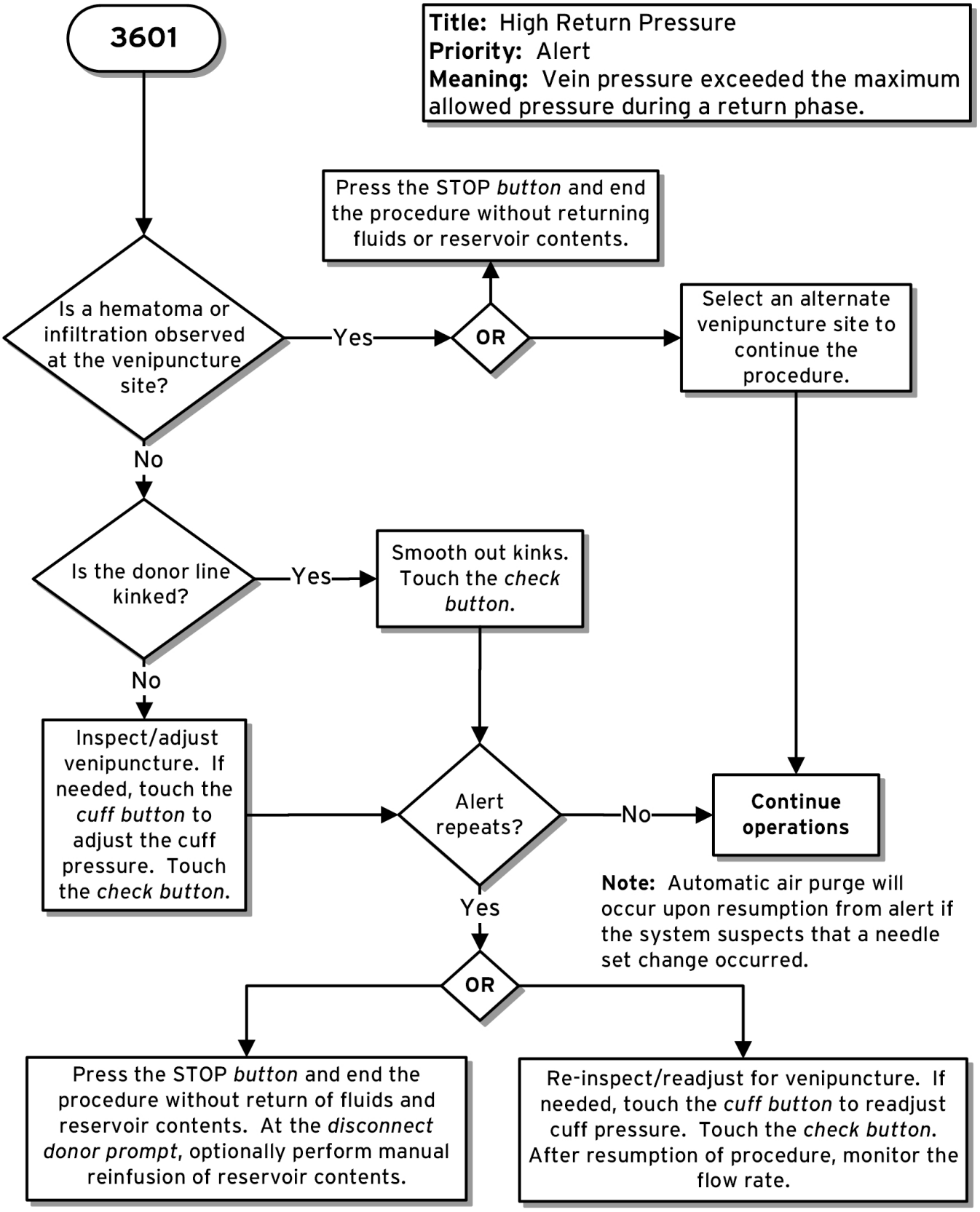


Figure 218: 3603 High Return Pressure

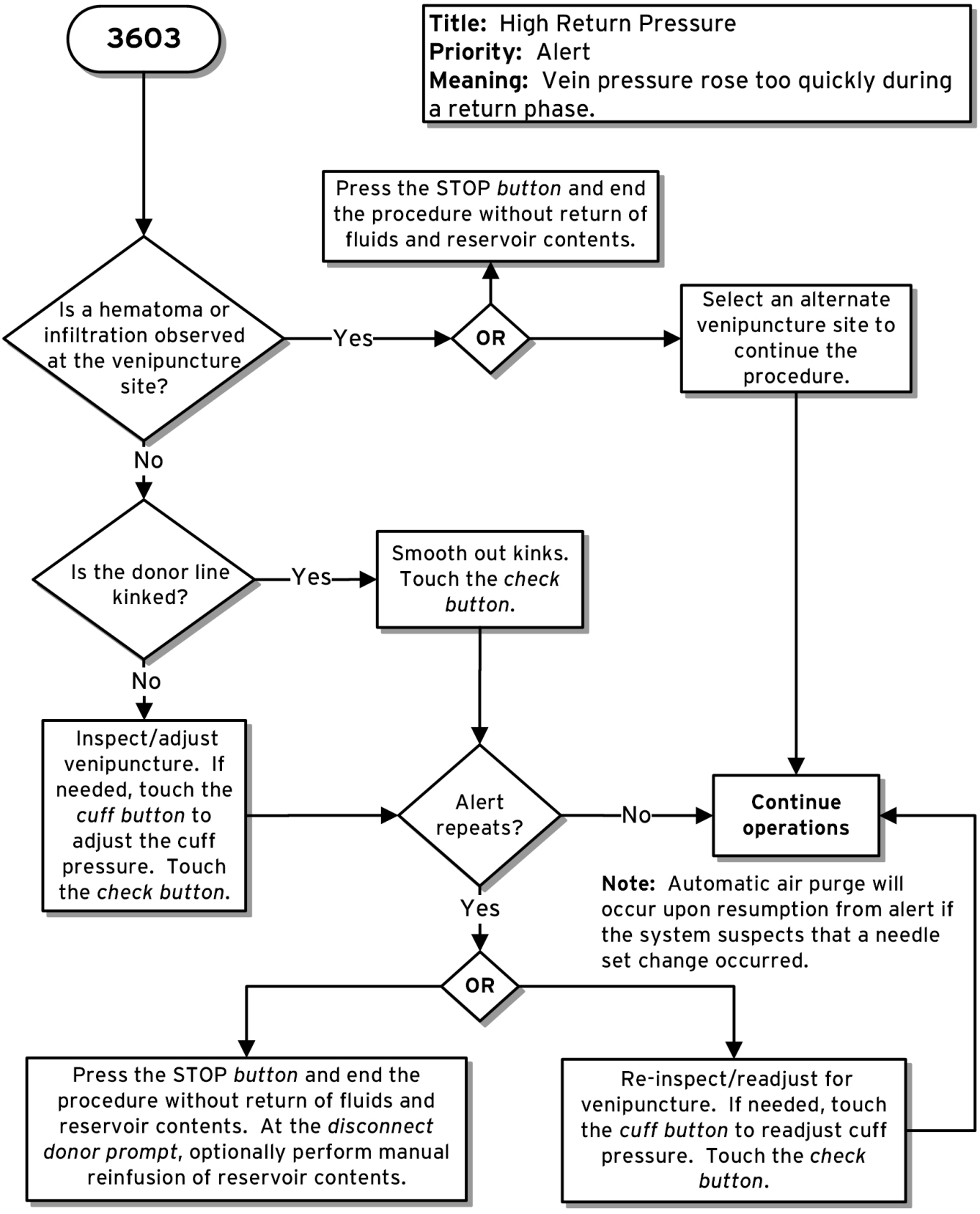
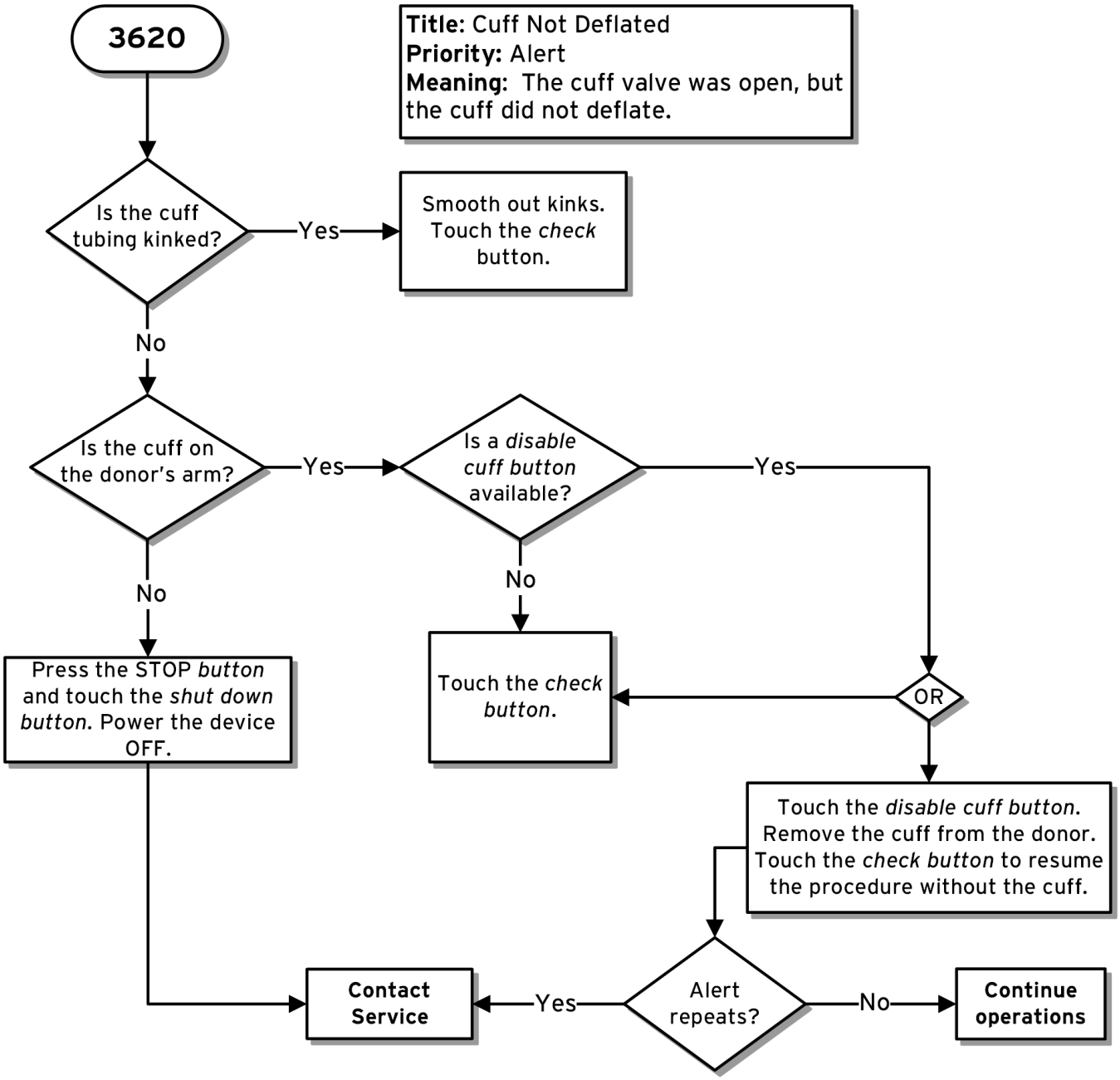


Figure 219: 3620 Cuff Not Deflated



Note: Automatic air purge will occur upon resumption from alert if the system suspects that a needle set change occurred.

Figure 220: 4001 Weight on Scale

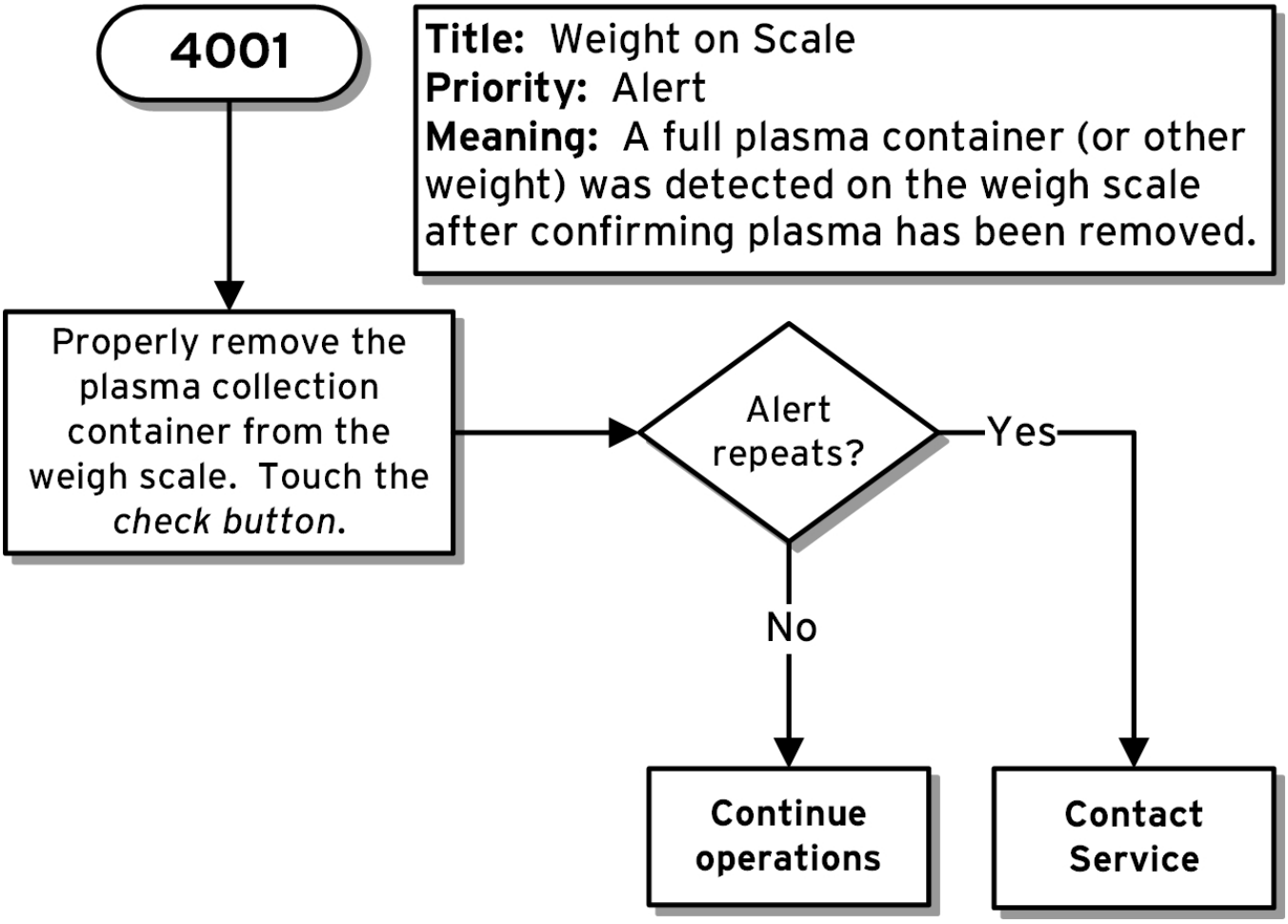


Figure 221: 8001 Invalid USB Accessory Connected

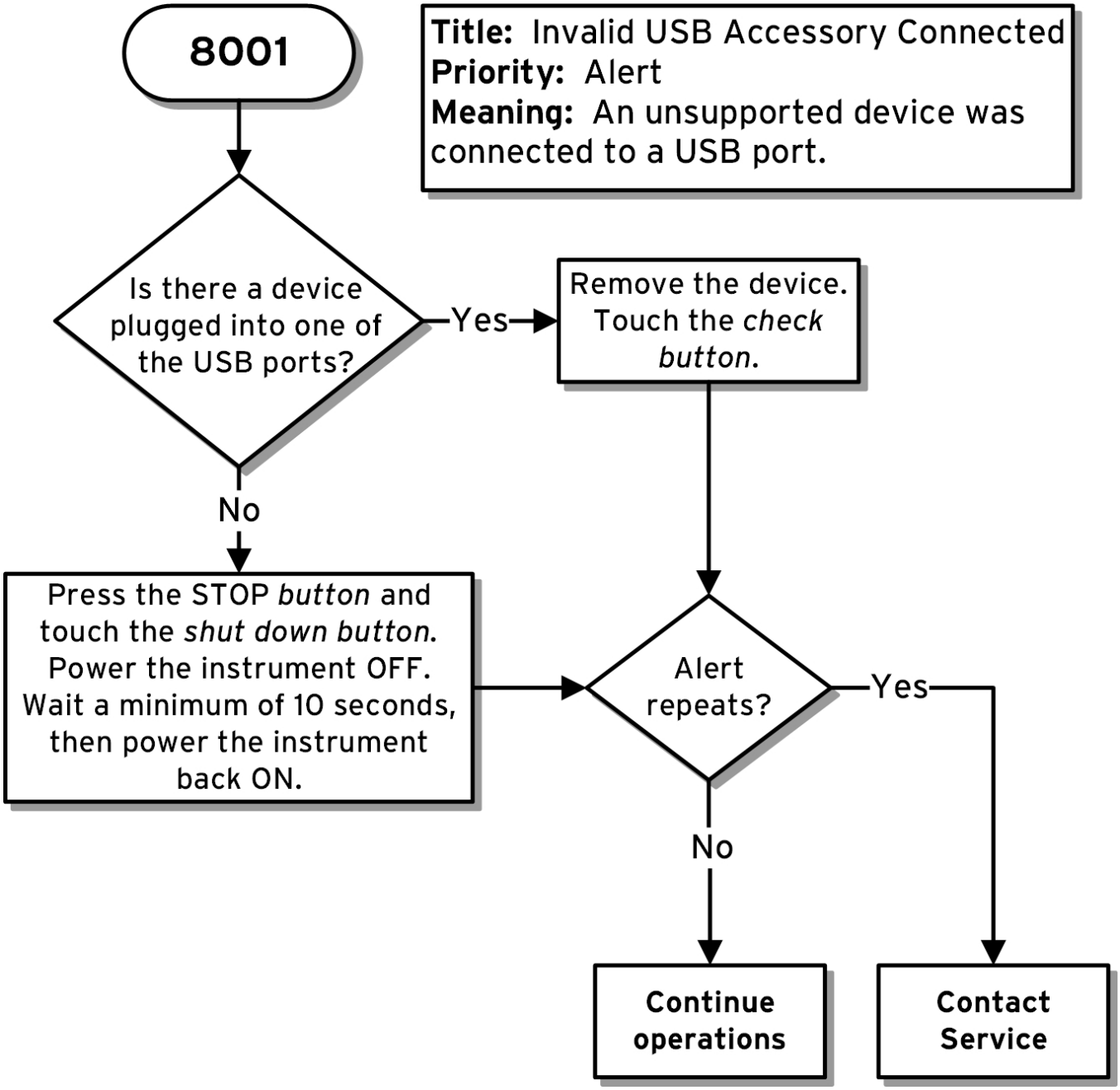


Figure 222: 10001 Hb Detector Hardware Failed

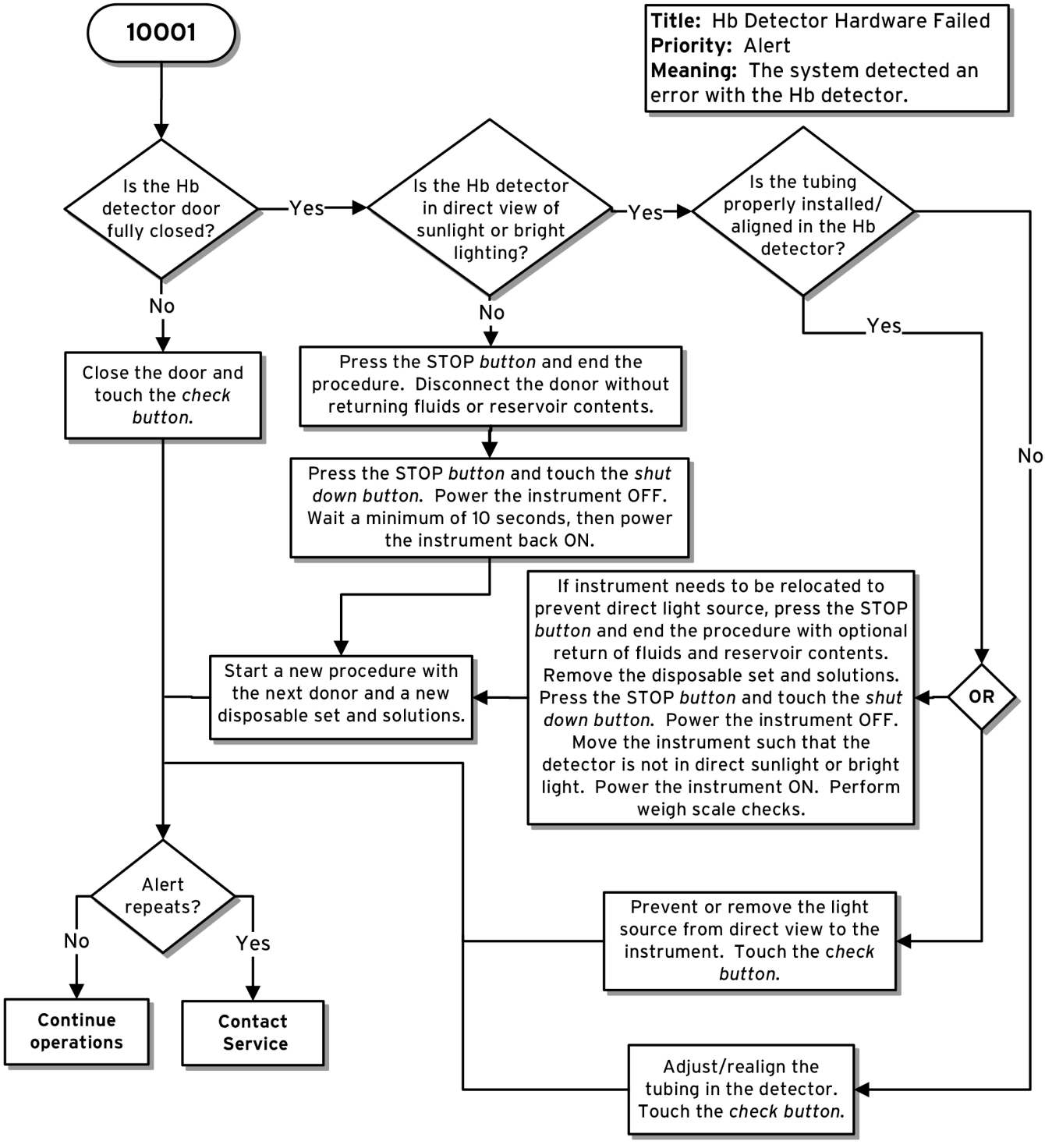


Figure 223: 10004 Air Detector Fault

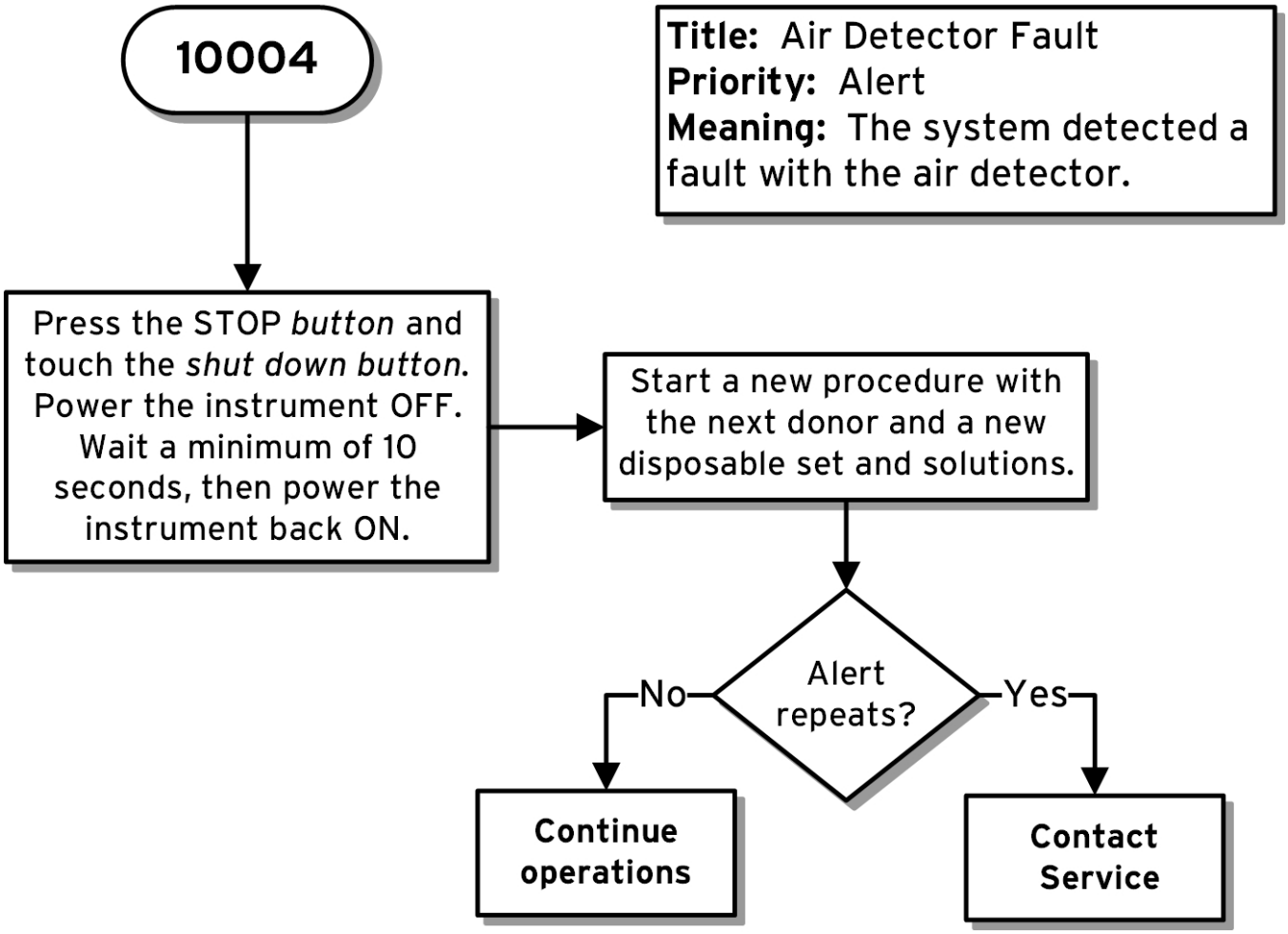


Figure 224: 10011 Scale Disturbed

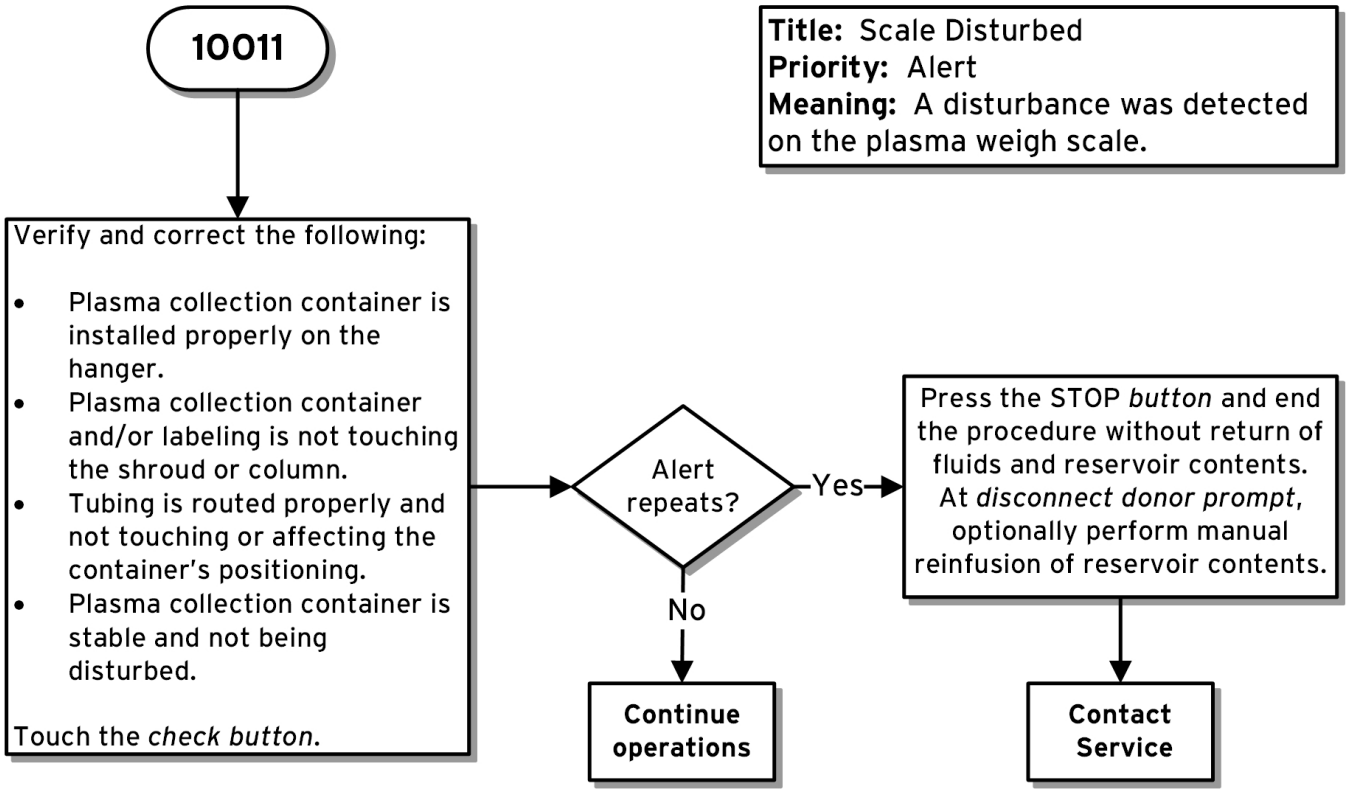


Figure 225: 10012 Scale Disturbed

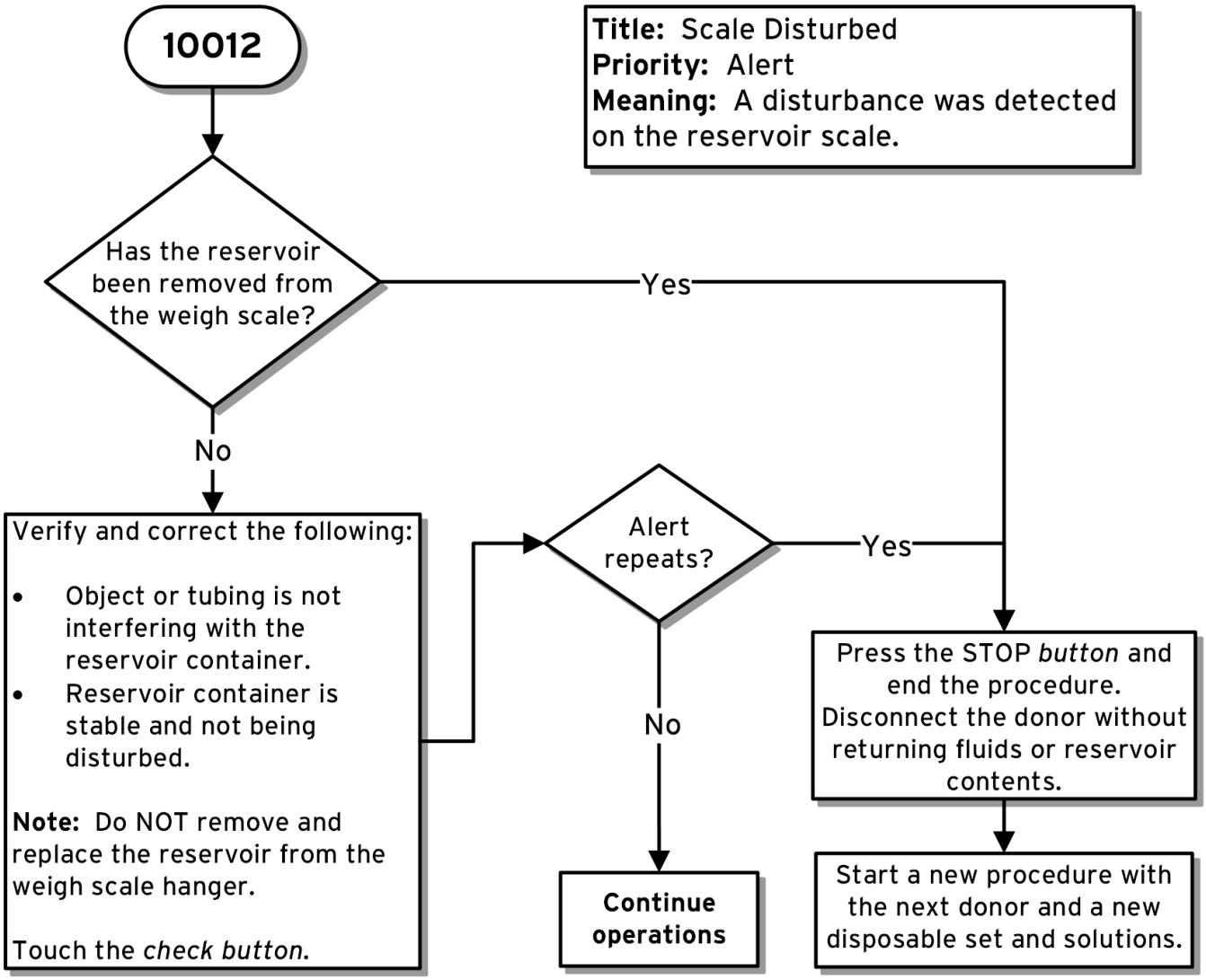


Figure 226: 10013 Scale Disturbed

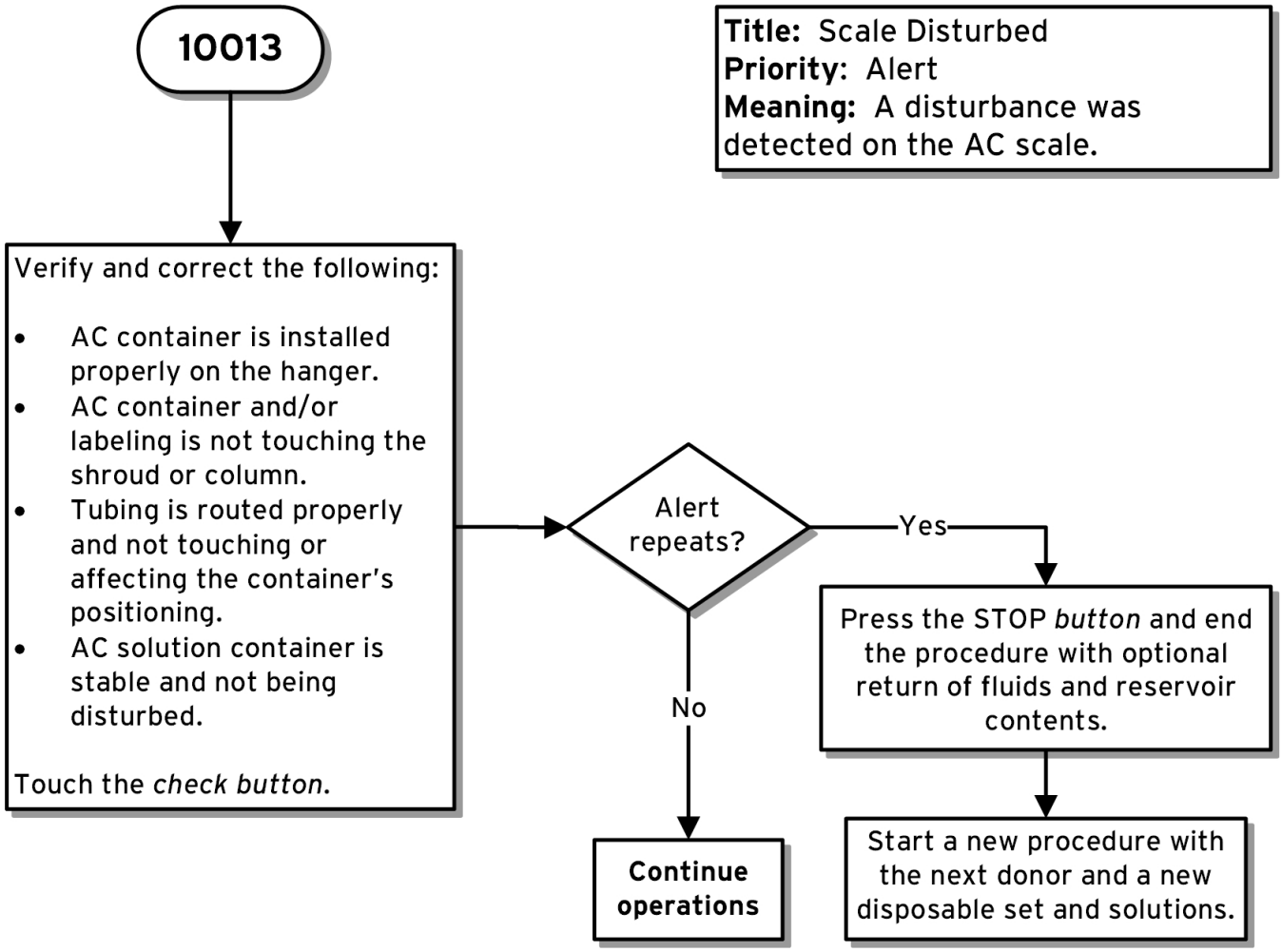


Figure 227: 10014 Scale and Pump Mismatch

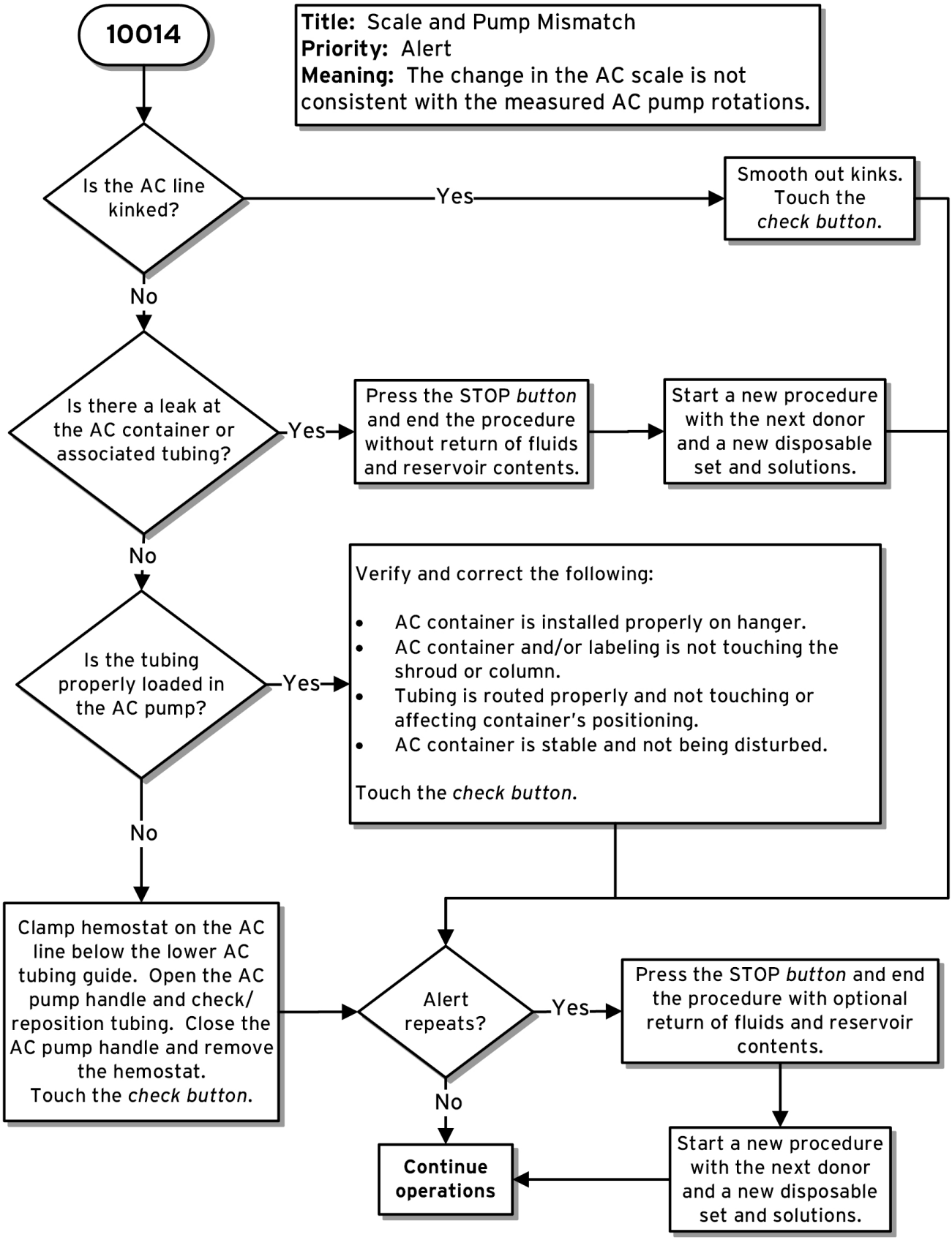


Figure 228: 10015 AC Volume Loss

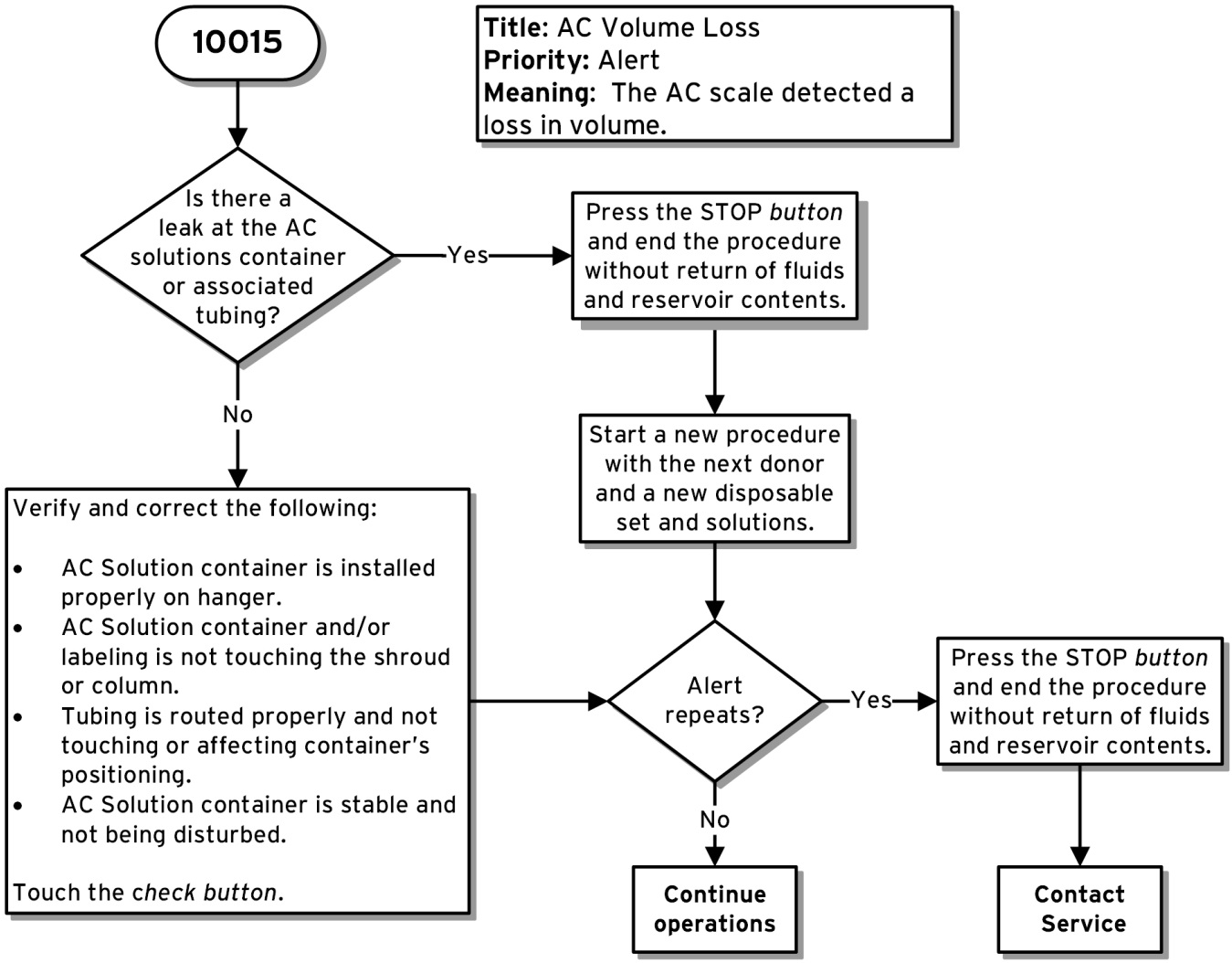


Figure 229: 10016 AC Volume Gain

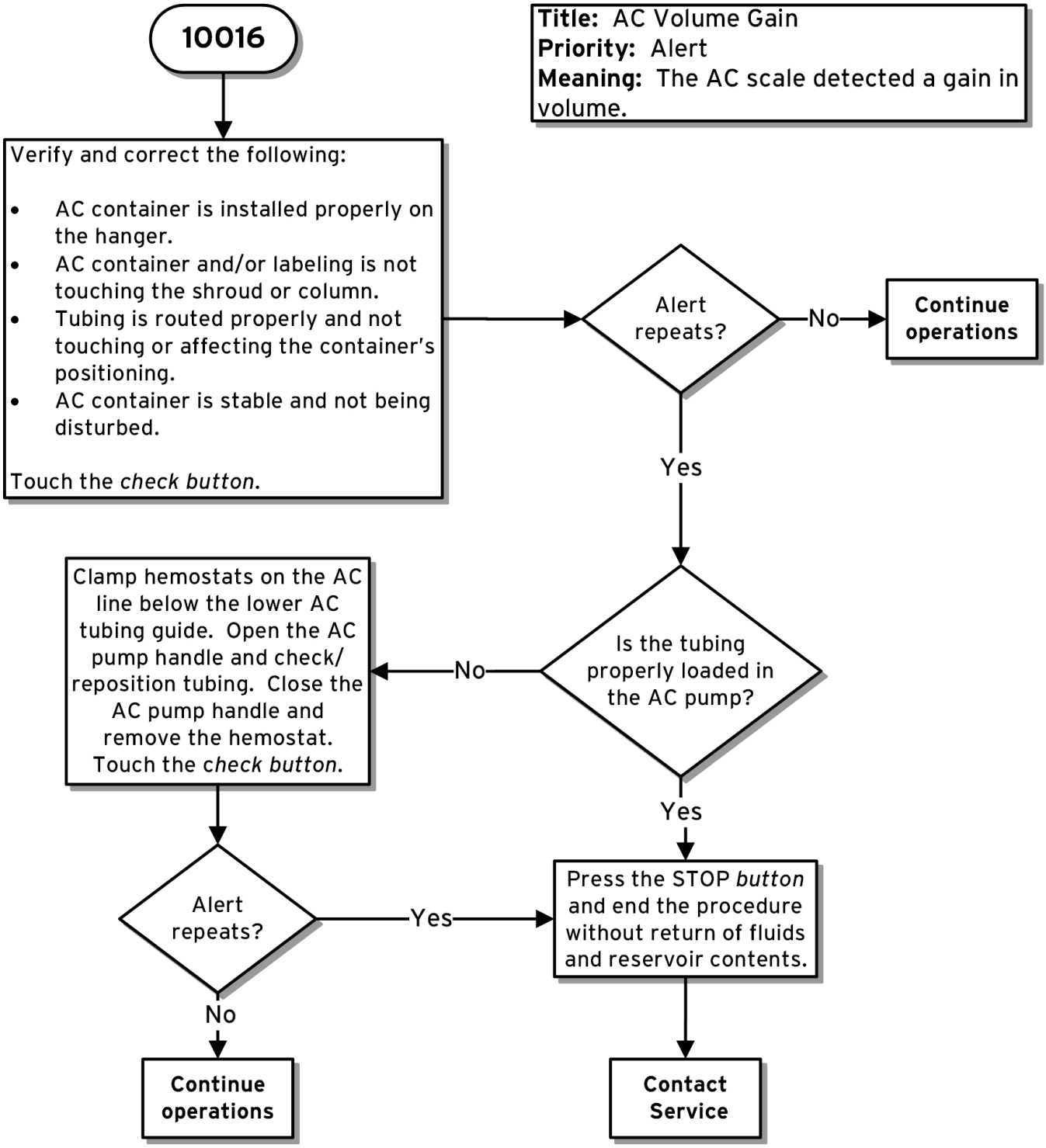


Figure 230: 10017 Reservoir Volume Loss

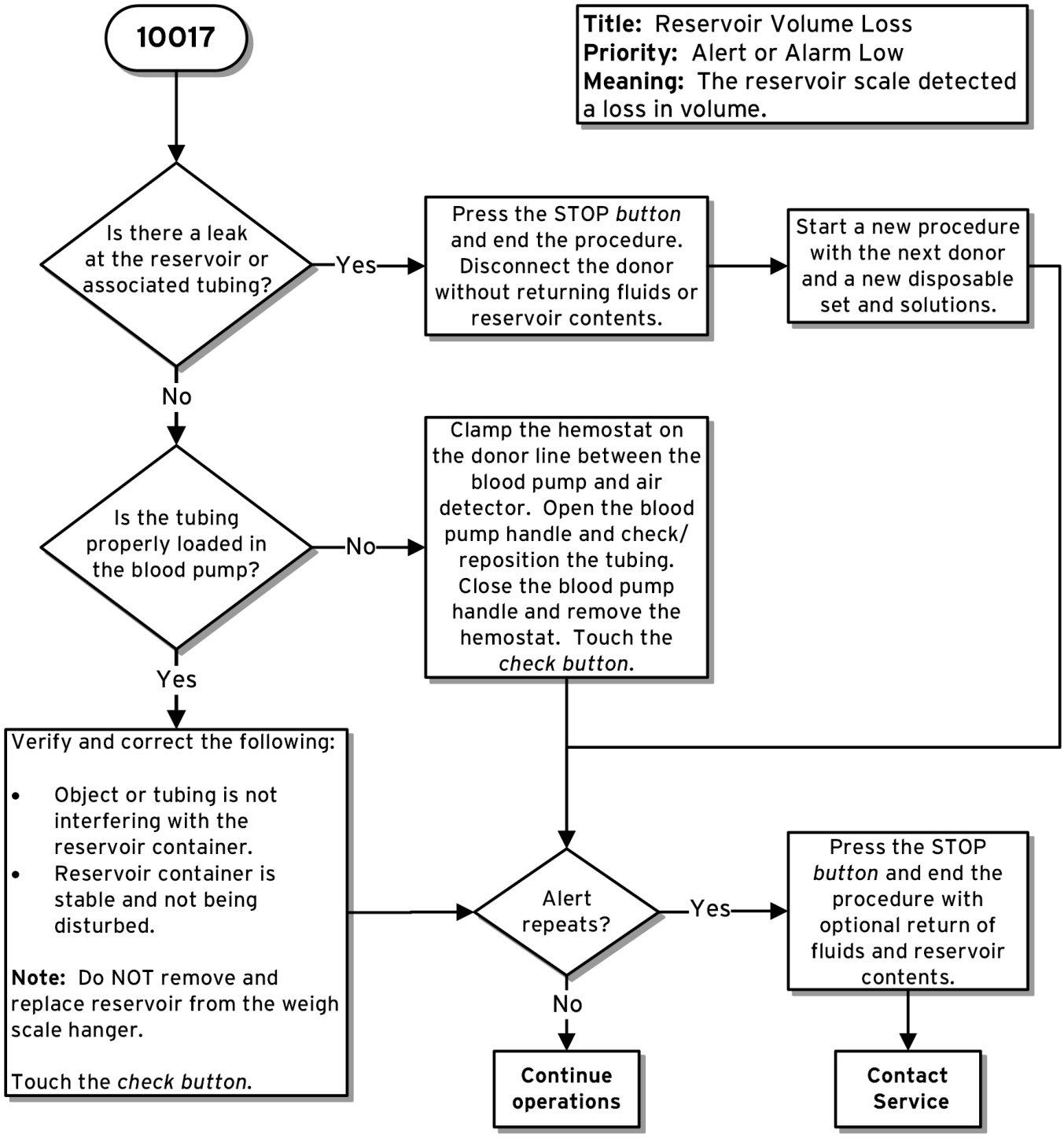


Figure 231: 10018 Reservoir Container Removed

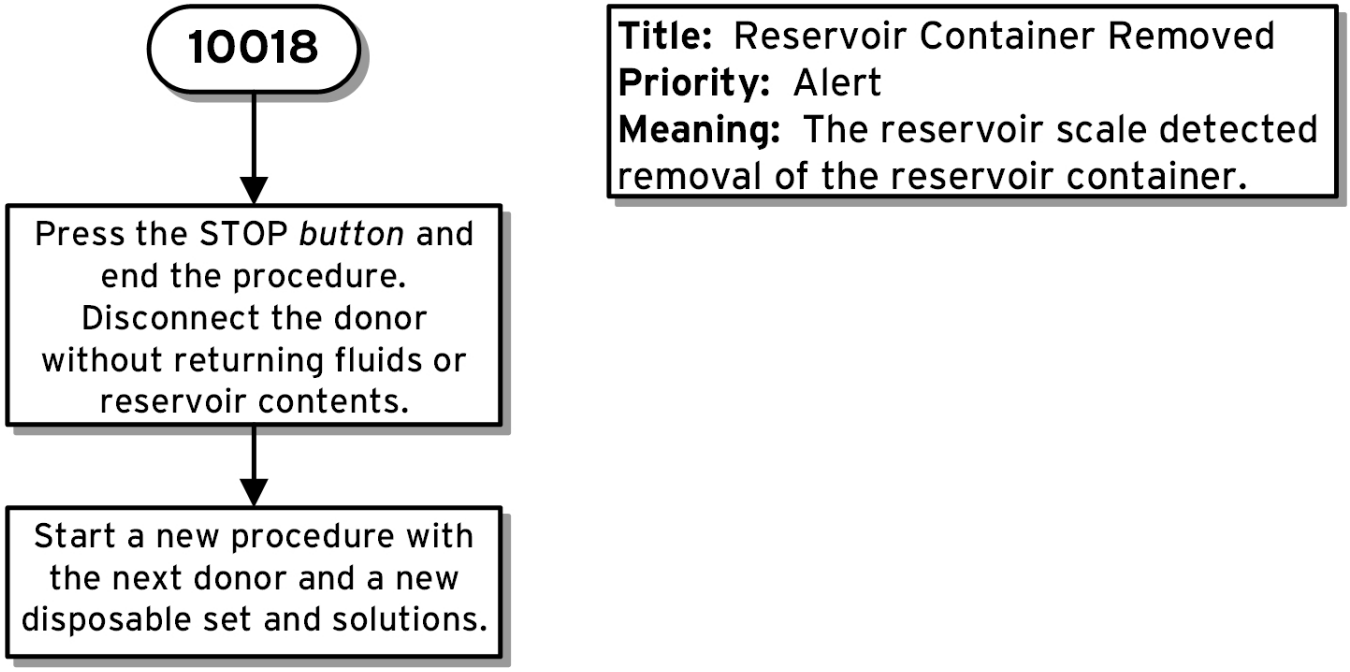


Figure 232: 10031 Collection Scale Overload

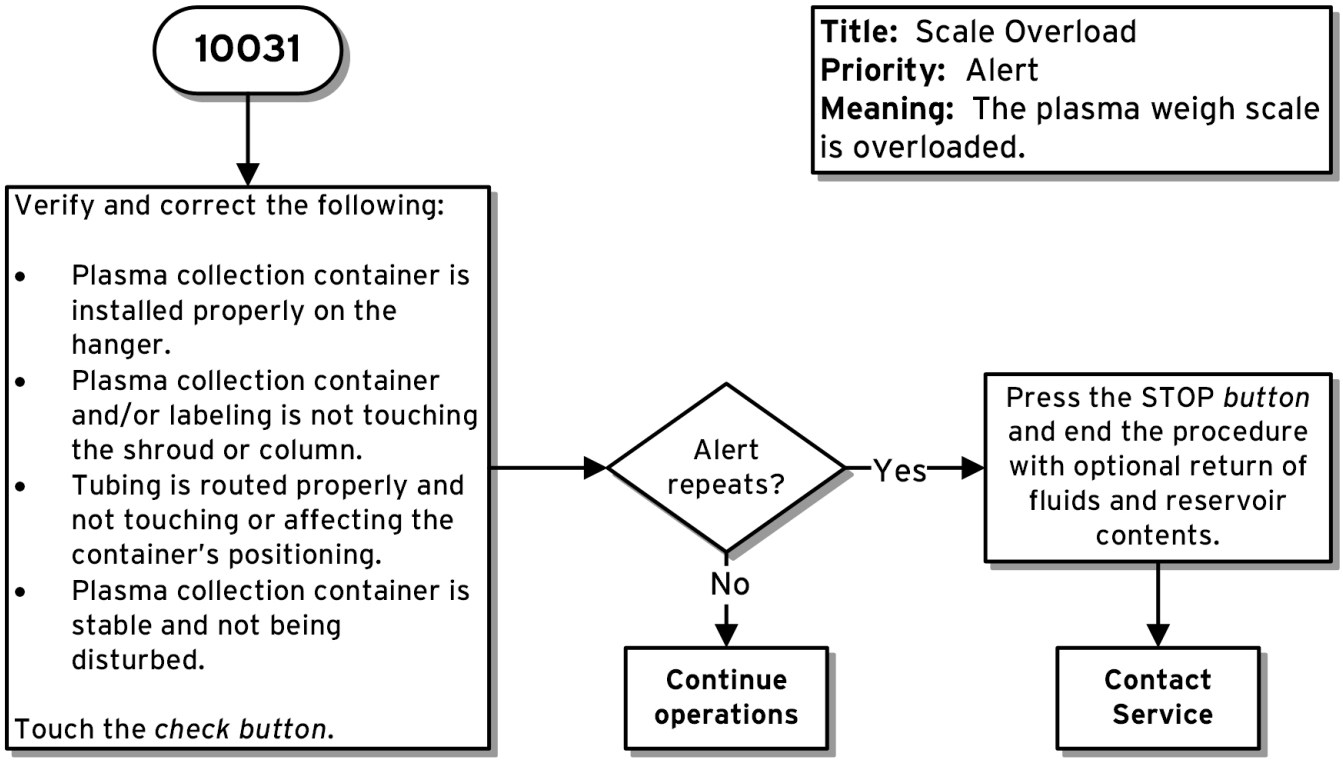


Figure 233: 10032 Reservoir Scale Overload

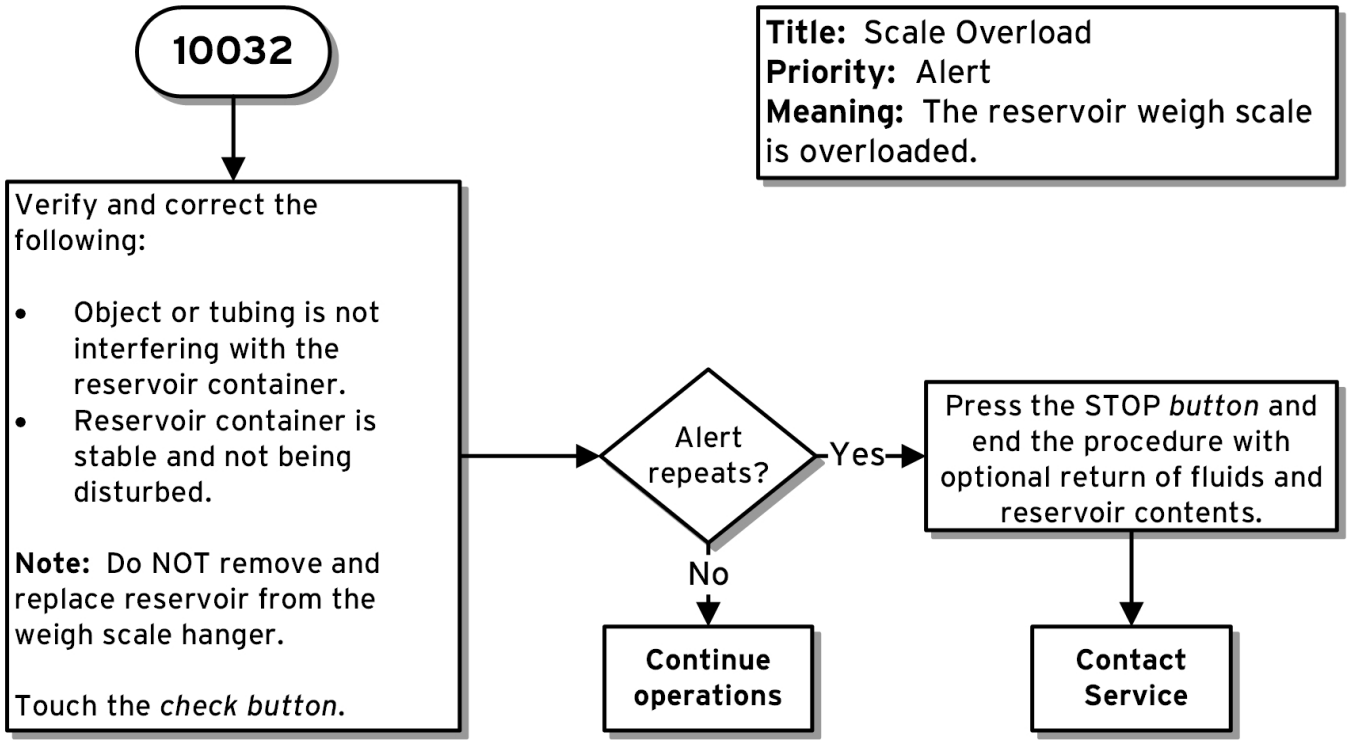


Figure 234: 10033 AC Scale Overload

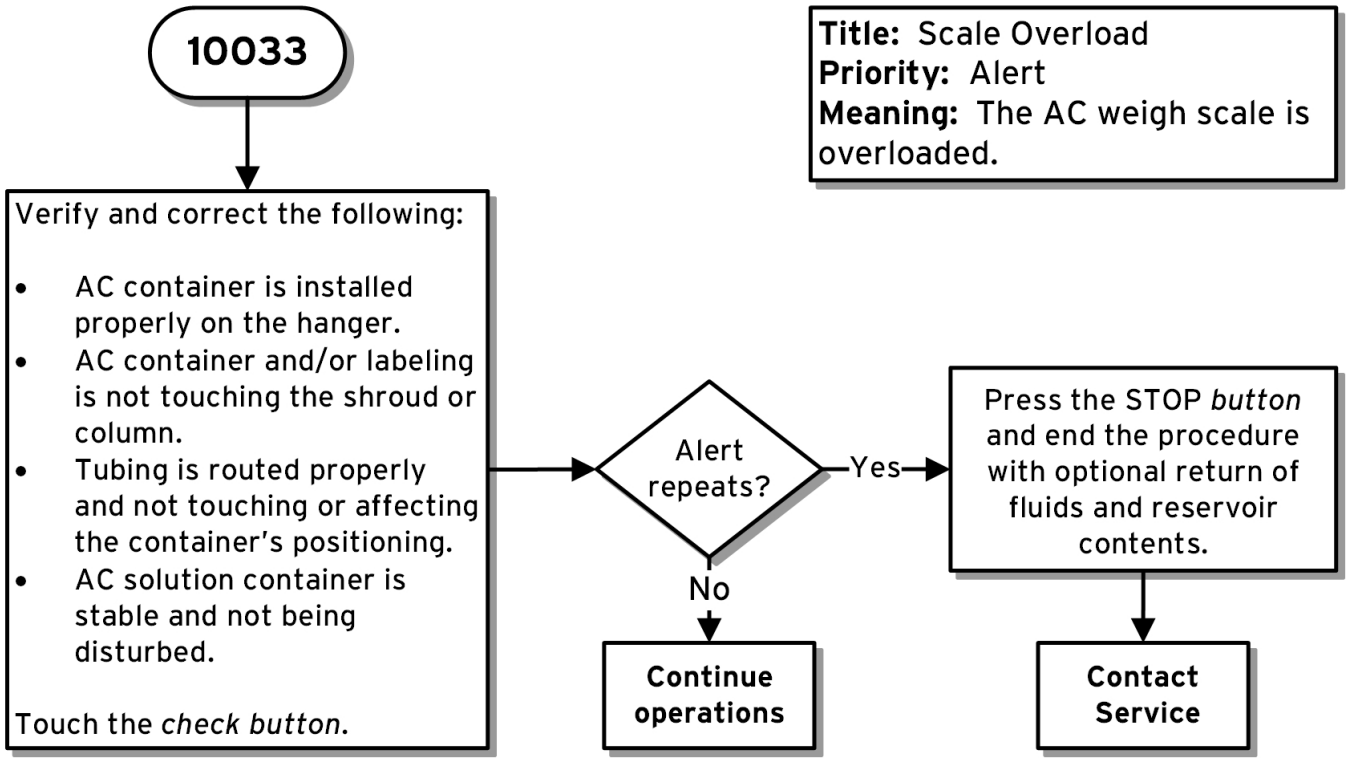


Figure 235: 10099 Pump Auto Recovery Failed

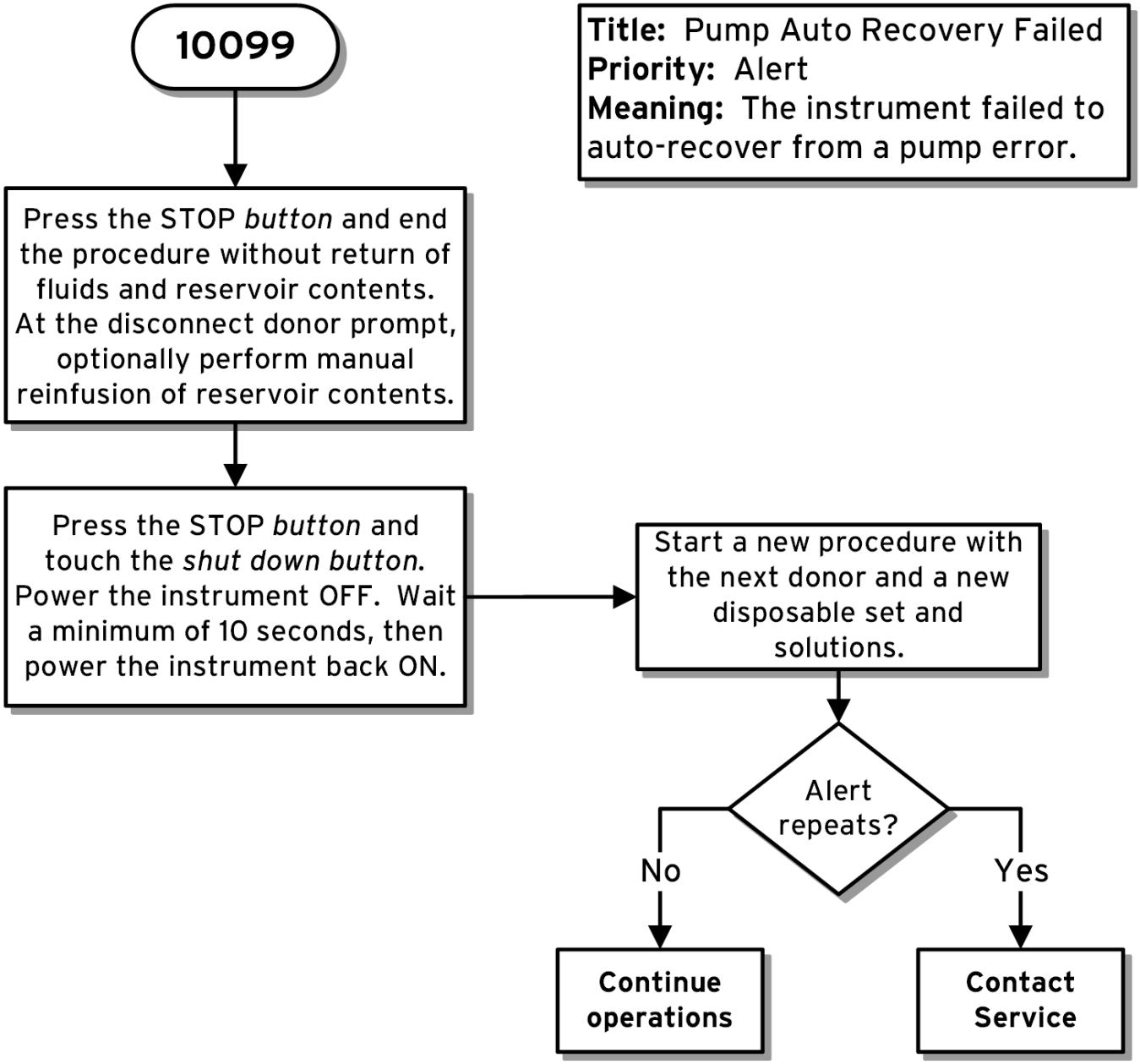


Figure 236: 10100 Auto Recovery Failed

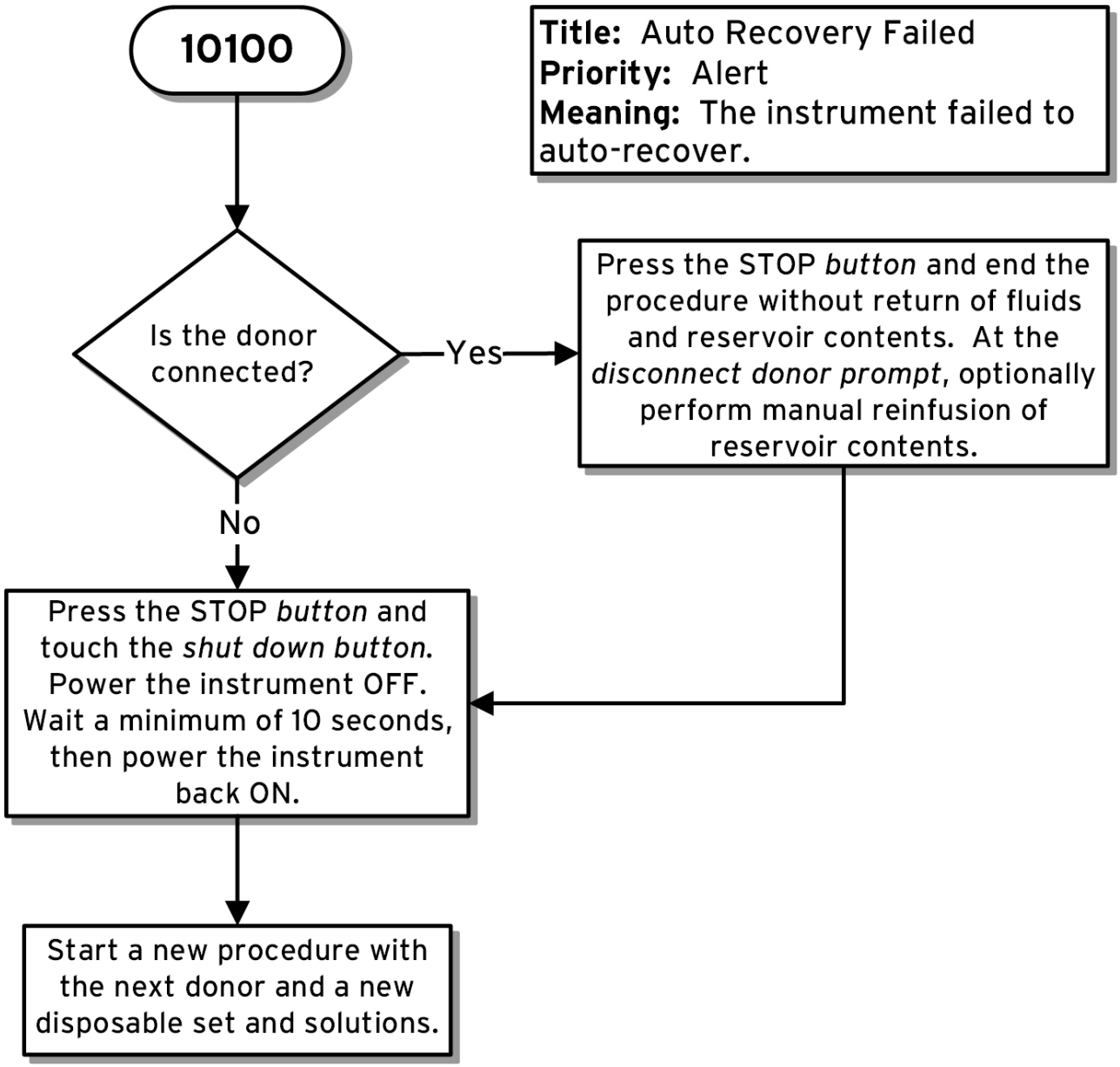


Figure 237: 10113 AC Moving Toward Donor

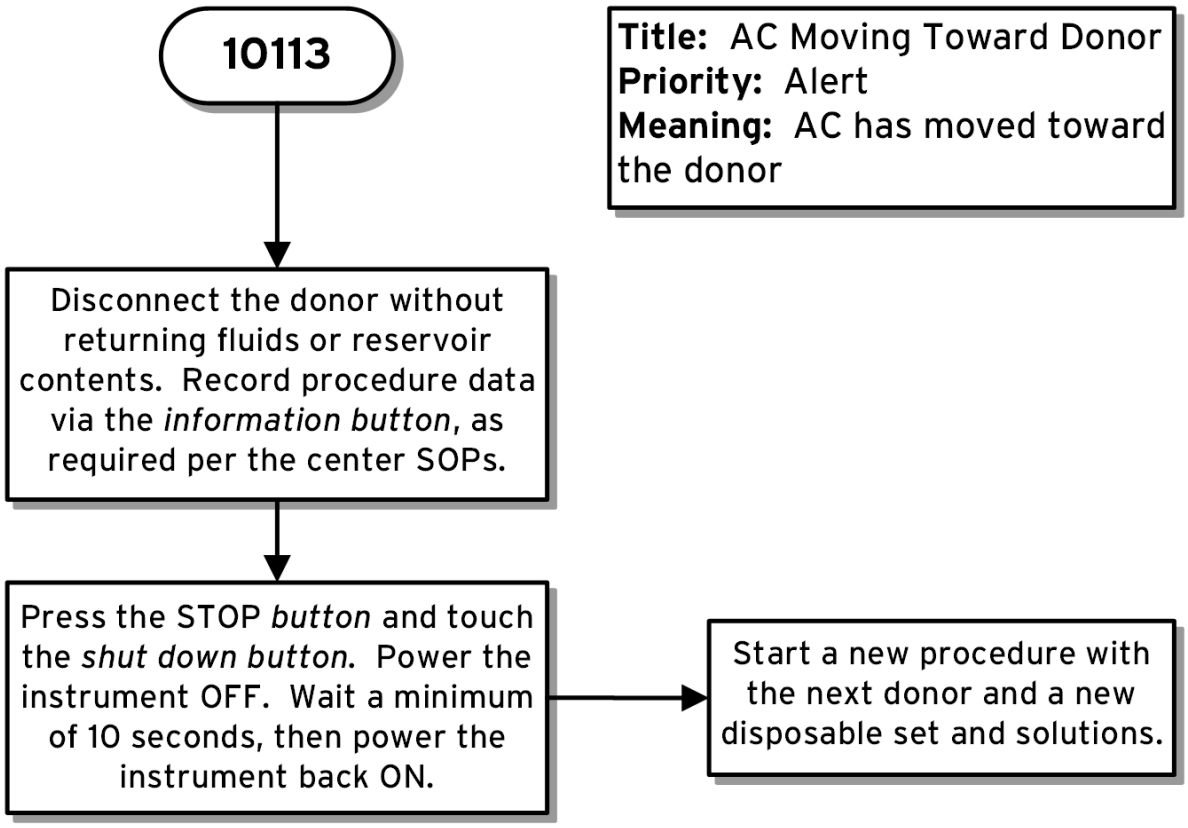


Figure 238: 10115 Unexpected Transition

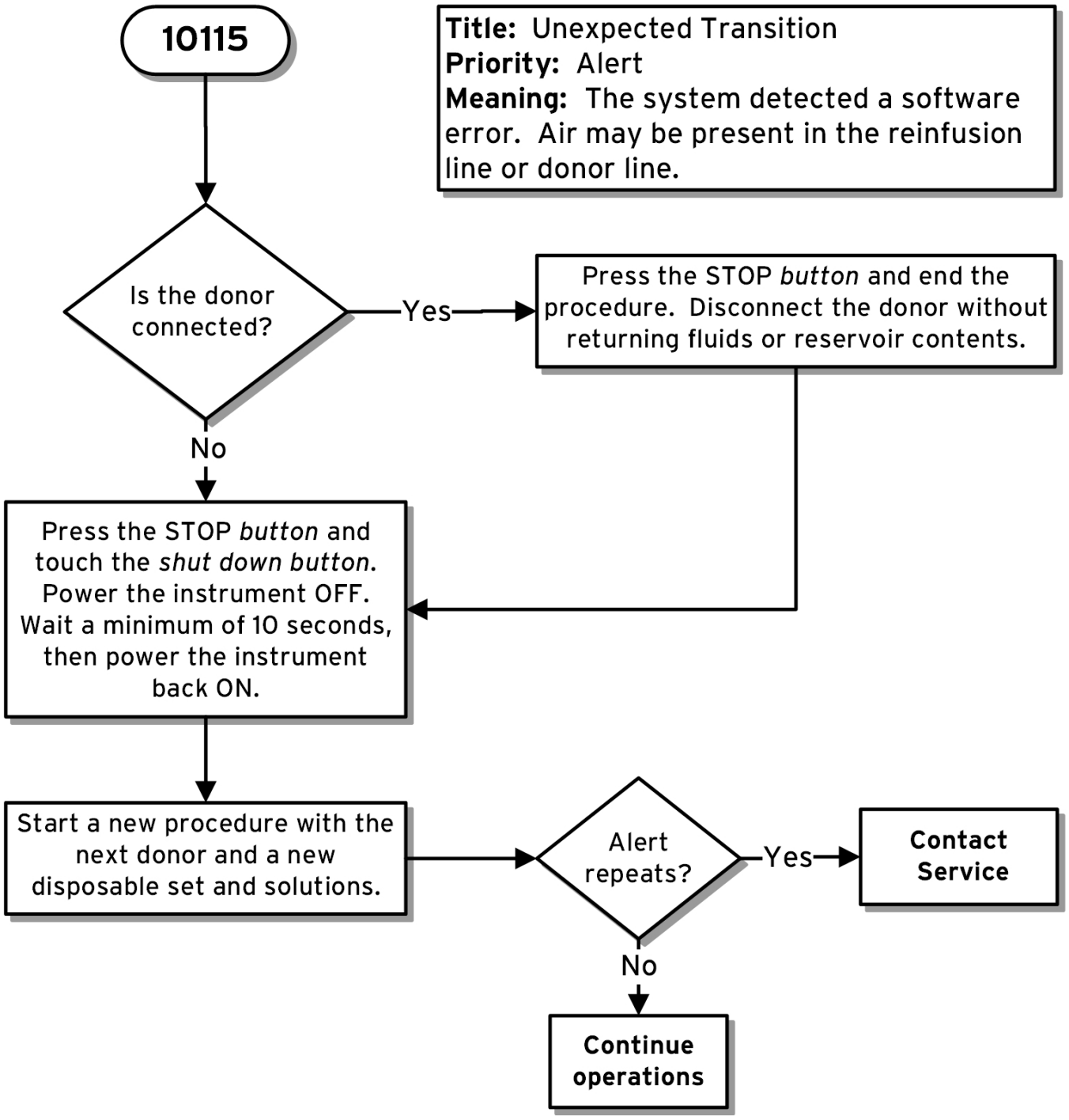


Figure 239: 10116 General System Fault

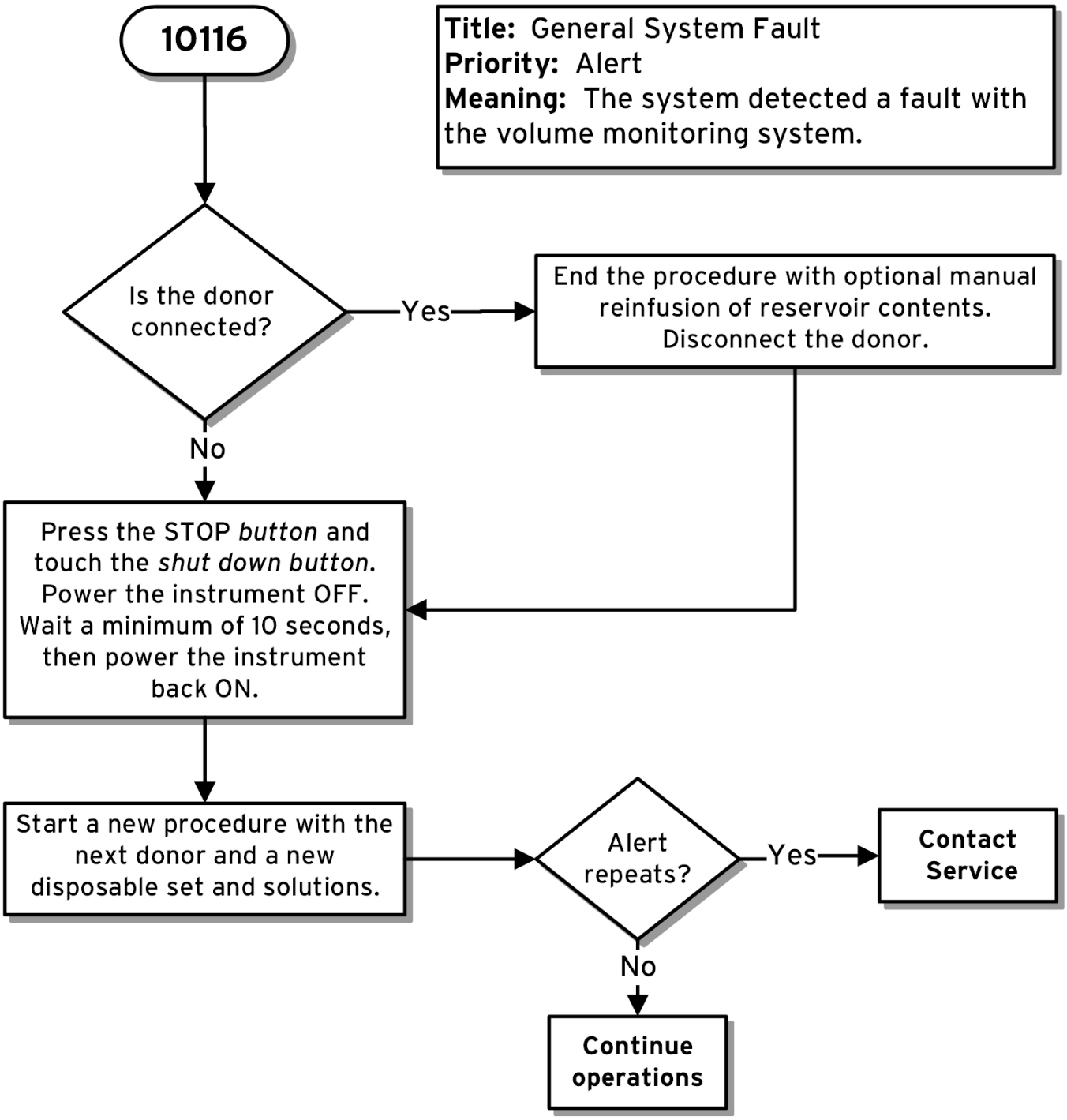


Figure 240: 10201 Max Draw, Purge Incomplete

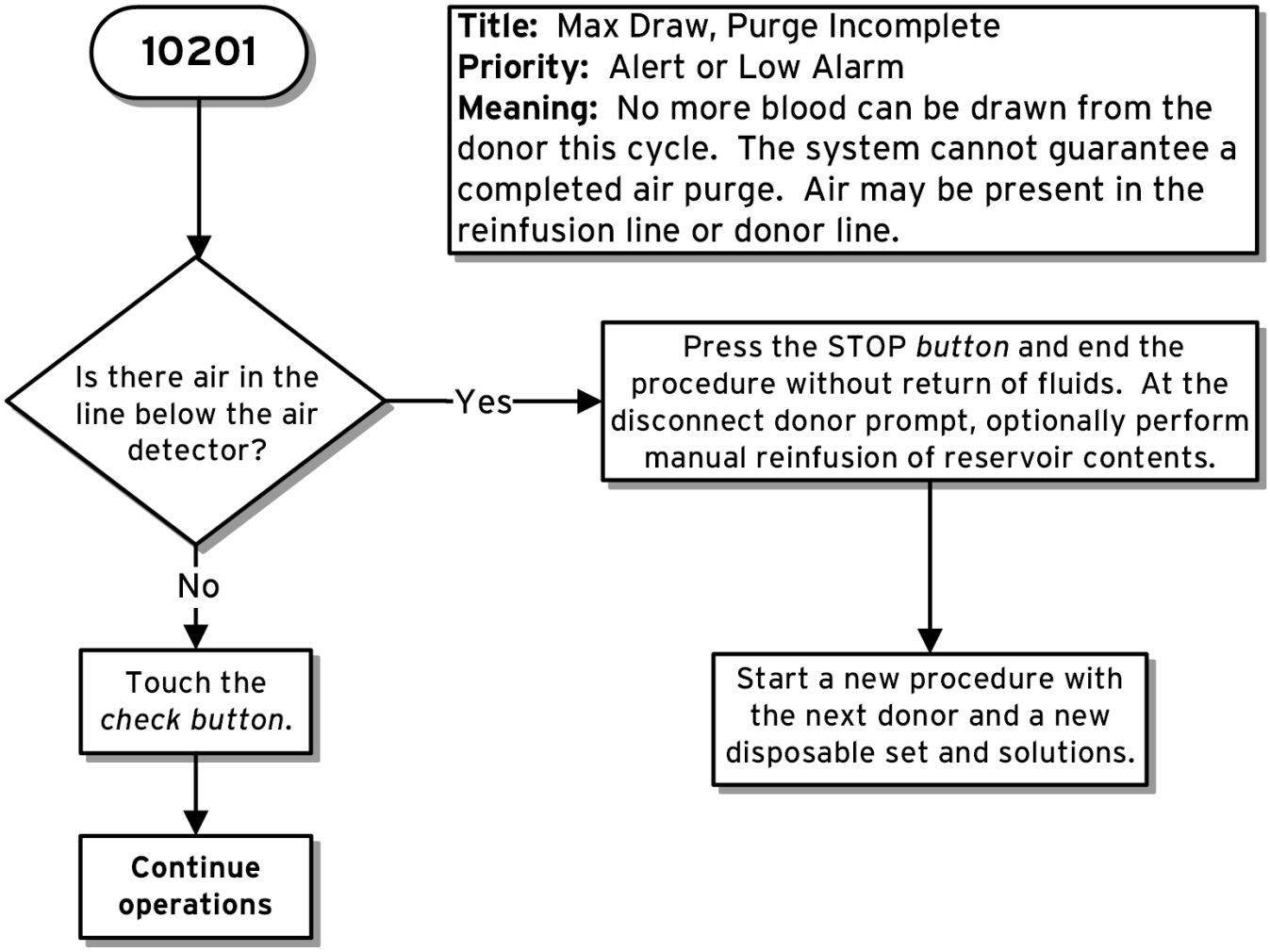


Figure 241: 10205 Max Draw, Air in Line

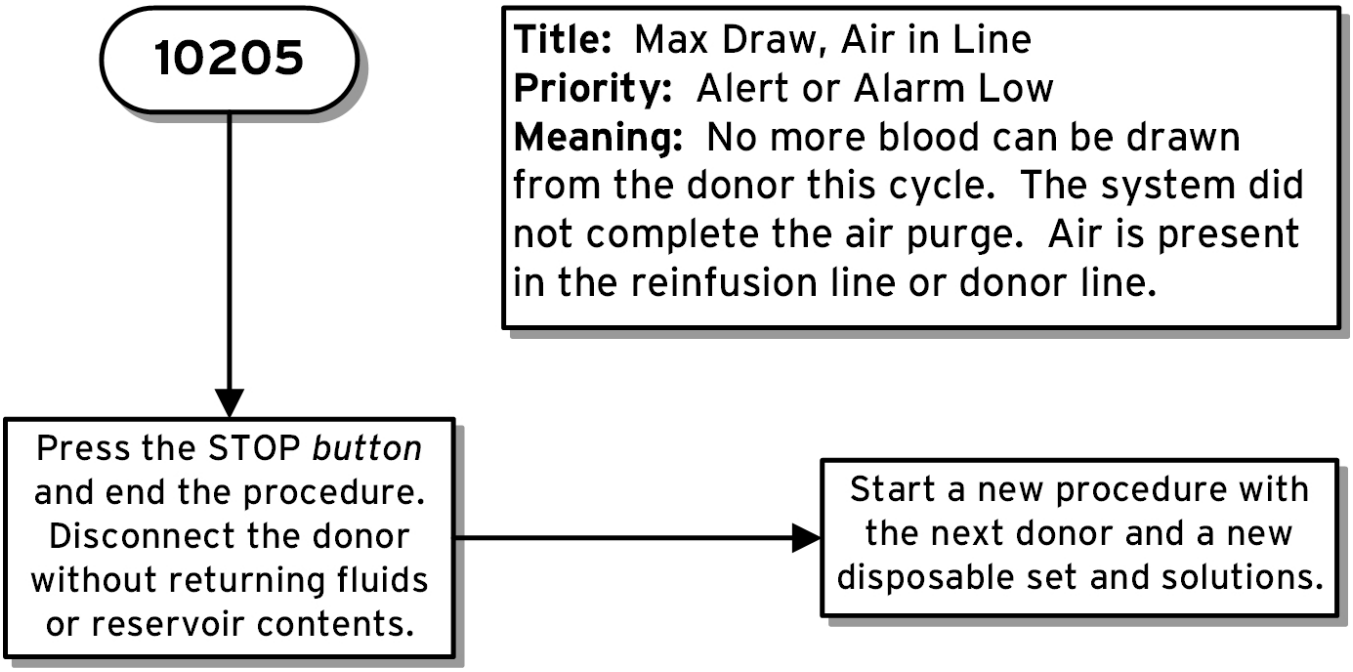


Figure 242: 10301 P1 Pressure Not Responding

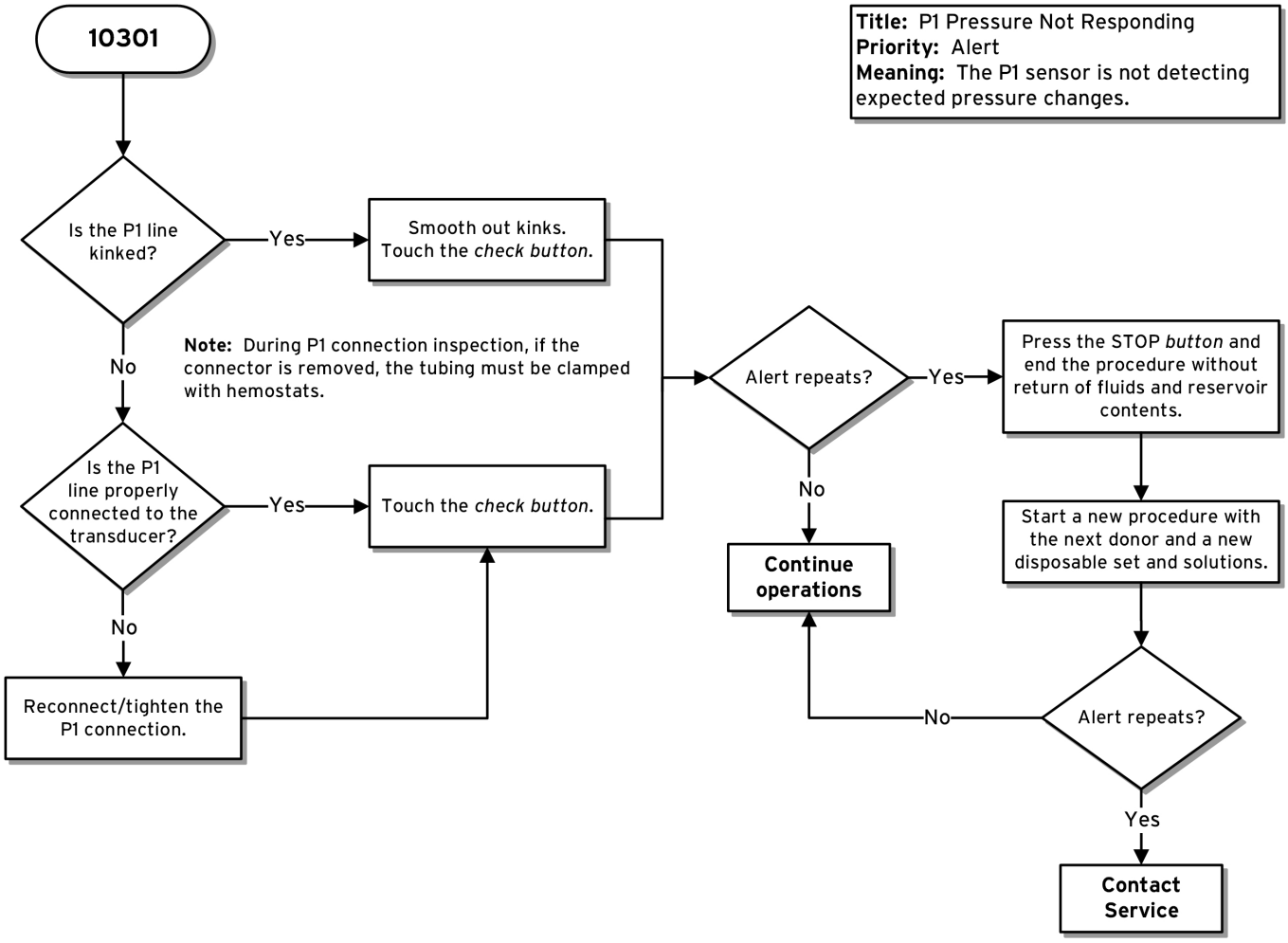


Figure 243: 10302 P2 Pressure Not Responding

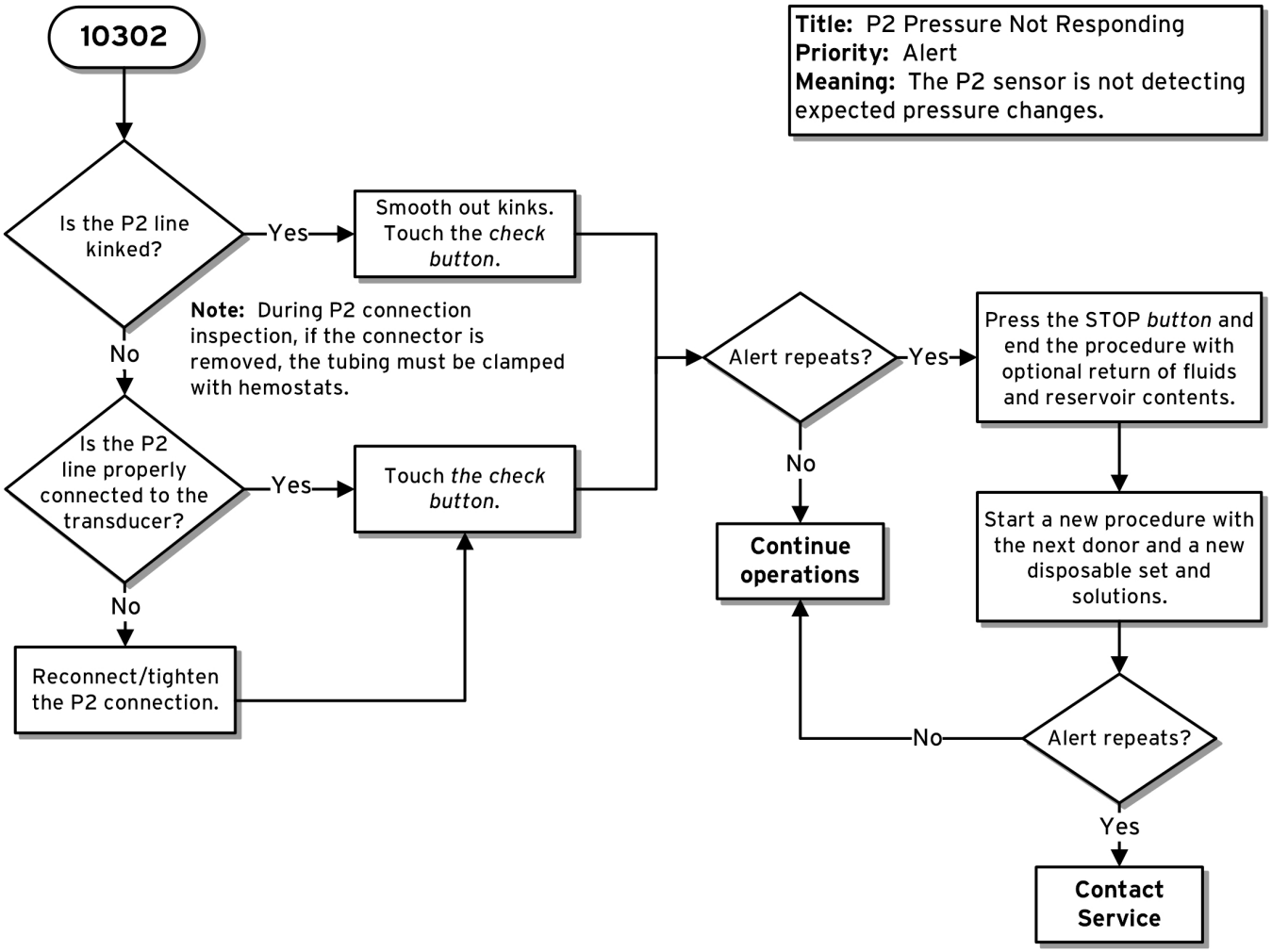
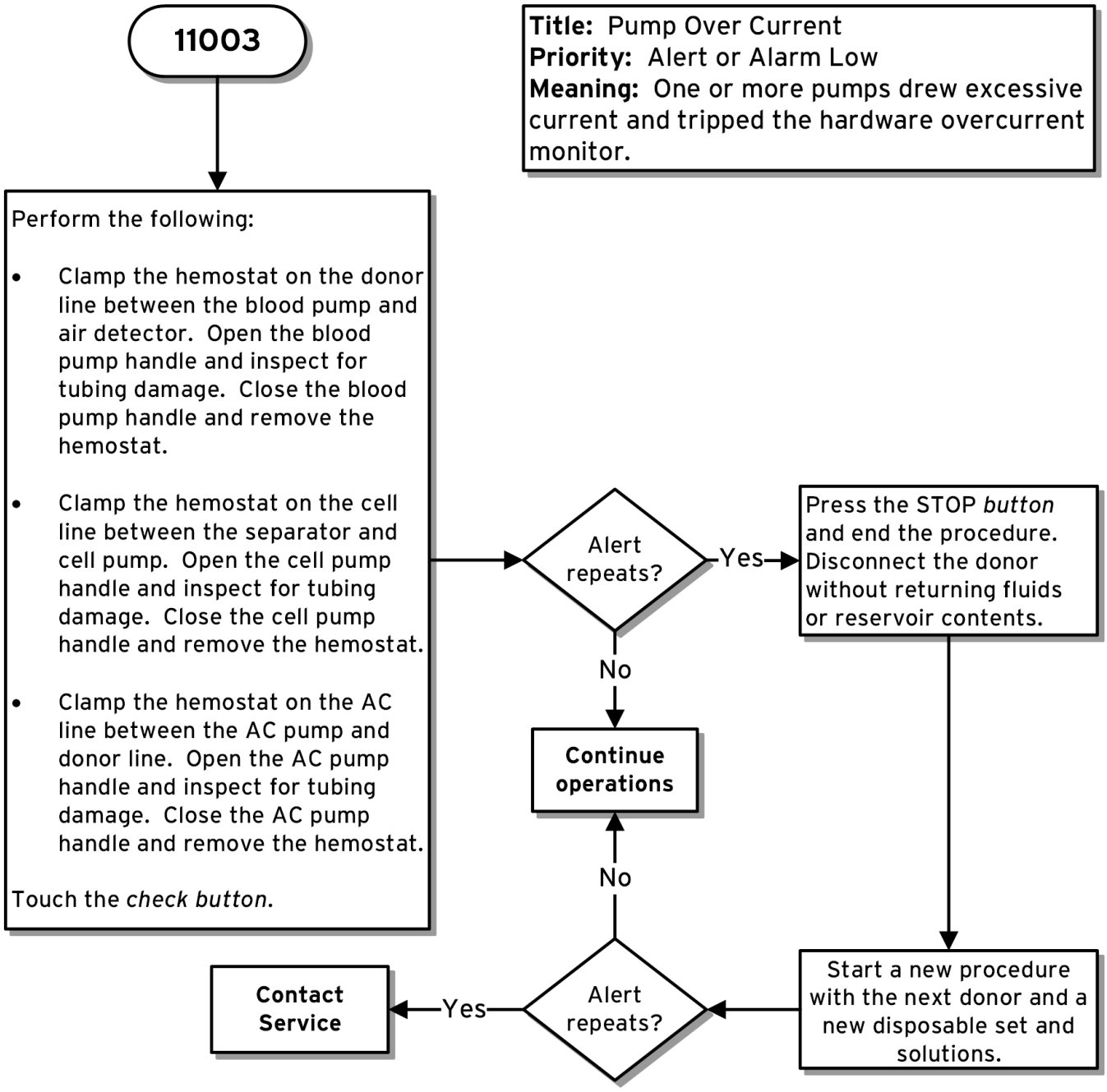


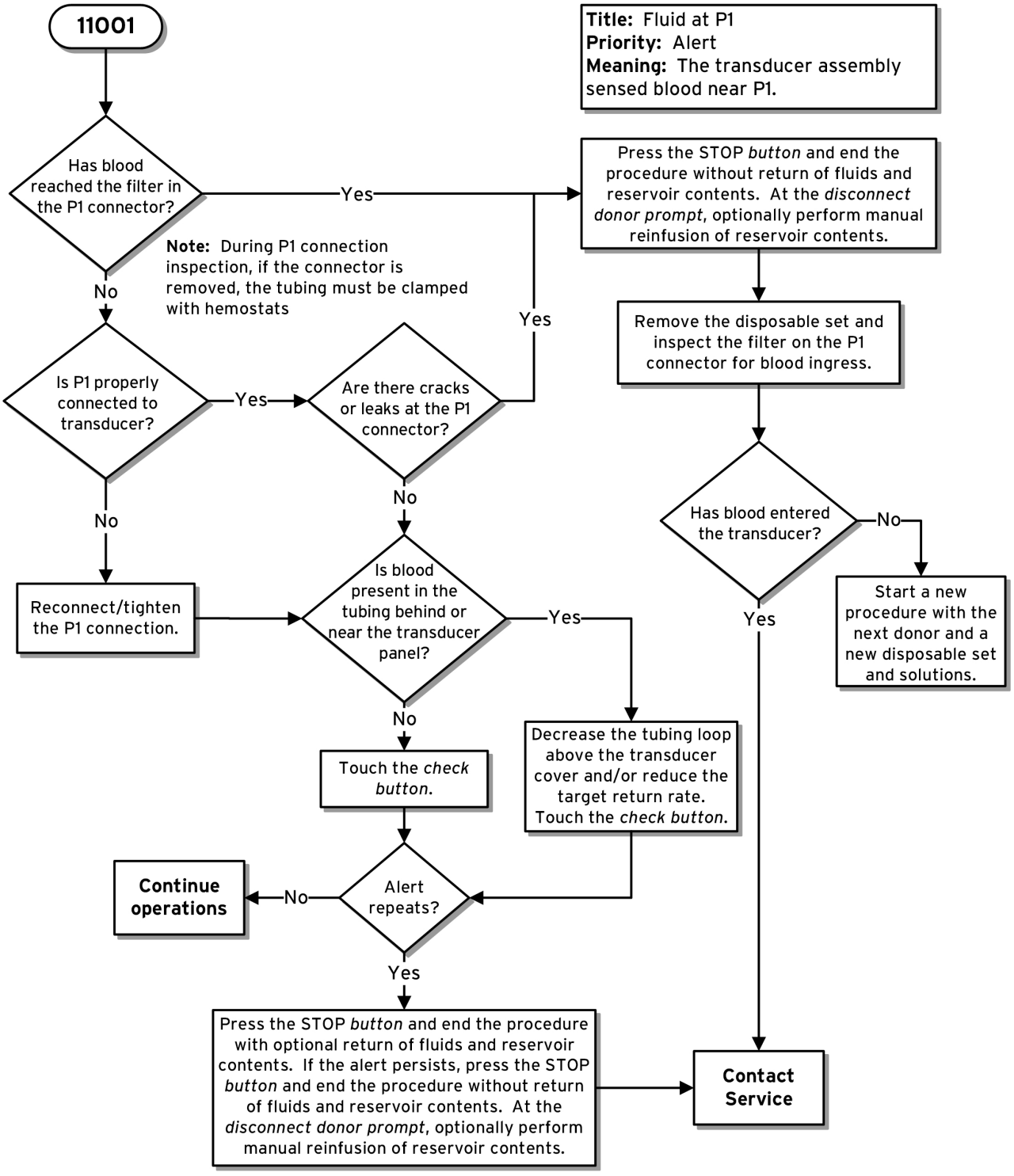
Figure 244: 11003 Pump Over Current



CAUTION

→ If damage to the tubing is observed, press the **STOP** button and end the procedure without returning fluids or reservoir contents.

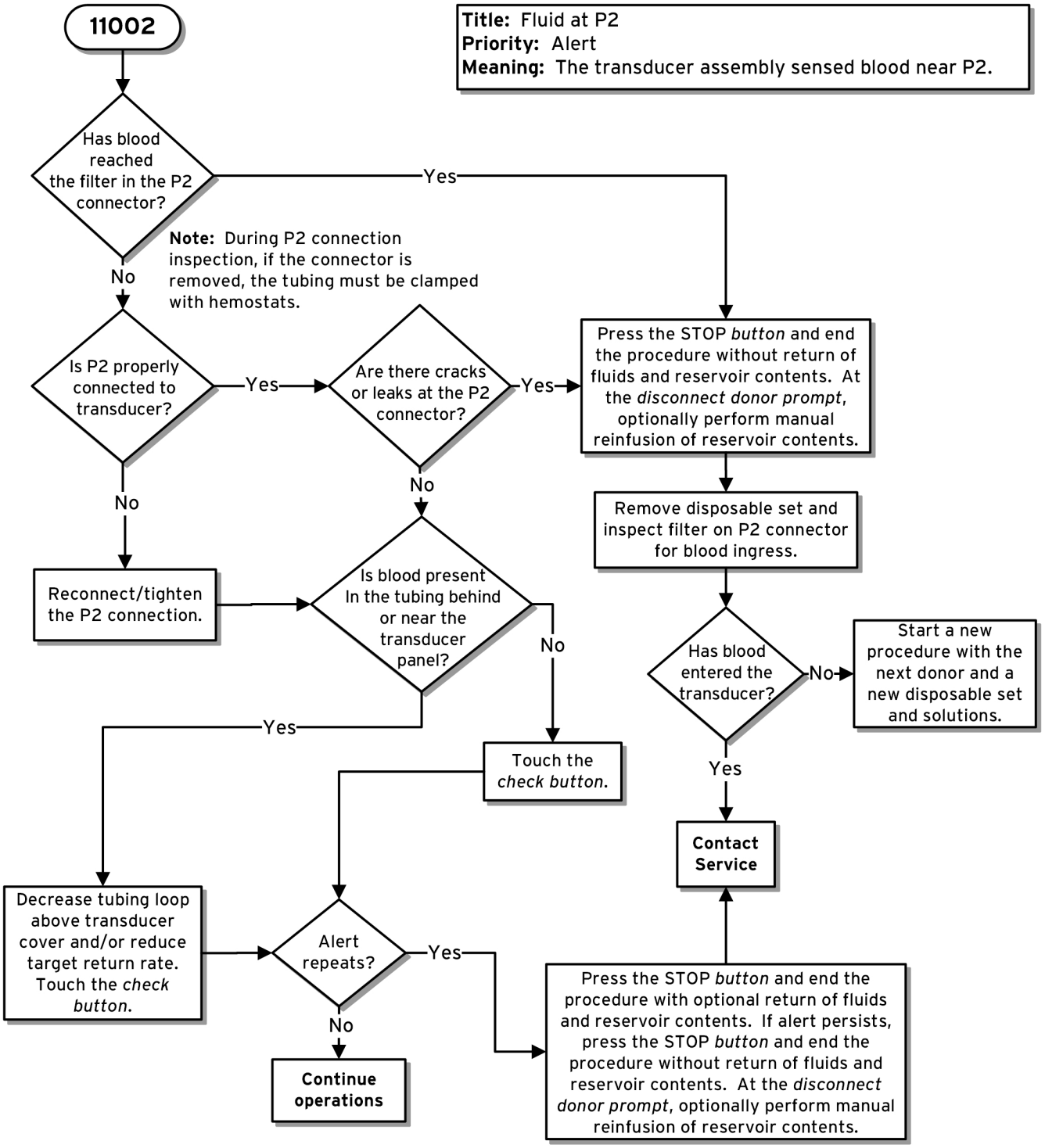
Figure 245: 11001 Fluid at P1



CAUTION

→ Be sure to not kink the P1 or P2 lines, especially when checking tubing when recovering from blood detection alerts.

Figure 246: 11002 Fluid at P2



CAUTION

→ Be sure to not kink the P1 or P2 lines, especially when checking tubing when recovering from blood detection alerts.

Figure 247: 11004 Power Loss

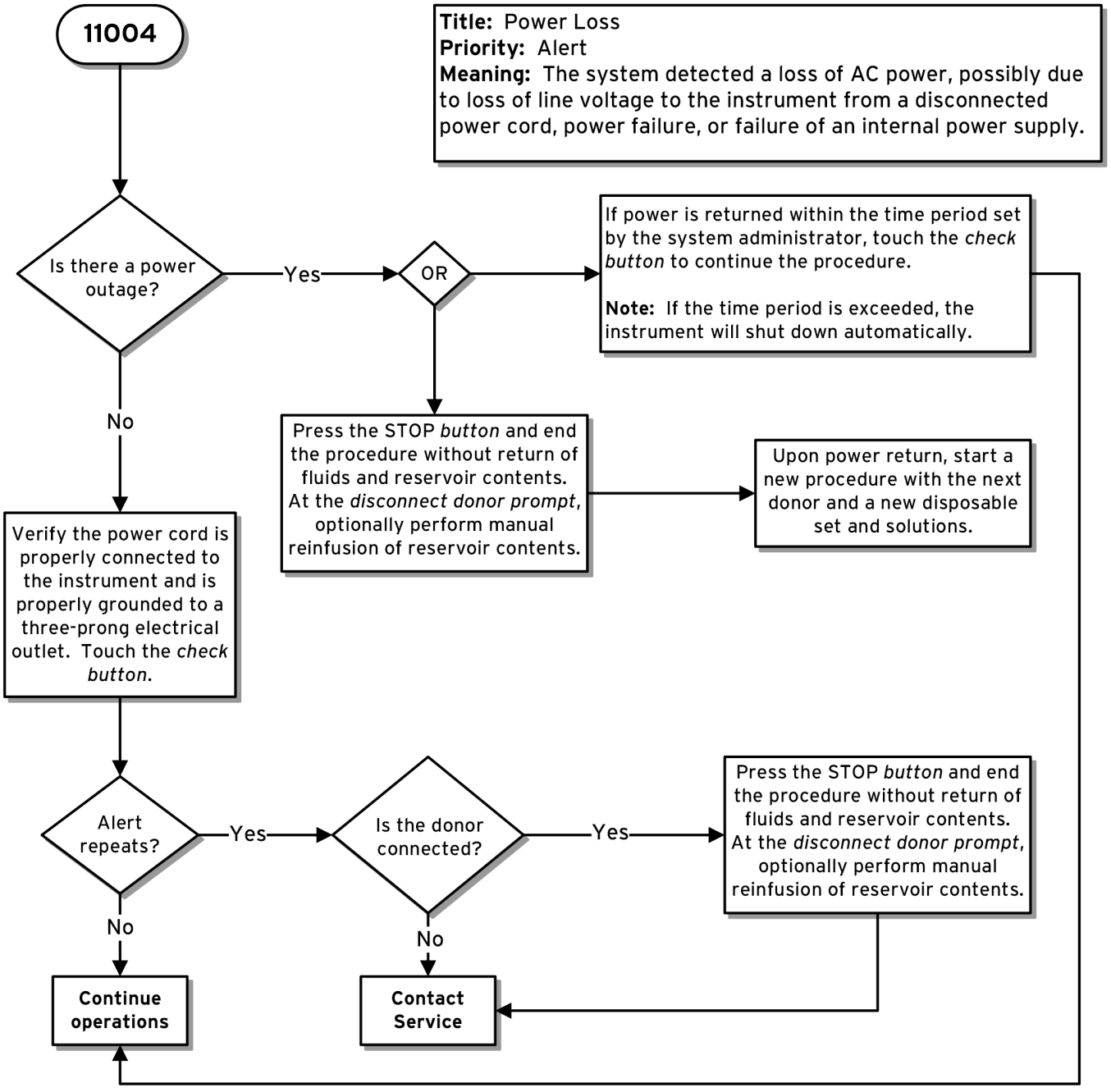


Figure 248: 11005 Transducer Cover Open

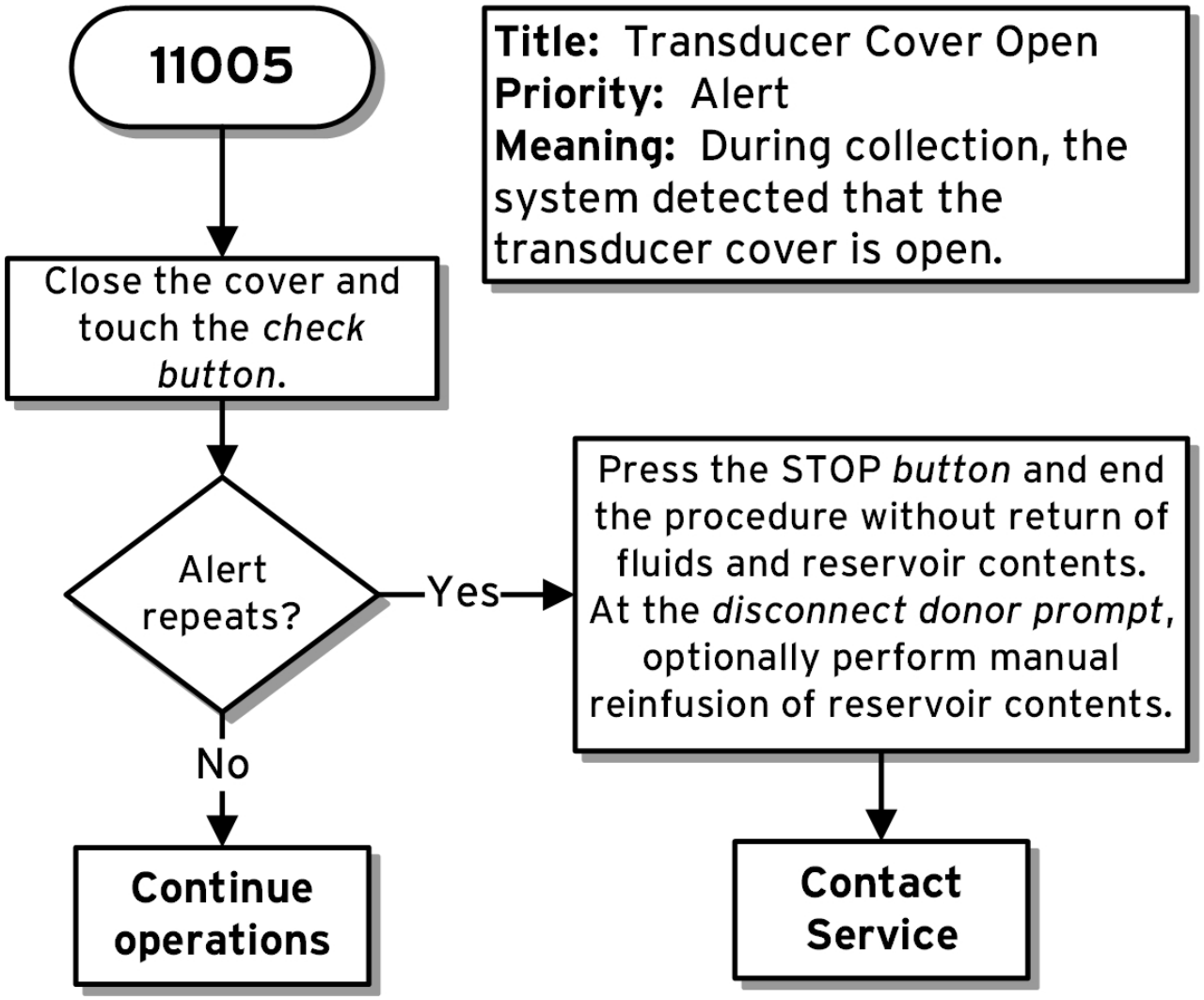


Figure 249: 11006 Software Error

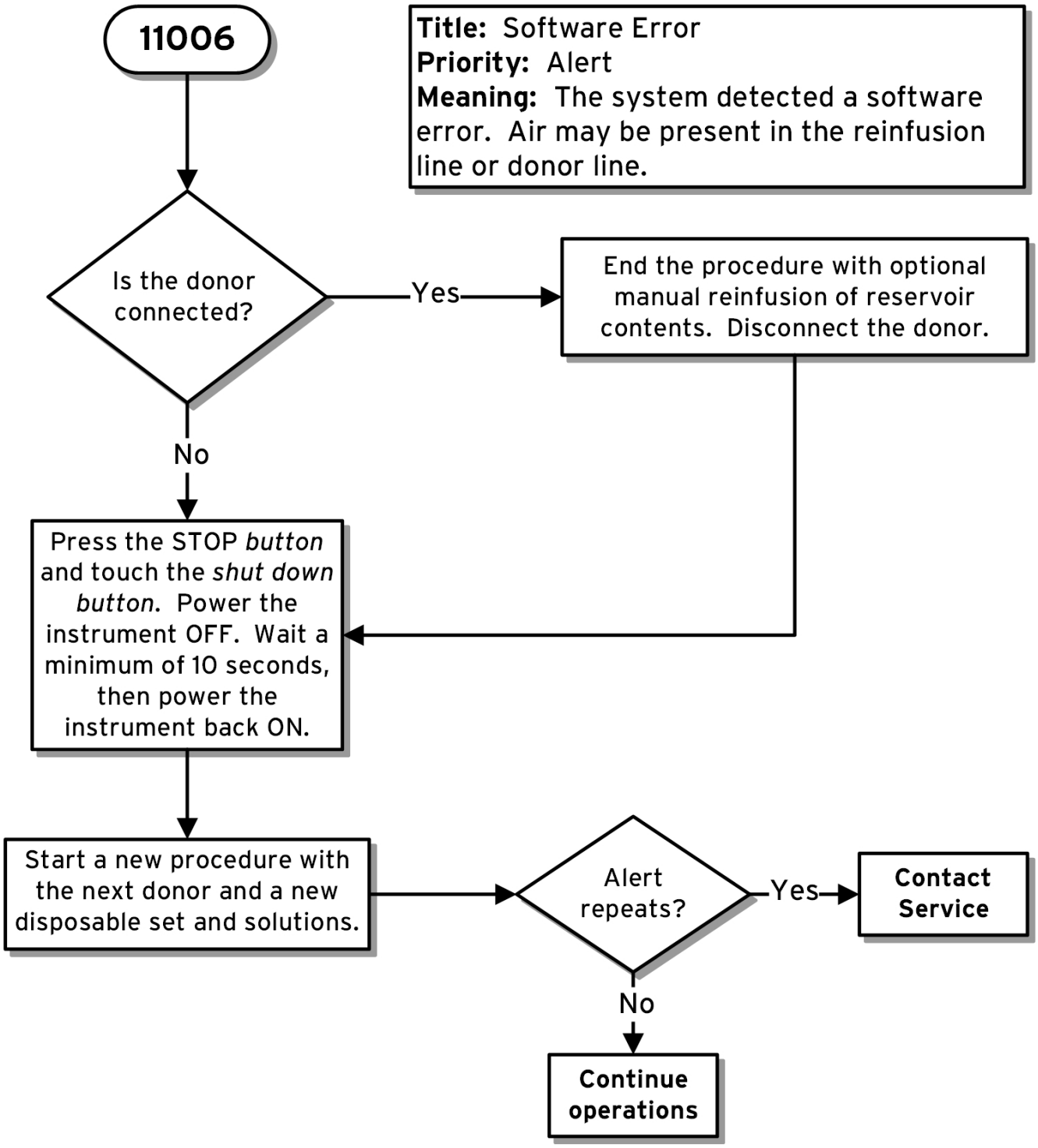


Figure 250: 11015 Software Error

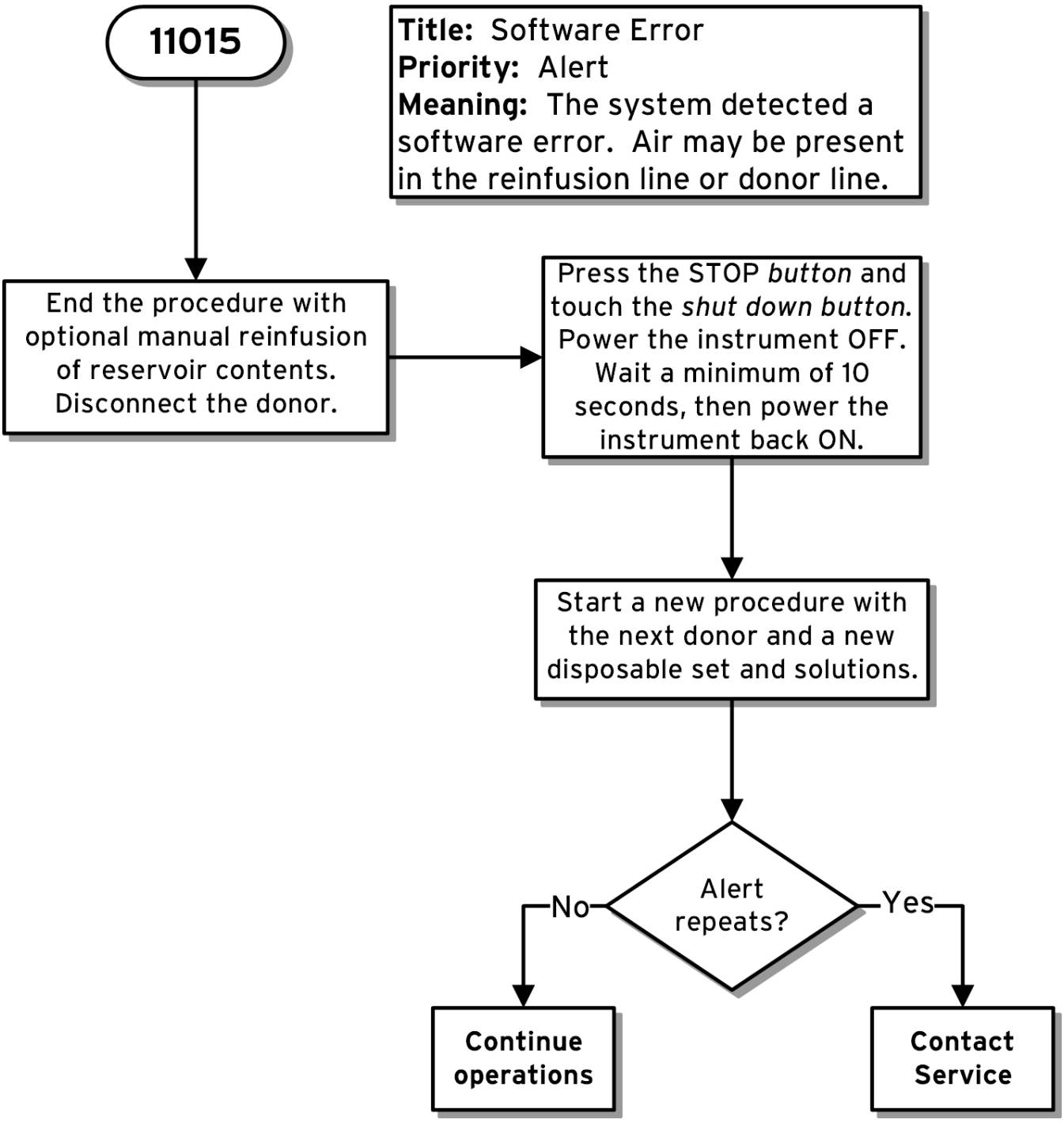


Figure 251: 11016 STOP Button Error

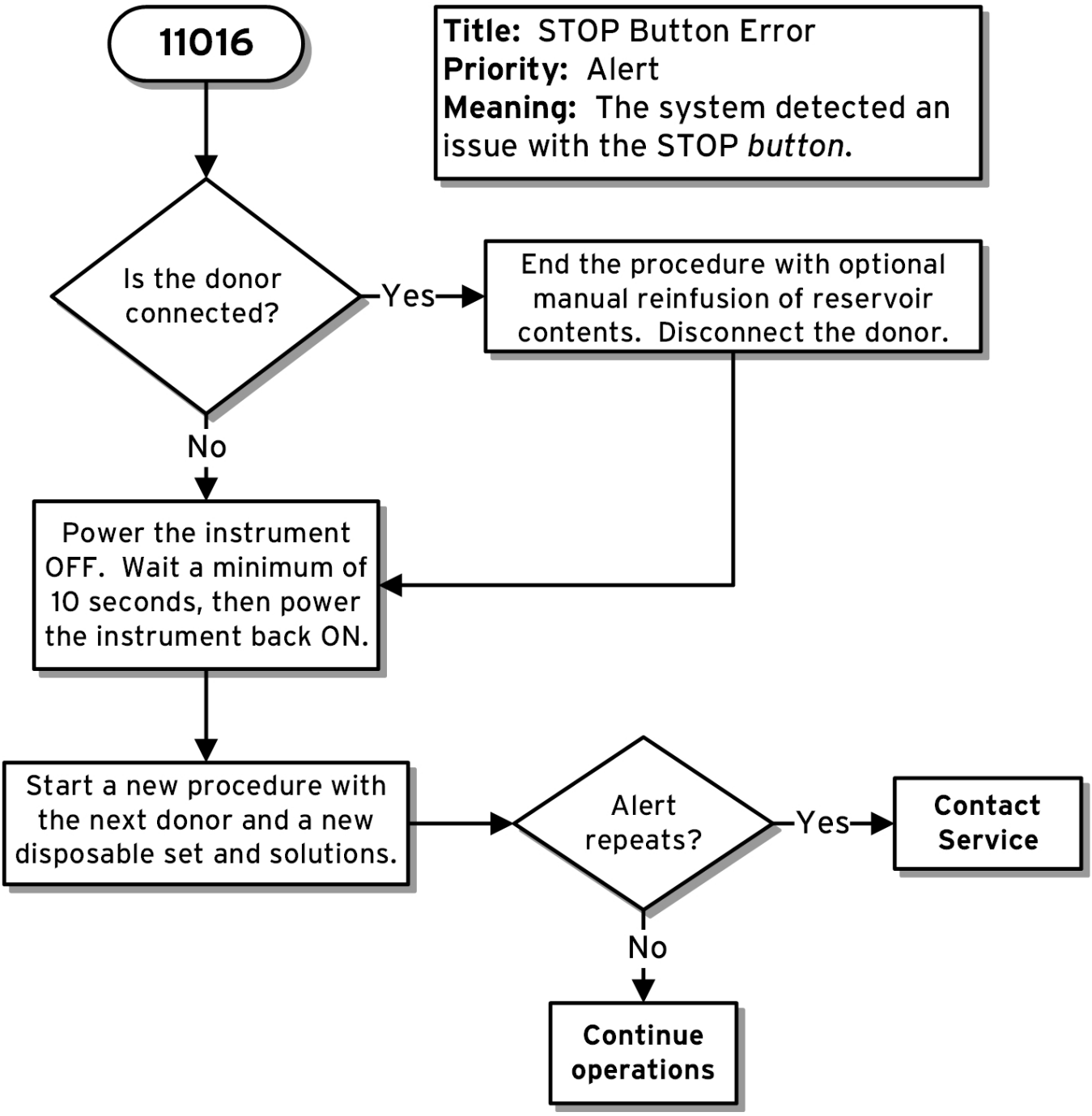


Figure 252: 11017 Software Error

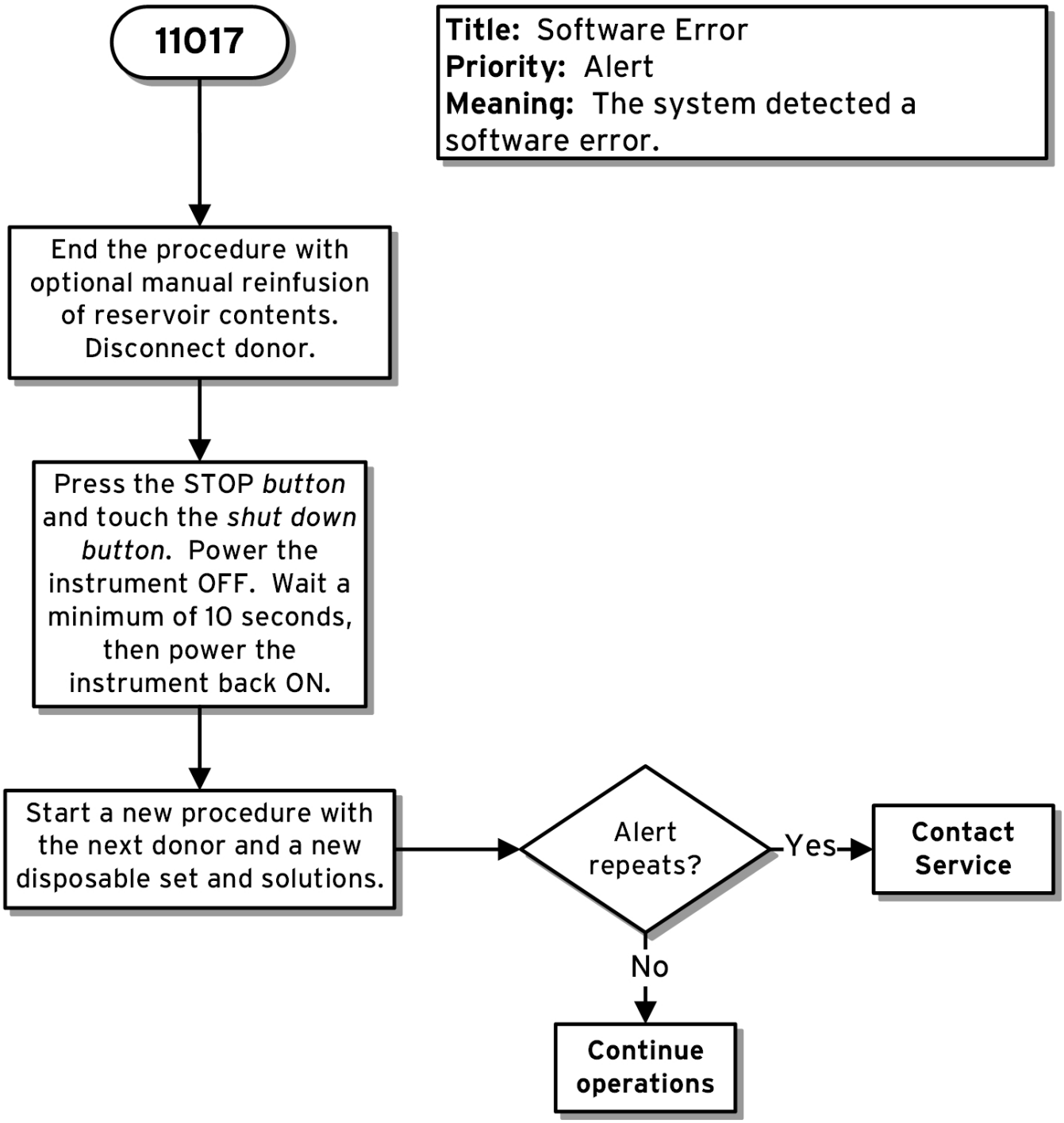


Figure 253: 11018 General System Fault

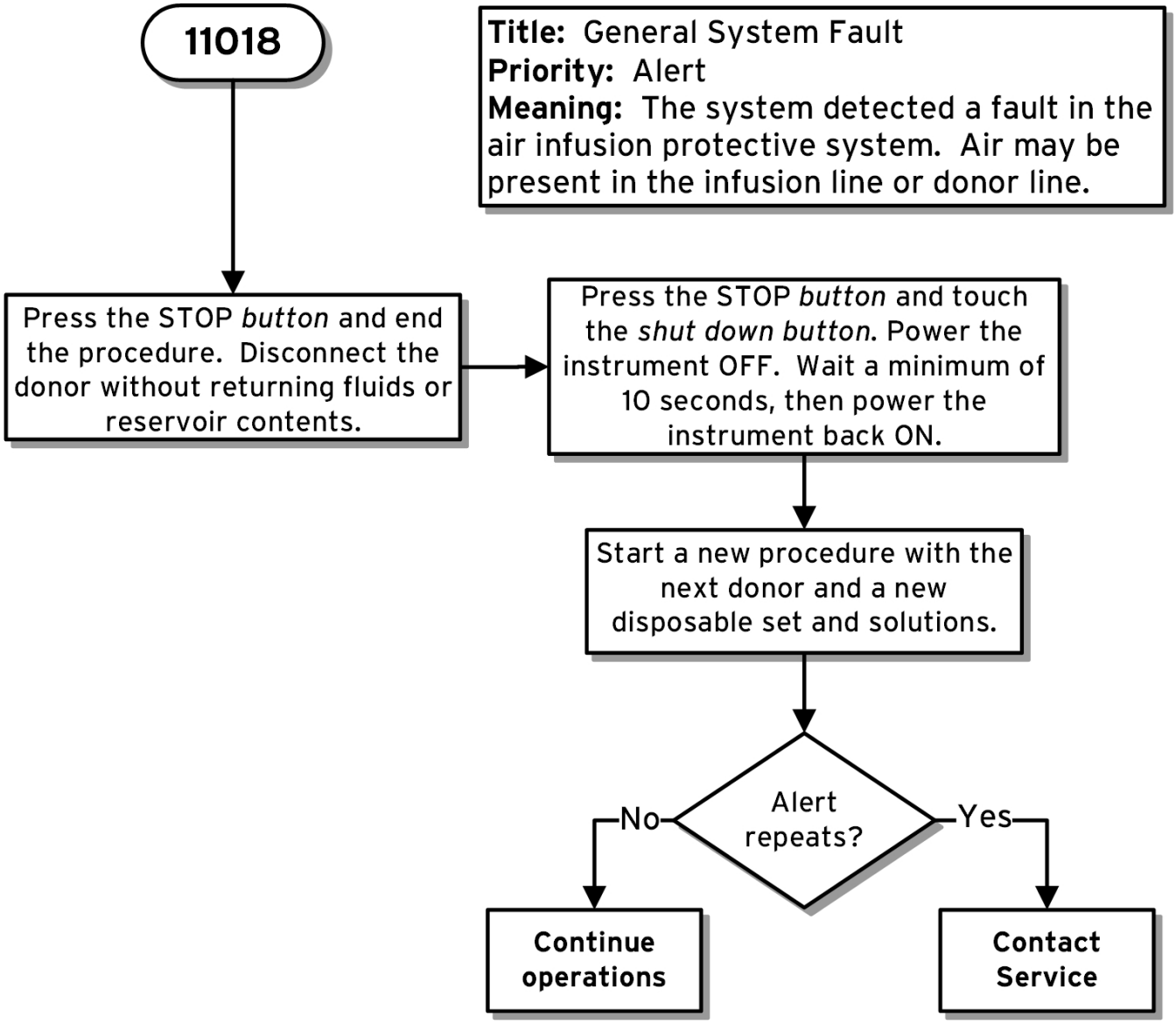


Figure 254: 11021 Pressure Sensor Fault

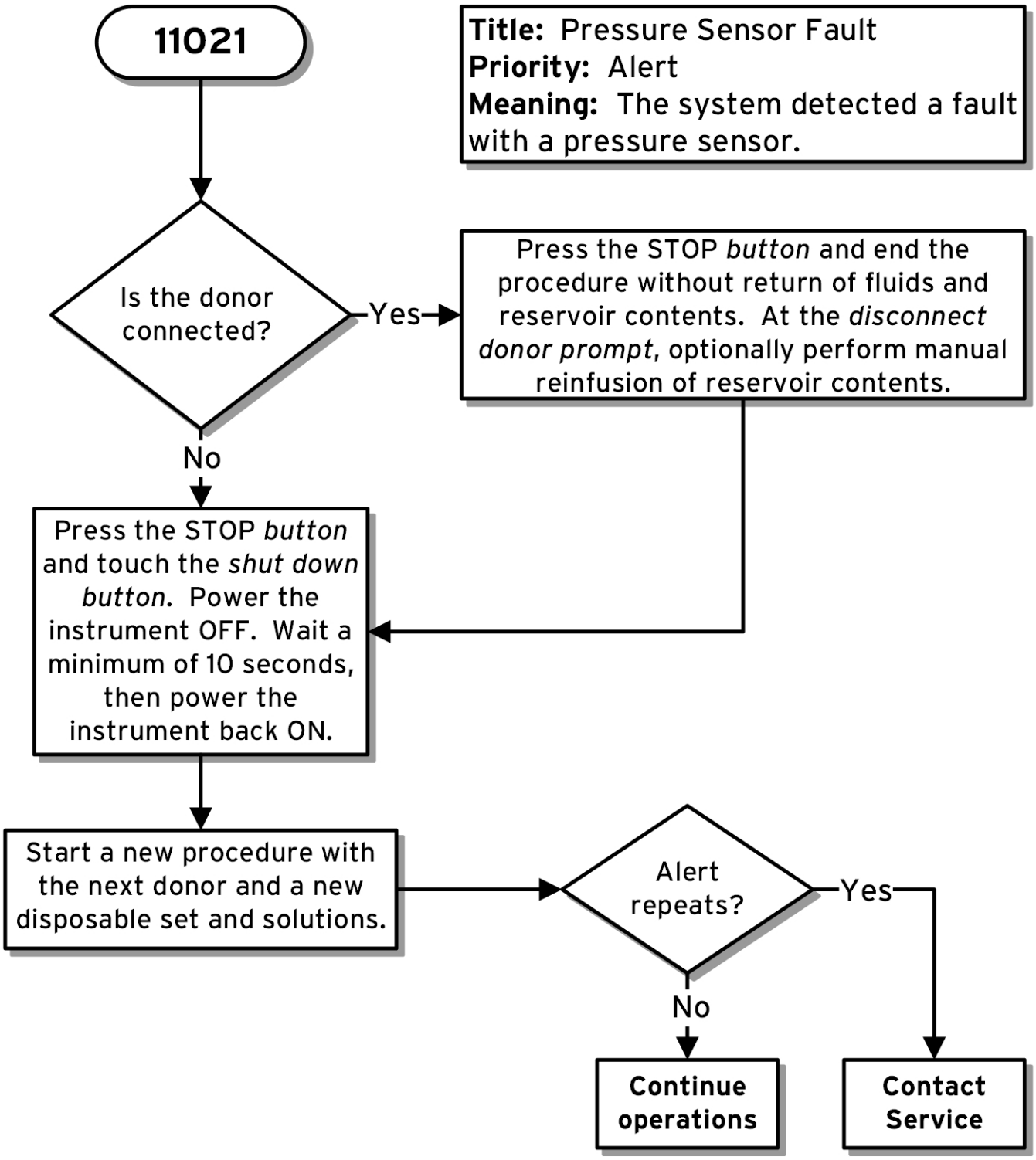


Figure 255: 11029 Software Error

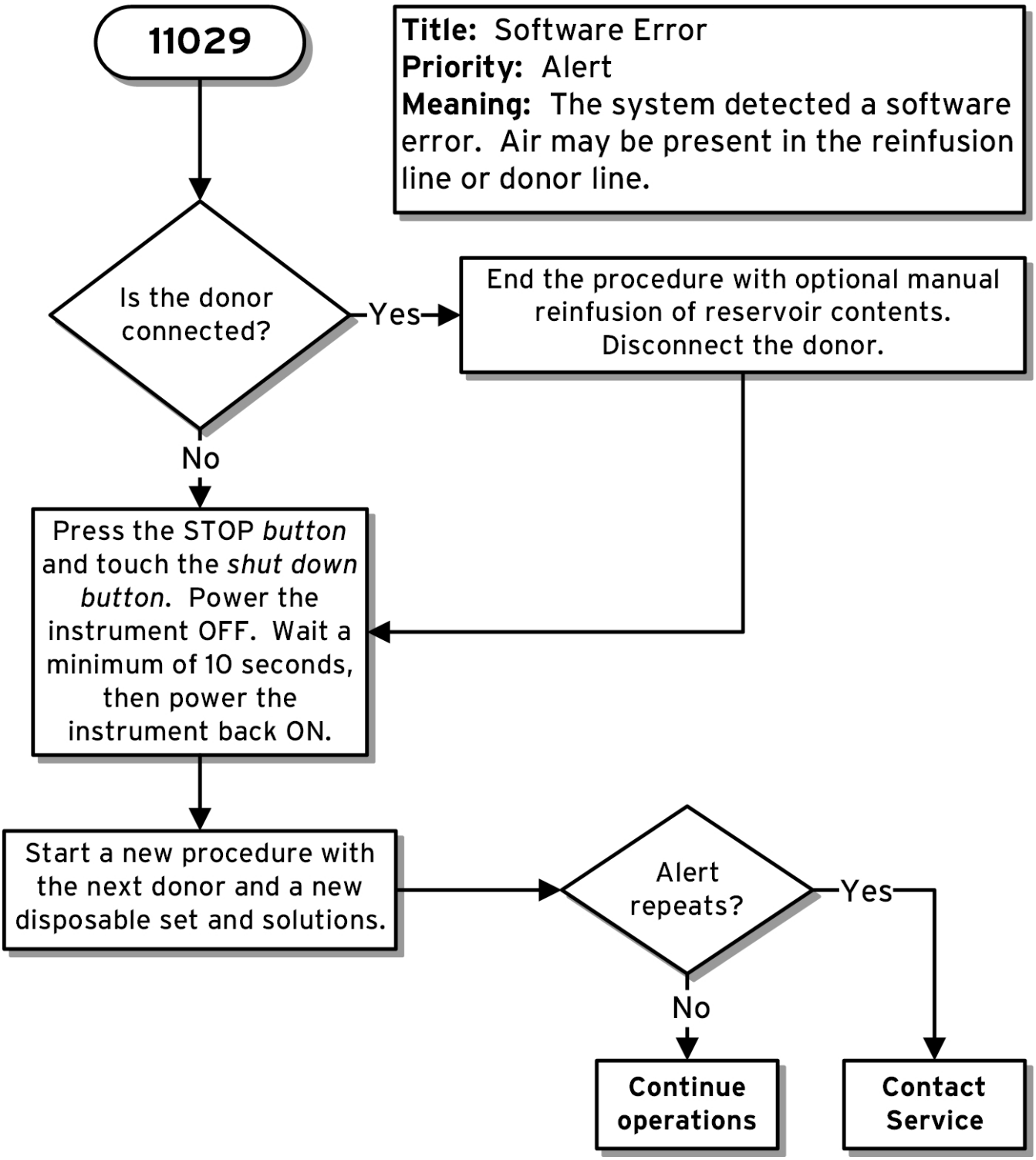


Figure 256: 11031 Software Error

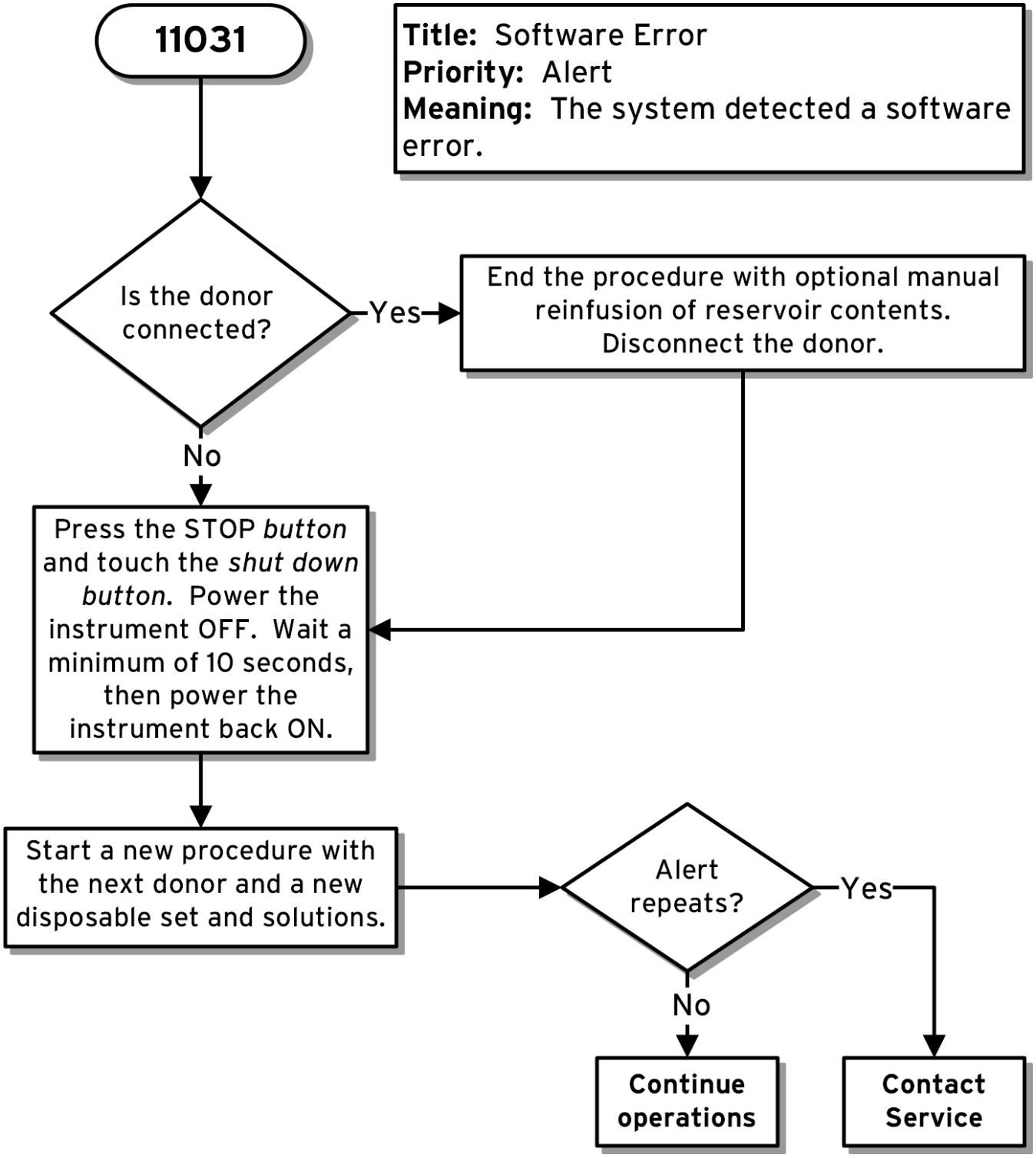


Figure 257: 11035 Clamp Fault

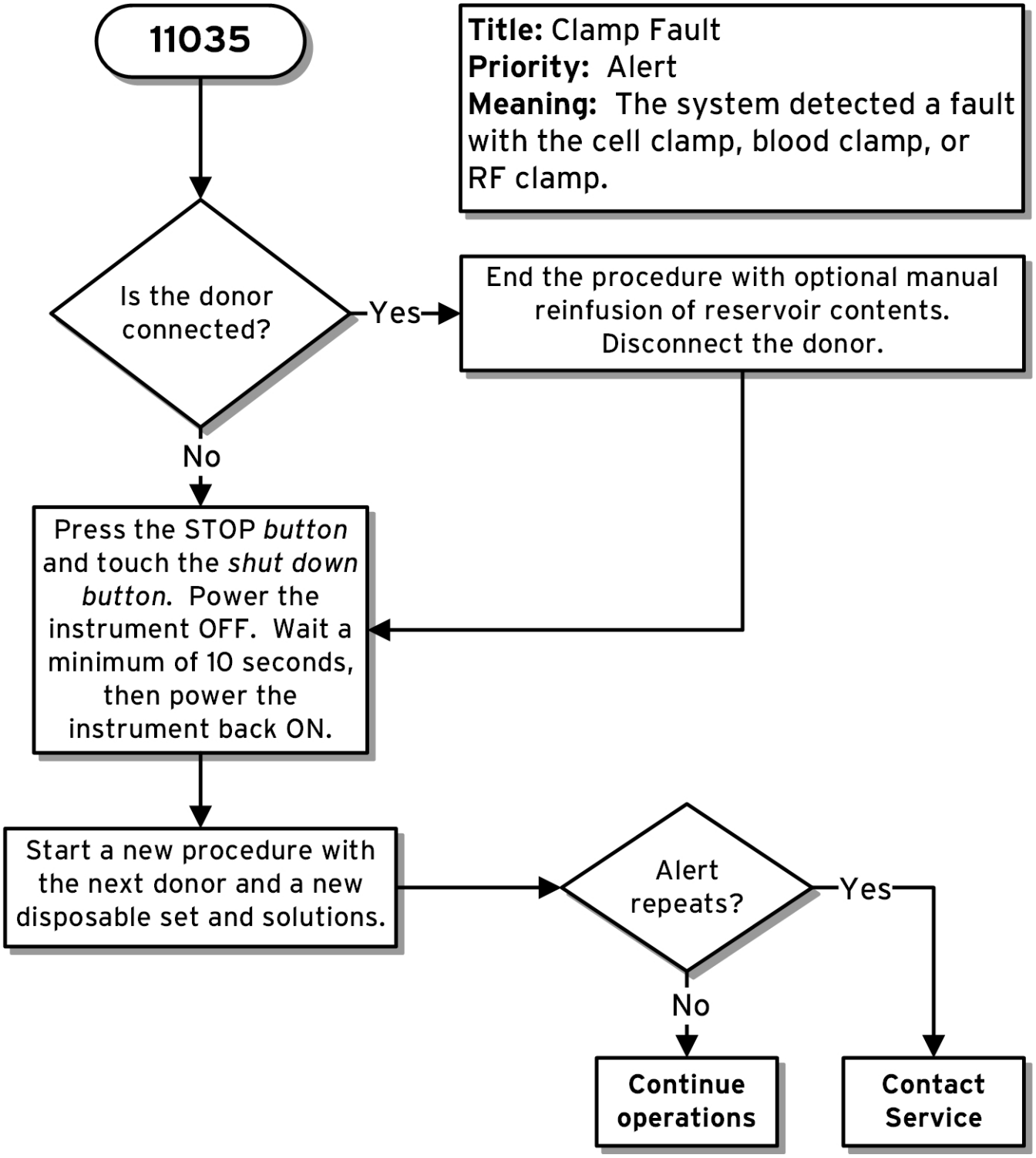


Figure 258: 11044 Power Failure

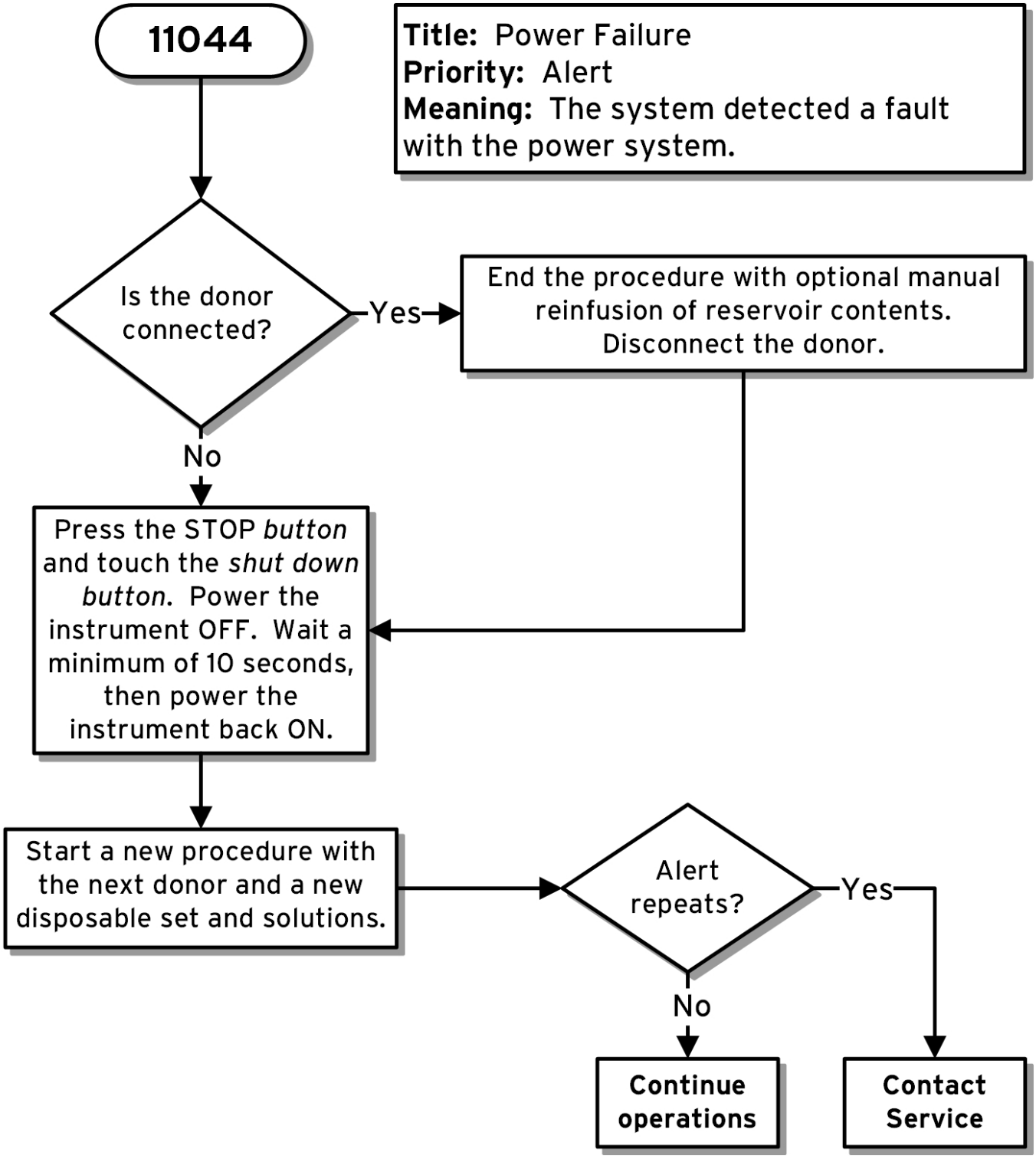


Figure 259: 11070 Cuff Left Inflated

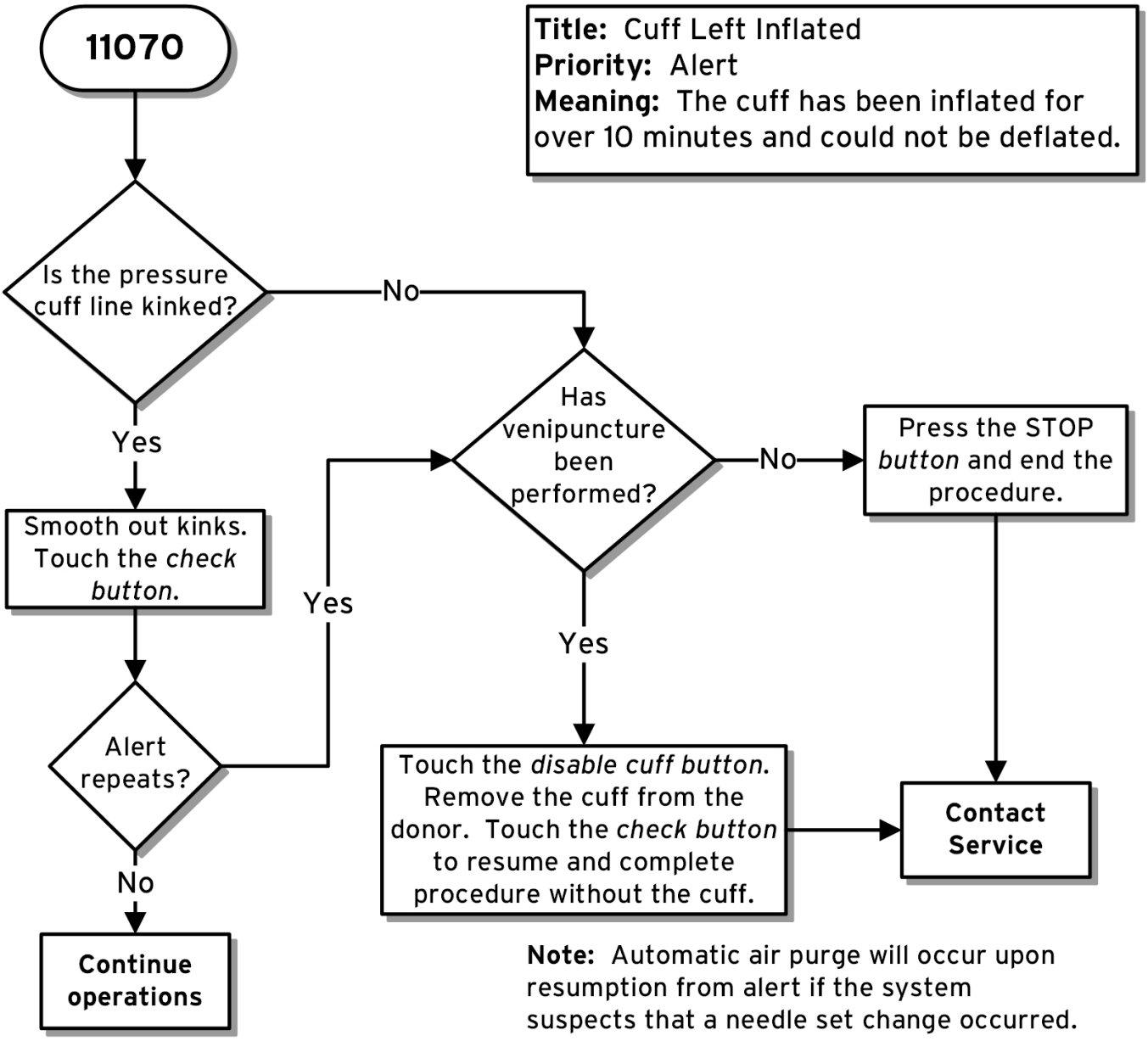


Figure 260: 14011 Software Error

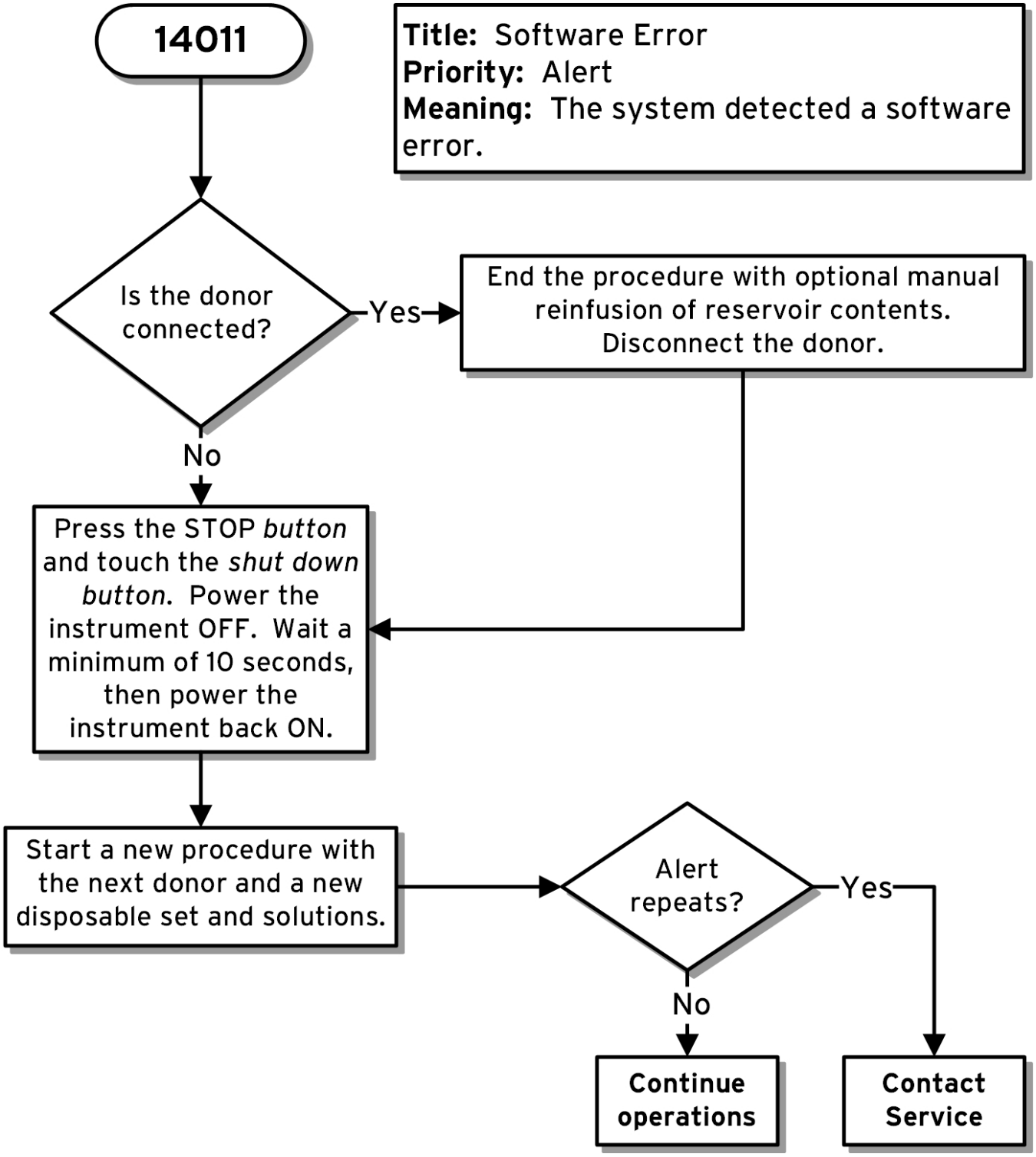


Figure 261: 15001 Software Error

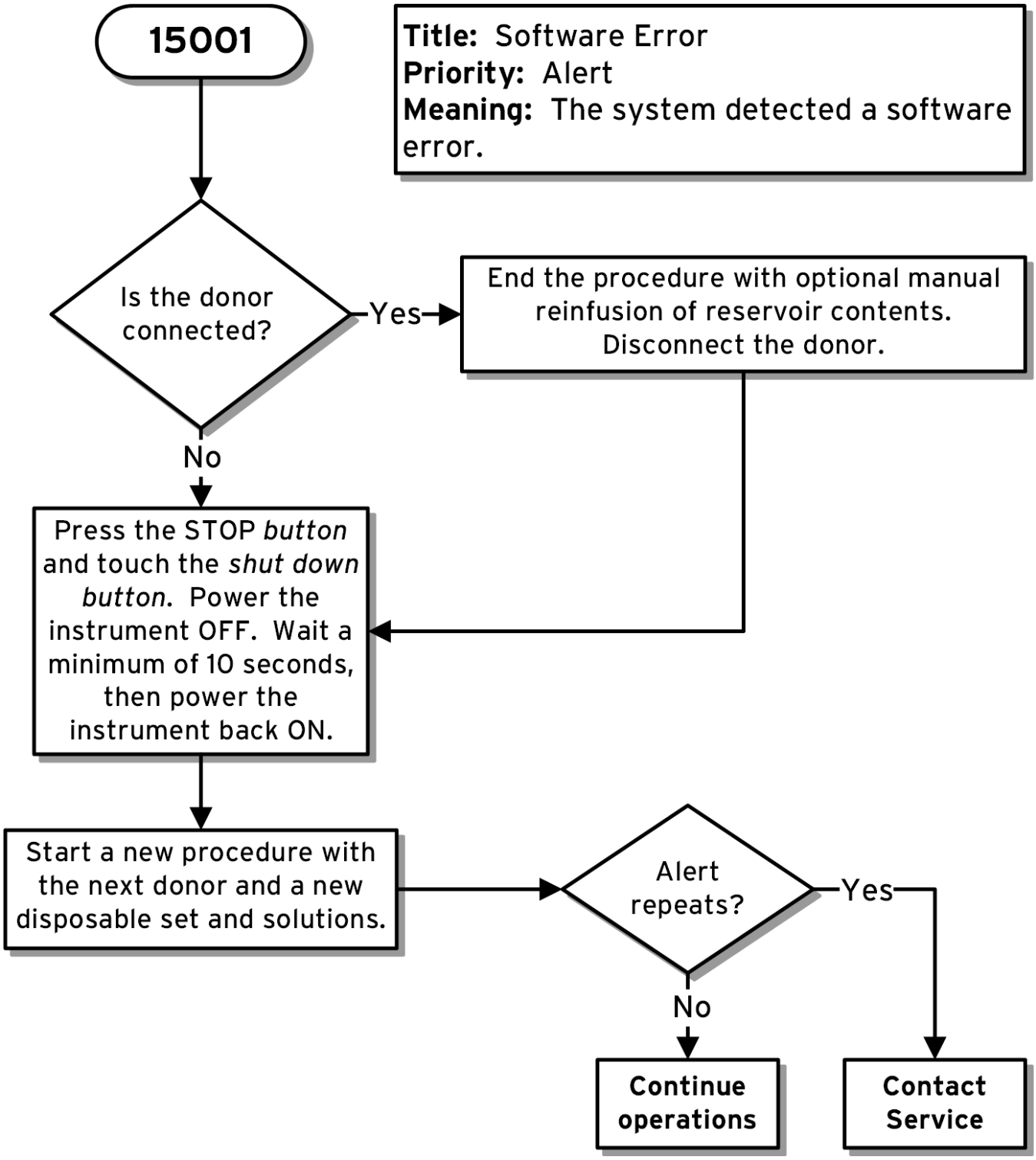


Figure 262: 15003 Software Error

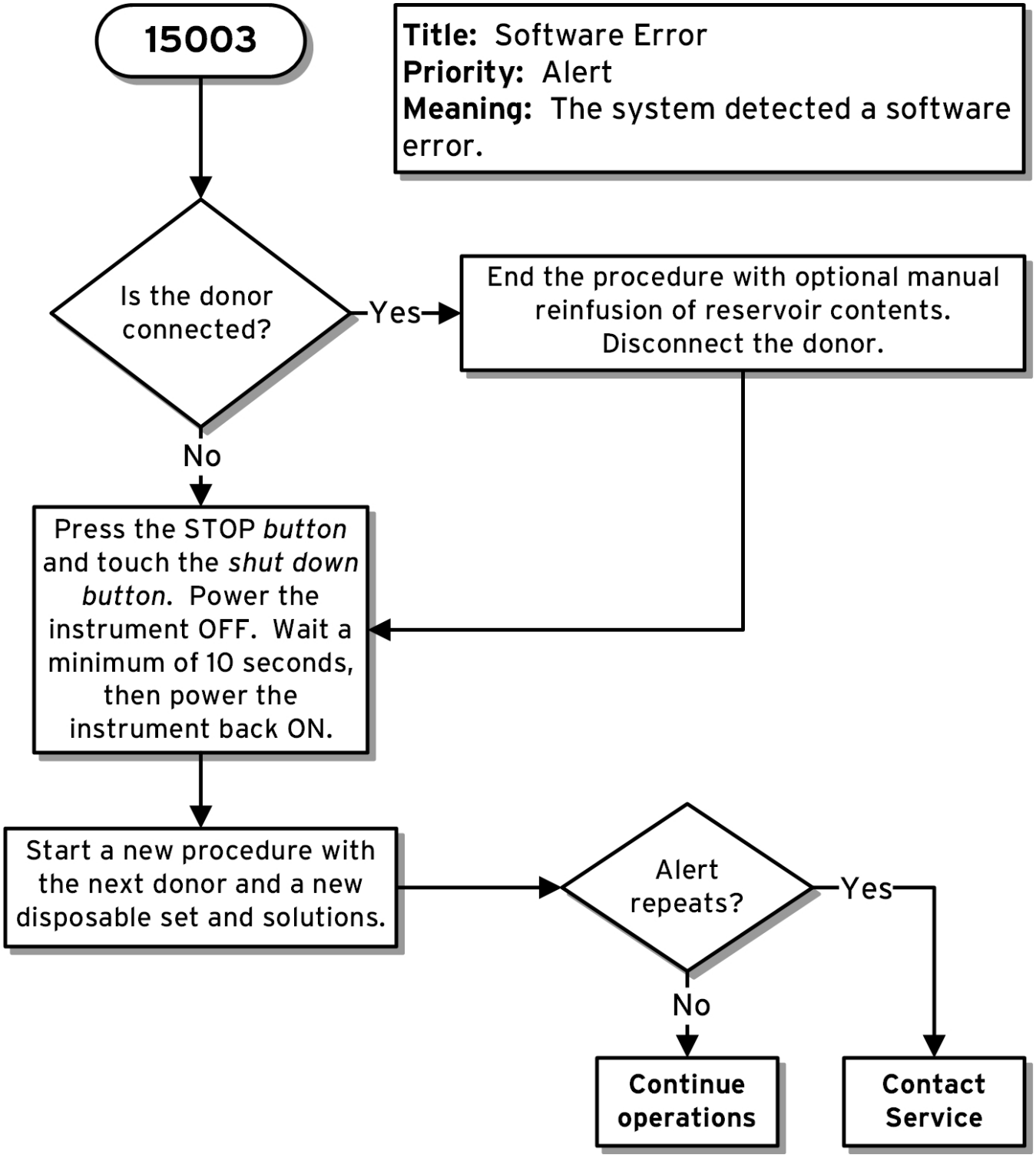
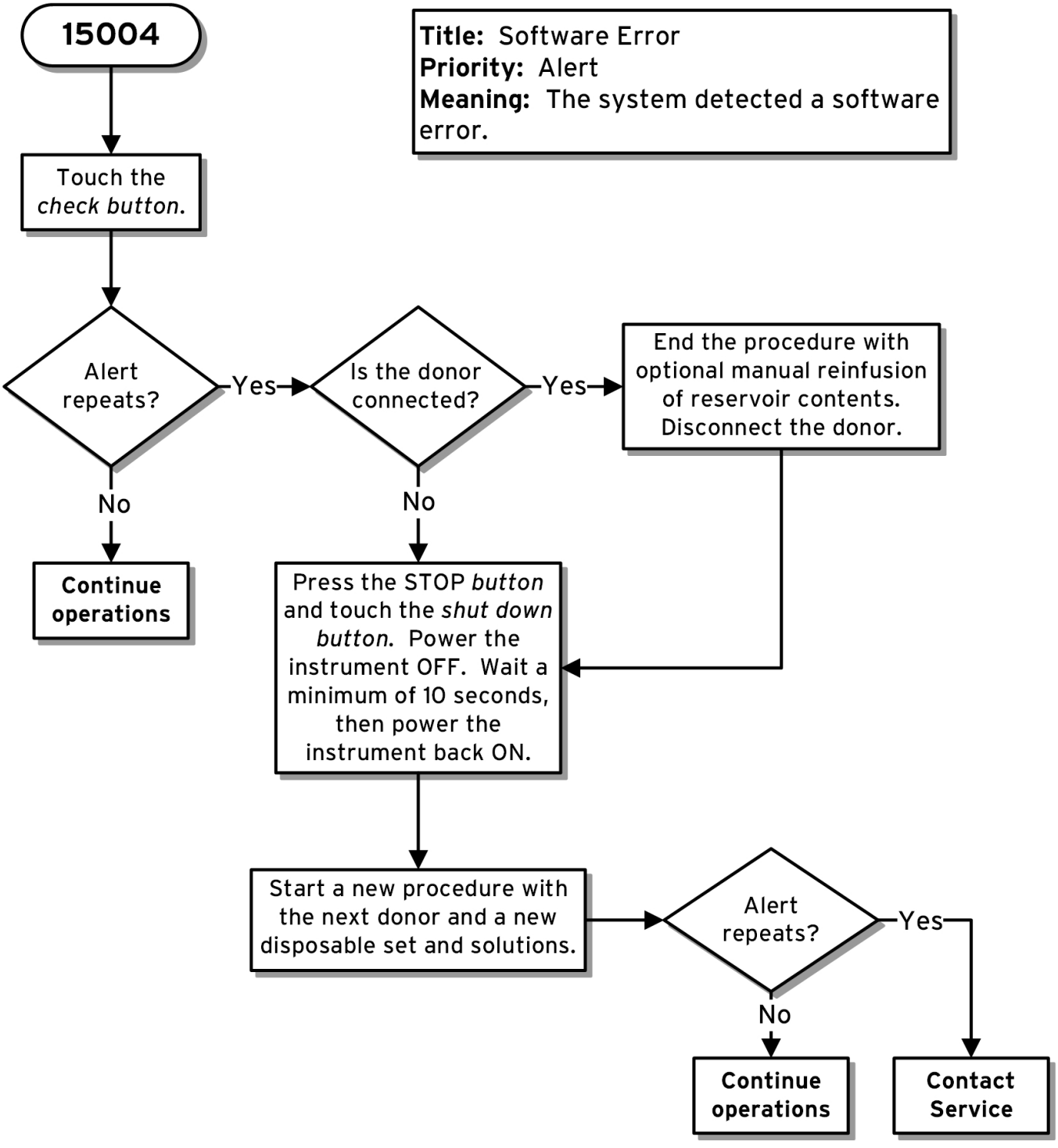


Figure 263: 15004 Software Error



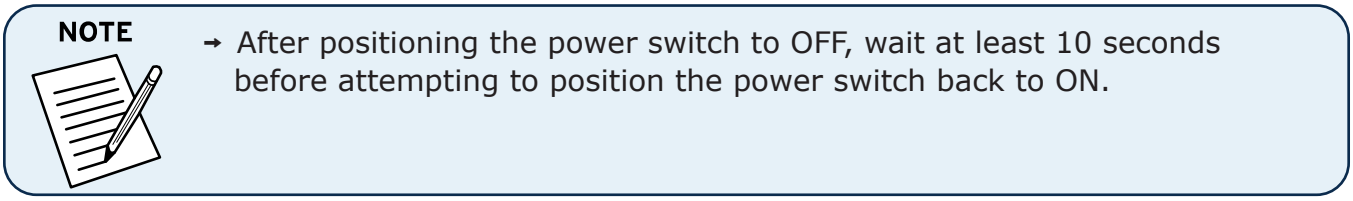
Section 5.3: Non-Alert/Alarm Troubleshooting

This section provides troubleshooting instructions for situations that do not involve an alert/alarm code generated by the device. Refer to the list below and go to the appropriate situation and follow all instructions.

No Display or Touchscreen Response

If the touchscreen has no display or does not respond to touch, follow the instructions below:

1. If a donor is connected, perform the following; otherwise, go to the next step.
   - Press the **STOP** button. If desired, perform manual reinfusion of reservoir contents according to your center's SOPs. Disconnect the donor and follow the center's SOPs for venipuncture site care. Seal the disposable set.
2. If total residual blood loss needs to be obtained, see **"Section A.3: Total Residual Blood Loss"**. If collection volume needs to be determined using an available device, see "Weigh Product" for additional information.
3. Power OFF the device.



4. Remove the disposable set.
5. Power ON the device.
6. If the display is responding, procedure results can be accessed by tapping the **Procedure View** button on the **Home** screen.
7. If there is still no display or touchscreen response, power OFF the device and contact your authorized service personnel or local service representative.

Unexpected Noise in Separation Device / Particulate Matter in Disposable Set

WARNING

➞ If particulate matter is observed in the disposable set, end the procedure without returning fluids or reservoir contents.

CAUTION

➞ End the procedure without fluid return if there is unexpected noise from the separation device.

If unexpected noise is heard from the separation device and/or particulate matter is observed in the disposable set, follow the instructions below:

1. Press the **STOP** button to end the procedure without fluid return. Follow the displayed instructions on subsequent screens.

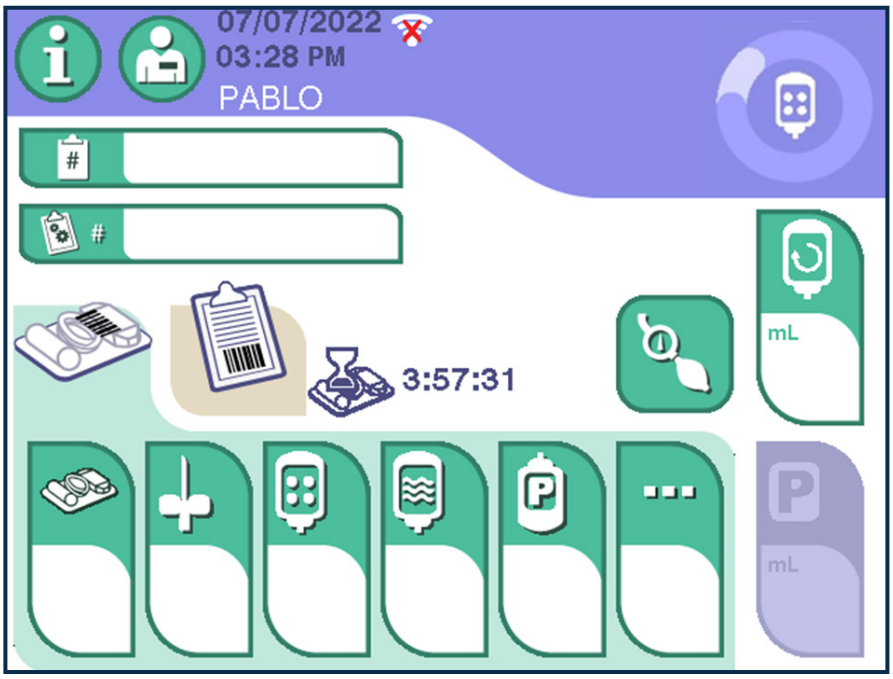
2. Disconnect the donor. Follow your center's SOPs for venipuncture site care, as appropriate.

Reverse Prime During Solutions Prime

If the system detects no solution at the air detector when fluid is expected during Solutions Prime, the system generates alert 2131. Following the instructions provided for alert 2131 in this chapter, once the donor line is placed in the air detector, the operator may resume.

Upon resumption from the alert, the system automatically goes into reverse prime. After reverse prime is complete, the system automatically attempts to perform Solutions Prime.

Figure 264: Typical Reverse Prime



Erroneous Collection Volume Displayed

If the plasma weigh scale is disturbed immediately after final red cell return, the **Procedure Information** screen may display an incorrect collection volume. Suspect collection volumes are displayed as "--- mL" in orange text.

NOTE

- If viewing the instrument status through DXT, the status will show the negative value.

For detailed instructions on how to weigh the collected product on the plasma weigh scale, see **"Weigh Product" on page 4-88**. For instructions on how to calculate the AC and plasma content of the final collection volume, see **"Section A.2: Formula Calculations of AC and Plasma Volume in Plasma Product"**.

Erroneous Red Blood Cell Loss Displayed

If the reservoir weigh scale is disturbed or the reservoir is removed, the **Procedure Information** screen may display an incorrect red blood cell loss. Suspect red blood cell loss volumes are displayed as "--- mL" in orange text. For detailed instructions on how to estimate the red blood cell loss, see **"Section A.3: Total Residual Blood Loss"**.

Fluid Spills or Leaks

For fluid spills or leaks, excluding leaks from the plasma collection container, perform the following steps:

CAUTION

- Clean and disinfect blood spills immediately. Treat all spills and potentially contaminated surfaces as potential biohazards.
- If there is a leak from the plasma collection container, end the procedure with optional fluid return. Estimate and record the collection volume according to the center's SOPs in order to ensure proper reporting of plasma loss.
- If any solution containers have been exposed to blood, treat the containers as potentially biohazardous.

1. Press the **STOP** button to end the procedure without fluid return.
2. Do not reinfuse reservoir contents. Follow the displayed instructions on subsequent screens.
3. Follow the center's SOPs for venipuncture site care, as appropriate.

For detailed instructions on how to clean the device, see **"Section 6.4: Cleaning/ Disinfecting the Device"**.

Unintentional Power OFF During a Procedure

CAUTION

- Procedure results may be inaccurate if the power switch is turned OFF during a procedure. RBC loss must be estimated manually in order to ensure proper reporting.

NOTE

- If the ON/OFF switch to the device is unintentionally positioned to OFF during a procedure, the last few seconds of the electronic record may be lost, resulting in inaccurate procedure data.
- If the power is unintentionally flipped from ON to OFF during a procedure, the battery will not resume the procedure.
- If the power is unintentionally interrupted (i.e., a power outage), the battery will resume the procedure for three minutes (after this time, the device shuts down).

1. If the device is powered OFF during a procedure, do not power the device ON with the donor connected. If desired, perform manual reinfusion of reservoir contents.

2. Disconnect the donor and follow the center's SOPs for venipuncture site care, as appropriate. Seal the disposable set.

3. If you need to check the amount of total residual blood loss, see "**"Section A.3: Total Residual Blood Loss"**. If collection volume needs to be determined using an available device, see **"Weigh Product" on page 4-88** for detailed instructions.

NOTE

- After flipping the power switch to OFF, wait at least 10 seconds before attempting to position the power switch back to ON.

4. Remove the disposable set.

5. Power ON the device.

6. Start a new procedure.

Blood in the AC Line or AC Container

CAUTION

- If blood has moved to the AC container side of the AC pump, end the procedure without fluid return.
- If any solution containers have been exposed to blood, treat the container as potentially biohazardous.

If the AC line tubing is not properly occluded by the AC pump, pressure generated by the blood pump during the Reinfusion Phase can displace the AC solution back past the AC pump, through the AC line, and possibly into the AC container.

If the operator discovers blood moving past the AC pump during the Reinfusion Phase, tap the **Pause** button and follow the troubleshooting flowchart for alert/alarm 10016.

Blood in Saline Line or Saline Container

CAUTION

- If there is blood on the saline container side of the saline clamp, end the procedure with optional fluid return.
- If any solution containers have been exposed to blood, treat the container as potentially biohazardous.

The saline line tubing must be fully occluded by the saline clamp. If it is not, the pressure present in the saline line tubing to the right of the saline clamp may be enough to push blood past the saline clamp and into the saline line tubing and possibly up into the saline container.

If the operator discovers blood in the saline line tubing to the left of the saline clamp or observes blood in the saline container, the operator should verify the following, which may requiring pausing the operation with the **Pause** button:

- The saline line tubing has been installed correctly in the saline clamp.
- The saline clamp is completely closed and properly occludes the saline line tubing.

If an installation error is suspected, the operator may clamp the saline line with a hemostat, make an adjustment to correct the issue, unclamp the saline line, and continue the procedure.

NOTE

- Do not push the saline clamp open at any time during the procedure without clamping the saline line with a hemostat. Only make adjustments to the installation while in the pause state.

If it is verified that the tubing has been installed correctly and the cause of blood in the saline line or saline container cannot be identified, press the **STOP** button to terminate the procedure. The procedure may be terminated with or without fluid return.

Low Saline Delivery (for Saline Protocol)

During a Saline Protocol, saline delivery may automatically end early, resulting in a lower than targeted saline delivery due to a mechanism that is meant to detect when the saline container empties completely. Do not manually open the saline clamp to infuse any remaining saline.

While saline is being delivered, the device is monitoring the air detector to determine if the container is empty. If air is detected multiple times during saline delivery, the saline delivery automatically stops, and the system advances to the end of the procedure. In this case, the volume of saline used presented on the **Procedure Results** screen may be less than the target saline volume. This may occur if the container is spiked improperly or is not hung properly. Always check that the saline container is fully spiked and hanging freely. The number of air detections to consider infusion complete may be adjusted via the setting Air in Rinse as described in the Administrator's Guide .

Also, kinks in the saline port or saline line may restrict the flow of saline, causing the pump-tracked volume to be incorrect and result in low saline delivery. In this case, the volume of saline used presented on the **Procedure Results** screen equals the target saline volume. Ensure that the port and saline lines are not kinked.

Low Blood Flow Rate

Flow rates may be limited due to venous pressure (IFC) and/or citrate infusion control. Citrate infusion rate control manifests during the Reinfusion Phase only, and is observed as an inability to increase the target return rate. This typically occurs during the first Reinfusion Phase of a No Saline Protocol with a low-weight, high-Hct donor or after repeated usage of the **Reverse Cycle** button**.** To resolve low blood flow rates due to the citrate infusion rate, allow the Reinfusion Phase and the next Collection Phase to run to completion.

Venous pressure, as managed by intelligent flow control (IFC), may slow flow rates during the Collection Phase and/or Reinfusion Phase, and is observed as an ability to increase the target draw or return rate, but an inability to maintain a high flow rate. The **Auto Occlusion Restart** icon is typically displayed. To resolve low blood flow rates due to IFC, follow the instructions below:

1. Check for kinks in the following areas:
    - Blood line
    - Donor line
    - P1 Sensor line
2. If there is a kink, tap the **Pause** button**,** untwist the tubing or smooth out the kinks, then tap the **Start** button to resume the procedure.

3. Check venipuncture for blockage. Adjust the apheresis needle as needed and adjust the cuff pressure, if necessary.

4. Check the blood pump tubing installation. Follow the instructions below:

5. Tap the **Pause** button.

6. Clamp the donor line with hemostats, then open the blood pump.

7. Confirm that the tubing is centered on the rollers. Close the blood pump and remove the hemostat from the donor line.

8. Tap the **Start** button to resume the procedure.

Manual Saline Administration (for No Saline Protocol)

When performing offline saline administration, follow the saline administration set manufacturer's directions for use to avoid air infusion.

During a No Saline Protocol, the **Infuse Saline** button is disabled. If saline infusion is considered necessary, the following steps should be taken:

1. Press the **STOP** button to end the procedure with optional fluid return. Follow the displayed instructions on subsequent screens.

2. Once all the reservoir contents are returned to the donor (if applicable), clamp the donor line on both sides of the apheresis needle connector with hemostats.

NOTE

➔ Once the disposable set is disconnected from the apheresis needle in the procedure, it must not be reconnected.

3. Disconnect the disposable set and connect an administration set to the apheresis needle assembly. Unclamp the apheresis needle tubing and adjust the saline drip.

4. When the desired amount of saline is infused, disconnect the donor. Follow the center's SOPs for venipuncture site care, as appropriate.

Change Apheresis Needle Set During the Procedure

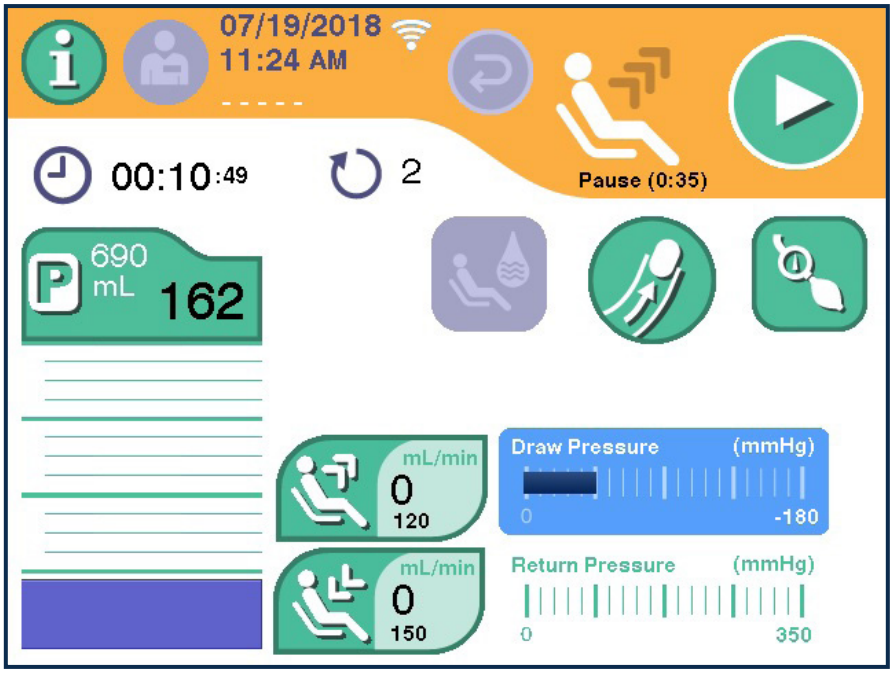
During the plasmapheresis procedure, venipuncture problems may halt the flow of blood. If the needle cannot be repositioned to provide adequate flow, a new venipuncture may be performed in the following manner:

CAUTION

- Perform venipuncture according to center's SOPs.
- Do not attempt to clear the donor line, blood line, or needle, or resolve a venipuncture problem by infusing saline to the donor.
- After changing a needle set, prime the needle set and clear air from the donor line to prevent infusion of air to the donor.
- The donor venipuncture site must be positioned above the fluid in a connected AC container, in order to provide redundant means of protection against citrate infusion.
- Secure the position of the fistula after venipuncture to reduce the likelihood of the needle being removed from the vein during the procedure.
- The operator should monitor the venipuncture site for any adverse effects (e.g., hematoma formation).

1. If the procedure has been started, tap the **Pause** button.

Figure 265: Typical Change Apheresis Needle Set During the Procedure – Paused



2. Clamp or seal the apheresis needle set tubing. Clamp the donor line with hemostats on the disposable set side of the needle connector.

3. Disconnect the apheresis needle set from the disposable set, then discard according to your center's SOPs.

4. Tap the **Cuff Pressure** button to open the **Cuff Pressure Adjustment** overlay, then deflate the cuff.

Figure 266: Typical Change Apheresis Needle Set During the Procedure – Cuff Pressure When Venipuncture Arm Selection Setting is Enabled

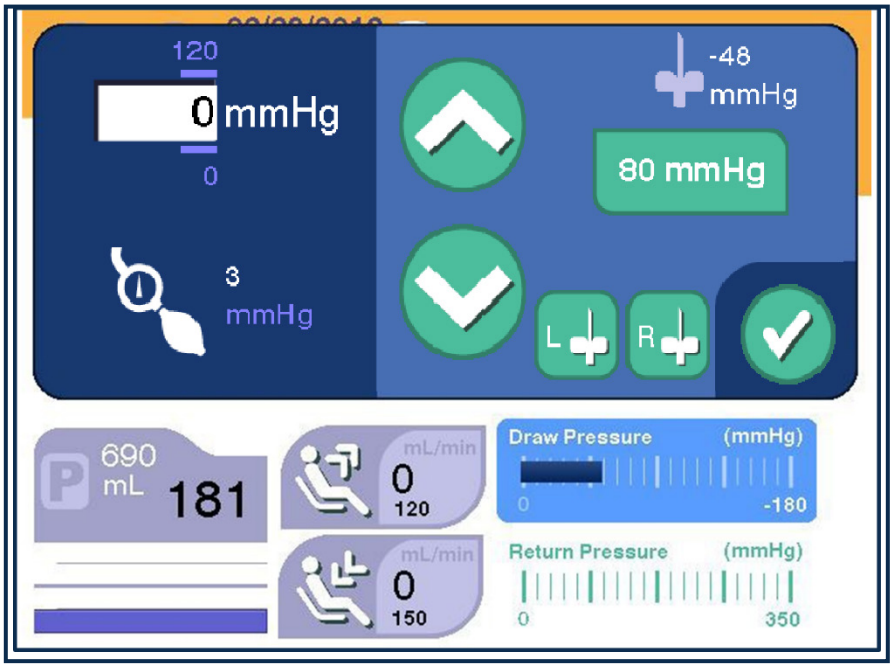
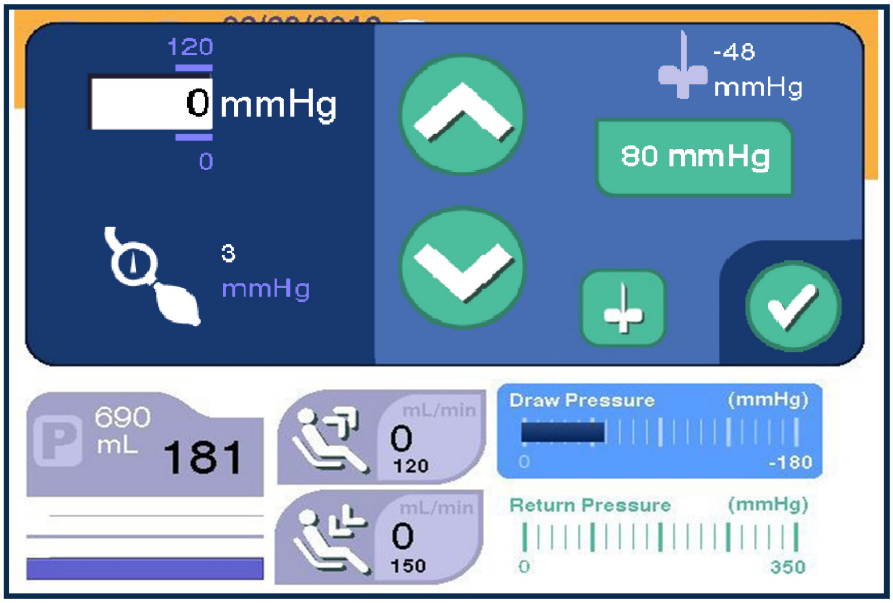


Figure 267: Typical Change Apheresis Needle Set During the Procedure – Cuff Pressure When Venipuncture Arm Selection Setting is Disabled



5. If needle data entry is required according to your center's SOPs, refer to **"Entering Disposables Data" on page 4-5** to add the data for the new needle in the Procedure Record.

6. Place the pressure cuff on the alternate arm. Then, inflate it to the desired pressure on the **Cuff Pressure Adjustment** overlay. The actual cuff pressure and P1 pressure are present on the overlay.

7. Perform a new venipuncture according to the center's SOPs. Allow the blood to flow to the needle connector.

8. Place a hemostat on the apheresis needle set. Connect the apheresis needle set to the disposable set, leaving hemostats in place.

NOTE

→ The P1 (venous) pressure can be used to monitor the pressure at the donor's vein while performing a new venipuncture.

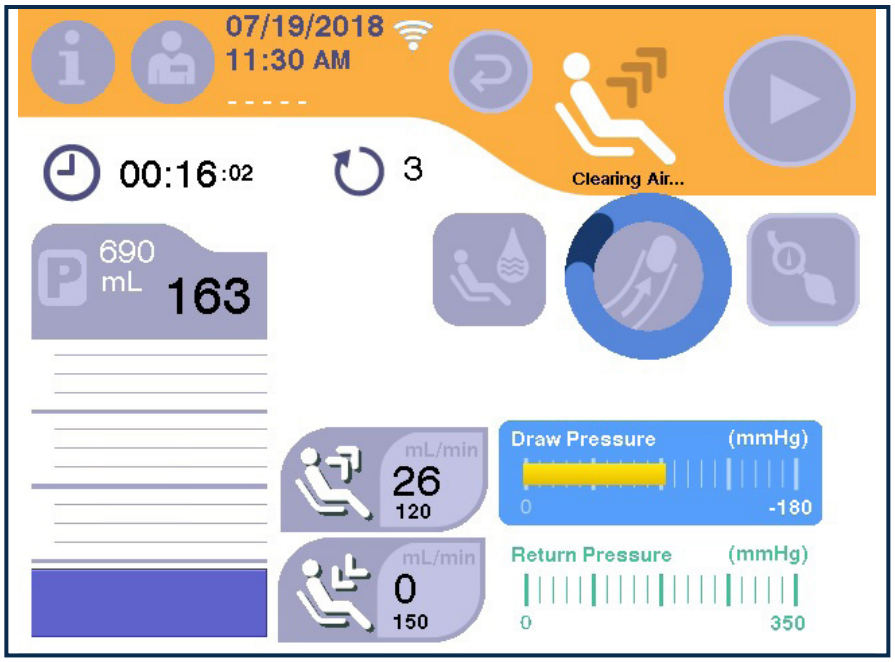
9. If venipuncture arm entry is required, tap the **Left** or **Right Needle Set Change** button for the selected arm. This records which arm the new venipuncture was performed on. If venipuncture arm entry is not required, tap the **Needle Set Change** button**.**

10. Exit the **Cuff Pressure Adjustment** overlay. Remove the hemostats.

11. Tap the **Clear Air In Line** button.

    - This primes the line and removes any air bubbles that were created during the connection process.
    - The button animates while the system clears air from the line. Repeat if necessary.

Figure 268: Typical Change Apheresis Needle Set During the Procedure – Clear Air in Line Button Tapped



NOTE

- The process cannot be cancelled from the touchscreen. To cancel a running action, the operator must press the **STOP** button.

12. To resume the procedure, tap the **Start** button**.**

Manual Reinfusion of Reservoir Contents

CAUTION

- Before performing optional manual reinfusion of reservoir contents, inspect the donor line and reinfusion line between the reservoir and apheresis needle for air bubbles. If air is present, do not proceed with the manual reinfusion process.
- While performing optional manual reinfusion of reservoir contents, the system will not be able to detect any air present in the line. Therefore, the operator must continuously monitor the donor line for air bubbles during the manual reinfusion process. If you observe air in the line, immediately clamp the line and end manual reinfusion.

NOTE

- If the operator performs optional manual reinfusion of reservoir contents, the RBC loss value in the device Procedure Record may be incorrect. To estimate RBC loss, see **"Section A.3: Total Residual Blood Loss"**.

Perform manual reinfusion of reservoir contents only as appropriate according to the center's SOPs.

1. Press the **STOP** button**.**

2. Carefully remove the reinfusion line from the closed reinfusion clamp by pressing the center of the clamp and gently pulling the line out.

3. Open the blood pump. Observe the level of concentrated cells in the reservoir. The level should drop slowly as the contents return by gravity to the donor.

4. To speed the reinfusion process, remove the tubing from the blood pump and cell pump. Remove the reservoir and hold it vertically as high as possible without kinking the reinfusion line tubing.

NOTE

- Avoid tipping the reservoir, which may wet the vent filter. Wetting the vent filter may prevent flow of fluid from the reservoir.
- Removal of the reservoir from the reservoir weigh scale may result in an alert/alarm.

5. Once the reservoir is empty (or if you observe air in the donor line), immediately clamp the line with hemostat.

6. Disconnect the donor. Follow your center's SOPs for venipuncture site care.

Plasma Collection Ends Automatically Prior to Reaching Target Collection Volume (Unit Under Nomogram)

If donor plasma loss may exceed the safety limit when processing blood to reach the target nomogram value, the system may complete plasma collection prior to reaching the target collection volume. This scenario is most common with low-weight, high-hematocrit donors. In this case, the system displays a notification highlighted in orange on the **Procedure Results** screen informing the operator that the Max Plasma Limit has been reached. Additionally, the **Event Summary** tab on the **Procedure Record** overlay indicates Donor Collection Volume Limit Reached; this also appears in the electronic record sent to the data management system.

The procedure may also time out and trigger the end of plasma collection. Components of Aurora Xi are qualified to perform to specification for up to 90 minutes of separation. Therefore, if 90 minutes has elapsed since venipuncture, the system may complete plasma collection prior to reaching the target collection volume. In this case, the system displays a notification highlighted in orange on the **Procedure Results** screen informing the operator that the Process Time Limit has been reached.

Investigating a Unit Over Nomogram that has Occurred

A Unit over Nomogram (UON) is defined as a plasma unit whose collected volume is over (greater than) the targeted volume by an unacceptable amount. The expected performance of Aurora Xi is that the displayed collection volume is within +/- 5 mL of the target collection volume. Refer to the center SOP's for their definition of a UON, as they may have a different threshold.

NOTE

- If the plasma collection container *has not* been disturbed (adjusted or removed from the weigh scale) and the final displayed collection volume exceeds the target collection volume by more than the expected threshold, begin at Step 1.
- If the plasma collection container *has* been disturbed (adjusted or removed from the weigh scale), begin at Step 3.

1. Examine the underside of the weigh scale to determine if the post connected to the hanger is in contact with the housing.

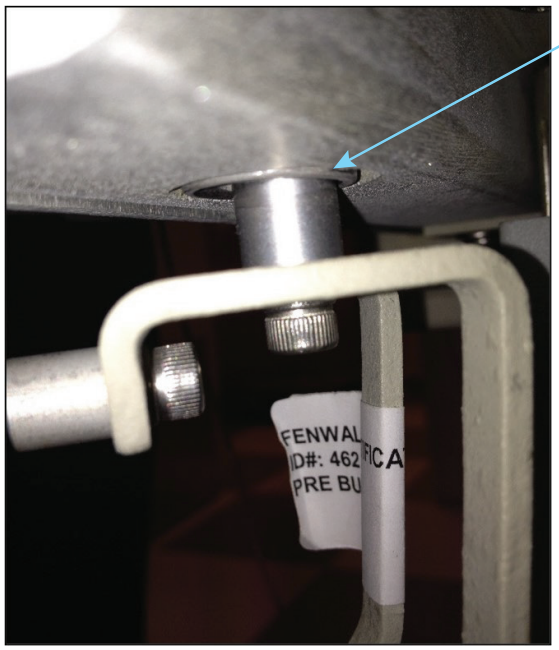
Is the post is in contact with the housing?

- **Yes:** proceed to Step 2.
- **No:** proceed to Step 3.

2. Inspect the device and disposable set to determine if an extraneous load is applied to the weigh scale.

- Is the plasma collection container correctly mounted on the hanger (i.e., placement of bottle onto hanger, placement of bag onto loading posts)?
- Does the pressure cuff tubing, donor line tubing, donor or donor's clothing, or external objects (e.g., waste receptacle) interfere with the plasma collection container or hanger?
- Do applied label(s) on the plasma collection container contact the shroud, column, or other objects?
- Is the plasma line tubing twisted or interfering with the plasma collection container or device?

Figure 269: Contact of Post with Housing



If an extraneous load is identified and corrected, and the post no longer contacts the housing, the cause for the UON event has likely been identified. For additional assurance that there are no other issues, proceed to Step 5. Otherwise, proceed to Step 6.

If an extraneous load cannot be identified, and post continues to contact with the housing, proceed to Step 3.

3. Perform an inspection of the plasma collection container, if available.

- **If a bottle is utilized:** Inspect the neck of the bottle for damage that prevent the bottle from hanging freely.
- **If a bag is utilized:** Inspect the hanger holes for position and/or damage that could prevent the bag from hanging freely.
- Record the total weight of the removed plasma collection container and the representative weight of the empty plasma collection container (including any applicable labeling). This information may be used in Step 6 if needed.

4. Review Procedure Records and download data.

- What is the calibration history of the weigh scale? Have there been any failed QC checks recently?
- Review the procedure record and identify if any plasma weigh scale-related alerts/alarms (e.g., Alert/Alarm 2030, 3021, 3024, 3025, 10011, 10021) or plasma flow disturbances (Alert/Alarm 3005) were recorded during the procedure. This information may be used in Step 6 if needed.
- Were any weigh scale issues observed during previous donations?
- Obtain log files of the procedure and representative files of previous donations. This information may be used in Step 6 if needed.

5. Perform an inspection of the device.

- Ensure that the hanger is correctly positioned for the collection container and shroud currently in use.

CAUTION

→ Only use the longer plasma collection bag with the elongated container shroud to prevent inaccurate weight readings.

- Inspect the screw attaching the hanger to the weigh scale to determine if it is loose.
- **If a bag hanger is utilized:** Inspect the hanger posts to determine if they are loose or out of position.
- **If a bottle hanger is utilized:** Inspect the geometry of the hanger to ensure that the bottle contact surface is parallel to the floor and is not bent.
- With the container removed and a hanger attached, examine the underside of the weigh scale to determine if the post connected to the hanger is in contact with the housing.

- ➞ If the post does contact the housing, is the device operating at an obvious inclination?
- ➞ If the post does contact the housing and the device is not inclined, remove the weigh scale and check if an obstruction exists between the weigh scale and the device housing (i.e., debris causing the weigh scale to be tilted at installation)?

- If there have been multiple UONs on the same device, evaluate the accuracy of the plasma collection scale and determine if replacement is needed.
- If no root cause has yet been identified, export Data Logs and Procedure Records for the procedure, as well as other previous donations.

6. Determine whether the cause for the UON was identified.

- **Yes:** take appropriate action to resolve the issue.
- **No:** share the information from the steps above with your Fresenius Kabi Service Personnel.

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Chapter 6
Maintenance and Cleaning

Section 6.1: Device Installation

Authorized service personnel or local service representatives must install the Aurora Xi device, following the instructions provided in the Aurora Xi Service Manual.

Section 6.2: Device Relocation

CAUTION

- The device must be used and stored in the proper operating environment (e.g., temperature, humidity, altitude, and surface incline requirements).
- When unplugging the power cord from the mains supply outlet, grasp the power cord at the plug and not by pulling the power cord wire.
- If the device has been moved or relocated, perform weigh scale checks before starting a plasmapheresis procedure to ensure scale accuracy.

When moving or relocating a device within a center, you should follow these instructions:

- Power OFF the device. Disconnect the power cord from the device.
- Remove any disposable set and solutions or collection containers from the device.
- Unlock the wheels before attempting to move the device.
- Hold the device by the side panels with both hands when moving.
- Do not grab or pull on any components or features on the front panel, upper housings, or solution pole.
- Do not push on any device surfaces labeled "no pushing" to prevent over-balancing.
- Do not move the device over large thresholds, objects on the floor, or other obstacles that may cause the device to tip over.
- Lock the wheels once the device is placed in its desired location.
- Perform weigh scale verification once the device is powered ON and before use. For detailed information about weigh scale verification, see **"Verifying Weigh Scales" on page 3-4**.

Section 6.3: Device Maintenance

CAUTION

- When maintaining the device, use only replacement components, cables, and accessories authorized by the device manufacturer, and be sure to replace all shields, covers, screws, and gaskets in their exact locations as described in the Aurora Xi Service Manual. Failure to do so may result in increased emissions or decreased electromagnetic immunity of the device.
- Do not perform maintenance tasks while a procedure is in progress, to prevent unsafe practices.
- Only a local service representative or authorized service personnel should open or close the rear door of the device.

Routine Maintenance

Routine maintenance and cleaning should be performed by qualified personnel and documented according to your center's SOPs. If any discrepancies are found during routine maintenance, service may be required. Contact authorized service personnel or your local service representative as necessary to make repairs to the device.

Daily

The device manufacturer recommends that all device weigh scales are verified daily. Administrative settings determine the frequency of prompting for verification of weigh scales.

CAUTION

- Power OFF the device at the end of each day to allow the system to self-test its safety systems.

Weekly

Verify the following:

1. The separator support turns freely when rotated.
2. When being closed, the Hb detector assembly and the pressure transducer door snaps shut and remains closed.
3. The plasma, AC, and reservoir weigh scale hangers are straight and securely attached.
4. The touchscreen display is clean.
5. Verify the wheels can lock and roll freely.

Monthly

1. Clean the Hb detector guide and channel in the air detector assembly.
2. Clean the pump rollers and verify that the pump rollers turn freely. Replace any worn or loose components.
3. Inspect transducer Luers for blockage or damage to the outside surface.
4. Remove and clean the lower the air filter per cleaning instructions. For more information, see "Air Filter" under **"Section 6.4: Cleaning/Disinfecting the Device"**.

Preventive Maintenance

Preventive maintenance items must be performed by authorized service personnel or local service representatives at least once every 12 months. See the Aurora Xi Service Manual for detailed instructions.

Section 6.4: Cleaning/Disinfecting the Device

Blood-processing equipment can become contaminated with hazardous and infectious substances. Assume that all equipment used is contaminated and take necessary precautions. Follow the device's manufacturer recommendation to clean and then disinfect components unless otherwise specified in this manual.

CAUTION

- When maintaining the device, use only replacement components, cables, and accessories authorized by the device manufacturer, and be sure to replace all shields, covers, screws, and gaskets in their exact locations as described in the Aurora Xi Service Manual. Failure to do so may result in increased emissions or decreased electromagnetic immunity of the device.
- Do not perform maintenance tasks while a procedure is in progress.
- Power OFF the device before replacing the air filter and tray, disassembling pump assembly components, or replacing the power cord.
- Allow cleaning and disinfecting agents to dry before installing the disposable set.
- Clean and disinfect blood spills immediately. Treat all spills and potentially contaminated surfaces as potential biohazards.
- Do not use solvents or abrasive cleaners (e.g., alcohol or 10% bleach solution) on the device or disposable set.

Components listed in this section may be cleaned and disinfected on an as-needed basis. This may be recorded according to your center's SOPs.

Cleaning Exterior Components

NOTE

- Many conventional cleaning solutions do not disinfect surfaces.

1. Only use a damp and/or lint-free cloth.
2. Only use the following cleaning agents recommended by the device manufacturer:
   - A mild detergent in tap water.
   - A small amount of mild ammonia window cleaner.
3. Follow the cleaning agent application instructions on how to apply to cloth and surface.
4. For detailed instructions on how to clean a device exterior component, refer to the desired component listed.

Disinfecting Exterior Components

NOTE

➔ Many disinfectants are not effective on dirt-covered surfaces, so the device surface must be cleaned first. For detailed information on how to clean device exterior components, refer to the desired component listed.

Perform the following:

1. Only use a damp and/or lint-free cloth.
2. Only use manufacturer-recommended disinfecting agents.
3. Follow disinfectant application instructions on how to apply to cloth and surface.

The device manufacturer recommends the following disinfecting agents:

- HEPACIDE QUAT II Virucidal Disinfectant EPA Reg. No. 5741-18 manufactured by Spartan Chemical Company, Inc.
- SANI-CLOTH Plus Super Germicidal Disposable Cloth EPA Reg. No. 9480-6 manufactured by PDI
- SANI-CLOTH Super Germicidal Disposable Wipes EPA Reg No. 9480-4 manufactured by PDI
- VIREX II 256 EPA Reg No. 70627-24 manufactured by Diversey
- VIREX Tb Germicidal Cleaner and Deodorant EPA Reg. No. 70627-2 manufactured by Diversey
- SPORICIDIN Disinfecting Solution EPA Reg. No. 8383-3 manufactured by Contec, Inc.

Air Detector Assembly

The air detector assembly should be free of debris so the ultrasonic signal can be transmitted and received optimally. Clean and disinfect the air detector with a manufacturer-recommended agent. Wipe the sensor dry with a lint-free swab or cloth.

CAUTION

➔ Allow cleaning and disinfecting agents to dry before installing the disposable set.

Hb Detector

Clean and disinfect the Hb detector's clear plastic lenses using manufacturer-recommended agents or mild soap on a lint-free swab or cloth to prevent scratching or damage.

Touchscreen

Clean the touchscreen with a small amount of mild ammonia window cleaner sprayed onto a lint-free cloth. Do not spray cleaner directly on the screen, as this may damage the device. Allow the screen to air dry.

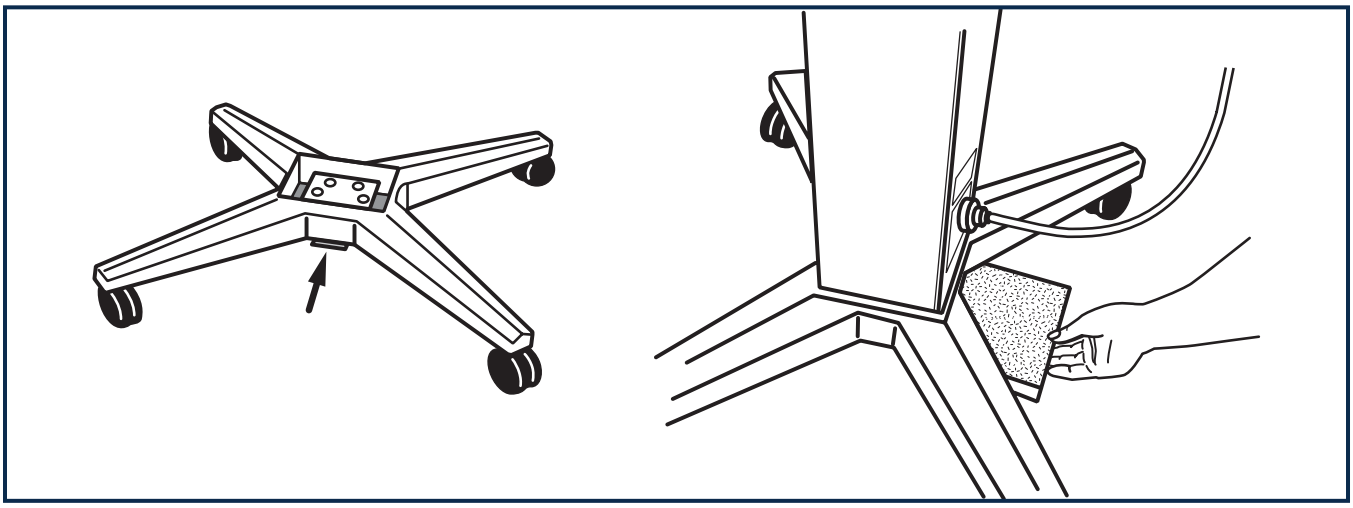
Air Filter

The air filter is located on the base of the device. Remove the filter from the tray. Wash the filter with soapy water. Rinse well and allow the filter to dry completely. Install the dry filter into the tray and reinsert the tray in the device base.

CAUTION

- Power OFF the device before replacing the air filter and tray, disassembling pump assembly components, or replacing the power cord.
- Allow the air filter and tray to dry completely after cleaning and before re-installing it onto the device.
- Do not operate the device unless the air filter and tray are installed.

Figure 270: Air Filter Location



Separator Motor Cup

Clean the motor cup if a leak occurs within the disposable set separator.

CAUTION

- ➞ Clean the separator's motor cup thoroughly after a spill. Ensure that you avoid misaligning the motor cup during cleaning, as misalignment can lead to malfunctions.
- ➞ Do not insert a tightly wadded cloth or a sharp device into the cup. Clean the inside of the motor cup with a mild soap and damp towel. If blood remains after cleaning, do not use the device. The interface between the separator and the motor cup may not function properly.
- ➞ Allow cleaning and disinfecting agents to dry before installing the disposable set.

Pressure Transducer Assembly

The pressure transducer assembly houses the following:

- Two optical blood detectors
- One venous pressure sensor (P1)
- One separator pressure sensor (P2)

In the event of a fluid spill/contamination, the pressure transducer assembly components should be carefully cleaned and disinfected with manufacturer-recommended agent to ensure proper functioning of optical detectors and pressure sensors.

CAUTION

- ➞ Do not use solvents or abrasive cleaners (e.g., alcohol or 10% bleach solution) on the device or disposable set.
- ➞ Allow cleaning and disinfecting agents to dry before installing the disposable set.
- ➞ Never attempt to clean foreign debris from the holes of the pressure sensor ports (P1 and P2). Invasive probing may damage the pressure sensors causing a malfunction.
- ➞ Clean the pressure transducers properly after a spill. If blood remains after cleaning, do not use the device. The pressure transducers may not function properly.

Removing the Pressure Transducer Cover

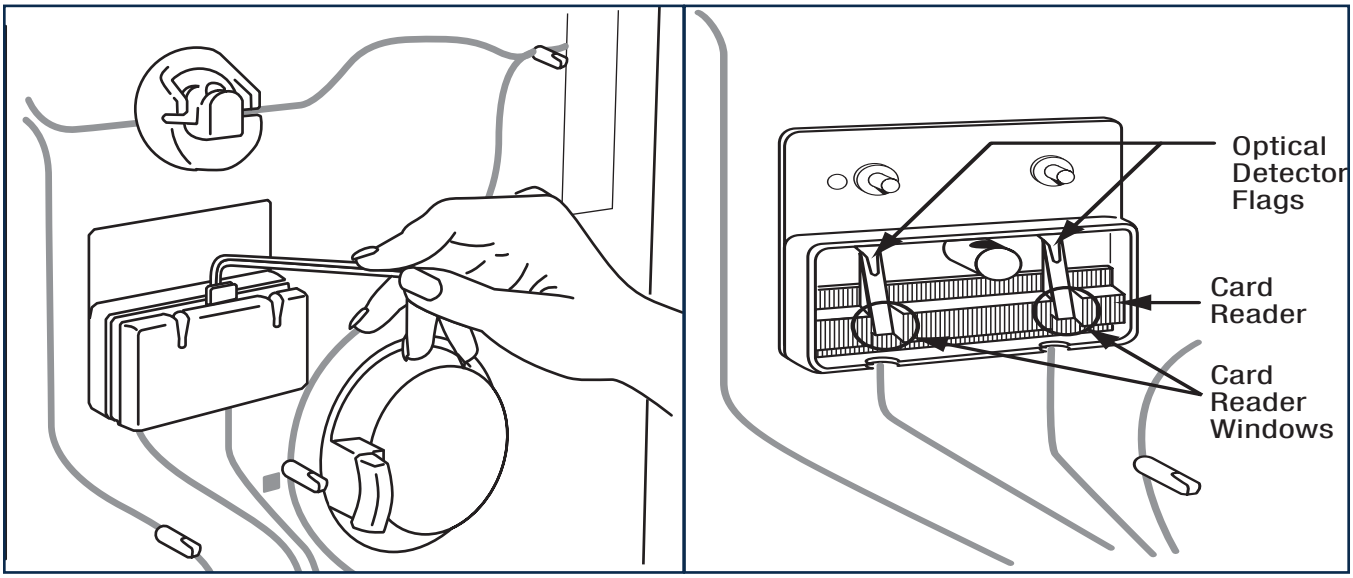
To clean and disinfect the pressure transducer assembly, components, and optical detectors, the cover must be removed as follows:

- Tools Required: 5/32" hex key

1. Pull the transducer cover out. Locate the socket head screw on top of the transducer cover.

2. Using a 5/32" hex key, remove the screw by turning the screw counterclockwise. Support the transducer cover with one hand, as it will be loose.

Figure 271: Removing the Pressure Transducer Cover



3. Remove the transducer cover and set it aside.

4. Observe the black flags between each optical detector. Gently press down on each flag and then release to verify the flags are spring loaded. The flags should return to their prior position.

CAUTION

→ Do not remove or adjust the flags of the optical blood detectors; any adjustment could interfere with cover reassembly and proper functioning of the optical detectors.

5. Clean and disinfect the optical detectors and transducer assembly components with a mild soap/water and manufacturer-recommended disinfectants.

6. Be sure to remove all remaining residue. Dry the transducer assembly components and the optical detector window covers by wiping with a lint-free swab.

Reinstalling the Pressure Transducer Cover

- Tools Required: 5/32" hex key

1. Place the pressure transducer cover plate over the two optical detectors.
2. Insert a socket head screw into the screw hole on the cover plate. Using a 5/32" hex key, securely fasten the screw by turning it clockwise.
3. Press to close the transducer cover.

Pumps

If blood or solution has entered any pump, it is necessary to disassemble, disinfect, and then clean with manufacturer-recommended agents, dry, and reassemble the pump. Disassembly involves removing the pump cover, roller cage, mandrel assembly, and pump cover retainer from the pump housing.

Do not remove the pump housing from the device.

CAUTION

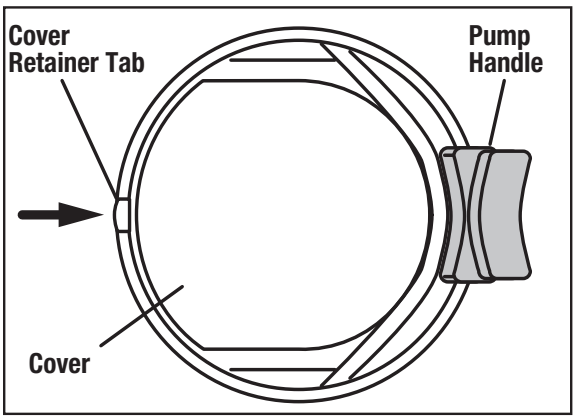
→ Disinfect and clean the pumps properly after a spill. If blood remains in the pumps after cleaning, do not use the device. The pumps may not function properly.

The disinfecting and cleaning instructions apply to the pump components as well as the pump housing.

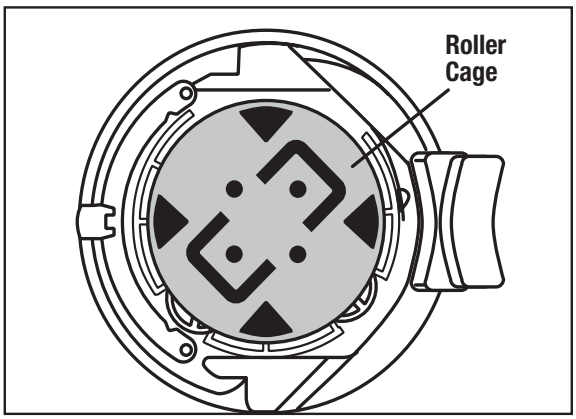
Disassembling Pump Components

1. Ensure the device is stopped.
2. Open the pump handle by rotating it in a clockwise direction.
3. Push the cover retainer tab down, then slide the pump cover toward the pump handle and lift off. See **Figure 272**, Step 1.
4. Remove the roller cage by pulling it away from the front of the device. See **Figure 272**, Step 2.
5. To remove the mandrel assembly, close the pump handle by rotating it counterclockwise. Rotate the mandrel assembly clockwise until the assembly slips out of the slot and pulls off. See **Figure 272**, Step 3.
6. Using a Phillips screwdriver, remove the two Phillips head screws holding the pump cover retainer to the pump housing. See **Figure 272**, Step 4.
7. Lift the pump cover retainer off and away from the device.

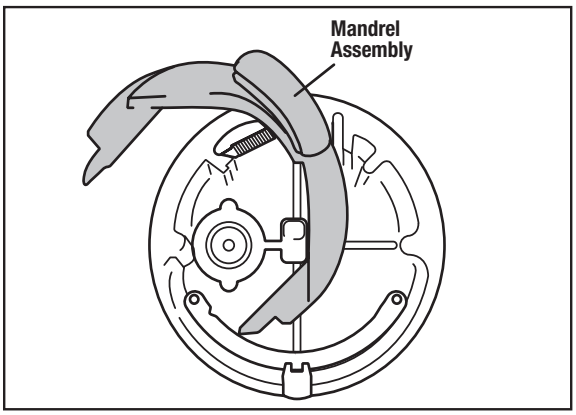
Figure 272: Disassembly of Pumps



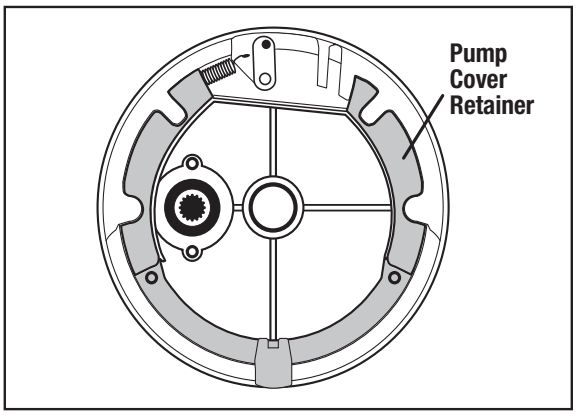
Step 1



Step 2



Step 3



Step 4

Disinfecting and Cleaning Pump Components

1. Immediately soak all pump components (mandrel assembly, roller cage, and pump cover retainer) in a manufacturer-recommended agent.

2. Swirl the components around in the agent to ensure disinfectant coverage on all surfaces of each component.

3. Remove the components from the disinfectant agent and place into a mild soap solution and swirl to ensure removal of all disinfectant agent.

4. Remove the components from the mild soap solution and rinse thoroughly under warm running water.

5. Using a cloth, thoroughly wipe and dry pump components. A hair dryer may be used to speed the process. Do not reassemble the pump until all components are completely dry.

Disinfecting and Cleaning Pump Housing

1. Spray disinfectant solution into the pump housing while holding an absorbent cloth under the housing to catch any overflow.

2. Soak the pump housing in a manufacturer-recommended agent.

3. Using a cloth, wipe the inside of the pump housing to remove the disinfectant agent.

4. Spray, or apply using a cloth, a mild soap solution into the pump housing to ensure all disinfectant solution has been removed. Hold an absorbent cloth under the housing to catch any agent overflow.

5. Using a cloth, wipe the inside of the pump housing to remove any excess water. Using a cloth, thoroughly wipe and dry pump housing. A hair dryer may be used to speed the process. Do not reassemble the pump until all components are completely dry.

Reassembling Pump Components and Pump Housing

1. Install the pump cover retainer onto the pump housing.
2. Using a Phillips screwdriver, install the two Phillips head screws that attach the pump cover retainer to the pump housing.
3. Insert the mandrel assembly, while the pump handle is in the closed position, by placing the mandrel assembly pin into the hole in the brass link and rotating the mandrel assembly counterclockwise.
4. Install the roller cage onto the pump shaft, ensuring that the white gear is on the side closest to the device. Once inserted, place the pump handle in the open position.
5. Install the pump cover by placing it over the roller cage and then pushing the cover towards the cover retainer tab until it snaps into place.

Section 6.5: Parts Replacement

CAUTION

- Only a local service representative or authorized service personnel should open or close the rear door of the device.
- Do not perform maintenance tasks while a procedure is in progress.
- Power OFF the device before replacing the air filter and tray, disassembling pump assembly components, or replacing the power cord.
- When maintaining the device, use only replacement components, cables, and accessories authorized by the device manufacturer, and be sure to replace all shields, covers, screws, and gaskets in their exact locations as described in the Aurora Xi Service Manual. Failure to do so may result in increased emissions or decreased electromagnetic immunity of the device.
- If the device has been moved or relocated, perform weigh scale checks to ensure scale accuracy before starting a plasmapheresis procedure.

The following device parts can be replaced by non-service personnel:

- Air Filter and Tray
- Pump Assembly Components
- Power Cord
- Pressure Cuff
- Plasma Weigh Scale Hanger

Air Filter and Tray

The air filter and tray can be removed and replaced per the instruction **"Section 6.4: Cleaning/Disinfecting the Device"**.

Pump Assembly Components

The pump cover, roller cage, mandrel assembly, and pump cover retainer can be removed and replaced as described in **"Section 6.4: Cleaning/Disinfecting the Device"**.

Power Cord

1. Power the device OFF. For detailed instructions, see **"Section 3.3: Powering OFF the Device"**.

2. Remove the power cord plug from the power source receptacle.

CAUTION

→ When unplugging the power cord from the mains supply outlet, grasp the power cord at the plug and not by pulling the power cord wire.

3. Remove the power cord from the device receptacle.

4. Attach the replacement power cord to the device receptacle and plug the power cord plug into the power source.

Pressure Cuff

1. Locate the pressure cuff fitting on the back lower-right of the device. Remove the fitting from the Luer by turning counterclockwise.

2. Install the replacement pressure cuff to the Luer by turning the fitting clockwise. Ensure that the cuff connector is locked to the device Luer.

Plasma Weigh Scale Hanger

1. Remove the old plasma weigh scale hanger by carefully removing the cap screw with a 5/32" hex key, and detach the hanger from the weigh scale assembly.

2. Install the replacement collection container hanger using the cap screw. Tighten cap screw using a 5/32" hex key.

NOTE

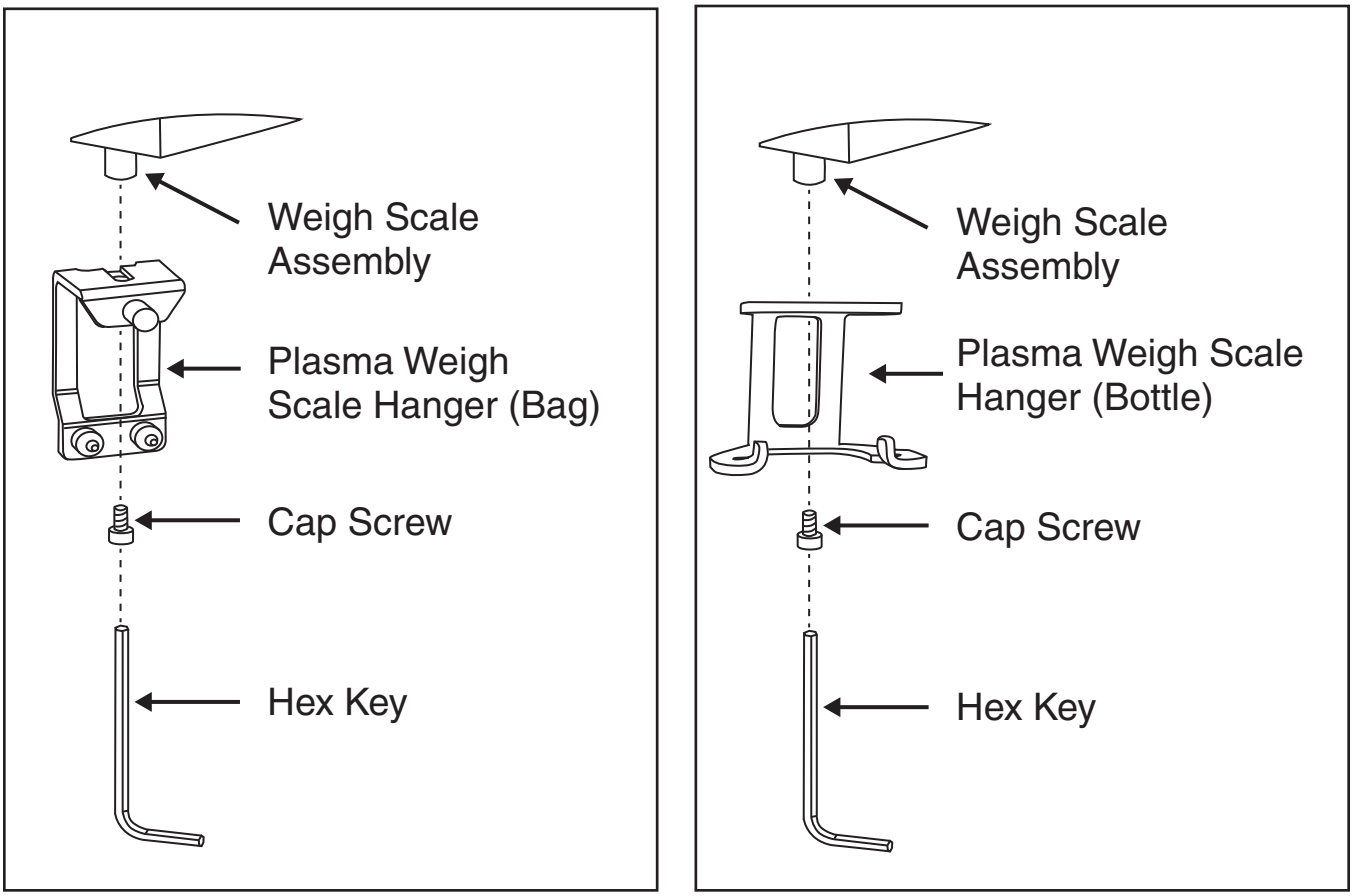
→ Ensure that the plasma weigh scale hanger is aligned with the keyed notch on the weigh scale assembly.

CAUTION

→ Only use the longer plasma collection bag with the elongated container shroud to prevent inaccurate weight readings.

3. Perform weigh scale verification.

Figure 273: Typical Plasma Weigh Scale Hangers



AC Weigh Scale Hanger

1. Remove the old AC weigh scale hanger by carefully removing the cap screw with a 5/32" hex key, and detach the hanger from the weigh scale assembly.

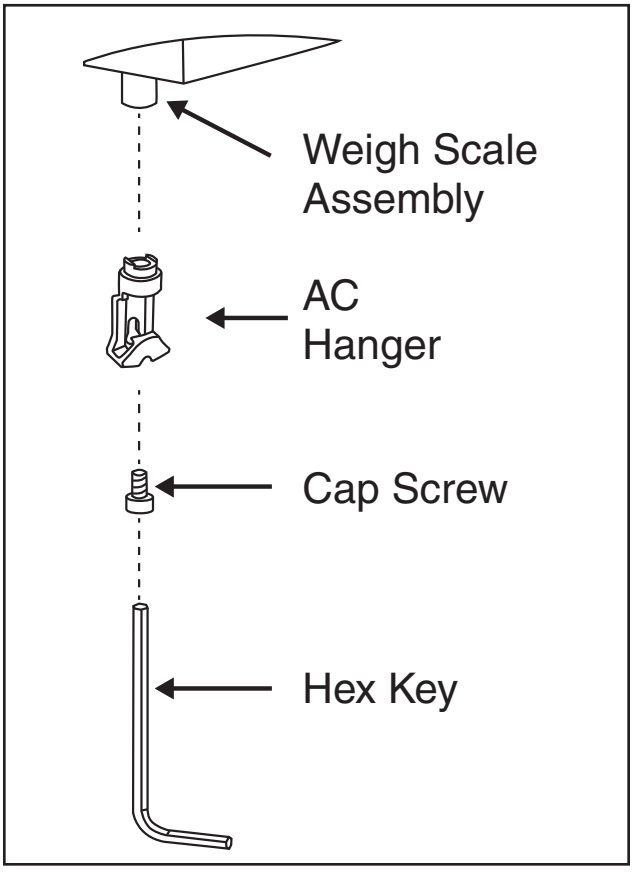
2. Install the replacement AC weigh scale hanger using the cap screw. Tighten the cap screw using a 5/32" hex key.

NOTE

- Ensure that the AC weigh scale hanger is aligned with the keyed notch on the weigh scale assembly.

3. Perform weigh scale verification.

Figure 274: Typical AC Scale Hanger



Section 6.6: Device and Parts Disposal

Device (Product) Disposal

According to Directive 2012/19/EU of the European Parliament and of the Council on waste electrical and electronic equipment (WEEE), for device (product) disposal, ensure the following:

- Do not dispose of this product as unsorted municipal waste.
- Collect this product separately.
- Use appropriate waste collection, product reclamation systems, and part return systems.

Disposing of WEEE correctly helps save valuable resources and minimize potential negative impacts on human health and the environment, which could otherwise arise from inappropriate waste handling.

For more information on return, recovery, or recycling of this product, please contact your authorized service personnel or local service representative.

Parts Disposal

Certain components of the device require appropriate disposal.
These include:

- Battery
- Electrical and Electronic Parts
- Disposable Set

Battery Disposal

CAUTION

→ The backup battery should be properly handled and disposed of to prevent exposure to harmful chemicals.

The Aurora Xi device contains a sealed lead acid rechargeable battery. The battery can only be replaced by an authorized service technician. This type of battery should be recycled after it has reached the end of its useful life. An automotive store or a local waste agency may accept these batteries for recycling. These batteries should not be disposed of in regular, unsorted, municipal waste. Consult your center's SOPs or contact a local service representative if you have any questions about battery recycling.

Electrical and Electronic Parts Disposal

After replacing an electrical or electronic part (e.g., pump, clamp, printed circuit board, etc.) in the Aurora Xi device, the authorized service technician should check if the part is under warranty. If it is, they should return it to the manufacturer. Otherwise, you should take it to a local electronic recycling center.

Disposable Goods Disposal

After use, the disposable set should be disposed of in an appropriate biohazard material container according to local regulations.

Section 6.7: Service

For service in the U.S., or to identify authorized service personnel or your local service representative, call: 1-800-448-5299. Outside the U.S., refer to the contact information on the back cover of this manual. For future reference you may want to record the following information:

In (Country): _____
Name: _____
Tel.: _____
Fax: _____

When you contact us for service, we require the following information from you:

- Device Serial Number
- Account Number and Name
- Description of the Problem
- If applicable, all alert/alarm and data 1/data 2 codes. For detailed information about these codes and their location, see **"Alert/Alarm Screen Elements" on page 5-2**.

Section 6.8: Warranty Statement

Contact authorized service personnel or your local service representative for a copy of the specific written warranty information applicable to your region.

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Chapter 7
System Specifications

Section 7.1: Physical Specifications

The following table provides the approximate physical specifications for Aurora Xi.

	US Customary	Metric
Height (to top of signal light)	63.5 in	161.3 cm
Height (to top of solution pole)	67.5 in	171.5 cm
Width	17.0 in	43.2 cm
Depth	12.0 in	30.5 cm
Weight	92.0 lb	41.7 kg
X-Base:		
Width	27.0 in	68.6 cm
Depth	22.0 in	55.9 cm
Touchscreen:		
Height	3.9 in	10.0 cm
Width	5.1 in	13.0 cm

CAUTION

➔ Aurora Xi is not intended for use as portable equipment.

Section 7.2: Audible Tone Specifications

Audible tones range from 60 – 120 dBA. General device operating tones range from 60 – 70 dBA. Alert/alarm tones range from 70 – 120 dBA at the default sound level, with the loudest tone as the highest priority alarm.

All values are dBA, measured in accordance with ISO3744:2010 at 1 m from the device and 1.5 m from the floor.

Section 7.3: Recommended Operating and Storage/Shipping Requirements

The device manufacturer recommends the following operating, storage, and shipping conditions:

Operating

	US Customary	Metric
Temperature	60 to 90° F	16 to 32° C
Humidity (non-condensing)	10 to 90% RH	
Altitude	0 to 8,000 ft	0 to 2,438 m
Incline	0° ± 2	

Storage/Shipping

	US Customary	Metric
Temperature	0 to 140° F	-18 to 60° C
Humidity (non-condensing)	0 to 90% RH	
Altitude (Storage)	0 to 15,000 ft	0 to 4,572 m
Shipping	The device in its packaging (palletized) is suitable for ground, rail, and air shipment.	

CAUTION

➞ The device must be used and stored in the proper operating environment (e.g., temperature, humidity, altitude, and surface incline requirements).

NOTE

➞ If the device is not plugged in and powered ON at least once every six months for 24 hours, the backup battery may need to be replaced.

Section 7.4: Electrical Specifications

Electrical Rating

100 – 240 V~, 4-2A, 50/60 Hz

Fuses

T4A, 250 V (100 – 120 V Supply)
T2A, 250 V (230 – 240 V Supply)

Power Consumption

Maximum Power: 350 watts
Nominal Power: < 300 watts

➔ Mains power quality should be that of a typical commercial or hospital environment.

Power Cord

Three wire (10 A), 12 ft (3.65 meter), with IEC receptacle.

Battery Specifications

A 12-volt rechargeable sealed lead acid (SLA) battery backup is used to maintain computer memory and display for approximately 5 minutes after a mains power loss. The device will shut down in 3 minutes on battery power in order to avoid an improper shutdown.

A 3-volt non-rechargeable lithium battery is included in the touchscreen SBC module. The battery can be used for backup power for the real-time clock, and has a life expectancy of 7 – 10 years. If the SBC battery fails such that the real-time clock is reset, the device will raise Alert 1003.

Contact your authorized service personnel or local service representative for service and maintenance of these components.

Section 7.5: Standards Compliance

IEC 60601-1:2005 + A1:2012 + A2:2020: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

Classification:

- Type of Protection Against Electrical Shock: Class I, Internally Powered
- Degree of Protection Against Electrical Shock: Type BF Applied Part
- Equipment Not Suitable for Use in the Presence of a Flammable Anaesthetic Mixture With Air or With Oxygen or Nitrous Oxide
- Mode of Operation: Continuous

IEC 60601-1-2:2014 + A1:2020: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests.

IEC 60601-1-8:2006 + A1:2012 + A2:2020: Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

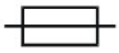
IEC 60601-1-6:2012 + A1:2013 + A2:2020: Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.

Section 7.6: Universal Markings

The following table provides a list of universal markings that may be seen on Aurora Xi or the carton, along with their meanings. This list does not include unique disposable set or device icons, prompts, or buttons displayed on the device's housing, disposable set, or touchscreen. For a complete list of icons, prompts, and buttons used with the Aurora Xi Plasmapheresis System, see the **"Glossary of Graphics"**.

Symbol	Meaning
	Fragile
	Consult instructions for use / consult electronic instructions for use

Symbol	Meaning
	Keep Dry
	This Way Up
	Stacking Limitation
	Do Not Use Sharp Objects to Open Carton
	Product Code
	Maximum Altitude
	Temperature Limit
	Humidity Limits
	Serial Number

Symbol	Meaning
	Unique Device Identifier
	ON (Power)
	OFF (Power)
	Date of Manufacture
	Manufacturer / Manufactured by
	Manufacturing Facility
	Country of Manufacture
Rx Only	For US Only. United States federal law restricts this device to sale by or on the order of a licensed health care practitioner.
	Fuse
	Type BF Equipment
	UL Classification Mark for the U.S.A. and Canada.

Symbol	Meaning
	Product Disposal WEEE 2012/19/EU
	USB Port
	Ethernet Port
	Wi-Fi
	Stop (of Action)
	General Warning Sign
	Warning: Dangerous Voltage
	No Pushing
	Refer to Instruction Manual; Follow Instructions for Use.

Section 7.7: Electromagnetic Compatibility

The following information is provided in accordance with IEC 60601-1-2:2014 + A1:2020 (Edition 4.1). It is well recognized that other corresponding regional standards, such as, EN IEC 60601-1-2, ANSI/AMMI IEC 60601-1-2, have been harmonized with this standard. For regulatory purposes, conforming to this standard implies conforming to other corresponding regional standards unless stated otherwise.

Fresenius Kabi has declared that this product is in compliance with the essential requirements and other relevant provisions of the Radio Equipment Directive (2014/53/EU).

Aurora Xi is designed to withstand the effects of electromagnetic interference (EMI) and is in compliance with the applicable standards in Electromagnetic Compatibility (IEC 60601-1-2).

CAUTION

- Equipment connected to the Aurora Xi device's communication ports must comply with all appropriate UL/CSA/IEC standards for the equipment type in order to prevent electromagnetic interference (EMI) hazards. Furthermore, the combination forms a medical system and may also require standards compliance. Consult a trained representative if there are any questions.
- Device performance may be affected by external electromagnetic fields generated by non-EMC compliant medical equipment and other electromagnetic sources (such as small hand-held radio transceivers).
- When maintaining the device, use only replacement components, cables and accessories authorized by the device manufacturer, and be sure to replace all shields, covers, screws, and gaskets in their exact locations as described in the Aurora Xi Service Manual. Failure to do so may result in increased emissions or decreased electromagnetic immunity of the device.

General Information

The device is designed to be used in a professional healthcare facility environment classified under IEC 60601-1-2. Within such an environment, however, the device is not suitable for use in the following locations, where the intensity of EM disturbances is expected to be very high:

- near active high frequency (HF) surgical equipment;
- close proximate of short-wave therapy equipment, or
- inside the radiated frequency (RF) shielded room of a medical electrical system for magnetic resonance imaging.

The user of this device should ensure the device operates in appropriate locations and avoids the specific locations mentioned above.

The device is expected to operate normally within the intended EM environment since the device has successfully passed all EM immunity tests specified in the Table for Electromagnetic Immunity, which represents reasonably foreseeable maximum levels that could occur in such an environment.

WARNING

➞ Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed.

To reduce the risk of EMI, follow these recommendations:

- Be aware that modifying the device or adding accessories or components, not specifically authorized by the device manufacturer, may make the device more susceptible to interference from radio waves.

The following cables, accessories, and transducers have been validated and approved by Fresenius Kabi for the safe use with the Aurora Xi device (see the System Specification section in this manual for additional details):

- Power Cord (approved by the device manufacturer)
- Ethernet Cable, shielded (approved by the device manufacturer)
- Barcode Scanner, USB (approved by the device manufacturer)
- Pressure cuff (approved by the device manufacturer)

WARNING

➞ Use of cables, accessories, and transducers other than those specified or provided by Fresenius Kabi for the Aurora Xi device could result in increased electromagnetic emissions or decreased electromagnetic immunity of the Aurora Xi device and result in improper operation.

➞ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be no closer than 30 cm (12 in) to any part of the Aurora Xi device, including cables specified by Fresenius Kabi. Otherwise, degradation of performance of the device could result.

Electromagnetic Emission

Aurora Xi is designed to fully comply with electromagnetic emissions requirements under the classification of CISPR11 specified by IEC 60601- 1-2. The table below provides emission compliance information for protection of radio services and other equipment as well as protection of public mains network. The information should help improve the safe use of the device throughout its expected service life in the events of electromagnetic (EM) disturbances.

Table 4: Electromagnetic Emission

Emission Test	Compliance Standards	Emission Precaution Guidance
Conducted and Radiate RF Emission	CISPR 11, Group 1, Class B	Only use cables, transducers, and accessories approved by Fresenius Kabi.
Harmonic Emissions	IEC 61000-3-2, Class A	None.
Voltage Fluctuations/ Flicker Emissions	IEC 61000-3-3	

Electromagnetic Immunity

Aurora Xi is designed to fully comply with electromagnetic immunity requirements for professional healthcare facility environment specified by IEC 60601-1-2. The table below provides immunity compliance information including type of tests, basic EMC standards and immunity test levels that are applicable to the device. The information should help improve the safe use of the device throughout its expected service life in the events of electromagnetic (EM) disturbances. The table also provides precaution guidance on how to reduce EM disturbances.

Table 5: Electromagnetic Immunity

Immunity Test [Basic EMC Standard]	Test Levels Specified by this Standard	Device Compliance Level	Immunity Precaution Guidance
Electrostatic Discharge (ESD) **[IEC 61000-4-2]**	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Compliance at all test levels.	Floors should be wood, concrete or ceramic tile or other anti- or low-static flooring materials. If floors are covered with synthetic material, the relative humidity should be at least 5%.
Electrical Fast Transient/Burst **[IEC 61000-4-4]**	± 2 kV for A.C. power supply lines	Compliance at all test levels.	None.
Surges **[IEC 61000-4-5]**	± 0.5 kV, ± 1 kV line-to-line ± 0.5 kV, ± 1 kV, ± 2 kV, line-to-ground	Compliance at all test levels.	None.
Voltage Dips, on A.C. Power Supply Input Lines **[IEC 61000-4-11]**	Dip: 0% during half cycle at phase angle 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°	Compliance at test level at all phase angles.	None.
	Dip: 0% residual voltage for 1 cycle	Compliance at all test levels.	
	Dip: 70% during 25 cycles for 50 Hz test or 30 cycles for 60 Hz test	Compliance at test level 30 cycle for 60 Hz.	
Voltage Interruptions, on A.C. Power Supply Lines **[IEC 61000-4-11]**	Interruptions: 0% during 250 cycles for 50 Hz test or 300 cycles for 60 Hz test	Compliance at test level: 0% during 300 cycles for 60 Hz test.	None.

Immunity Test [Basic EMC Standard]	Test Levels Specified by this Standard	Device Compliance Level	Immunity Precaution Guidance
Rated Power Frequency Magnetic Fields **[IEC 61000-4-8]**	30 A/m at 50 Hz or 60 Hz	Compliance at test level 30A/m at 60 Hz.	None.
Radiated RF EM Field **[IEC 61000-4-3]**	3 V/m, 80 MHz to 2.7 GHz	Compliance at test level: 3 V/m 80 MHz to 6 GHz.	Portable RF communications equipment should be used no closer to any part of this device, including cables, than 30 cm (12 inches) separation distance. If a minimum separation distance is not maintained, interference may occur in close proximate to equipment marked with the following symbol:  Field strengths from RF transmitters should be less than the compliance level in each frequency range. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level, the device should be observed to verify normal operation. If abnormal performance is observed, additional control measures may be necessary, such as reorienting or relocating the device.
Proximity Fields from RF Wireless Communication Equipment **[IEC 61000-4-3]**	385 MHz, 18 Hz Pulse mod, 1.8 W, 27 V/m 450 MHz, FM mod, ± 5 kHz dev,1 kHz sine, 2 W, 28 V/m 710 MHz, 745 MHz, 780 MHz, 217 Hz pulse mod, 0.2 W, 9 V/m 810 MHz, 870 MHz, 930 MHz, 18 Hz pulse mod, 2 W, 28 V/m 1720 MHz, 1845 MHz, 1970 MHz, 217 Hz pulse mod. 2 W, 28 V/m 2450 MHz, 217 Hz pulse mod, 2 W, 28 V/m 5240 MHz, 5500 MHz, 5783 MHz, 217 Hz pulse mod, 0.2 W, 9 V/m.	Compliance at all test levels.	

NOTE

- The frequencies, field strengths, and services described in the last row of **"Table 5: Electromagnetic Immunity"** represent RF wireless communication equipment in use, known by this standard, and recognized by Fresenius Kabi at the time of publication of this addendum. It does not cover every frequency and service used in every country.
- Field strengths from fixed transmitters – such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast – cannot be predicted with accuracy. To assess the EM environment due to fixed RF transmitters, an EM site survey should be performed.

CAUTION

- If additional frequencies or field strengths are identified that are not presented in **"Table 5: Electromagnetic Immunity"** (last row), the user of this device should conduct additional testing and ensure that the device is operating normally.

RF Transmitter

The table below provides key characteristics of the RF transmitter, including each frequency or frequency band, type and frequency characteristics of modulation and effective radiated power.

Table 6: RF Transmitter

Frequency Band	Frequency Characteristics of the Modulation	Effective Radiated Power
802.11a 5 GHz	802.11a uses a multi-carrier modulation scheme called orthogonal frequency division multiplexing (OFDM). The following modulation formats are available for OFDM: BPSK, QPSK, 16-QAM, 64-QAM.	Meets ETSI EN 301 893 v2.1.0
802.11b 2.4 GHz	802.11b uses direct sequence spread spectrum (DSSS) with CCK or PBCC coding schemes. For the 1 Mbps and 2 Mbps data rates, this cell is called Low Rate Modulation and the modulation format is automatically set to DBPSK and DQPSK respectively and cannot be changed. For 5.5 Mbps and 11 Mbps data rates, this cell is called High Rate Modulation and you can select CCK or PBCC as the modulation scheme.	Meets ETSI EN 300 328 v2.1.1
802.11g 2.4 GHz	802.11g uses either OFDM or DSSS as the modulation scheme. When 802.11g uses a multi-carrier modulation scheme called orthogonal frequency division multiplexing (OFDM), the following modulation formats are available for OFDM: BPSK, QPSK, 16-QAM, 64-QAM.	Meets ETSI EN 300 328 v2.1.1

Frequency Band	Frequency Characteristics of the Modulation	Effective Radiated Power
802.11n/ac 5 GHz	802.11n/ac uses a multi-carrier modulation scheme called orthogonal frequency division multiplexing (OFDM). The following modulation formats are available for 802.11n/ac OFDM: BPSK, QPSK, 16-QAM, 64-QAM, 256-QAM.	Meets ETSI EN 301 893 v2.1.0

Section 7.8: USA Federal Communications Commission (FCC) Notice

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

CAUTION

➔ Exposure to Radio Frequency Radiation. The equipment contains a transmitter; see the device label near the antenna for the FCC ID. The antenna(s) used for this transmitter must be installed to provide a separation distance of at least 20 cm (0 feet 7.87 inches) from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter. End users must follow the instructions from this document for transmitter operating conditions to satisfy Radio Frequency exposure compliance.

Section 7.9: Wireless Protocols and Standards

The device contains an RF transmitter that allows the device to connect to other equipment or networks wirelessly. Wireless functionality on Aurora Xi references and uses the following industry protocols and standards:

- 802.11a, 802.11b, 802.11g, and 802.11 n/ac are wireless networking standards developed by the Institute of Electrical and Electronics Engineers (IEEE). 802.11b/g apply to wireless LANs and work in the 2.4GHz band and operate at a maximum raw data rate of 11Mbps for 802.11b and 54 Mbps for 802.11g. 802.11g devices are backwards compatible with 802.11b devices.
- 802.11a, 802.11b, 802.11g, and 802.11n/ac are wireless networking standards developed by the Institute of Electrical and Electronics Engineers (IEEE):
  - → 802.11b/g: 2.4 GHz, maximum raw data rate of 11 Mbps (b) and 54 Mbps (g); 802.11g devices are backward compatible with 802.11b devices.
  - → 802.11a: 5 GHz, maximum raw data rate of 54 Mbps.
  - → 802.11n: 5 GHz, maximum raw data rate of 600 Mbps.
  - → 802.11ac: 5 GHz, maximum raw data rate of 1.3 Gbps.
  - → Refer to ISO/IEC 8802-11:2005 standards for local and metropolitan area networks for more information.
- 802.11i (Wi-Fi Protected Access) is a security standard for wireless networks:
  - → Configured to 802.11i-PSK with AES-CCMP encryption or equivalent.
  - → Refer to IEEE 802.11i-2004 for more information.
- TCP/IP (Transmission Control Protocol/Internet Protocol) is a standard data transport protocol used for the Internet and other similar networks:
  - → Refer to RFC 1122 for more information.

NOTE

→ Some Aurora Xi devices may support 5 Ghz network configuration.

Section 7.10: Electronic Records

Aurora Xi can be configured to export data to be used to create an electronic record. In this context an electronic record is data stored for official quality or regulatory purposes. To create an electronic record, the operator is required to enter all required information according to the center's SOPs related to the donor and procedure.

NOTE

- Compliance with USFDA's 21 CFR Part 11 for Electronic Records is only achievable when integrated at a system-wide level. The data from Aurora Xi on its own is not fully Part 11 compliant.
- Consult with the center's RA/QA representative for details on the center's specific adaptation of manufacturing and electronic records.
- Required information according to the center's SOPs must be entered to qualify as an electronic record.

When a procedure is completed, the data is automatically transmitted to the data management system for reporting. The transfer of electronic files will not interfere with the procedure.

Section 7.11: Data Communication

Aurora Xi, when connected to the network of the center's donor management system, permits remote communication with a data management system to perform the following functions:

- Remote time synchronization of Aurora Xi with network time server to ensure accuracy of recorded/reported dates and times during collection.
- Remote Procedure Set-Up, which allows the administrator to send a procedure parameters file from the donor data management system to the data management system. Depending on the transmit method selected for the device (see the Aurora Xi Administrator’s Guide — "Procedure Setup Method" section for additional information), the procedure setup file can be retrieved by the operator onto the device by entering a procedure ID or donation setup ID, or the procedure setup file can be sent directly to the device.
- Remote transfer of electronic Procedure Records from the device to the data management system.

Aurora Xi should be deployed within a secure network perimeter to prevent access from unauthorized external system(s). It is further recommended that Aurora Xi and data management system be deployed within a secure network segment that is logically separate from other internal IT use such as email and messaging.

NOTE

➞ The manufacturer recommends that organization IT policy be compliant with IEC 80001-1. Application of risk management for IT networks incorporating medical devices.

Failure to deploy Aurora Xi and data management system within a secure network perimeter may increase the likelihood of the following hazards:

- Unauthorized device access leading to compromised device integrity and functionality,
- unauthorized network access leading to exposure/compromise of other connected devices.

CAUTION

➞ The Aurora Xi Plasmapheresis System and data management system should be deployed within a secure network perimeter to prevent access from unauthorized external system(s).

➞ Equipment connected to the Aurora Xi device's communication ports must comply with all appropriate UL/CSA/IEC standards for the equipment type in order to prevent electromagnetic interference (EMI) hazards. Furthermore, the combination forms a medical system and may also require standards compliance. Consult a trained representative if there are any questions.

Aurora Xi is equipped with a wireless or wired Ethernet interface which is used for data communication. Initial configuration should be performed by a local service representative or authorized service personnel.

When using a cabled (wired) configuration, Aurora Xi must be configured for wired Ethernet. When using a wireless configuration, the exchange of data uses an IEEE 802.11b/g or 802.11 a/n/ac based network to replace the requirement for Ethernet cabling between Aurora Xi and the plasma collection center’s network.

When using a wireless configuration, the user must ensure compatibility between the settings of the Aurora Xi Wi-Fi interface and those of the wireless access point. Consult a local service representative or authorized service personnel for the configuration settings of the Aurora Xi Wi-Fi interface. Incorrect configuration of the wireless network may cause decreased functionality or performance. This appears to the user as slow response times, intermittent failures, or inability to use the system.

CAUTION

➞ Exposure to Radio Frequency Radiation. The equipment contains a transmitter; see the device label near the antenna for the FCC ID. The antenna(s) used for this transmitter must be installed to provide a separation distance of at least 20 cm (0 feet 7.87 inches) from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter. End users must follow the instructions from this document for transmitter operating conditions to satisfy Radio Frequency exposure compliance.

Each facility is unique in its layout and equipment setup; therefore, the user is responsible for the installation, setup, validation, and maintenance of the local area network.

The user must consider appropriate physical placement of Aurora Xi and other wireless devices in order to limit the impact of RF interference. Refer to **"Table 5: Electromagnetic Immunity" on page 7-11** for more information on the separation distance.

The maximum output power of the Aurora Xi Wi-Fi transmitter is 0.1 W at a frequency of 2.4 GHz. Based on this information, it is recommended that the Aurora Xi Wi-Fi antenna is kept at least 0.74 meters (2.5 feet) away from all other Aurora Xi devices and other sensitive electronic equipment. See the **"Section 7.7: Electromagnetic Compatibility"** for more information.

Other wireless devices may interfere with or be susceptible to interference from the wireless functionality of Aurora Xi. See the **"Section 7.7: Electromagnetic Compatibility"** for more information.

The user is responsible for ensuring the wireless coexistence and security of their individual wireless environment in accordance with these recommendations and FDA guidance documents. It is recommended that a thorough RF site survey be performed, depending on the complexity and physical environment of the wireless installation, to ensure coverage and identify areas of electromagnetic disturbance. (For more information, see the FDA/CDRH Guidance document "Radio-Frequency Wireless Technology in Medical Devices Guidance, August 14, 2013"). The user should periodically monitor Aurora Xi for symptoms of RF interference.

With a properly configured network, there should be no issues with data integrity or quality of service when an Aurora Xi device is set up and maintained properly by a local service representative or authorized service personnel. It is recommended that network installation and use be consistent with commonly accepted industry best practices related to cyber and information security.

The system has been tested to withstand additional potentially-interfering emissions from other devices (e.g., donors with Bluetooth mobile phones or headsets); however, in the unlikely event that emissions do interfere with the data transfer, there are no safety implications, since any data communication failures are retried and any data which may be

corrupted are detected using the checksum functionality within the system. The operation of Aurora Xi is not affected by interference with the data transfer.

Section 7.12: Barcode Symbologies

The Aurora Xi Plasmapheresis System supports a variety of barcode symbologies that may be encountered when using the barcode scanner to enter information for a procedure. The symbologies and information recognized by the device when using the barcode scanner are outlined below. More information regarding each symbology can be obtained from the source provided. Refer to Chapter 4 for information and procedures on using a barcode scanner.

Eurocode: Eurocode IBLS International Blood Labeling System Technical Specification Version 2.0 September 2010; published by Eurocode IBLS e.V. (http://www.eurocode.org/guides/index.html)

- Donor ID
- Procedure ID (equivalent to blood product UPN)

ISBT-128: Refer to the ISBT-128 Standard Technical Specification Version 5.6.0 October 2016 (ISBN-13: 978-1-933243-63-4, ISBN-10: 1-933243-63-5); published by ICCBBA (http://www.iccbba.org)

For ISBT-128 barcodes, application identifiers may allow auto-recognition of the associated fields. The application identifiers recognized by Aurora Xi are shown below in parentheses.

- Operator ID: (=’)
- Donor ID: (=;)
- Procedure ID: (=α)
- Donation Setup ID: (&a)
- Code number (REF): includes the apheresis needle, anticoagulant, disposable set, saline, and plasma container (for items other than blood containers ((=) or =-)
- Lot number: includes the apheresis needle, anticoagulant, disposable set, saline, and plasma container (for items other than blood containers (&) or &-)
- Expiration date: includes the apheresis needle, anticoagulant, disposable set, saline, and plasma container (for items other than blood containers (=> or =])

NOTE

➙ Donation setup ID uses custom data identifier characters (&a). The data string content for donation setup ID is the same as procedure ID.

GS1-128: (Previously referred to as UCC/EAN-128 or EAN-128.) Refer to GS1 General Specification 24.0, Jan-2024; published by GS1 (www.gs1us.org).

For GS1-128 barcodes, application identifiers may allow auto-recognition of the associated fields. The application identifiers recognized by Aurora Xi are a barcode containing multiple application identifiers, followed by any application identifier used individually or as part of a combined barcode. Both single and multi-element GS1 barcodes may be linear (GS1 Databar) or two dimensional (GS1 Datamatrix).

NOTE

- If any element of a combined barcode does not meet the length or range requirements for that element, the entire combined barcode will be rejected.
- Ensure that the donor parameter being scanned into the device is within the configured limits while using GS1-128 combined barcodes. Barcodes that have donor parameters outside of the configured limits will be rejected by the device.

- Procedure ID (90), must be the final element if used in a combined barcode
- Operator ID (91), must be the final element if used in a combined barcode
- ECV Limit (92), must be three digits if used in a combined barcode
- Donor ID (93), must be the final element if used in a combined barcode
- Donor Height (94), must be three digits if used in a combined barcode (e.g., 060 for 60 inches or 150 for 150 cm)
- Donor Gender (95), must be one digit, where 0 = male and 1 = female
- Procedure Note (96), must be the final element if used in a combined barcode
- Undercollection Reason or Overcollection Reason in Post-Collection (96), the Undercollection Reason or Overcollection Reason keypad MUST be displayed in order for the scanned barcode to be associated with the Undercollection Reason or Overcollection Reason. Otherwise, the scanned barcode will be stored as a procedure note.
- Donor Weight (97), must be three digits if used in a combined barcode (e.g., 060 for 60 kg or 150 for 150 lbs)
- Donor Hematocrit/Hemoglobin (98), must be four characters if used in a combined barcode (e.g., 13.0 for 13.0 g/dL or 0039 for 39% Hct)
- Donation Setup ID (99), must be the final element if used in a combined barcode
- Global Trade Item Number (GTIN) for disposable components (01) (includes the apheresis needle, anticoagulant, disposable set, saline, plasma collection container, and user-defined soft good); must be 14 digits
- Lot number for disposable components (10) (includes the apheresis needle, anticoagulant, disposable set, saline, plasma collection container, and user-defined soft good)
- Expiration date for disposable components (17) (includes the apheresis needle, anticoagulant, disposable set, saline, plasma collection container, and miscellaneous soft good); must be six digits in YYMMDD format

Codabar: AIM BC3-1995 - USS - Codabar

- Operator ID
- Donor ID
- Procedure ID
- Donation Setup ID
- Saline Volume
- Target Collection Volume
- Donor Weight
- Donor Height
- Donor Hematocrit/Hemoglobin
- Procedure Note
- Undercollection Reason or Overcollection Reason in Post-Collection
- Code Number (REF) for disposable components (includes the apheresis needle, anticoagulant, saline, disposable set, plasma collection container, and user-defined soft good)
- Lot Number for disposable components (includes the apheresis needle, anticoagulant, saline, disposable set, plasma collection container, and user-defined soft good)

Code-128: ANSI/AIM BC4-1999, ISS - Code 128 (ISO/IEC 15417)

- Operator ID
- Donor ID
- Procedure ID
- Donation Setup ID
- Saline Volume
- Target Collection Volume
- Donor Weight
- Donor Height
- Donor Hematocrit/Hemoglobin
- Procedure Note
- Undercollection Reason or Overcollection Reason in Post-Collection
- Code Number (REF) for disposable components (includes the apheresis needle, anticoagulant, disposable set, saline, plasma collection container, and user-defined soft good)
- Lot Number for disposable components (includes the apheresis needle, anticoagulant, disposable set, saline, plasma collection container, and user-defined soft good)

Code-39: ISO/IEC 16388:2007 - Code 39

- Operator ID
- Donor ID
- Procedure ID
- Donation Setup ID
- Saline Volume
- Target Collection Volume
- Donor Weight
- Donor Height
- Donor Hematocrit/Hemoglobin
- Procedure Note
- Undercollection Reason or Overcollection Reason in Post-Collection
- Code Number (REF) for disposable components (includes the apheresis needle, anticoagulant, disposable set, saline, plasma collection container, and user-defined soft good)
- Lot Number for disposable components (includes the apheresis needle, anticoagulant, disposable set, saline, plasma collection container, and user-defined soft good)

Code-93: ANSI/AIM BC5-2000, USS - Code 93

- Operator ID
- Donor ID
- Procedure ID
- Donation Setup ID
- Saline Volume
- Target Collection Volume
- Donor Weight
- Donor Height
- Donor Hematocrit/Hemoglobin
- Procedure Note
- Undercollection Reason or Overcollection Reason in Post-Collection
- Code Number (REF) for disposable components (includes the apheresis needle, anticoagulant, disposable set, saline, plasma collection container, and user-defined soft good)
- Lot Number for disposable components (includes the apheresis needle, anticoagulant, disposable set, saline, plasma collection container, and user-defined soft good)

Interleaved 2 of 5: ISO/IEC 16390:2007 - Interleaved 2 of 5 (ISO/IEC 16390)

- Operator ID
- Donor ID
- Procedure ID
- Donation Setup ID
- Saline Volume
- Target Collection Volume
- Donor Weight
- Donor Height
- Donor Hematocrit/Hemoglobin
- Procedure Note
- Undercollection Reason or Overcollection Reason in Post-Collection
- Code Number (REF) for disposable components (includes the apheresis needle, anticoagulant, disposable set, saline, plasma collection container, and user-defined soft good)
- Lot Number for disposable components (includes the apheresis needle, anticoagulant, disposable set, saline, plasma collection container, and user-defined soft good)

Monarch 11:

- Operator ID
- Donor ID
- Procedure ID
- Donation Setup ID
- Saline Volume
- Target Collection Volume
- Donor Weight
- Donor Height
- Donor Hematocrit/Hemoglobin
- Procedure Note
- Undercollection Reason or Overcollection Reason in Post-Collection
- Code Number (REF) for disposable components (includes the apheresis needle, anticoagulant, disposable set, saline, plasma collection container, and user-defined soft good)
- Lot Number for disposable components (includes the apheresis needle, anticoagulant, disposable set, saline, plasma collection container, and user-defined soft good)

Appendix A
Calculations and Tables

This appendix contains nomograms, calculations, and other reference tables.

Section A.1: Overview of Nomogram Options

Aurora Xi supports three nomograms: Standard, Optimized, and Adaptive. All nomograms are configured in the administrative settings. In all cases, donor parameters are programmed into the Aurora Xi device for each plasmapheresis procedure, and the system calculates the target collection volume.

Standard and Optimized Nomograms

When a donor weight (Standard Nomogram) and Hct/Hb (Optimized Nomogram) is entered, the configured nomogram is used to determine the target collection volume.

NOTE

- Do not enter a target collection volume or a target plasma volume that has not been cleared by the appropriate regulatory body. Failure to use a cleared nomogram may lead to overcollection of plasma.
- If using the Adaptive Nomogram, the informed consent provided to donors should be updated with information regarding the increase in target collection volume based on the donor's gender, weight, and height.

The nomogram defines the appropriate target collection volumes and target plasma volumes for eligible donors. Donor eligibility should be determined by the collection facility, following all applicable regulatory requirements.

On November 4, 1992, the FDA issued a memorandum for all licensed Source Plasma Establishments entitled "Volume Limits for Automated Collection of Source Plasma". It informed centers that they could adopt, without notice and under certain conditions, a simplified nomogram.

The conditions indicated in the memorandum are that:

- 4% Sodium Citrate solution be delivered at a rate yielding a 1:16 (6%) ratio of AC to anticoagulated blood.
- Do not use the equipment manufacturer's nomogram simultaneously in the same center. Do not use portions of the table in combination with some other set of limits.

The following table shows the FDA's simplified nomogram:

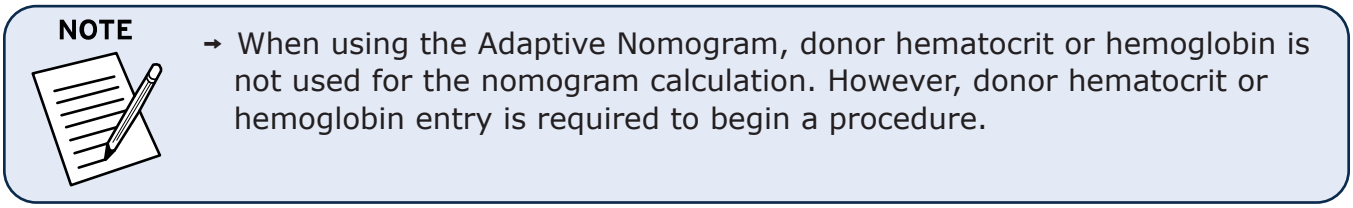
Donor Weight	Plasma Volume (Weight)	Collected Plasma Volume* (Weight) [Plasma + Anticoagulant]
110 – 149 lb	625 mL (640 g)	690 mL (705 g)
150 – 174 lb	750 mL (770 g)	825 mL (845 g)
175 lb and up	800 mL (820 g)	880 mL (900 g)

*The total collection volume displayed is the volume of plasma and anticoagulant. In some cases, plasma volume (excluding anticoagulant) is also displayed.

This is the default configuration for Aurora Xi's Standard Nomogram (using Collection Volumes from the table) and Optimized Nomogram (using Plasma Volumes from the table).

Adaptive Nomogram

When using the Adaptive Nomogram, the target collection volume is calculated as a percentage of a donor-specific volume, related to the donor's height, weight, and sex. Example volumes are provided in the tables below. Note that administrative settings may further limit the collection volume.



Example Volumes for Male Donors at 5.7% Adaptive Nomogram Percent

Weight (lb)	Height (in)	Target Collection Volume (mL)
110	60	649
110	66	680
149	60	783
149	66	821
150	66	824
174	66	903
174	72	943
175	72	947
250	72	1098
300	72	1098

Example Volumes for Female Donors at 5.7% Adaptive Nomogram Percent

Weight (lb)	Height (in)	Target Collection Volume (mL)
110	60	609
110	66	646
149	60	732
149	66	776
150	66	779
174	60	804
174	66	853
175	72	903
250	72	1098
300	72	1098

Example Volumes for Male Donors at 5.6% Adaptive Nomogram Percent

Weight (lb)	Height (in)	Target Collection Volume (mL)
110	60	637
110	66	668
149	60	769
149	66	806
150	66	810
174	66	888
174	72	927
175	72	930
250	72	1098
300	72	1098

Example Volumes for Female Donors at 5.6% Adaptive Nomogram Percent

Weight (lb)	Height (in)	Target Collection Volume (mL)
110	60	598
110	66	634
149	60	719
149	66	763
150	66	766
174	60	790
174	66	838
175	72	888
250	72	1098
300	72	1098

Section A.2: Formula Calculations of AC and Plasma Volume in Plasma Product

In the following equations:

- V_C = Total collection volume (mL)
- V_P = Plasma volume (without AC) in the collected plasma product (mL)
- V_{AC} = Volume of anticoagulant in the plasma product (mL)
- Hct = Donor hematocrit
- ACR = Ratio of whole blood to anticoagulant, expressed as the second half of the AC ratio setting (i.e., if the ratio is 1:16, use 16)

The equations in this section assume:

- uniform and accurate mixing between AC and whole blood
- constant donor hematocrit throughout the procedure
- estimated hematocrit as Hct (%) = 3 * Hb (g/dL) if donor hemoglobin (g/dL) is known

Volume of Anticoagulant in the Plasma Product

The volume of anticoagulant (AC) in the collected plasma product is dependent on the ratio of anticoagulant to whole blood and the hematocrit of the donor. Calculate this using the following equation:

$$V_{AC} = \frac{V_C}{1 + (ACR * \left(1 - \frac{Hct}{100}\right))}$$

For example, for a 825 mL plasma product collected with a donor hematocrit of 44% and an AC Ratio of 1:16, the volume of anticoagulant in the plasma product would be:

$$V_{AC} = \frac{V_C}{1 + (ACR * \left(1 - \frac{Hct}{100}\right))} = \frac{825}{1 + (16 * \left(1 - \frac{44}{100}\right))} = 83\ mL$$

The following table summarizes example calculations using the above equation.

Collection Volume (mL)	AC Volume in Product (mL) for a 1:16 AC Ratio																			
	Donor Hematocrit (%)																			
	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55
200	18	18	18	19	19	19	19	20	20	20	21	21	21	22	22	23	23	23	24	24
250	22	23	23	23	24	24	24	25	25	26	26	26	27	27	28	28	29	29	30	30
300	27	27	27	28	28	29	29	30	30	31	31	32	32	33	33	34	35	35	36	37
350	31	32	32	33	33	34	34	35	35	36	36	37	38	38	39	40	40	41	42	43
400	36	36	37	37	38	38	39	40	40	41	41	42	43	44	44	45	46	47	48	49
450	40	41	41	42	42	43	44	44	45	46	47	47	48	49	50	51	52	53	54	55
500	44	45	46	46	47	48	49	49	50	51	52	53	54	55	56	57	58	59	60	61
550	49	50	50	51	52	53	54	54	55	56	57	58	59	60	61	62	63	65	66	67
600	53	54	55	56	57	57	58	59	60	61	62	63	64	66	67	68	69	70	72	73
650	58	59	60	60	61	62	63	64	65	66	67	69	70	71	72	74	75	76	78	79
690	61	62	63	64	65	66	67	68	69	70	72	73	74	75	77	78	79	81	83	84
750	67	68	69	70	71	72	73	74	75	77	78	79	80	82	83	85	86	88	90	91
800	71	72	73	74	75	77	78	79	80	82	83	84	86	87	89	90	92	94	96	98
825	73	74	76	77	78	79	80	82	83	84	86	87	89	90	92	93	95	97	99	101
850	76	77	78	79	80	81	83	84	85	87	88	90	91	93	94	96	98	100	102	104
880	78	79	81	82	83	84	86	87	88	90	91	93	94	96	98	100	101	103	105	107
950	85	86	87	88	90	91	92	94	95	97	99	100	102	104	106	107	109	112	114	116
1000	89	90	92	93	94	96	97	99	100	102	104	105	107	109	111	113	115	117	120	122
1050	93	95	96	98	99	101	102	104	105	107	109	111	113	115	117	119	121	123	126	128
1098	98	99	101	102	104	105	107	108	110	112	114	116	118	120	122	124	126	129	131	134

Plasma Volume (without AC) in the Plasma Product

The plasma volume (without anticoagulant) in the collected plasma product is dependent on the ratio of anticoagulant to whole blood and the hematocrit of the donor. Calculated this using the following equation:

$$V_P = V_C * (1 - \frac{1}{1 + ACR * \left(1 - \frac{Hct}{100}\right)})$$

For example, for a 825 mL plasma product collected with a donor hematocrit of 44% and an AC Ratio of 1:16, plasma volume (without anticoagulant) in the plasma product would be:

$$V_P = V_C * \left(1 - \frac{1}{1 + \left(ACR * \left(1 - \frac{Hct}{100}\right)\right)}\right) = 825 * \left(1 - \frac{1}{1 + \left(16 * \left(1 - \frac{44}{100}\right)\right)}\right) = 742\ mL$$

The following table summarizes example calculations using the above equation.

Collection Volume (mL)	Plasma Volume in Collected Product (mL) for a 1:16 AC Ratio																			
	Donor Hematocrit (%)																			
	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55
200	182	182	182	181	181	181	181	180	180	180	179	179	179	178	178	177	177	177	176	176
250	228	227	227	227	226	226	226	225	225	224	224	224	223	223	222	222	221	221	220	220
300	273	273	273	272	272	271	271	270	270	269	269	268	268	267	267	266	265	265	264	263
350	319	318	318	317	317	316	316	315	315	314	314	313	312	312	311	310	310	309	308	307
400	364	364	363	363	362	362	361	360	360	359	359	358	357	356	356	355	354	353	352	351
450	410	409	409	408	408	407	406	406	405	404	403	403	402	401	400	399	398	397	396	395
500	456	455	454	454	453	452	451	451	450	449	448	447	446	445	444	443	442	441	440	439
550	501	500	500	499	498	497	496	496	495	494	493	492	491	490	489	488	487	485	484	483
600	547	546	545	544	543	543	542	541	540	539	538	537	536	534	533	532	531	530	528	527
650	592	591	590	590	589	588	587	586	585	584	583	581	580	579	578	576	575	574	572	571
690	629	628	627	626	625	624	623	622	621	620	618	617	616	615	613	612	611	609	607	606
750	683	682	681	680	679	678	677	676	675	673	672	671	670	668	667	665	664	662	660	659
800	729	728	727	726	725	723	722	721	720	718	717	716	714	713	711	710	708	706	704	702
825	752	751	749	748	747	746	745	743	742	741	739	738	736	735	733	732	730	728	726	724
850	774	773	772	771	770	769	767	766	765	763	762	760	759	757	756	754	752	750	748	746
880	802	801	799	798	797	796	794	793	792	790	789	787	786	784	782	780	779	777	775	773
950	865	864	863	862	860	859	858	856	855	853	851	850	848	846	844	843	841	838	836	834
1000	911	910	908	907	906	904	903	901	900	898	896	895	893	891	889	887	885	883	880	878
1050	957	955	954	952	951	949	948	946	945	943	941	939	937	935	933	931	929	927	924	922
1098	1000	999	997	996	994	993	991	990	988	986	984	982	980	978	976	974	972	969	967	964

Total Collection Given Plasma Without Anticoagulant

The total collection volume is dependent on the target plasma volume (without AC), the ratio of anticoagulant to whole blood, and the hematocrit of the donor. Calculated using the following equation:

$$V_c = V_P * (1 + \frac{1}{ACR * \left(1 - \frac{Hct}{100}\right)})$$

For example, for a 750 mL plasma product (without AC), a donor hematocrit of 44% and an AC Ratio of 1:16, the total collection volume is:

$$V_C = V_P * \left(1 + \frac{1}{ACR * \left(1 - \frac{Hct}{100}\right)}\right) = 750 * \left(1 + \frac{1}{16 * \left(1 - \frac{44}{100}\right)}\right) = 834\, mL$$

The following table summarizes example calculations using the above equation.

Plasma Product Volume (mL)	Target Collection Volume Given Plasma Volume without Anticoagulant (mL) for a 1:16 AC Ratio																			
	Donor Hct (%)																			
	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55
200	220	220	220	220	221	221	222	222	222	223	223	224	224	225	225	226	226	227	227	228
250	274	275	275	276	276	276	277	277	278	278	279	279	280	281	281	282	283	283	284	285
300	329	330	330	331	331	332	332	333	333	334	335	335	336	337	338	338	339	340	341	342
350	384	385	385	386	386	387	388	388	389	390	391	391	392	393	394	395	396	397	398	399
400	439	440	440	441	442	442	443	444	445	445	446	447	448	449	450	451	452	453	454	456
450	494	495	495	496	497	498	498	499	500	501	502	503	504	505	506	507	509	510	511	513
500	549	550	550	551	552	553	554	555	556	557	558	559	560	561	563	564	565	566	568	569
550	604	605	605	606	607	608	609	610	611	613	614	615	616	617	619	620	622	623	625	626
600	659	660	660	661	663	664	665	666	667	668	669	671	672	674	675	677	678	680	682	683
625	686	687	688	689	690	691	692	694	695	696	697	699	700	702	703	705	706	708	710	712
650	713	714	716	717	718	719	720	721	723	724	725	727	728	730	731	733	735	736	738	740
700	768	769	771	772	773	774	775	777	778	780	781	783	784	786	788	789	791	793	795	797
750	823	824	826	827	828	829	831	832	834	835	837	838	840	842	844	846	848	850	852	854
800	878	879	881	882	883	885	886	888	889	891	893	894	896	898	900	902	904	906	909	911
825	906	907	908	910	911	912	914	915	917	919	920	922	924	926	928	930	932	935	937	940
850	933	934	936	937	939	940	942	943	945	947	948	950	952	954	956	958	961	963	965	968
875	960	962	963	965	966	968	969	971	973	974	976	978	980	982	984	987	989	991	994	997
900	988	989	991	992	994	995	997	999	1000	1002	1004	1006	1008	1010	1013	1015	1017	1020	1022	1025
950	1043	1044	1046	1047	1049	1051	1052	1054	1056	1058	1060	1062	1064	1066	1069	1071	1074	1076	1079	1082
1000	1098	1099	1101	1102	1104	1106	1108	1110	1112	1114	1116	1118	1120	1123	1125	1128	1130	1133	1136	1139

Section A.3: Total Residual Blood Loss

On December 4, 1995, the FDA issued a memorandum titled "Donor Deferral Due to Red Blood Cell Loss During Collection of Source Plasma by Automated Plasmapheresis". This memorandum states:

- "If a donor loses more than 200 mL of red blood cells during a plasmapheresis procedure, the donor should be deferred for eight weeks. However, it would not be necessary to defer a donor for any single incident as long as the red blood cell loss does not exceed 200 mL.
- During the eight week period following the first observable red blood cell loss of less than 200 mL, a second observable red blood cell loss (exceeding any residual red blood cells remaining in the tubing) should result in an eight-week deferral from the date of the most recent red blood cell loss."

Additional deferrals may be required due to the extracorporeal volume of the system, in accordance with the applicable regulatory requirements.

If technical difficulties necessitate discontinuing a procedure, the information that follows is meant to help determine extracorporeal red cell loss on the Aurora Xi device.

When using the Aurora Xi device, the total extracorporeal red blood cell volume and plasma volume that can be lost during a procedure typically depends on:

- the weight and hematocrit of the donor, the cycle of the procedure
- the volume of blood remaining in the reservoir at the time the procedure was ended

Throughout the procedure, the system limits the nominal extracorporeal red blood cell volume to no greater than 15% of the donor's estimated red blood cell volume, or the ECV Limit setting, whichever is less.

The residual blood loss is the volume of blood left in the kit, excluding the collection container after a procedure is completed. If the Final Reinfusion Phase has completed, the residual blood losses are given in the table below:

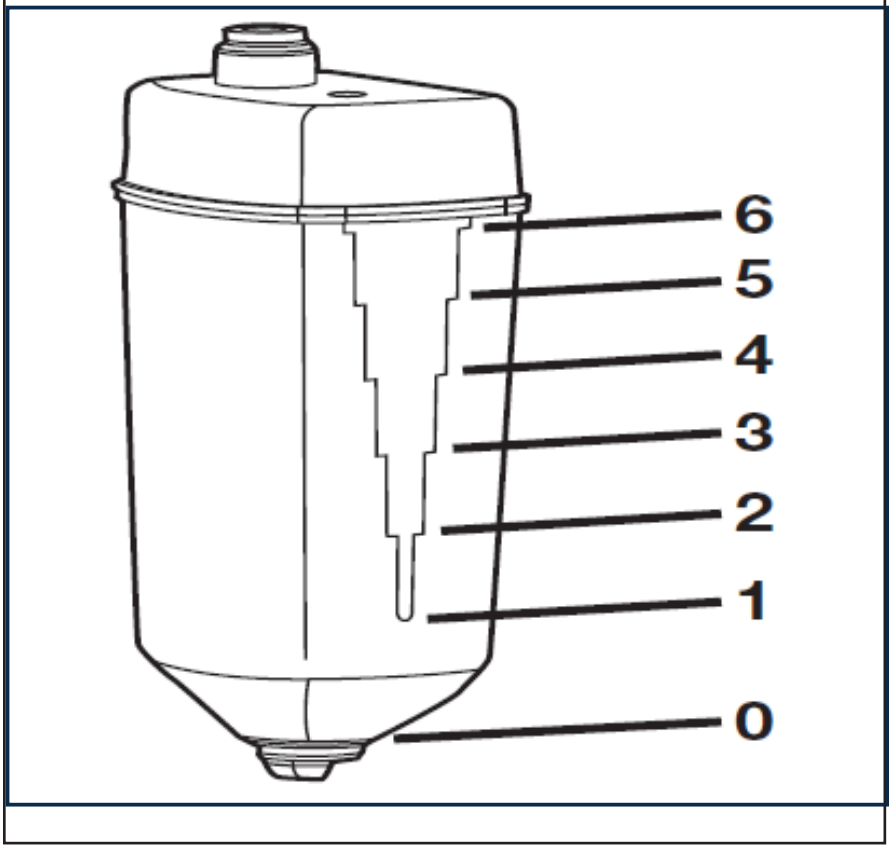
Protocol	Residual Plasma Loss	Residual RBC Loss
Saline	12 mL typical	6 mL typical (10 mL max)
No Saline	23 mL typical	17 mL typical (20 mL max)

The operator must account for recording losses due to sampling separately from this value.

Whether or not the Final Reinfusion Phase has completed, the residual RBC loss is reported on the **Procedure Results** screen.

If the **Procedure Results** screen is not available, the residual RBC loss and residual plasma loss can be estimated by examining the reservoir fill level on the right side of the reservoir.

Figure 275: Reservoir Fill Level Marks



The following tables give an approximate volume (± 15% or 10 mL, whichever is greater) of RBC loss and plasma loss in the disposable set, in mL, for the first cycle of the procedure and then for subsequent cycles.

It is important to note that total extracorporeal red blood cell volume will not exceed the administrative setting for maximum RBC loss.

→ The residual plasma loss does not account for the plasma volume in the collection container, only the plasma that remains in the kit.

Residual RBC and Plasma Loss

Approximate Residual Loss (mL) for Cycle 1

Reservoir Level	Plasma	RBC
Over 6	126	250
6	111	227
5	96	194
4	81	160
3	66	127
2	50	94
1	35	61
0	20	27

* apply the number in the table or the administrative setting for maximum RBC loss, whichever is less.

Approximate Residual Loss (mL) for Cycle 2+

Reservoir Level	Plasma	RBC
Over 6	N/A	N/A
6	88	250
5	76	215
4	65	178
3	53	141
2	42	104
1	30	67
0	18	30

* apply the number in the table or the administrative setting for maximum RBC loss, whichever is less.

These estimations assume:

- the Reinfusion Phase has started,
- the needle set is 12 in long,
- the reservoir Hct is 64% for cycle 1, and 74% for cycle 2+,
- the AC ratio 1:16 is applied, and
- the donor Hct range is between 36% to 55%.

These estimates do not account for sampling. The operator must account for recording losses due to sampling separate from this value.

Use the last row of these tables to estimate RBC and plasma loss for a procedure where manual reinfusion of reservoir contents was performed.

Glossary of Graphics

This glossary provides the names/meanings of the graphics for tabs, buttons, icons, and prompts that are displayed on the Aurora Xi touchscreen or donor displays.

Tabs and buttons are operator inputs, while icons and prompts are informational. The tables and explanations below describe each type of system graphics.

Tabs

Tabs provide a link to the data that is available for either viewing or entering individual pieces of data.

Data Entry Tabs

Tab	Name
	Disposables Data
	Donor Data

I-Menu Tabs

Tab	Name
	Instrument Settings
	Procedure Information

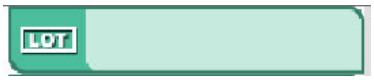
Alphanumeric Keypad Tabs

	Characters
	Letters
	Shift

Summary Tabs

	Donor Parameters
	Event Summary
	Procedure Summary
	Set Summary

Fields

Field	Name
	Code Number
	Lot Number
	Expiration Date

Buttons

Buttons allow the operator to indicate that a step has been completed or command the device to proceed to another task or step.

Button	Name
	AC Container
	AC Container Data
	Audio
	Back/Backspace
	Calibrate Scale
	Cancel
	Check

Button	Name
	Clear
	Clear Air In Line
	Collection Volume
	Cuff Pressure
	Disable Cuff
	Disposable Set

Button	Name
	Donation Setup ID
	Donor Gender
	Donor Gender – Female
	Donor Gender – Male
	Donor Hb/Hct
	Donor Height
	Donor ID
	Donor Weight
	Down

Button	Name
	Draw Rate
	ECV Limit
	Enable Admin
	End Procedure
	Help
	Information
	Infuse Saline
	Keypad
	Left Arm
	Mute
	Needle Set Data

Button	Name
	Needle Set
	New Procedure
	No
	No Saline Protocol
	Notepad
	Open Clamp
	Operator ID
	Page Back
	Page Down
	Page Forward
	Page Up
	Pause

Button	Name
	Plasma Container Data
	Preset View
	Procedure ID
	Procedure View
	Resume
	Return
	Return Rate
	Reverse Flow
	Right Arm
	Saline Container
	Saline Container Data

Button	Name
	Saline Protocol
	Scale Check
	Scroll Down
	Scroll Up
	Service
	Set Data
	Shut Down
	Sound Level
	Space Bar
	Start
	System Info

Button	Name
	Tare Scale
	Target Collection Volume
	Target Saline Volume
	Up
	User-Defined Soft Goods
	User-Defined Soft Goods Data
	Venipuncture Arm Entry
	Weigh Product
	Yes

Icons

Icons are symbols displayed on the touchscreen, device, or disposable set that help the operator in understanding various functions or procedural events. Touching an icon will not result in any action being taken by the device. Icons are for informational use only.

Types of icons are:

- General Operating
- Alert/Alarm

General Operating

These icons appear on the touchscreen or donor display to provide additional information to the operator/donor regarding procedural events.

Icon	Name
	AC
	Auto Occlusion Restart Icon
	Auto Recovery
	Auto Recovery – AC Scale Disturbed
	Auto Recovery – Collection Scale Disturbed
	Auto Recovery – Purging
	Auto Recovery – Reservoir Scale Disturbed
	Collection
	Collection Volume

Icon	Name
	Cycle
	Donor Gender
	Donor Gender – Female
	Donor Gender – Male
	Donor Hct/Hb
	Donor Height
	Donor ID
	Donation Setup ID
	Donor Weight

Icon	Name
	ECV Limit
	Increase Squeeze (Low Venous Pressure)
	Increase Squeezing (Very Low Venous Pressure)
	Network Connected
	Network Not Connected
	Pause
	Pause Collection
	Pause Reinfusion
	Plasma Volume
	Prime
	Procedure ID
	Procedure Time
	Red Cell Loss

Icon	Name
	Reinfusion
	Saline to Administer
	Saline Used
	Scale Fail
	Scale Pass
	Self Check
	Separator Pressure (P2)
	Set Timer
	Squeeze (Adequate Venous Pressure)
	Venous Pressure (P1)

Alert/Alarm Icons

Alert/Alarm icons appear on the touchscreen during alert/alarm situations. They provide the operator with information regarding the alert/alarm, possible causes, and possible resolutions. More information regarding alerts/alarms and troubleshooting is provided in **Chapter 5 – Troubleshooting**.

Icon	Name
	AC Container Misaligned
	AC Line in Air Detector
	AC Low
	AC Not Present
	AC on Scale
	AC Weight Unstable
	Air in Collection Line
	Air in Line
	Air Leak
	Blood in Line

Icon	Name
	Cell Leak
	Clamp Tubing Misalignment
	Close Pump
	Cracks
	Cuff Sensor Not Connected
	Damaged Tubing
	Data Not Entered
	Disconnect Donor
	Do Not Return Fluid
	Excessive Sunlight

Icon	Name
	External Pressure on Cuff
	Fixture Unstable
	Fluid In Plasma Collection Container
	Hb Detector Door Opened
	Hemolysis (plasma color change)
	Hemostat Open
	Kinks
	Leaks
	Lipids
	Luer Cap Not Removed
	Open Pump
	Plasma Collection Container Disturbed

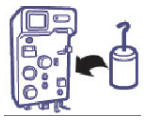
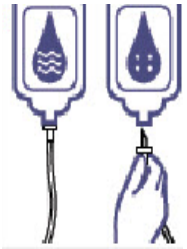
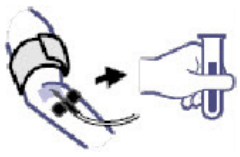
Icon	Name
	Plasma Collection Container Full
	Plasma Collection Container Misaligned
	Plasma Collection Container Not Connected
	Plasma Container Not Present
	Plasma Product on Scale
	Power Loss
	Press STOP Button
	Pressure Cuff Not Inflated/Deflated
	Remove Invalid Accessory
	Reservoir Full
	Reservoir Misalignment
	Reservoir Not Present

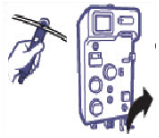
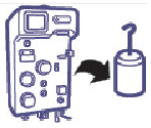
Icon	Name
	Reservoir on Scale
	Reservoir Weight Unstable
	Scale Overload
	Separation Device Misalignment
	Solution Connection
	Solutions Connected Too Early
	Transducer Connection
	Transducer Connections Reversed
	Transducer Cover Opened
	Tubing in Hb Detector
	Tubing Misalignment (Air Detector)
	Tubing Misalignment (Clamp)

Icon	Name
	Tubing Misalignment (Hb Detector)
	Tubing Misalignment (Pump)
	Tubing Not in Transducer
	Tubing Reversed
	System Info
	Switch to Power OFF
	Uninstall Set
	Venipuncture

Prompts

Prompts are graphics displayed on the touchscreen that tell the operator the action the operator should perform. Generally, the operator will have to touch the **Check** button to acknowledge that the prompted task has been completed before the system can continue.

Prompt	Name
	Add Weights
	Connect AC Container
	Connect AC Container and Saline Container
	Disconnect Donor
	Enter Data
	Install Set
	Perform Venipuncture
	Perform Venipuncture and Take Venipuncture Sample

Prompt	Name
	Power OFF
	Press STOP Button (Test)
	Remove Plasma Collection Container and Seal Tubing
	Remove Weights
	Unload Set
	Verify Audio / Visual Signals

Aurora Xi Plasmapheresis System

Operator's Manual

SW v2.1

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