Cardiosave Enhanced Blood Detection

D.03 Software

Cardiosave Update

Introduction

Learning Objectives:

- Evaluate the causes, clinical indicators, and appropriate actions for IAB catheter perforation
- Explain the updated blood surveillance algorithm
- Implement interventions in response to intra-aortic balloon pump (IABP) alarms
- Describe the function of the blood containment filter in the IABP system

Topics Covered:

- Software Version D.03
- Intra-Aortic Balloon (IAB) Perforation
- Cardiosave Enhancements
- Blood Surveillance Algorithm
- Blood Containment Filter

Software Version

Confirming Software Version on IABP

Software Version

Confirming Software Version on IABP

Access to Software Version

- Verify the current version on the Cardiosave during clinical mode

Software Version Display

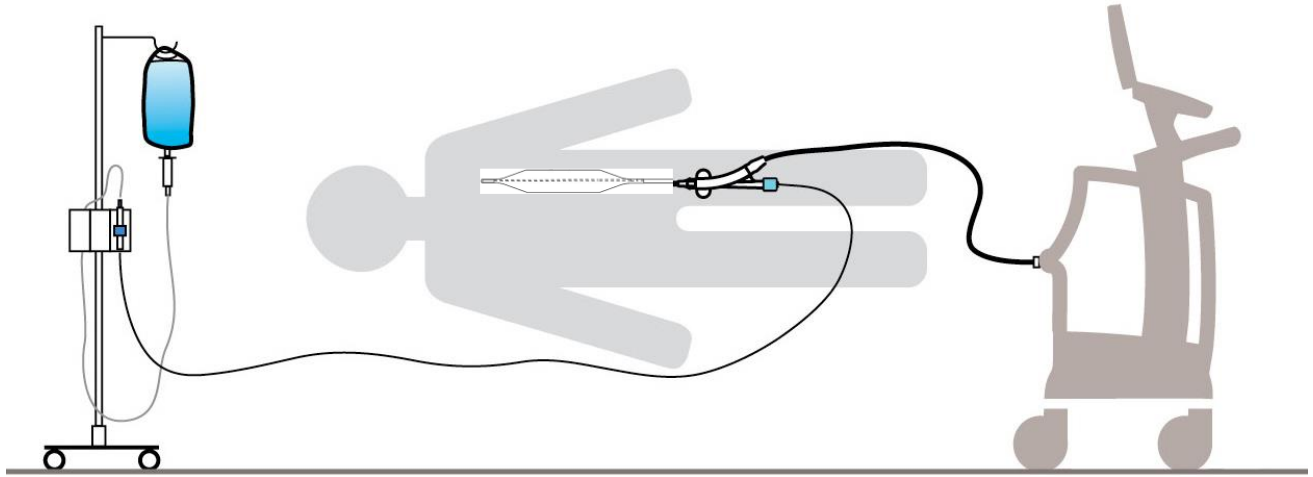
- The installed software (SW) version is prominently displayed in the lower-left corner of the Preferences Menu

IAB Perforation

Review and Clinical Management

Suspected IAB Perforation

Clinical Assessment



Causes	Assessment	Alarms
• Contact with pre-existing calcified plaque, resulting in abrasion and eventual perforation • Fatigue failure due to unusual (biaxial) folding of the balloon membrane • Contact with a sharp instrument	• Blood present in IAB catheter tubing (extracorporeal) and/or helium extender tubing • Sudden change in diastolic augmentation • IABP Alarms	• Blood Suspected – Check Catheter and Tubing • Autofill Failure • Gas Gain in IAB Circuit • Gas Loss in IAB Circuit • IAB Catheter Restriction

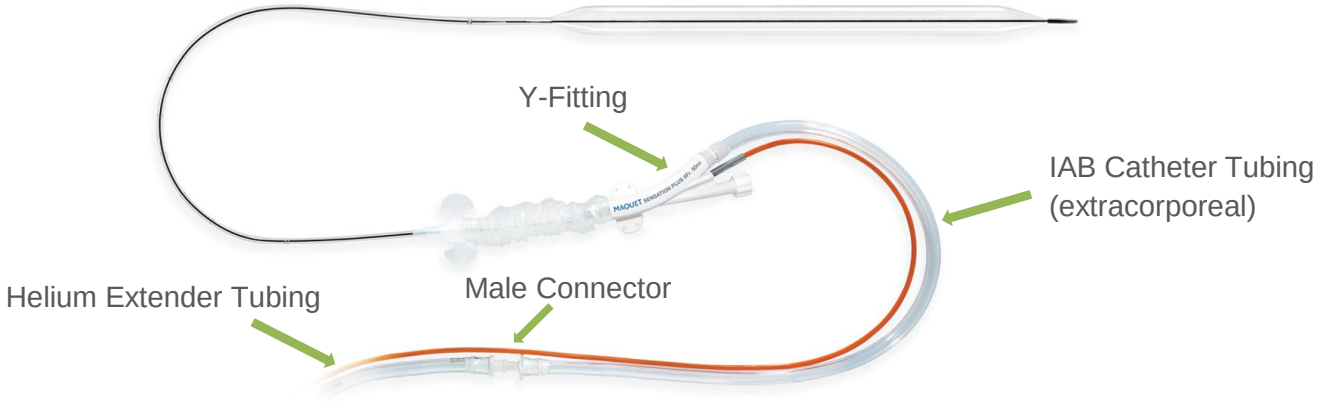
Suspected IAB Perforation Indicators

Assess from insertion site to IABP:

- IAB catheter tubing (extracorporeal)
- Helium extender tubing

Blood seen in IAB catheter tubing (extracorporeal) and /or helium extender tubing as evidenced by:

- Bright red blood
- Dried blood particles
- Serosanguineous fluid



IAB Catheter Perforation Management

If blood is seen in the IAB catheter tubing (extracorporeal) and/or helium extender tubing, perform these steps:

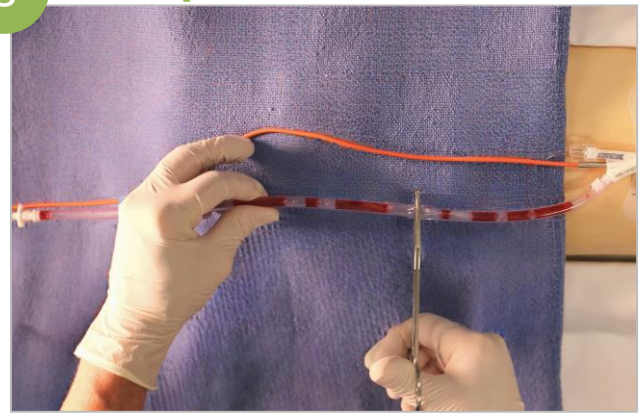
1 Standby

If not in Standby, press Standby key to stop pumping

2 Disconnect

Disconnect helium extender tubing from back of pump

3 Clamp



Clamp IAB catheter tubing between white Y-fitting and male connector

4 Notify

Notify physician and prepare for removal and IAB catheter replacement if patient condition warrants

5 Next Steps

If blood is suspected of entering the IABP:

- Remove affected IABP from service to be assessed by Biomedical/Technical service to determine if contamination has occurred before next use
- To continue therapy, replace IAB catheter and obtain a new IABP

Cardiosave Enhancements

Safety Features

Cardiosave Enhancements

Safety Features

IAB catheter perforation is a potential complication

In the event of an IAB catheter perforation, blood may enter the pump

- Can result in contamination of internal components
- May lead to an unexpected device shutdown

New features added to protect the patient and the IABP

- Blood Surveillance Algorithm
- Blood Containment Filter

Blood Surveillance Algorithm

Blood Surveillance Algorithm

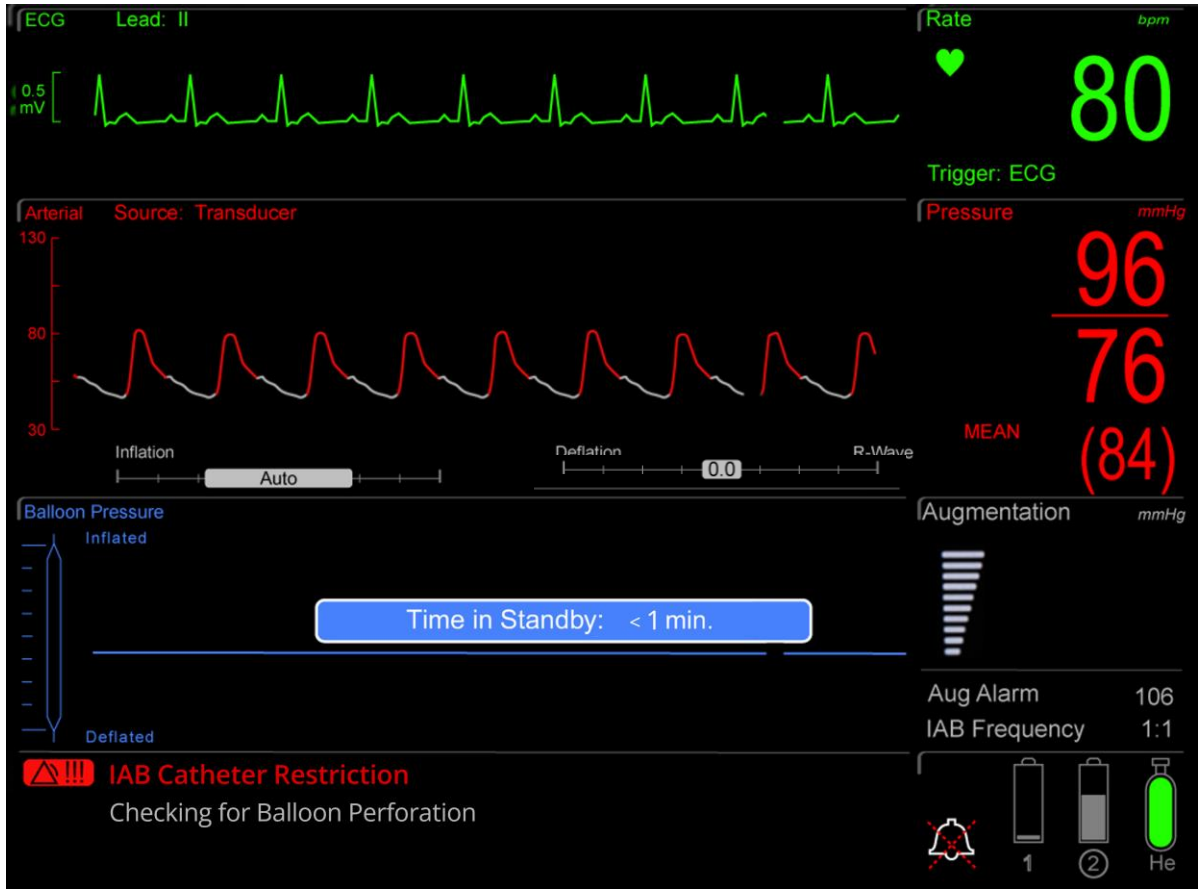
Overview

The surveillance algorithm is designed to:

- Alert the user if an IAB catheter perforation is suspected
- Minimize the risk of blood entering the IABP

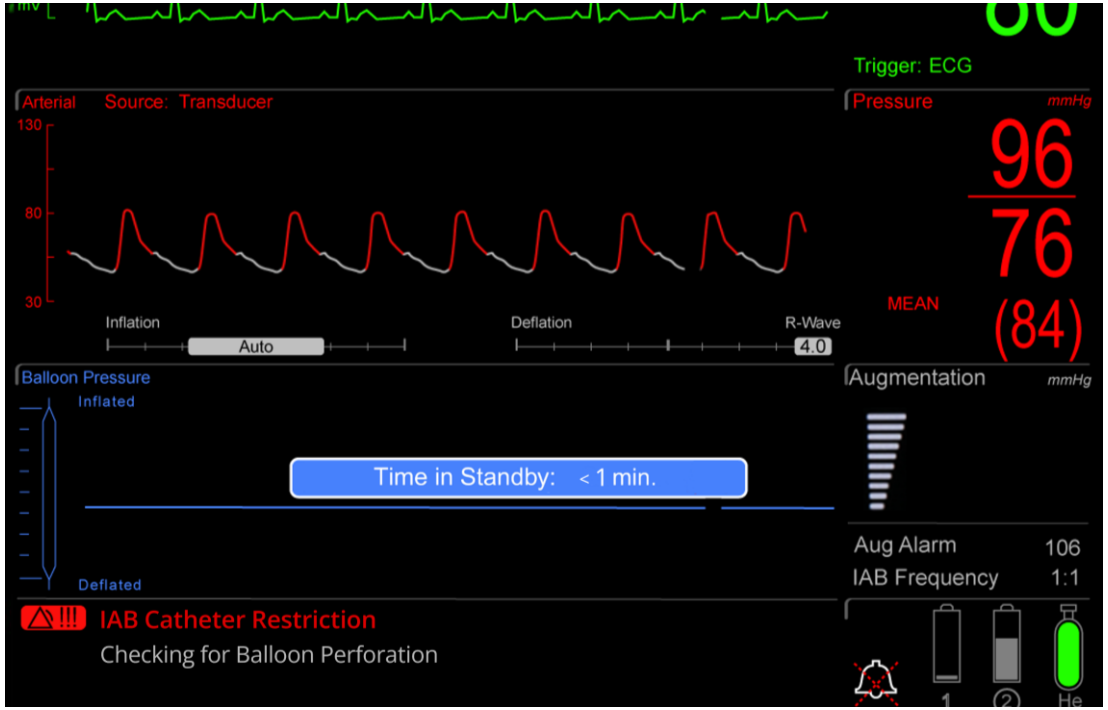
The system checks the IAB catheter for perforation during the following situations:

- High priority alarms that indicate a potential IAB catheter perforation
- Autofills (Q2 Hours + User Initiated IAB Fill)
- Placed into Standby

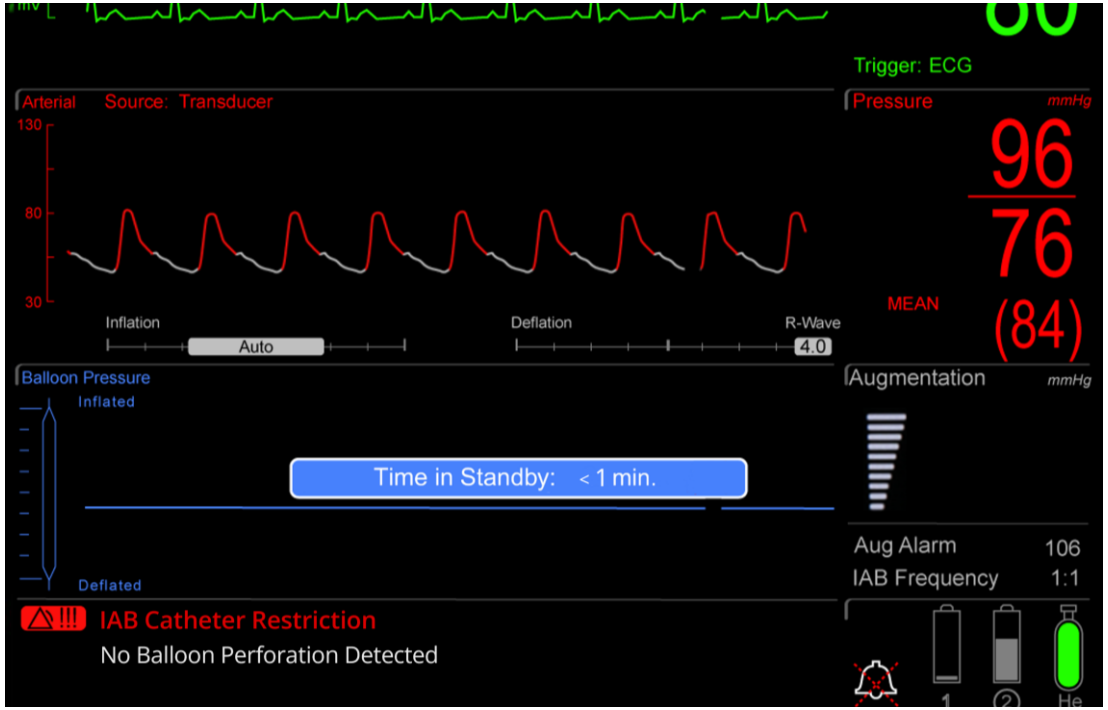


Blood Surveillance Algorithm

Informational Messages



"Checking for Balloon Perforation"



"No Balloon Perforation Detected"

"No Balloon Perforation Detected" indicates the IABP did not detect any evidence of a perforation at that time. Continue vigilant monitoring, as IAB catheter perforation remains a potential risk.

Blood Surveillance Algorithm

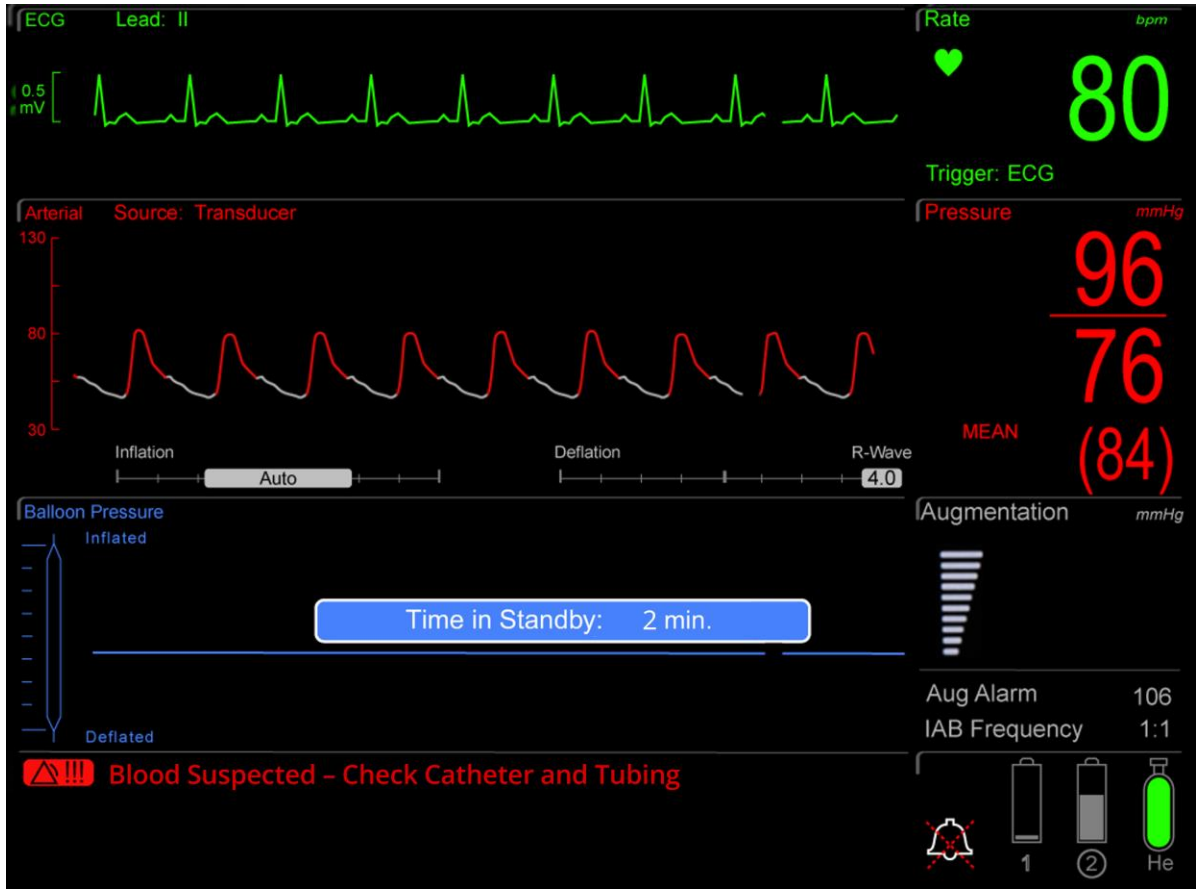
High Priority Alarm

Alarm: “Blood Suspected – Check Catheter and Tubing”

- High priority alarm to alert the user that a catheter perforation is suspected

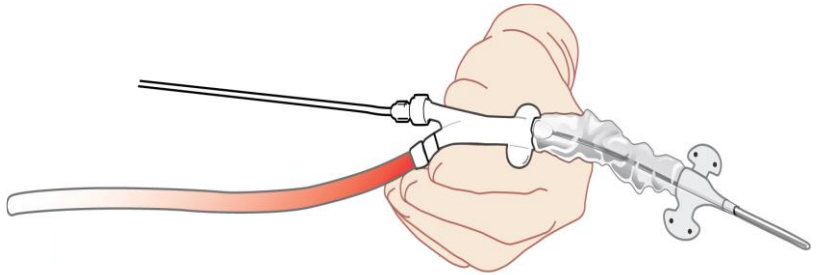
Inspect IAB catheter tubing (extracorporeal) and helium extender tubing for evidence of blood

- Utilize **Help Available** key to determine next steps

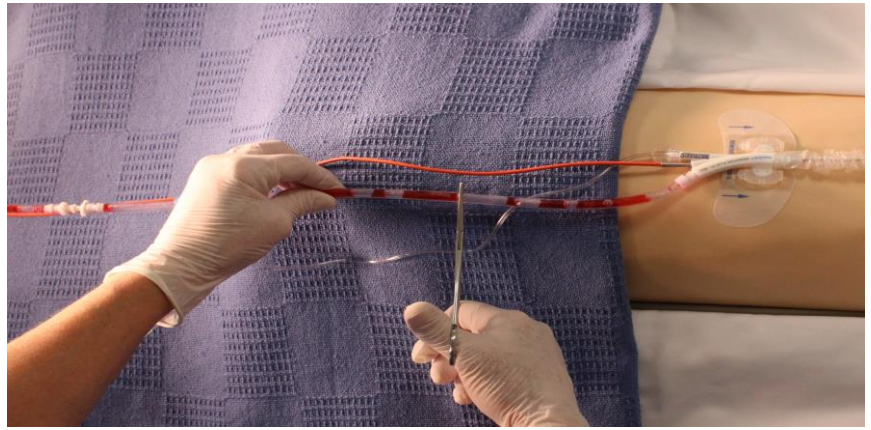


Alarm: “Blood Suspected - Check Catheter and Tubing”

Action Steps: Blood Seen



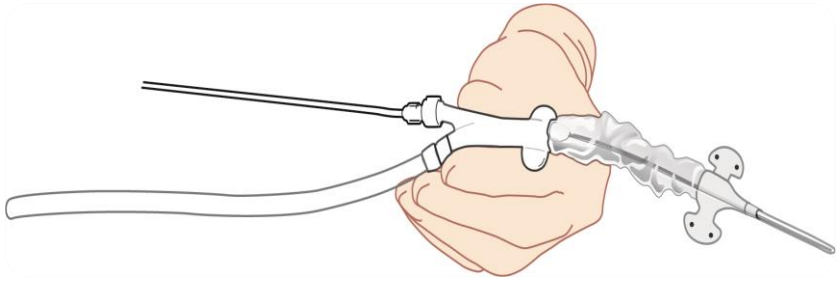
Blood seen



1. Press Standby to stop pumping, if not in Standby already
2. Disconnect helium extender tubing from pump
3. Clamp IAB catheter tubing (extracorporeal) between white Y-fitting and male connector
4. Notify provider and prepare for removal; replace if patient condition warrants
5. If blood is suspected of entering the IABP, remove affected pump from service to be evaluated by Biomedical/Technical Service

Alarm: “Blood Suspected - Check Catheter and Tubing”

Action Steps: No Blood Seen



No blood seen

1. Power *off* IABP, press and hold power button for 2 seconds
2. Wait 10 seconds, power *on* IABP
3. If alarm reoccurs, there is likelihood the IAB catheter is perforated, even if blood is not seen
    - Therapy should be stopped and the IAB catheter replaced

Blood Containment Filter

Blood Containment Filter

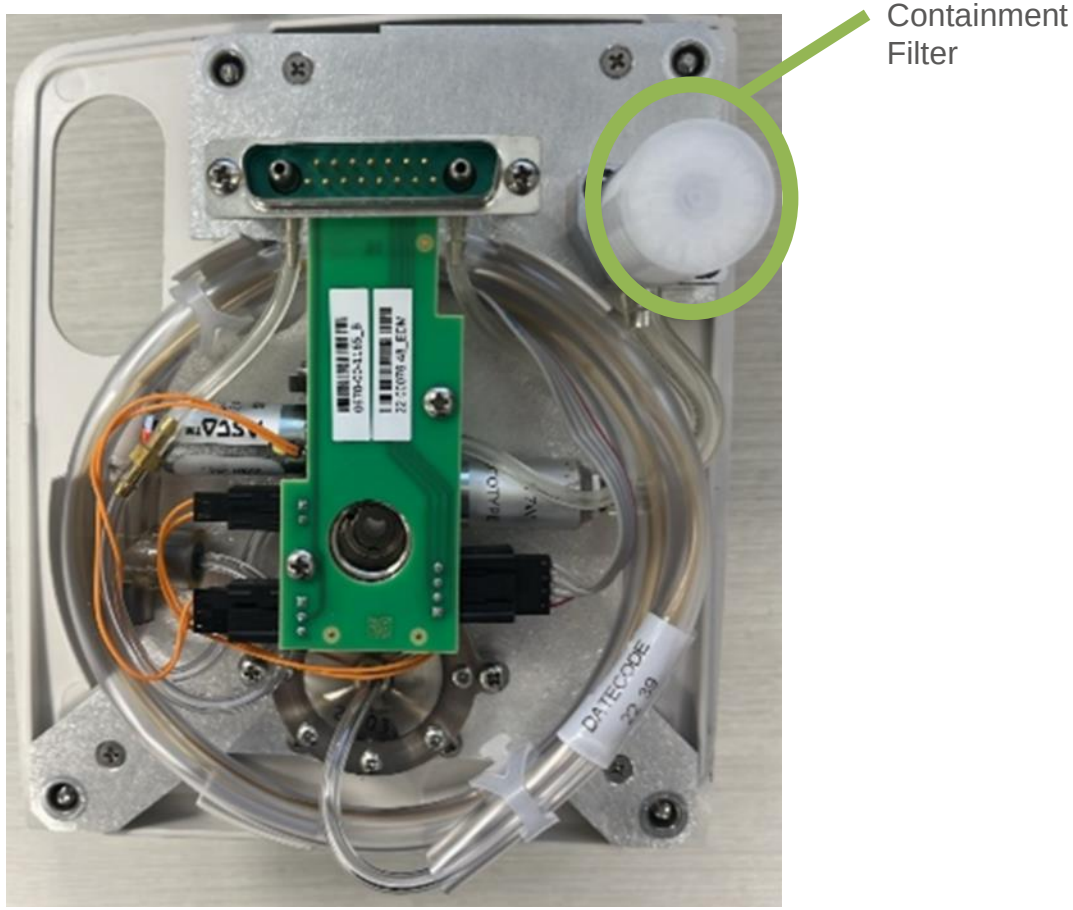
If an IAB catheter perforation occurs and blood is pulled into the IABP console, blood will be contained in this filter

- Pumping is suspended - IABP is automatically placed into Standby
- Technical alarm “Pump Failure - Service Required” is activated and a high-pitched alarm sounds

The IABP is inoperable and cannot be used until service is completed

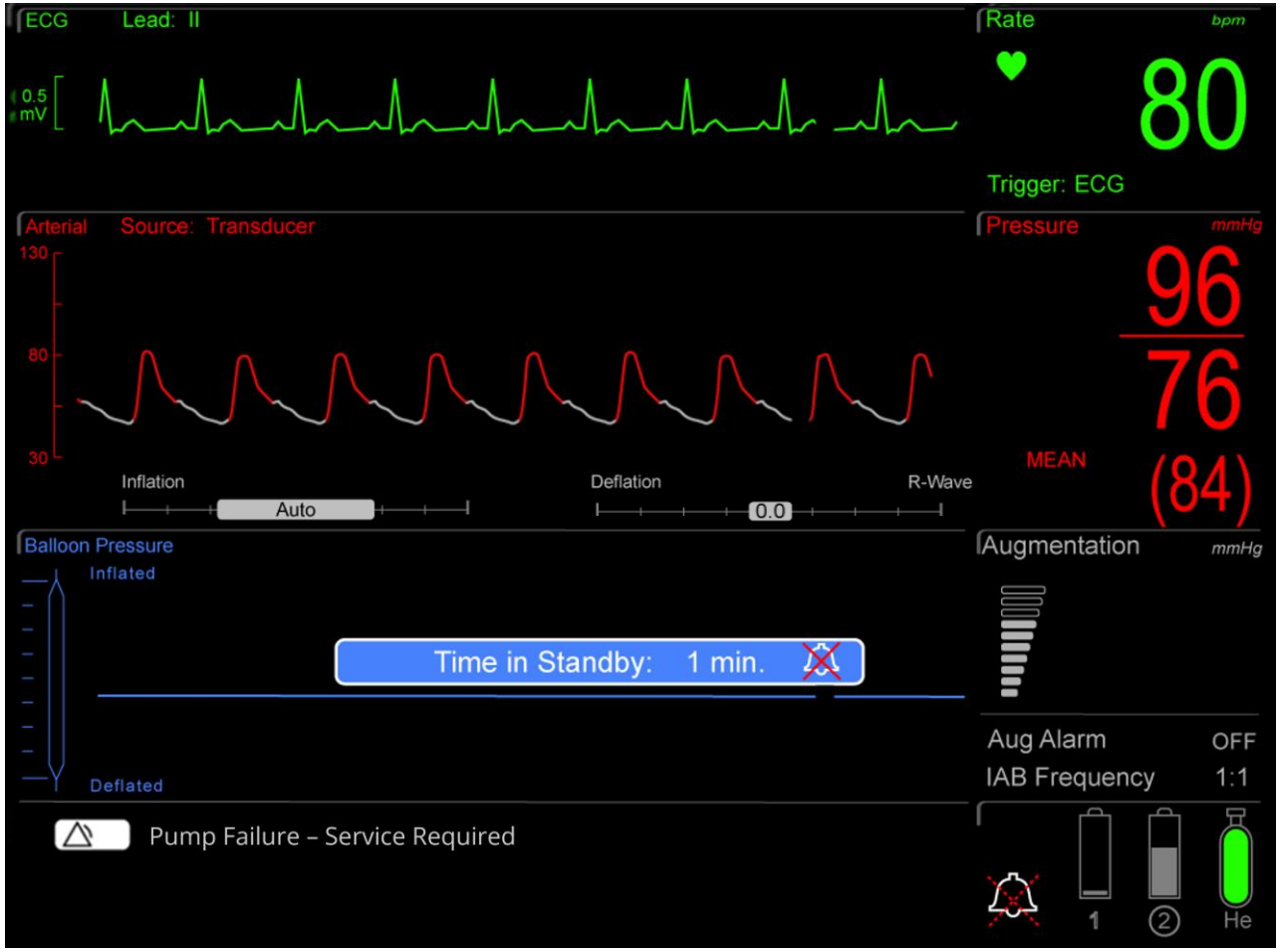
Technical Alarm: “Power-Up Test Fails Code #15

- If the IABP has not been serviced and is restarted, a new technical alarm “Power-Up Test Fails Code #15” is activated
- IABP is not operational and must be taken to Biomedical/Technical Service



Alarm: “Pump Failure - Service Required”

Technical Alarm



Alarm: “Pump Failure - Service Required”

Technical Alarm

Probable Cause	Corrective Action
IABP inoperable due to blood entering the IABP console. Blood seen in IAB catheter or helium extender tubing.	1. Disconnect the helium extender tubing from IABP console to allow the balloon to deflate. 2. Clamp IAB catheter tubing (extracorporeal) between white Y-fitting and male connector. 3. Notify physician and prepare for IAB catheter removal. 4. Consider IAB catheter replacement if the patient condition warrants. 5. Remove affected pump from service and have it evaluated by Biomed/Technical Service before using it on another patient.
IABP inoperable, no blood seen.	1. Therapy may continue with a replacement IABP. 2. Remove affected pump from service and have it evaluated by Biomed/Technical Service. 3. The IABP cannot be used on another patient until serviced.

Cardiosave Additions

Summary

Blood Surveillance Algorithm

- New algorithm added to IABP
  - IABP evaluates for evidence of IAB catheter perforation during:
    - ✓ High priority alarms that indicate a potential IAB catheter perforation
    - ✓ Q 2-hr scheduled autofill
    - ✓ User initiated IAB Fill
    - ✓ Manually placed into Standby
- High Priority Alarm: “Blood Suspected – Check Catheter and Tubing”

Blood Containment

- Addition of containment filter inside the IABP
- New Technical Alarm: “Pump Failure – Service Required”

Knowledge Check

What new safety features have been introduced in the latest Cardiosave update?

1. Updated safety disk
2. Improved data encryption
3. Blood Containment Filter and Blood Surveillance Algorithm
4. A new noise cancelling compressor

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1. Updated safety disk
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3. **Blood Containment Filter and Blood Surveillance Algorithm**
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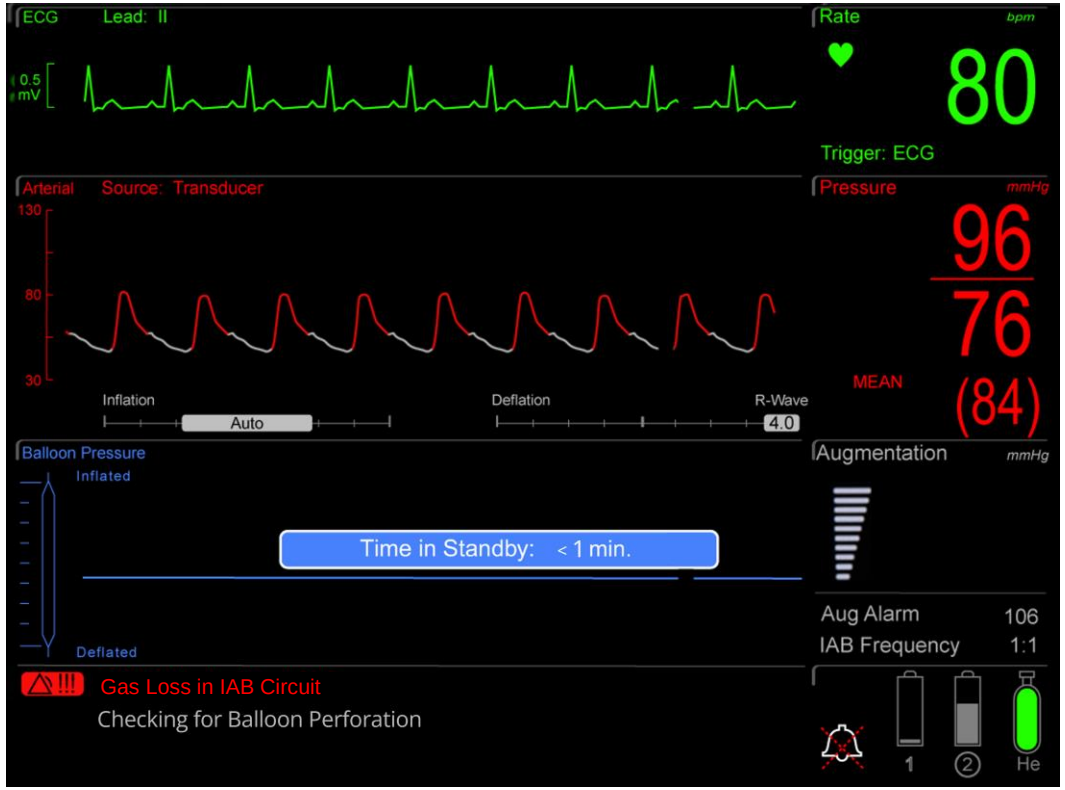
Knowledge Check

The alarm “Gas Loss in IAB Circuit” is activated and you see the following screen.

List the priority action steps in the correct order:

- Press **Start** to resume pumping
- Check the IAB catheter tubing (extracorporeal) or helium extender tubing for evidence of blood
- Press **IAB Fill**



Knowledge Check

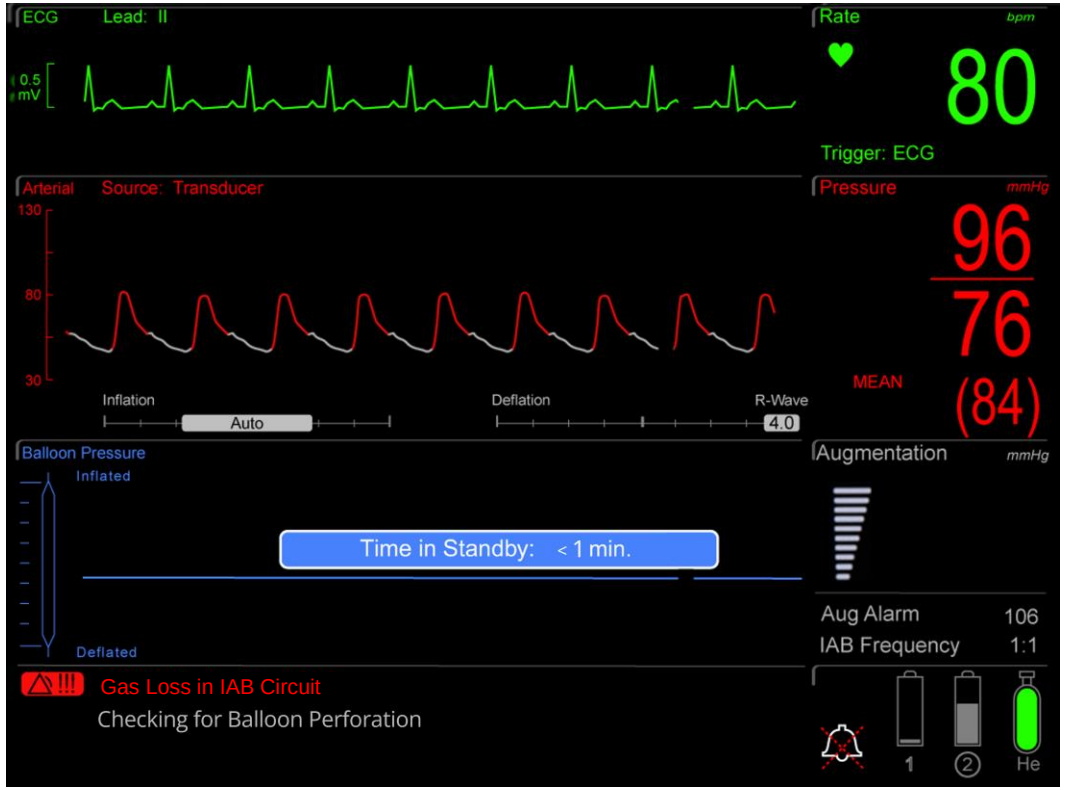
The alarm “Gas Loss in IAB Circuit” is activated and you see the following screen.

Correct Action steps:

1. Check IAB catheter tubing (extracorporeal) or helium extender tubing for evidence of blood

2. Press **IAB Fill** – ONLY if no blood is seen

3. Press **Start** to resume pumping



Knowledge Check

If blood is suspected of having entered the Cardiosave IABP, what action(s) should be taken?

1. Take the affected pump out of service
2. Ensure the pump is evaluated by Biomedical or Technical Services
3. Confirm the affected pump is not used on another patient until serviced
4. All of the above

Knowledge Check

If blood is suspected of having entered the Cardiosave pump what action should be taken?

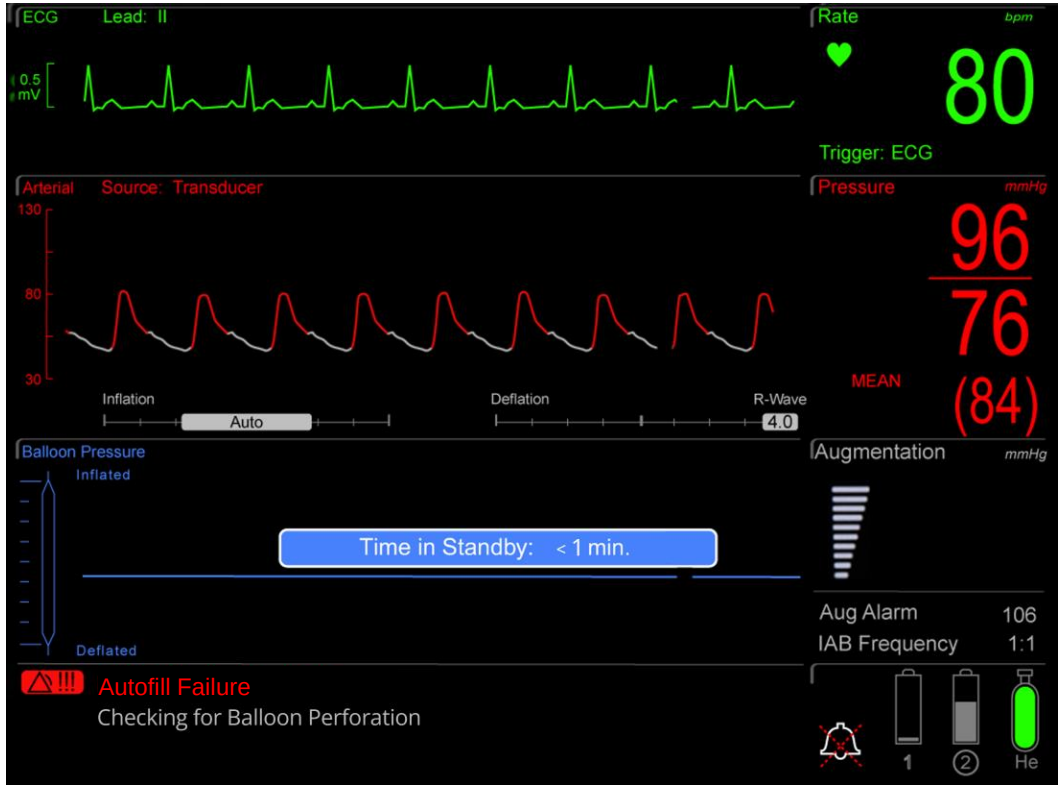
1. Take the affected pump out of service
2. Ensure the pump is evaluated by Biomedical or Technical Services
3. Confirm the affected pump is not used on another patient until serviced
4. **All of the above**

Knowledge Check

The IABP alarms and displays the following screen.

What is the potential cause for this alarm?

1. The patient is agitated and likely kinked the IAB catheter
2. There is a potential IAB catheter perforation
3. The IAB catheter became disconnected
4. There is a change in the patient's hemodynamics



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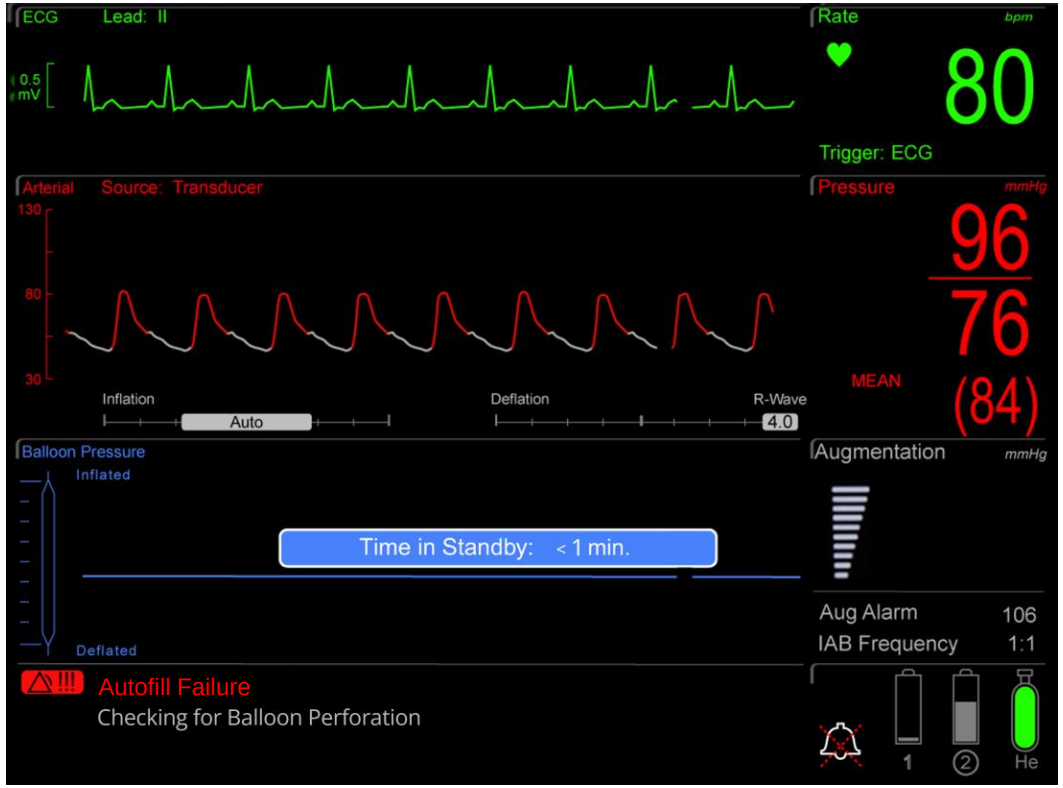

Knowledge Check

The alarm “Blood Suspected – Check Catheter and Tubing” is activated. You assess the patient and do not see any blood in the IAB catheter tubing (extracorporeal) or helium extender tubing.

What is your next step?

1. Do nothing and ignore it
2. Therapy should be stopped – there is a likelihood the IAB catheter is perforated
3. Reset the alarm by turning the IABP *off* and then back *on*
4. Notify the medical team immediately to assess the situation and take appropriate action

Knowledge Check

The alarm “Blood Suspected – Check Catheter and Tubing” is displayed. You assess the patient and do not see any blood in the IAB catheter tubing (extracorporeal) or helium extender tubing.

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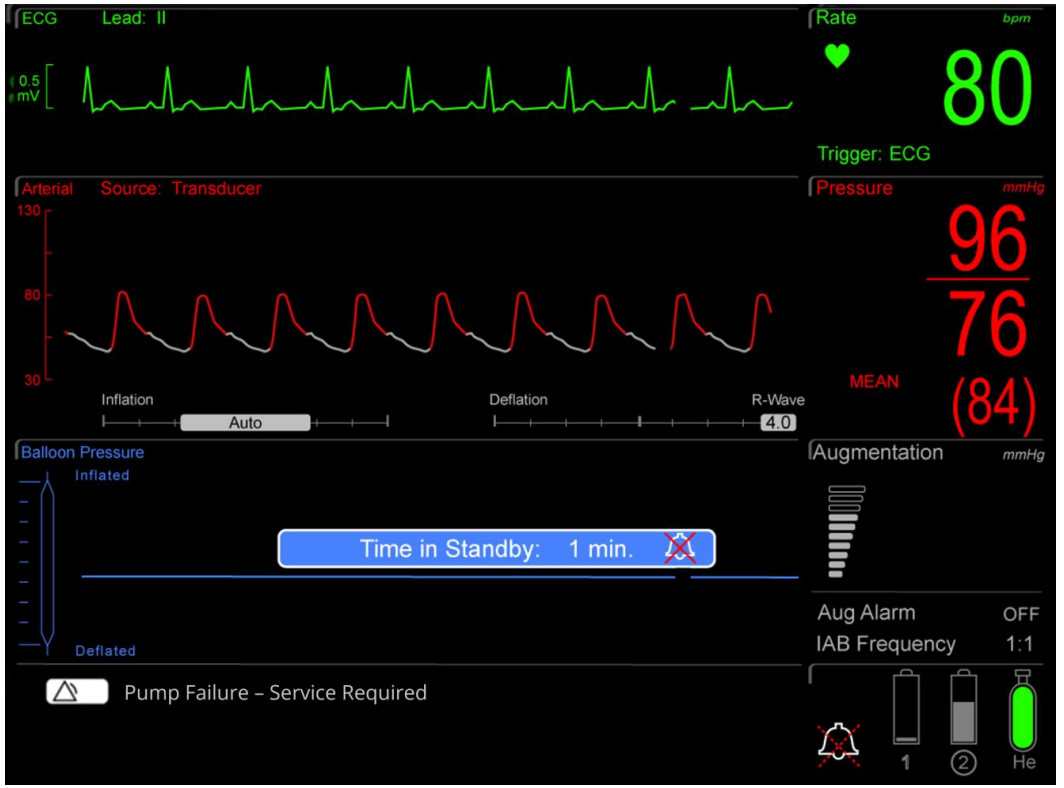
Knowledge Check

You respond to a high-pitched alarm and see the message “Pump Failure-Service Required.”

What is your next step?

1. IABP alarm needs to be reset by powering *off* and turning IABP *on*
2. Remove affected pump from service
3. Select “Pause Audio” Key and wipe the pump down with Sani-wipes and store for next patient use
4. Replace IAB catheter and IABP to continue therapy



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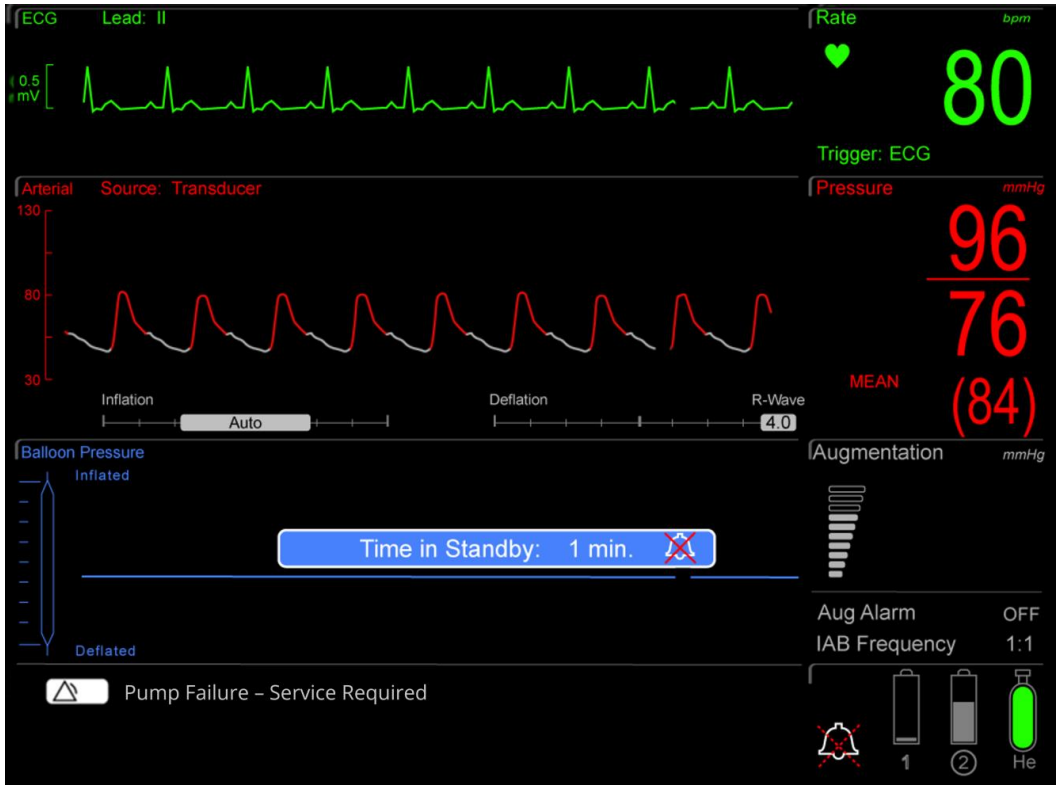

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Questions?

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