

Cardiosave Software Revisions

B.17 / C.06 - D.00 Software

Cardiosave Version B.17 / C.06 to D.00 Software

Background

- Creates one version of Cardiosave software for Getinge markets worldwide.
 - Currently, different software versions exist because of different regulatory requirements around the world.
- Adds software enhancements and addresses maintenance items.
- Enhances battery messages, supports battery maintenance, and provides additional battery capacity information.
- Enhances cybersecurity protections.
- Improves service diagnostics.
- Corrects software anomalies.

Cardiosave Version B.17 / C.06 to D.00 Software

Background

- The following slides outline the changes that may be apparent during everyday use of Cardiosave.
- The revisions can result in the following:
 - Change in operation.
 - New messages on the monitor display.
 - Additional information in the Help Screens.
 - New key and additional information on the Touchscreen.

Cardiosave Version B.17 / C.06 to D.00 Software

Background

Field Safety Corrective Actions Addressed

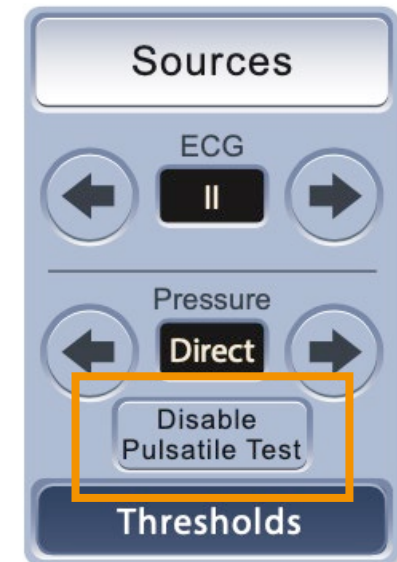
- Cardiosave Software Version D.00 Addresses three (3) open Field Safety Corrective Actions (FSCA).
 - Cybersecurity Vulnerabilities– Ripple20
 - Battery Usage, Charging, Maintenance and Storage Instructions
(Part of this FSCA was completed at an earlier date as part of the release of the Cardiosave Li-Ion Battery Transport and Storage Case.)
 - Shutdown Upon Battery Removal

Flat Arterial Pressure (A.P.) surveillance

Flat Arterial Pressure (A.P.) surveillance

Applicable software versions

- Cardiosave with C.06 software currently has this feature and will continue to have this feature when the system is upgraded to D.00.



Flat Arterial Pressure (A.P.) surveillance

Reason for update

- This change was implemented to comply with new regulatory standards, which require detection and an alarm for a blood pressure monitoring fault.

Description

- With this software change, the system performs a flat A.P. surveillance check of the arterial pressure source.
 - Monitors for sustained loss of pulsatility on the A.P. waveform when pulsatility is expected.
- If a sustained loss of pulsatility is detected, **No Pressure Source Available** - Medium Priority Alarm will occur.



Flat Arterial Pressure (A.P.) surveillance

Newly added probable cause for existing Medium Priority Help Screen

- Prior to updating B.17 software, the only probable cause listed for the **No Pressure Source Available** alarm was "No DIRECT or EXTERNAL arterial pressure (A.P) source was detected."

The newly added probable causes include:

- The A.P. transducer has been vented to the atmosphere for more than 10 seconds.
- The pressure monitoring tubing has become disconnected.
- The pressure monitoring lumen of the IAB may have become restricted due to clot formation and is producing a flat A.P. waveform.
- A defective A.P. transducer or pressure transducer cable produces a flat A.P. waveform.

Flat Arterial Pressure (A.P.) surveillance

Current probable cause for existing Medium Priority Help Screen

No Pressure Source Available

No DIRECT or EXTERNAL arterial pressure (A.P) source was detected.

1. If using a Fiber-Optic IAB, ensure that the Fiber-Optic Sensor Cable is connected. Once connected, a calibration will occur automatically in 20 seconds.
2. If a transducer is in use, ensure that the pressure cable is connected to the transducer and the IABP. If the alarm persists, consider replacing the pressure cable.
3. If an A.P. source is still unavailable, consider providing an A.P. signal using an interface cable from the high level output of an external monitor to the IABP. Manually switch the IABP's pressure input to EXTERNAL using the PRESSURE ARROW keys in the SOURCES Menu.

Flat Arterial Pressure (A.P.) surveillance

Newly added probable cause for existing Medium Priority Help Screen

No Pressure Source Available

The A.P. transducer has been vented to atmosphere for more than 10 seconds.

1. Verify that the transducer is not vented to atmosphere.
2. If vented, reestablish A.P. pulsatility by closing the vent stopcock.

The pressure monitoring tubing has become disconnected.

1. Verify the integrity of the pressure monitoring lines and luer connectors.
2. Correct per hospital pressure monitoring procedures.

Flat Arterial Pressure (A.P.) surveillance

Newly added probable cause for existing Medium Priority Help Screen

No Pressure Source Available

The pressure monitoring lumen of the IAB may have become restricted due to clot formation and is producing a flat A.P. waveform.

1. Attempt to aspirate the inner lumen. If you met resistance during aspiration, consider the inner lumen to be occluded. Discontinue the use of the inner lumen by placing a luer cap on the female luer hub of the inner lumen. Provide an alternate A.P. source (i.e. radial) by connecting and zeroing a standard transducer. If an alternate A.P. source (i.e. radial pressure source) is not available, connect an interface cable from the A.P. high level output of an external monitor to the IABP. Manually switch the IABP's pressure input to EXTERNAL using the PRESSURE ARROW keys in the SOURCES Menu.
2. If an alternate A.P. source is not available, override the alarm by pressing the DISABLE PULSATILE TEST button in the SOURCES menu.

Flat Arterial Pressure (A.P.) surveillance

Newly added probable cause for existing Medium Priority Help Screen

No Pressure Source Available

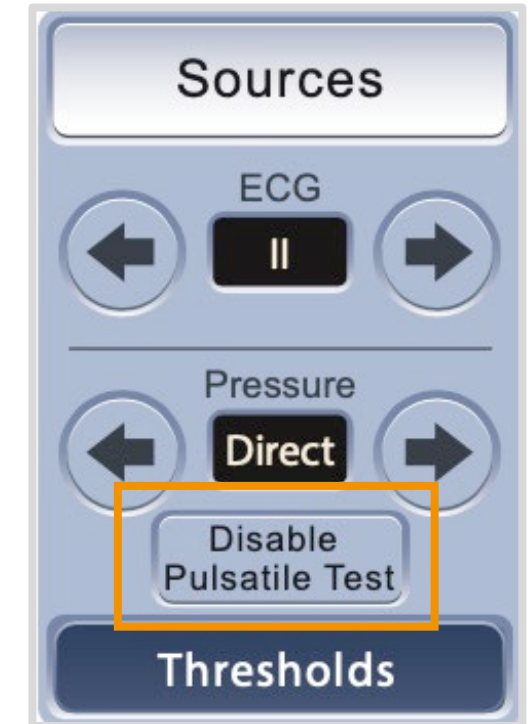
A defective A.P. transducer or pressure transducer cable is producing a flat A.P. waveform.

1. Check for damage to the pressure transducer cable.
2. Consider replacing the pressure transducer cable and pressure transducer.
3. If alarm persists, provide an alternate A.P. source (i.e. radial) by connecting and zeroing a standard transducer or by connecting an interface cable from the A.P. high level output of an external monitor to the IABP. Manually switch the IABP's pressure input to EXTERNAL using the PRESSURE ARROW keys in the SOURCES Menu.
4. If an alternate A.P. source is not available, override the alarm by pressing the DISABLE PULSATILE TEST button in the SOURCES menu.

Flat Arterial Pressure (A.P.) surveillance

Clinical considerations

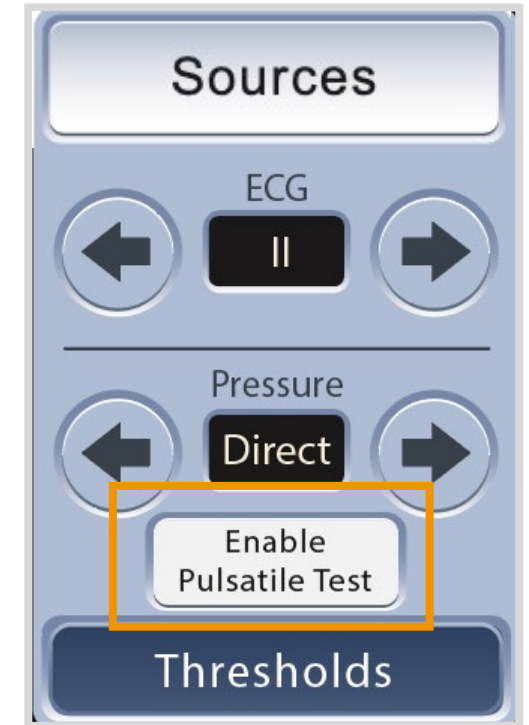
- The **Disable Pulsatile Test** key allows the user to suspend the Flat Arterial Pressure (A.P.) Surveillance checks.
 - Disabling the pulsatility check can accommodate the following:
 - The absence of pulsatility, which can exist when IAB support is temporarily paused while the patient is concurrently being supported with a non-pulsatile mechanical circulatory support device.
 - When persistent conditions persist, such as a clotted A.P. lumen.
 - If the pressure monitoring lumen of the IAB is clotted, provide an alternate A.P. source.



Flat Arterial Pressure (A.P.) surveillance

Clinical considerations

- The flat A.P. surveillance can be resumed by pressing the **Enable Pulsatile Test** key.
- The pump will also automatically resume the flat A.P. surveillance check after detecting 30 continuous seconds of pulsatility on the waveform.



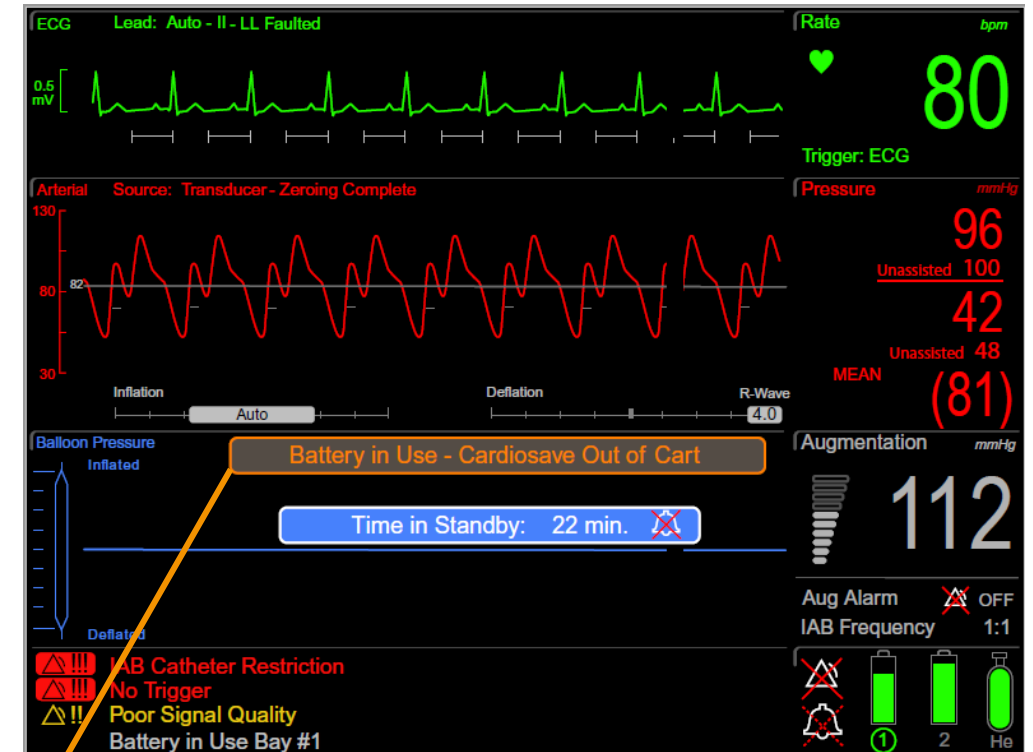
Docking Status Banner on Monitor Display

Docking Status Banner on Monitor Display

Newly added Status Indicators

Reason for update

- Operators of the Cardiosave IABP may be unaware that the IABP Console has not been fully docked into the cart.
- This software change is intended to increase the user's awareness that the IABP Console is not properly docked into the cart.
- ***If not securely docked into the cart, Cardiosave will continue to operate on battery power until the batteries are fully depleted, leading to a shutdown of the IABP Console.***



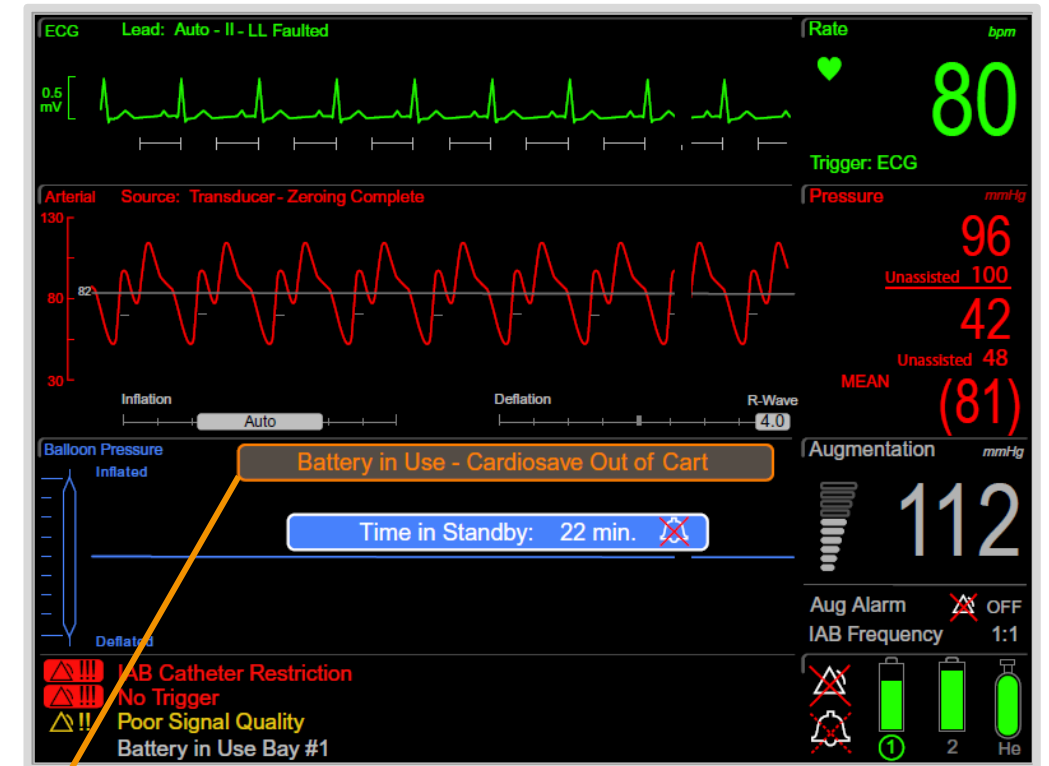
Battery in Use - Cardiosave Out of Cart

Docking Status Banner on Monitor Display

Newly added Status Indicators

Description

- The following changes were made to the **Monitor Display**:
 - The **Time in Standby** banner was relocated slightly lower.
 - The new banner, **Battery in Use – Cardiosave Out of Cart**, will be displayed whenever the Cardiosave IABP Console is not securely docked into the hospital cart and running on battery power.



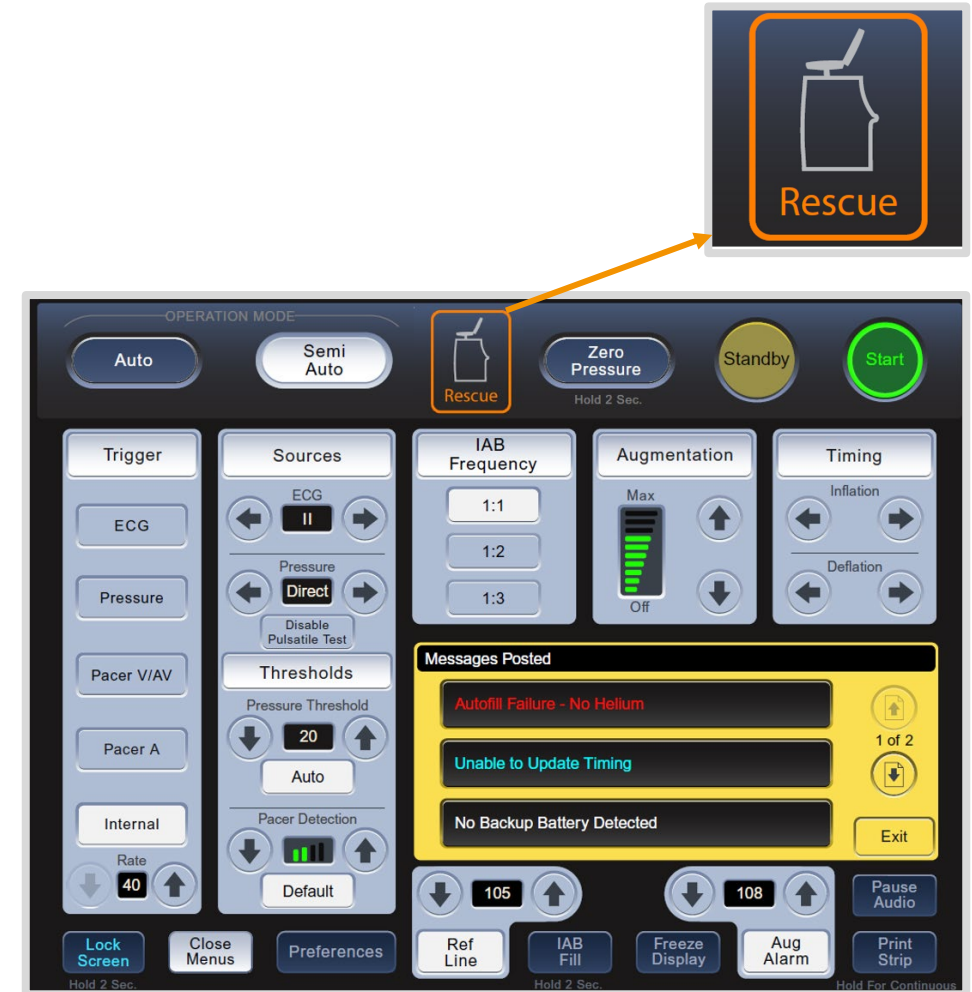
Battery in Use - Cardiosave Out of Cart

Docking Status Banner on Monitor Display

Newly added Status Indicators

Description

- The following changes were made to the **Touchscreen** :
 - An orange border has been added around the Rescue icon when the IABP Console is not securely docked in the Hospital Cart.
 - When the IABP is in Rescue Mode, the orange border will continuously flash between dark orange and light orange.
- If the IABP is set up in the Hybrid Mode and the Rescue icon is displayed on the Touchscreen, ensure that the IABP Console is securely docked in the Hospital Cart.



Software Version added to Preferences Menu

Software Version in Preferences Menu

Reason for update

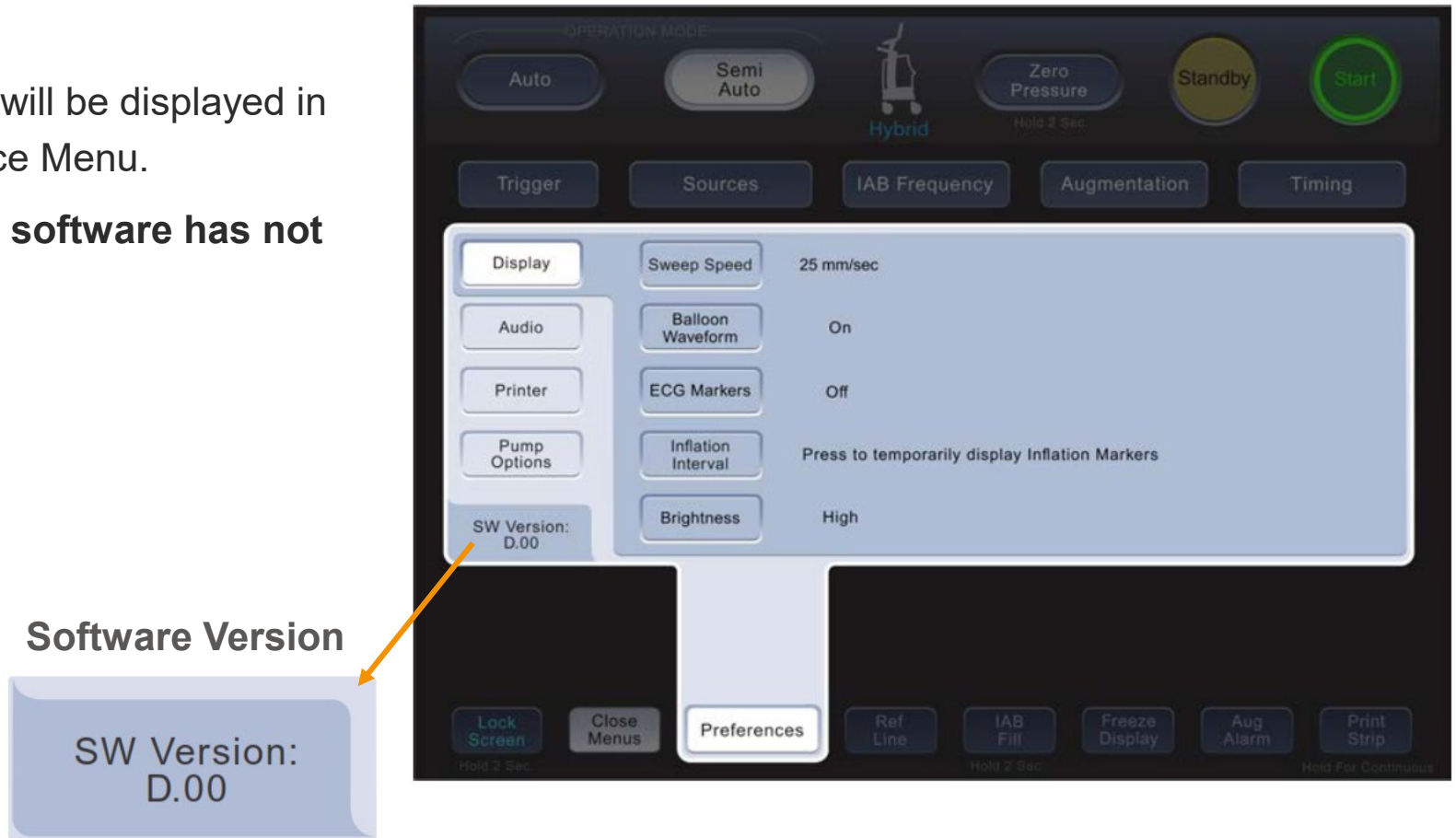
- This allows the user access to Cardiosave's current software version while in clinical mode.
 - For ease in identifying current software version when required:
 - When contacting Getinge with questions
 - For proper assistance while troubleshooting
 - Product complaint reporting

Software Version in Preferences Menu

Description

The installed software (SW) version will be displayed in the lower-left corner of the Preference Menu.

- If this information is absent, the software has not been updated to D.00 SW.



System power down/power up

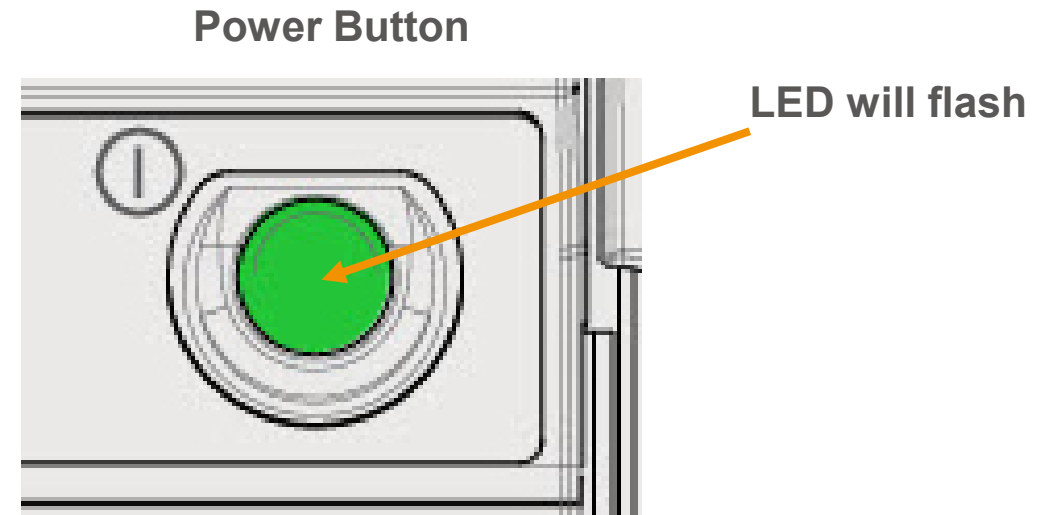
System power down/power up

Reason for update

- Due to characteristics of electronic components, rapidly powering down and then powering up the system can have undesirable effects on operation.
- There are no known issues with the previous B.17 or C.06 software, but this will ensure safer power down/power up sequences.
- This update will prevent the user from restarting the unit within 10 seconds of a previous shutdown.

Description

- Whenever the Cardiosave system is powered down, the user will be unable to restart the unit for 10 seconds.
- The power button LED will flash during this 10 second period.



Unexpected Shutdown Upon Battery Removal

Unexpected Shutdown Upon Battery Removal

Reason for update

- Previously Datascope/Getinge initiated a voluntary Medical Device Correction for the Cardiosave Hybrid Intra-Aortic Balloon Pump (IABP) due to unexpected shutdown upon battery removal.
- Prior to D.00 software, during a very specific set of conditions, the Cardiosave Hybrid IABP could unexpectedly shut down when the device was running on AC power, only one battery installed in the IABP, and the battery was physically removed while the battery was being charged.

Description

- The system will now recognize the charging battery's removal, disconnect the battery charging system and also switch to AC power without interruption of therapy.



Cardiosave Hybrid

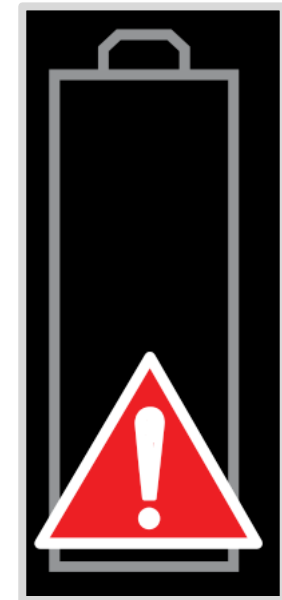
Battery Charge Level Unavailable Bay #____

Battery Charge Level Unavailable Bay #____

Newly added High Priority Alarm

Note

- With this revision, it is possible to have a functioning battery but not have current battery information on the screen.
- A High Priority Alarm and Help Screen has been added to the system.



Battery icon

Battery Charge Level Unavailable Bay #____

Newly added High Priority Alarm

Alarm event

- The indicated battery is unable to communicate its charge level to the IABP.

IABP response

- *Cardiosave will continue to deliver active IABP therapy.*
- The High Priority Alarm Icon - red flashing alarm icon with three (3) exclamation points will be visible on the Monitor Display.
- The uniform audio tone for High Priority Alarms will be played in the following sequence:
 - five notes - short pause - five notes - long pause; the cycle repeats.

Alarm reset event

- When the battery is replaced.



High priority alarm icon

Battery Charge Level Unavailable Bay #____

Newly added High Priority Help Screen

Battery Charge Level Unavailable Bay #____

The battery in the identified bay or bays is unable to communicate the battery charge level.

1. Immediate battery replacement is required.
2. Replace the battery that is currently in use. If a fully charged battery is not available, connect to an AC power source as soon as possible.
3. If battery operation on the indicated battery is required, monitor the system closely for a system shutdown, the Low Battery Alarm will not be displayed.
4. Contact MAQUET Service to obtain a new battery.

Battery Maintenance Required Bay #____

Battery Maintenance Required Bay #____

Newly added Informational Message

Alarm event

- Previous Maintenance date is past due.

IABP response

- An informational message will be posted on startup and remain displayed for 5 minutes or until the Cardiosave IABP starts assisting.
- The Informational audio tone shall sound for 60 seconds or until the pump begins assisting.

Informational message reset event(s)

- When battery maintenance has been performed, the battery requiring maintenance has been replaced, or the START key is pressed, initiating IABP assistance.

Battery Maintenance Required Bay #____

Newly added Informational Message

During the initiation of therapy

- Verify that the power cord is plugged into an appropriate AC power outlet and continue operation on AC power.
- If battery operation is required, the battery run time may be reduced and the battery gauges may not reflect the remaining battery charge accurately.
 - Consider replacing the affected battery with a fully charged replacement battery, if available.
 - Monitor the system closely for a Low Battery alarm.
 - If a Low Battery alarm occurs, immediately connect the system to AC power or install a fully charged battery.
- Contact your facility's Biomedical Services department to inform them of the Battery Maintenance Required Informational Message.

Battery Maintenance Required Information

Newly added Informational Message Help Screen

Battery Maintenance Required Bay #____

The battery in the identified bay requires maintenance.

1. Continue operation on AC power.
2. If battery operation is required, the battery run time may be reduced. Monitor the system closely for a Low Battery alarm.
3. If a Low Battery alarm occurs, immediately connect the system to AC power or install a fully charged battery.
4. As soon as possible, execute the Battery Maintenance process as follows:
5. Connect the IABP to an AC power source.

Battery Maintenance Required Information

Newly added Informational Message Help Screen

Battery Maintenance Required Bay #____

The battery in the identified bay requires maintenance.

6. Power down the IABP.
7. Pressing and continue to hold the Pressure “Vent” button. This button is on the rear panel and is labeled in red with “->0<-“.
8. Press the “Power” button to turn on the system.
9. Wait until the rotating symbol on the lower display changes direction to a clockwise rotation.
10. Release the “Vent” button.
11. Wait for the Special Menu to display.

Battery Maintenance Required Information

Newly added Informational Message Help Screen

Battery Maintenance Required Bay #____

The battery in the identified bay requires maintenance.

12. Press the Battery Maintenance key in the touch screen display.
13. Press the Run button to start the process.
14. Wait for the status field to indicate the process has been completed.

Battery Maintenance Required Information

Warning

- The battery maintenance process will take up to 22 hours for each battery and will completely drain the selected battery.
- Ensure a second fully charged battery is available before starting the Battery Maintenance process.

Note

- Turning off the unit or aborting the battery maintenance procedure before completion will end the process without saving the final results.
- Battery maintenance will need to be repeated from the beginning without interruption to completion for proper conditioning of the battery to occur.

Battery Replacement Required Bay #____

Battery Replacement Required Bay

Newly added Informational Message

Alarm event

- The indicated battery has failed a system check for battery reliability.

IABP response

- An informational message will be posted on startup and remain displayed for 5 minutes or until the Cardiosave IABP starts assisting.
- The Informational audio tone shall sound for 60 seconds or until the pump begins assisting.

Informational message reset event(s)

- The reset shall occur when either the battery has been replaced or the START key is pressed and therapy is initiated.

Battery Replacement Required Bay #____

Newly added Informational Message Help Screen

Battery Replacement Required Bay #____

The battery in the identified bay or bays has become unreliable and requires replacement.

1. Battery replacement is required.
2. Continue operation on AC power.
3. If battery operation on the indicated battery is required, the battery run time will be reduced.
Monitor the system for a Low Battery alarm
4. If a Low Battery alarm occurs, immediately replace the battery or return to AC power.
5. Contact MAQUET Service to obtain a new battery.

Battery in Use Bay #____

Battery in Use Bay #____

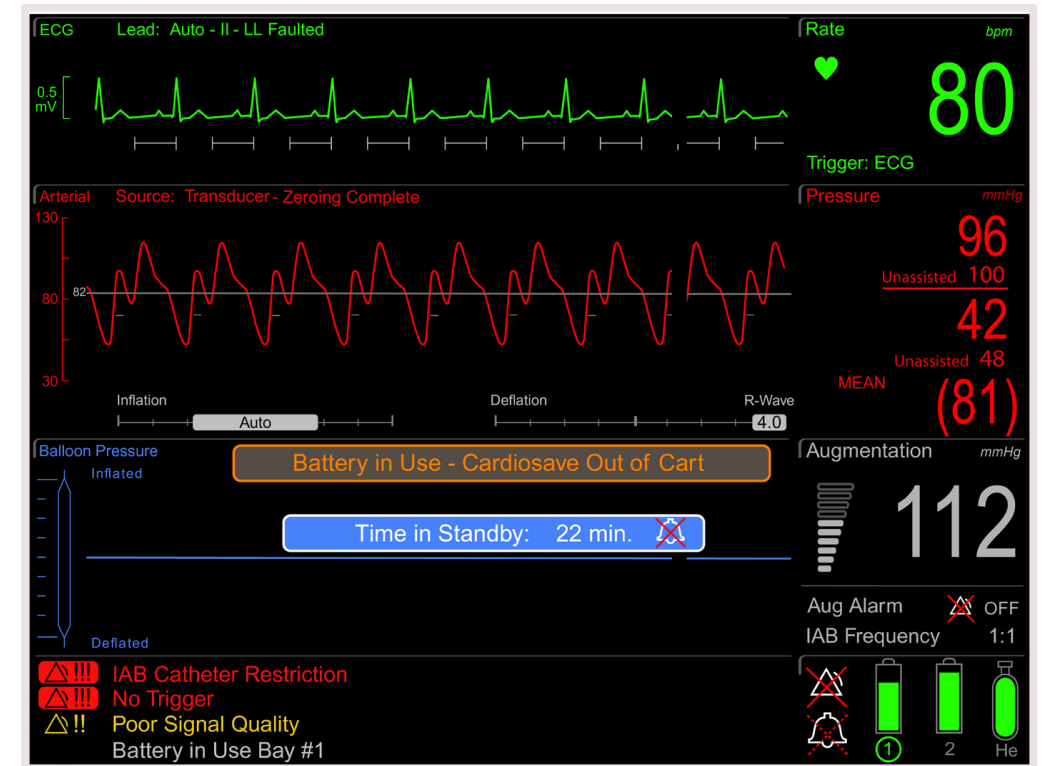
Newly added Bay Indicator on current Informational Message

Reason for update

- To inform the user which of the two batteries is currently in use.

Description

- A battery bay indicator was added to the current **Battery in Use** Informational Message on the Monitor Display to indicate which of the two batteries is currently in use.



Battery in Use Bay #1

Battery in Use Bay #____

Newly added Informational Message Help Screen

Battery in Use Bay #____

The IABP is on battery power.

1. If available, switch to an AC power source.

Low Battery Alarm

Low Battery Alarm

Reason for change

- Improve warning time to the IABP operator of the impending end of battery operating run time.

Description

- Currently, a **Medium Priority Alarm** exists for Low Battery Alarm when there are *less than 30 minutes* of battery operating time.
- With this software update, a **High Priority Alarm** is added for when *less than 15 minutes* of battery operating time is remaining.

Low Battery Alarm

Current Medium Priority Alarm

Alarm event

- Cumulative reserve of both batteries falls below 30 minutes of operating time.

IABP response

- *Cardiosave will continue to deliver active IABP therapy.*
- The Medium Priority Alarm Icon - yellow flashing alarm icon with two (2) exclamation points will be visible on the Monitor Display.
- The uniform audio tone for Medium Priority Alarms will be played in the following sequence:
 - three notes - pause; the cycle repeats.

Alarm reset event(s)

- Automatically removes message and turns off tone when an AC power source is restored or when a charged battery is inserted.



Medium priority alarm icon

Low Battery Alarm

Current Medium Priority Alarm Help Screen

Low Battery

There is less than 30 minutes of battery operating time remaining

1. Connect system to an AC power source.
2. If an AC power source is unavailable, insert a charged battery into the battery bay not currently in use.

Low Battery Alarm

Newly added High Priority Alarm

Alarm event

- Cumulative reserve of both batteries falls below 15 minutes of operating time.

IABP response

- *Cardiosave will continue to deliver active IABP therapy.*
- The High Priority Alarm Icon - red flashing alarm icon with three (3) exclamation points will be visible on the Monitor Display.
- The uniform audio tone for High Priority Alarms will be played in the following sequence:
 - five notes - short pause - five notes - long pause; the cycle repeats.

Alarm reset event(s)

- Automatically removes message and turns off tone when an AC power source is restored or when a charged battery is inserted.



High priority alarm icon

Low Battery Alarm

Newly added High Priority Alarm Help Screen

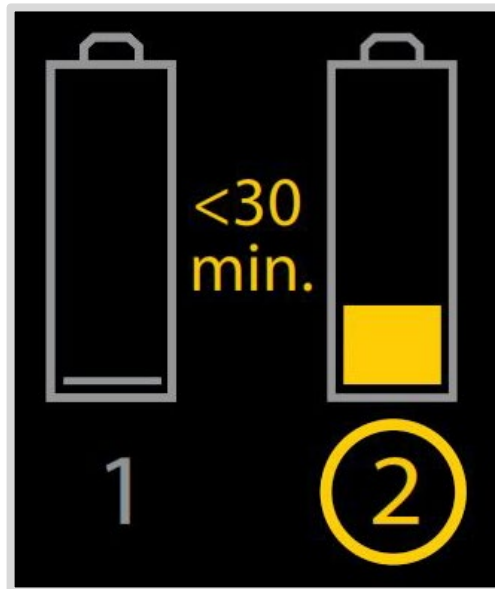
Low Battery

There is less than 15 minutes of battery operating time remaining.

1. Connect system to an AC power source.
2. If an AC power source is unavailable, insert a charged battery into the battery bay not currently in use.

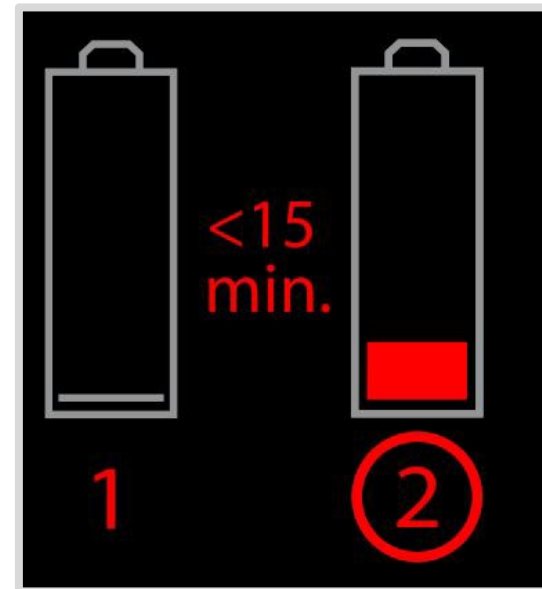
Low Battery Alarm

Battery status on Monitor Display (examples)



Medium Priority alarm

Battery 1 is depleted and battery 2 has less than 30 minutes of charge remaining.



High Priority alarm

Battery 1 is depleted and battery 2 has less than 15 minutes of charge remaining.

Video Executive Circuit Board

Video Executive Circuit Board

Board reset

Reason for update

- Prior to D.00 software, Cardiosave did not tolerate the presence of long communication issues between the executive and video processors.
 - The system's response was to declare a system failure and stop therapy.
- The D.00 update allows the system to continue delivering therapy during brief video failures.

Video Executive Circuit Board

Board reset

Description

- In the event of a loss of communication or unrecoverable error on the video processor, by allowing the executive processor to power down and repower the video head whenever communication is lost.
 - IABP will continue to deliver active therapy during resetting.
 - These reset events will cause a brief blanking of the Monitor Display.
 - An Informational Message will inform the operator that the IABP internal self-checks have detected a video communication condition, and the IABP may require service.

Video Executive Circuit Board

Newly added probable cause for existing Informational Message Help Screen

IABP May Require Maintenance

IABP Internal self-checks have detected a video communication condition that may require service.

1. If available, switch to another MAQUET IABP and contact MAQUET Service for system diagnosis.
2. If another MAQUET IABP is not available, verify IABP functionality and continue use. IABP may reset the User Interface display causing a brief blanking of the video display screens.
3. Once IABP use is discontinued, contact MAQUET Service for system diagnosis.

Cybersecurity vulnerabilities - Ripple20

Cybersecurity vulnerabilities - Ripple20

Reason for update

- Previously Datascope/Getinge initiated a voluntary Medical Device Correction for the Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pump (IABP) due to cybersecurity vulnerabilities.
- These vulnerabilities may have resulted in a loss of communication to the Hospital Information System/Clinical Information System (HIS/CIS).

Cybersecurity vulnerabilities - Ripple20

Description

- With this Field Safety Corrective Action users were instructed to disconnect the Ethernet cable from the Cardiosave Ethernet Port identified [Figure 1].
- Additionally customers were given instruction for turning off Network Connections.
- With the installation of D.00 software this issue is resolved.
- The user is now able to reconnect the Ethernet cable to the Cardiosave Ethernet port and turn on Network Connections via the Network Connections settings in the Pump Options menu [Figure 2].

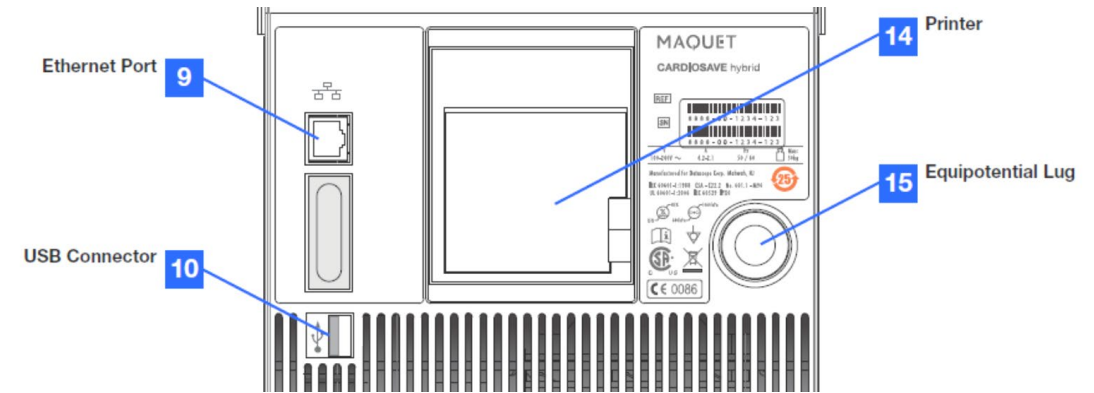


Figure 1

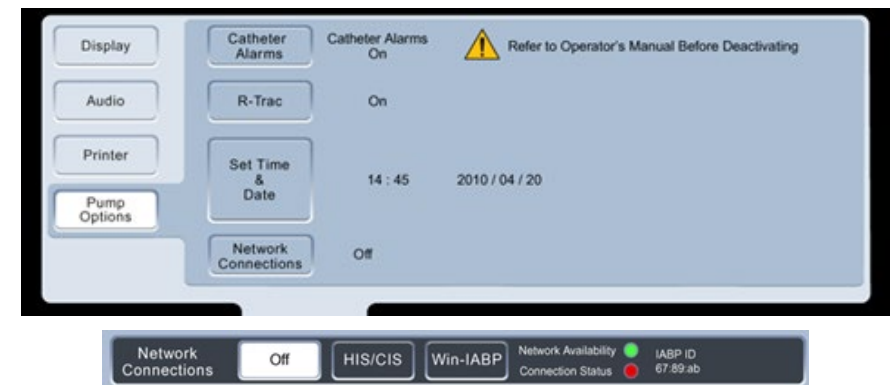


Figure 2

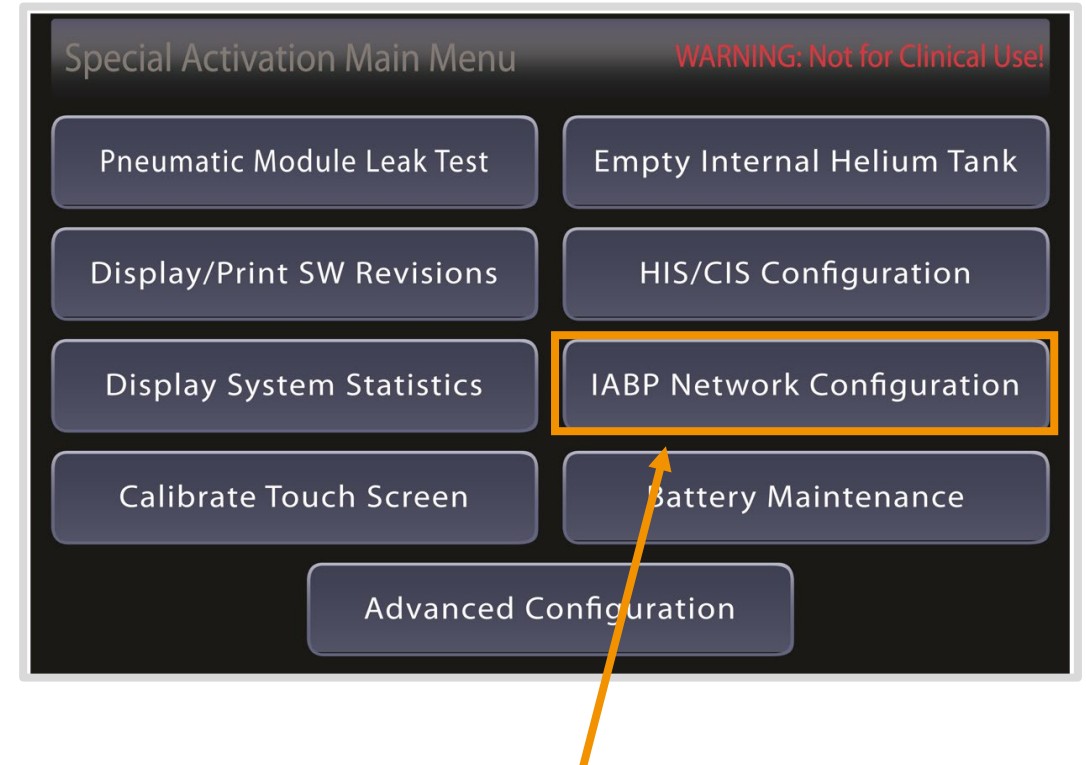
Network IP Address Configuration Relocated

Configuration of HIS/CIS

Network IP Address Configuration Relocated

Reason for update

- Service departments have requested an update to the System Diagnostics menu structure to allow hospital personnel to set the system IP address from the Special Activation Menu.



Configuration of HIS/CIS

Network IP Address Configuration Relocated

Description

- The appropriate hospital personnel (i.e. biomedical engineer, hospital IT specialist, etc.) will now be able to set the system IP address from the Special Activation Menu.

Note


The settings in this menu should only be changed by an authorized technician that is familiar with data communication protocols HIS/CIS configuration.

HIS/CIS Configuration

WARNING: Not for Clinical Use!

HIS/CIS Revision

Selection of the protocol revision to be used by the IABP when communicating to the HIS/CIS System

 Warning: Selecting a protocol revision other than the revision noted in "Current Protocol Revision" may result in the loss of some or all HIS/CIS data.

Current Software HIS/CIS Protocol Revision - D

Version D: Includes all of the alarms and electrical test failures as of version D of the HIS/CIS Protocol, refer to the Cardiosave HIS/CIS Communications Protocol for document specifics.

Version CVersion D

Server Address

Contact your network administrator to obtain the IP address of the HIS/CIS Server

Edit Server Address

Back to Main Menu

Questions

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Intra-Aortic Balloon Pumps & Catheters Video Library

Educational Videos

Visit <https://getinge.training/iabp-int/videos/>

Intra-Aortic Balloon Pumps & Catheters Video Library


Educational Videos



Sensation Plus IAB Catheter Insertion
16min 30sec

Review the insertion steps of the Sensation Plus IAB catheter and the initial setup of the Cardiosave intra-aortic balloon pump.


[Download insertion guide](#)



Sensation 7 Fr IAB Catheter Insertion
25min 52sec

Review the insertion steps of the Sensation 7 Fr IAB catheter.


[Download insertion guide](#)



Getinge IAB Sheathless Insertion
6min 19sec

Review the insertion steps for sheathless insertion of Getinge IAB catheters.

[Download insertion guide](#)




Cardiosave Software Revisions
Version B.17 or C.06 to D.00 Software
26min 54sec

This video is intended for Cardiosave users outside of the US.

This video does not generate a certificate. If you need to generate a certificate, please view this presentation [\[link\]](#).


[Download here: D.00 presentation slides](#)



IABP the Numbers Game
10min 28sec

Characteristics of the intra-aortic balloon pump (IABP) and differences between the IABP pressure vs. non-invasive blood pressure and bedside monitor pressures are discussed in this video.

[Download here: program booklet](#)



Cardiogenic Shock It Is Not One-Size-Fits-All
19min 21sec


The need for early identification of cardiogenic shock (CS) and its underlying etiology to develop an appropriate treatment plan and differences between CS attributed to acute myocardial infarction (AMI) vs. acute heart failure are presented.

[Download here: program booklet](#)



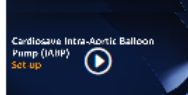
Intra-aortic Balloon Catheter Removal
1min 29sec

[Download here: bedside insertion guide](#)




StatLock Application & Removal
1min 42sec

[Download here: bedside insertion guide](#)



Cardiosave IABP Set-up
4min 33sec
(this video has no audio)

[Click here: Cardiosave quick reference guides](#)



Cardiosave Intra-aortic Balloon Pump (IABP) Inservice
48min 17sec



GETINGE

PASSION FOR LIFE

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