

The CS300™



Abbreviated Operator's Guide

CS300 BEZEL AND KEYPAD



The CS300 provides comprehensive **HELP SCREENS** with easy to follow step-by-step instructions on set-up as well as alarm and advisory conditions.

QUICK REFERENCE – INITIAL SET-UP

1. Establish power and verify the **MAINS ON/OFF** and the **IABP ON /OFF** switches are on.
2. Open the Helium Tank.
3. Establish ECG and Pressure.
4. If using a Sensor IAB, ensure that the IAB sensor cable (orange) has been connected.* Otherwise, zero the transducer**:
 - Open the transducer to air
 - Press the **ZERO PRESSURE** key for 2 seconds
 - Close the transducer
5. Confirm that the operation mode is **AUTO**.
6. Attach the IAB catheter and the appropriate extender to the safety disk.
7. To initiate pumping, press the **START** key. In response the IABP will Autofill and then begin pumping. If desired, IAB DEFLATION timing can be fine-tuned using the IAB DEFLATION controls.
8. Verify the setting of the AUG. ALARM:
 - Verify that the AUG. ALARM setting is approximately 10 mmHg less than the patient's diastolic augmented pressure.
 - If needed, adjust by pressing the AUG ALARM key and using the NAVIGATION ARROW keys to change the value displayed on the screen.
9. Initial setup is now complete.

* For Sensor IAB Calibration:

- On initial insertion, pressing the START key automatically purges and fills the IAB and calibrates the Sensor IAB if connected.
- While assisting, press and hold the Zero Pressure key for two (2) seconds to perform an operator-initiated calibration of the Sensor IAB. The displayed blood pressure parameters from the IAB Sensor are only valid if the IAB Sensor is properly calibrated.

To prevent calibration of the IAB Sensor at inappropriate times, the Zero Pressure key is disabled when:

- The IABP is in **STANDBY**.
- The IAB Sensor is disconnected.
- The **Pressure Source** is set to External.
- The IAB Fill Mode is set to Manual Fill.

** For conventional IAB/Transducer:

- Zero the transducer as noted above

To prevent zeroing the transducer at inappropriate times, this key is disabled when:

- Pulsatility is detected on the AP waveform.
- The transducer is disconnected.
- The **Pressure Source** is set to **External**.

Note: A connected and functional Sensor IAB takes priority over an arterial pressure transducer, as the Direct pressure source. The Sensor IAB must be disconnected to activate the arterial pressure transducer input. The pump automatically searches for a viable pressure source when multiple sources are available.

IAB Sensor Low Level Pressure Output – to Bedside Monitor

This output connector is used to provide an electrical signal from the IAB Sensor module to the physiologic pressure transducer input on the patient's bedside monitor when a Sensor IAB is connected and calibrated. Its low level output emulates that of a typical Arterial Pressure Transducer, allowing direct connection to the patient inputs of the bedside monitor when a Sensor IAB is connected and calibrated.

IAB Sensor Output – Vent

This button facilitates the zeroing process required for proper calibration of the physiologic pressure channel of an attached bedside monitor. When pressed, the IAB Sensor Output signal will simulate that of an atmospheric vented transducer. Venting will be simulated for 15 seconds to give users adequate time to zero the pressure channel on the bedside monitor.

The pressure signal will then be restored automatically to permit monitoring through the bedside and centralized monitoring systems.

OPERATING MODES

AUTO Operation Mode

All aspects of pump Operation are automated

- Most appropriate trigger source is automatically selected.
- Inflation and deflation timing is automatically set.
- Lead I, II, III, or External ECG source is automatically selected.
- System searches for the next best trigger source in the event of a loss of trigger source.
- Timing adjusts automatically if trigger source changes, heart rate changes, rhythm changes.
- With sustained unpredictable rhythms, R-wave deflation is automatically selected. The message **"Auto R-Wave Deflate"** will be displayed. The deflation indicator will automatically be repositioned to the far right, "R-Trac" will be displayed in the IAB deflation indicator. The system will return to predictive timing once the rhythm becomes predictable.

SEMI AUTO Operation Mode

- Operator selects the most appropriate trigger source.
- Operator establishes initial timing and thereafter, software algorithms automatically track changes in patient heart rate or rhythm and adjusts timing accordingly.
- Changing the trigger source will cause the pump to go to Standby. Pumping will resume when the **START** key is pressed.
- Leads I, II, III, AVR, AVL, AVF, V or External ECG source can be selected.

- With sustained unpredictable rhythms and a valid ECG Trigger, R-wave deflation is automatically selected. The message “**Auto R-Wave Deflate**” will be displayed. The deflation indicator will automatically be repositioned to the far right, “R-Trac” will be displayed in the IAB deflation indicator. The system will return to predictive timing once the rhythm becomes predictable.
- Loss of trigger causes an alarm and pumping will stop.

Manual Operation Mode

- Trigger source and timing of IAB inflation and deflation is determined by the operator.
- Changing the trigger source will cause the pump to go to Standby. Pumping will resume when the **START** key is pressed.
- Leads I, II, III, AVR, AVL, AVF, V or External ECG source can be selected.
- Timing must be readjusted by the operator if heart rate or rhythm changes.
- Loss of trigger causes an alarm and pumping will stop.
- Manual timing is typically used for **pediatric** IABP patients.

WARNING: The CS300 must be in Semi Auto Operational mode whenever no aortic pulse is present, and IAB assist is desired. For example, whenever circulatory bypass or a laminar flow, left ventricular assist device is in use.

TRIGGER SOURCE

- Trigger is the signal the CS300 uses to identify the beginning of the cardiac cycle.
- The Trigger Source keys are only active in the **SEMI AUTO and Manual Operation Modes**.
- Regardless of the Operation Mode, the active trigger source is indicated by a flashing diamond in the upper right corner of the screen.

ECG

- The R wave of the ECG is the trigger event.
- Pacer spikes are rejected.
- ESIS (electrosurgical interference suppression) is automatic in this mode.
- When using SEMI AUTO or Manual Operation modes, the ECG gain can be adjusted from 0.15 to 3.00, relative to a normal gain of 1.0. The amount of gain will be displayed next to ECG GAIN on the monitor screen. Go to Pump Options – ECG Gain to adjust.

Pressure

- The systolic upstroke of the arterial waveform is the trigger event.
- The CS300 will automatically adapt the pressure trigger threshold to the systolic pulse height of the arterial pressure waveform.
- The pressure trigger threshold is displayed just below the trigger source on the monitor screen and the arterial waveform is marked with a horizontal tick to indicate the trigger point.

- When using the **SEMI AUTO or Manual Operation modes**, a fixed pressure threshold can be manually set. Go to Pump Options - Pressure Threshold to adjust.

When using **PRESSURE**, the balloon must be fully deflated before the upstroke of systole.

Caution: If an irregular rhythm develops while using pressure trigger, the CS300 will automatically adjust deflation timing early to avoid interfering with systolic ejection. Do not attempt to adjust the deflation control. Pressure triggering is NOT recommended for use with sustained irregular rhythms.

Pacer V/A-V

- This trigger mode is **only** available in the **SEMI AUTO and Manual Operation modes**.
- The ventricular spike of a ventricular or an atrial-ventricular pacemaker is the trigger event.
- Patient must be 100% paced.
- It is typically used when ECG triggering is unsuccessful and a ventricular or atrial-ventricular sequential pacemaker is in use.

Pacer V: Assists 100% ventricular paced rhythms up to a rate of 185 beats per minute.

Pacer A-V: Assists 100% atrial-ventricular paced rhythms provided the A-V interval is between 80-224 msec. and the pacing rate is less than 125 beats per minute.

Pacer A

- This trigger mode is only available in the **SEMI AUTO and Manual Operation modes**.
- The R-wave of the ECG is the trigger event.
- Atrial pacer spikes are enhanced and rejected.
- Atrial pacemaker pulse rejection time is expanded in this mode.
- This trigger mode is recommended only if atrial pacer tails interfere with R-wave detection when using the ECG trigger.
- Fixed or demand atrial pacing can be used in this trigger.

Caution: Never use Pacer A trigger in the presence of a ventricular paced rhythm.

Internal

- This trigger mode is only available in the **SEMI AUTO and Manual Operation modes**.
- Internal trigger is used when there is no mechanical cardiac cycle, i.e. cardio-pulmonary bypass or asystole.
- In normal Operation, the rate is fixed at 80 BPM.
- The internal trigger rate can also be adjusted from 40 to 120 BPM, in increments of 5 BPM. Go to Pump Options – Internal Rate to adjust.

Note: If an R-wave is detected when using this mode, the System automatically deflates the IAB and the message ECG Detected will be displayed on the monitor screen.

Warning: Never leave the system set in the Internal Trigger Mode if the patient is generating a cardiac output.

TIMING

Timing refers to the positioning of inflation and deflation points on the arterial waveform.

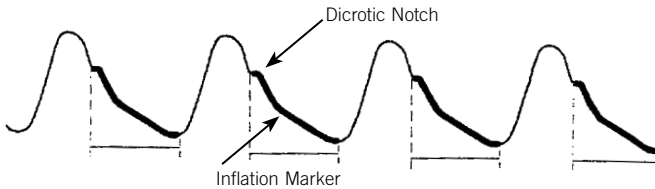
In the **STANDBY** mode an inflation marker appears as a highlighted interval on the Arterial Pressure Waveform. To supplement the marker, a horizontal bar is drawn beneath the Arterial Pressure Waveform.

To Set Initial Inflate Timing [not applicable in AUTO Operation mode.]

- Use the IAB Inflation arrows until the highlighted segment of the arterial pressure trace begins at the diastolic notch.

To Set Initial Deflate Timing [optional with ECG Trigger in the AUTO Operation mode.]

- Use the IAB Deflation arrows to adjust the end of the highlighted segment prior to ventricular ejection.



Highlighted Inflation Marker

After initiating assist, the IAB INFLATION [only operational in the Semi Auto and Manual Operation modes] and IAB DEFLATION controls can be adjusted to maximize augmentation and hemodynamic unloading.

Timing at a frequency of 1:2 is illustrated below:



CLINICAL TROUBLESHOOTING – CLINICAL CONSIDERATIONS DURING OPERATION

ECG:

There are several methods to correct conditions that alter or hamper the acquisition of a reliable ECG. Reposition or replace ECG electrodes and check that the patient cable is properly connected. In **SEMI AUTO** Operation mode, choose an alternate lead selection or change **ECG Gain** setting.

PRESSURE:

Sensor IAB

The IAB Sensor Connector must be securely inserted into the IAB Sensor Module. Always take care to avoid contaminating the tip of the Sensor Connector. Confirm that the Sensor Connector is firmly seated in the IAB Sensor Module. If the Sensor Connector is reconnected to the Sensor Module, the pump will automatically calibrate the sensor within one minute or a calibration may be manually invoked by pressing the Zero Pressure key while the pump is assisting.

Conventional IAB/Transducer

Flush arterial line at regular intervals per standard hospital procedure. Adequate flushing to maintain pressure line patency and alignment of stopcock in the proper position will prevent the majority of possible pressure trace problems.

ATRIAL FIBRILLATION:

In **AUTO** Operation mode, there are no special pump considerations for handling atrial fibrillation. In **SEMI AUTO** Operation mode, use ECG Trigger. This will track random rhythm most consistently, by automatically holding the IAB inflated until the detection of the next R-Wave. Pressure triggering is NOT recommended in atrial fibrillation.

TRIGGERING ON ECTOPICS:

The **CS300** automatically deflates on and assists the ectopic beat, if the ectopic R-wave is sensed. In **SEMI AUTO** Operation mode, if the ectopic beat is of small amplitude, reliable triggering can be maximized if an ECG Lead is selected which minimizes the amplitude difference between the normal QRS complex and that of the ectopic beat. No special adjustments are necessary.

CARDIAC ARREST – VENTRICULAR FIBRILLATION:

When defibrillating the patient, the **CS300** has protection and is completely isolated from the patient and the defibrillator's electrodes. However, the operator should stand clear of the pump during defibrillation. This is particularly important when the **CS300** is operated while disconnected from an earth grounding point, such as the A.C. power receptacle.

VENTRICULAR STANDSTILL OR PROLONGED CARDIAC ARREST:

If possible, use **ECG** or **Arterial Pressure trigger** during CPR. This facilitates synchronization of the assist to the rate and rhythm of chest compressions. In **AUTO** Operation mode, the **ECG** (R-wave) or **Arterial Pressure** signal will automatically be selected as the **Trigger Source**. Choice is dependent upon relative signal quality. If neither the **ECG** nor the **Arterial Pressure** signals produce adequate trigger reliability to allow for **AUTO** Operation, the IABP may be triggered by its own internal clock. Select the **SEMI AUTO** Operation mode and set the **Trigger Source** to **Internal**. The default internal rate is 80 bpm but can be varied between 40 and 120 bpm by accessing the **Pump Options** menu and setting the **Internal Rate**.

Prolonged Time in Standby and Thrombus on the IAB membrane:

If the **CS300** is inadvertently placed in **STANDBY**, the time in **STANDBY**, will appear on the left side of the monitor screen. After 10 minutes an alert message will appear. The audible alert is user selectable. Verify whether it is appropriate to resume assist. If so, press the **START** key to resume assist.

WARNING: The patient balloon should not remain inactive (i.e., no inflating and deflating) for more than 30 minutes; due to the potential for thrombus formation.

USE IN ELECTRO-SURGICAL ENVIRONMENT

The **CS300** IABP has built in Electro-Surgical interference suppression that minimizes Electro-Surgical Unit (ESU) noise from disturbing system performance. While the system will suppress ESU noise, it cannot eliminate it all together. Sparking to tissue occurs when an ESU is operated. This generates noise that extends into the ECG frequency range. Since the system must pass these frequencies, some ESU noise may interfere with the ECG signal, particularly with high ESU power settings. Limiting the power of this noise energy is desirable. The magnitude of interference is directly related to the power setting of the ESU, which should be as low as possible for the intended effect. Successful **ECG** triggering in the presence of ESU noise depends, to a large extent, on proper patient preparation and ESU use. Following the guidelines listed will minimize the amount of energy coupled from the ESU to the ECG input of the **CS300**, generally resulting in stable ECG triggering. When the **CS300** is in **AUTO** Operation mode, it will automatically select **Pressure Trigger** when ESU interference is detected and return to **ECG** a short interval after interference ceases. If the clinician prefers to stay in Pressure Trigger during the operating room procedure, this can be accomplished by selecting **SEMI AUTO** Operation mode. Then select **Pressure Trigger Source**. Return to **AUTO** Operation mode when appropriate. When the **CS300** is used in an electrosurgical environment, the following techniques are recommended to minimize interference from electrosurgical devices:

- Always use supplied Datascope Operating Room ECG patient cable and lead wire option. See “ECG Patient Cable Options” on page 10-7 of the CS300 Operating Instructions for more information.
These cables are shielded and incorporate ESU suppression components
- Keep the ECG cables at right angles to the electrosurgical cables to the greatest extent possible
- Locate the ECG electrodes as far away from the surgical site as possible
- Locate the ECG electrodes approximately equidistant from the surgical site to minimize any difference in potential between electrodes
- Place all ECG electrodes on the same plane (either anterior or posterior) to minimize any difference in potential between electrodes
- Place the electrosurgical return plate directly under the surgical site
- Use the minimum required electrosurgical setting

WARNING: External bedside monitors used with the CS300 in the operating room, must be equipped with Electro-Surgical interference suppression.

CHANGE IN PRESSURE MONITORING SITE:

If patient's pressure monitoring site is changed while assisting in **SEMI AUTO** or **Manual** Operation mode, the **INFLATION INTERVAL** key can be quickly pressed and released to recalculate arterial pressure transmission delay (APD). This will assure accurate digital pressure display values and arterial pressure trace inflation interval markers.

ALARMS AND ADVISORY MESSAGES

Help screens are provided to guide the user through set-up procedures and for consultation regarding alarm message descriptions and alarm configurations. Help screens are context sensitive and available based on the information displayed on the screen. Detailed information on all Alarm and Advisory messages is provided in the CS300 Operating Instructions. The IABP utilizes both auditory and visual alarm signals to communicate the need for attention or awareness by the pump operator. ALARM messages are displayed in the **ALARM MESSAGES** section of the monitor display.

HIGH PRIORITY ALARMS



High Priority Alarms indicate situations that require immediate Operator response. Pumping is suspended for the majority of High Priority Alarms. A red flashing alarm icon is displayed as seen above. The audio tone for a High Priority Alarm is a combination of five notes a short pause, five notes a long pause and then this cycle repeats.

ALARM MESSAGE [ALL OPERATION MODES]

PROBABLE CAUSE

Augmentation Below Limit Set
(Pumping is NOT suspended)

Diastolic Augmentation has dropped below the user selected limit.

TRIGGER ALARMS

These alarms indicate the selected trigger source is either not available or not reliable. Pumping is suspended and a steady tone sounds. Pumping will automatically resume once the trigger has been reestablished.

ALARM MESSAGE [AUTO OPERATION MODE]

PROBABLE CAUSE

No Trigger

Valid ECG and Arterial Pressure trigger do not exist or are lost.

Poor Signals Persist

Both ECG and Arterial Pressure signal quality have been poor for a sustained period.

Operator Intervention

For No Trigger

- Reattach or reposition the electrode and check the integrity of all cable/lead connections.
- Switch Operation to **SEMI AUTO** and increase the ECG Gain setting in the **PUMP OPTIONS** menu.
- Use IAB Inflation and IAB Deflation controls to adjust timing and resume pumping by pressing the **START** key.
- Verify that the transducer was not left vented; check all transducer cable connections.
- Attempt to restore A.P. pulse height by flushing the circuit.

For Poor Signals Persist

- Attempt to restore A.P. pulse height by flushing the circuit, verify transducer was not left vented; check integrity of all cable connections.
- Attempt to improve ECG signal by ensuring electrode contact and optimal placement
- If signal problem persists, switch Operation mode to **SEMI AUTO**. Verify trigger source.
- Use IAB Inflation and IAB Deflation controls to adjust timing and resume pumping by pressing the **START** key.

ALARM MESSAGE [SEMI AUTO OR MANUAL OPERATION MODE]

PROBABLE CAUSE

No Trigger	Valid trigger, as defined in Specification section, does not exist or is lost in ECG or Pacer Trigger mode.
No Pressure Trigger	Valid trigger is unavailable or is lost while in Pressure Trigger.
Check Pacer Timing	The patient is not 100% paced or V/A-V pacer trigger interval varies >25% or an A-V pacer rate is >125 bpm.
Trigger Interference	Electro-Surgical Noise [ESU] detected while the Pacer Trigger Source is selected.
ECG Detected (Pumping is NOT suspended)	ECG activity is detected persistently for 4-6 seconds while in the Internal Trigger mode.

Operator Intervention

For No Trigger

- Reattach or reposition the electrode and check the integrity of all cable/lead connections.
- Try ECG lead selections via the ECG/AP Sources menu, or select EXT. ECG, if appropriate.
- Adjust the ECG Gain by accessing the **PUMP OPTIONS** menu.
- Select a different trigger source using the **TRIGGER SOURCE** arrow keys. Resume pumping by pressing the **START** key.

For No Pressure Trigger

- Verify that the desired Pressure Source, DIRECT/EXTERNAL, is selected. Use the ECG/AP Sources menu to select the Pressure Source.
- Verify that the transducer was not left vented; check all transducer cable connections.
- If pressure trigger is required and manual threshold is selected, reduce the pressure trigger threshold by using the **PRESSURE THRESHOLD** sub menu from the **PUMP OPTIONS** menu.
- If appropriate, select a different trigger source using the TRIGGER SOURCE arrow keys. Resume pumping by pressing the **START** key.

For Check Pacer timing:

- Select ECG trigger source, using the TRIGGER SOURCE arrow keys, when demand pacing a patient.
- Reduce the Pacer rate.
- Adjust the A-V time interval to between 80 and 224 msec.

For Trigger Interference:

- Pumping automatically resumes when interference clears.
- If the condition persists, then select pressure trigger using the **TRIGGER SOURCE** arrow keys.
- Verify timing and press the **START** key to resume pumping.

For ECG Detected

- Select ECG as the trigger source using the TRIGGER SOURCE arrow keys
- Verify proper timing
- Resume pumping by pressing the **START** key

CATHETER ALARMS

The CS300 continually monitors specific parameters within the closed patient pneumatic system. If a change is detected or a specific parameter is violated, IABP Assist is suspended and the High Priority Alarm tone will sound.

ALARM MESSAGE [ALL OPERATION MODES]	PROBABLE CAUSE
Leak in IAB Circuit	There is a small leak or gas gain in the IAB circuit, a loose connection, or a high rate of helium diffusion.
Rapid Gas Loss	A large leak has been detected in the IAB pneumatic circuit.
IAB Disconnected	The IAB catheter or extender tubing is disconnected.
Check IAB Catheter	The IAB membrane is not completely unfolded, or the IAB remains in the sheath immediately after insertion or there is a kink in the IAB catheter or tubing.
Blood Detected	Blood is detected in the IAB catheter.
Autofill Failure – No Helium	The Helium tank is closed or empty.
Autofill Failure	The IABP cannot fill the IAB catheter system automatically.
Autofill Required	The IAB fill mode has been changed from Manual to AUTO without an autofill.

Operator Intervention

- Inspect the IAB and catheter extender tubing for any evidence of a leak, including the safety disk/condensate removal assembly connections, IAB catheter connections, autofill tubing and drain port. Check for blood in the tubing, if noticed, stop pumping and notify a Physician.
- Verify all connections are leak free.
- For “Autofill Failure-No Helium” open or replace Helium tank if necessary.
- Inspect the IAB catheter and catheter extender for evidence of a kink or restriction to Helium flow.
- Fill the IAB, if instructed, by pressing the IAB FILL key for 2 seconds. Resume pumping by pressing START.

Warning: If blood is observed within the catheter or catheter extender tubing at any time during the IAB procedure, stop pumping, notify the physician immediately, and prepare for IAB removal.

Warning: When the System is operated in MANUAL FILL, the IAB gas loss and catheter alarms are disabled. The message, “Gas Loss And Catheter Alarms Disabled” will be displayed in the Advisory section of the display. The IAB status bar will not be active.

Warning: Under certain heart rate and timing conditions, catheter alarms may be suspended. Refer to the Operating Instructions for further detail.

MEDIUM PRIORITY ALARMS



Medium Priority Alarms indicate situations in which a prompt Operator response is required. This class of alarm does not suspend pumping, but may indicate a need for corrective action. A yellow flashing alarm icon is displayed as seen above. The audio tone for a Medium Priority Alarm is three notes, a pause, and then this cycle repeats.

ALARM MESSAGE [AUTO OPERATION MODE]	PROBABLE CAUSE
Poor Signal Quality	Both ECG and Arterial Pressure signal quality are poor while in ECG trigger.
No Pressure Source Available	Neither a direct nor external blood pressure source was detected.
IAB Optical Sensor Failure	There has been a failure of the Optical Sensor in the IAB.
Low Battery	Battery reserve falls below 30 minutes of operating time.

Operator Intervention

For Poor Signal Quality

- Attempt to improve ECG signal by ensuring electrode contact and optimal placement. Check integrity of all cable/lead connections.
- Attempt to improve Arterial Pressure by checking integrity of all cable connections. If conventional transducer in use, verify the transducer was not left vented and/or flush the lumen per standard hospital procedure

For No Pressure Source Available

- If using a Sensor IAB, ensure that the sensor cable has been connected. Otherwise provide an A.P. source by connecting a standard transducer or an interface cable from the A.P. output of an external monitor to the pump

For IAB Optical Sensor Failure

- Ensure that the sensor cable has been connected
- Provide an alternate A.P. source by connecting a standard transducer or an interface cable from the A.P. output of an external monitor to the pump

For Low Battery

- Verify the Mains Power Switch, located above the AC power cord connector, is ON
- Connect the system to an AC power outlet

LOW PRIORITY ALARM



Low Priority Alarms are indications that Operator awareness is required. A yellow flashing alarm icon is displayed as seen above. The audio tone for a low priority alarm is two notes, a pause, and then this cycle repeats.

ALARM MESSAGE [AUTO OPERATION MODE]	PROBABLE CAUSE
Unable to Update Timing	Waveform quality is poor.

Operator Intervention

For Unable to Update Timing

- Check integrity of all cable connections. If transducer is in use, verify transducer was not left vented.
- If pulse height is unusually low or over damped and transducer is in use, flush the fluid lumen per standard hospital procedure.
- If not properly triggering or signal problems persist, switch OPERATION MODE to SEMI AUTO. Verify trigger source and timing and resume pumping by pressing the START key.

INFORMATIONAL MESSAGES

Informational Messages provide system information to the Operator. Informational Messages display textual messages and, in some cases, are accompanied by an infrequently repeating audio reminder tone.

- Status/Prompts apply to all Operation modes unless otherwise indicated:
A = Auto / SA = Semi Auto / M = Manual Operation modes.

MESSAGE	PROBABLE CAUSE
IAB not filled [SA / M]	System is in Manual Fill and user pressed the START key when no fill had been performed.
Verify Proper Timing [SA / M]	Operator has changed the trigger source.
Manual Fill IAB [SA / M]	Notifies the operator when to manually fill the IAB catheter with shuttle gas. Displayed in the MANUAL FILL mode when the FILL key is activated, venting the safety disk.
Leak Testing Safety Disk Autofilling	Indicates safety disk leak test is in progress.
Automatic Operation mode is disabled [SA / M]	Indicates that the system is in the process of Automatically purging and refilling the IAB with Helium.
Gas Loss and Catheter Alarms Disabled	System is set to Manual Fill mode and the operator tries to select AUTO Operation mode.
Slow Gas Loss Alarm is Off	All leak and catheter alarms are disabled when the manual fill mode is selected.
Function Not Available	Slow gas loss alarm has been disabled by the user. NOTE: Rapid gas loss function is still active.
Function unavailable in AUTO Operation mode [A]	Displayed when the operator presses an unavailable key.
Battery in Use	Displayed when the operator presses an unavailable key while in the AUTO Operation mode.
System Test OK	Indicates system is operating from an internal battery.
System Trainer	All systems passed power-up diagnostics.
	Displayed when the System Trainer is being used as ECG and Pressure source.

Auto R-Wave Deflate [A /SA]	The patient's rhythm is too random to predict the occurrence of the next beat. In response, the system has automatically selected the R-Wave Deflation Mode.
R-Wave Deflate [A /SA]	Operator has enabled R-Wave deflation by moving the deflate key to the extreme right position.
Irregular Pressure Trigger [SA]	While Pressure is the Trigger source, erratic trigger is due to: <ol style="list-style-type: none"> 1. Arrhythmic patient rhythm. 2. Late deflation; inhibiting pressure pulse detection.
Manual Timing selected – See Help [M]	The operator selected the Manual Operation mode.
Verify Proper Timing [SA]	The operator selected the Semi Auto Operation mode.
Maintenance Required Code # ____	System maintenance may be required.
Low Helium	Helium supply is below a preset reserve as determined by tank pressure.
Prolonged Time in Standby	Pump has been in STANDBY for at least 10 minutes.
A.P. Optical Sensing Module Failure	There has been a failure of the A.P. Optical Sensing Module in the pump console.
Unable to Calibrate IAB Optical Sensor	A calibration is not completed for one or more of the following reasons: <ul style="list-style-type: none"> – the patient's arterial pressure is too low to reliably establish or update IAB Optical Sensor Calibration – there is a restriction in the catheter – the IAB Fill Mode is set to Manual
IAB Optical Sensor Calibration Expired	A calibration update has been intentionally postponed for one or more of the following reasons: <ul style="list-style-type: none"> – the patient's Mean Arterial Pressure may be too low – less than 15 minutes have elapsed since last calibration – pump is either in STANDBY or the IAB FILL mode is set to MANUAL

MENU GUIDE

The CS300 uses menus to provide rapid access to infrequently used functions. The menu guide, below, is also located on the top of the CS300 console.

MENU NAVIGATION

The first step in the menu navigation is to open the desired menu by pressing the associated key. The highlighted bar is always used as a pointer [cursor] to select menu entries. The arrow keys in the menu navigation circle control the movement of the highlighted bar. To select an alternative item, use the **UP** and **DOWN** arrow keys.



PRINTER OPERATION

The dual trace recorder provides a hard copy record of patient waveforms. Printouts follow the format defined by the setting in the **Printer Preferences** submenu, located in the **User Preferences** menu. Dual or single trace formats may be selected.

Waveform choices are: **ECG, Arterial Pressure and Balloon Pressure Waveforms**. At the completion of the recording, an annotated trailer is appended to the print.

The annotation describes patient and system status. The format of the annotation depends upon the IAB **Assist Frequency** selection. When **1:2** or **1:3** is selected as the IAB frequency, the recorder will print both assisted and unassisted systolic and diastolic pressure information.

To initiate a printout, press the **PRINT STRIP** key. To start a continuous printout, hold the **PRINT STRIP** key for two (2) seconds. The associated LED will blink as printing continues. To stop the continuous printout, press the **PRINT STRIP** key again.

DOPPLER INFORMATION

The doppler used with the IABP uses ultrasound techniques to detect vascular blood flow.

To Use the Doppler:

1. Open the right hand compartment on the storage bag. The doppler is located inside this compartment.
2. Remove the doppler from the storage bag.
3. Press the button on the tether reel to retract the doppler.
4. If battery replacement is necessary, remove the cover of the battery compartment, and lift out the old battery. Install a new 6LR61, 6LF22, or equivalent 9V alkaline battery.
5. Replace cover.
6. Place a liberal amount of coupling gel on the transducer or on the patient's skin.
7. Turn the unit on and position the probe over the artery to be examined.
8. Hold the probe at a 45° angle to the surface of the skin.
9. Adjust the position and angle of the probe to obtain the optimum audio signal.

SAFETY DISK LEAK TEST

This optional test measures the pneumatic leak rate(s) of the Safety Disk. The test requires multiple interactions with the operator. Specifically during the course of the test, the operator is requested to plug and unplug the outlet of the safety disk. The IABP prompts the user at the appropriate times for this action.

WARNING: Safety Disk Leak Test MUST NOT be performed with the pump connected to a patient's IAB.

1. Press and hold the **IAB Fill** key while switching **IABP ON/OFF** to **ON**. Release the **IAB Fill** key when the message **LEAK TESTING SAFETY DISK** appears in the advisory section of the screen.
2. Using the supplied Luer plug, cap the IAB Catheter Extender Input when the message **PLUG DISK OUTLET** appears on the display.
If the message **UNPLUG DISK OUTLET** appears, remove any connections that may exist to the IAB Catheter Extender Input.
3. A double beep will sound at the end of the safety disk test. If the system passes the test, the message **SYSTEM TEST OK** is displayed in the advisory section of the screen.
Remove the Luer plug.
If IABP therapy is being started, then proceed to initial set up or return to the Power-Up Procedure section on page 2-2 of the CS300 Operating Instructions to continue the setup of the pump.
4. If the safety disk leak test fails, inspect all pneumatic connections and press the **IAB Fill** key for two (2) seconds to repeat the test. If in doubt about the integrity of the safety disk, replace it. See "Safety Disk/Condensate Removal Module" on page 7-7 of the CS300 Operating Instructions.

BATTERY OPERATION

The system automatically switches to battery power if AC power is not available (intentionally or due to power loss). When AC power is restored, the system automatically reverts from internal battery operation to AC Mains usage. The internal battery pack charges while the system operates from AC Mains power. Prior to portable operation, the battery should be fully charged. A fully charged battery is indicated by a continuously illuminated battery-charging LED (located on the front panel).

- Verify that the “Battery in Use” Informational Message and the Battery Indicator are displayed when in battery operation.
- Battery charging is not active when the battery is in use.
- When the battery has approximately 30 minutes of operating time remaining, the following occurs:
 - The Medium Priority Alarm tone is activated.
 - The “Low Battery” Medium Priority Alarm message is displayed on the screen continuously.
 - The Battery Indicator is displayed as empty and it starts flashing.
 - The condensate removal module will not operate (to conserve remaining power).

Battery Charging

To charge the internal battery:

1. Leave the system power cord plugged in and set the MAINS On/Off to ON.
2. Check that the Battery Charging LED is illuminated (continuously or flashing depending on state).
3. Allow a minimum of 8 hours to fully charge a low battery.
4. A fully charged new internal battery will provide at least 135 minutes of portable Operation.

NOTE: A reduction in run time will occur over a battery's life due to age, storage temperature and discharge depth. Batteries which are continually subjected to complete discharge cycles without the recommended immediate recharging, can incur permanent damage. See “User Maintenance” on page 7-10 of the CS300 Operating Instructions for additional information.

OPERATION FROM DC-TO-AC INVERTER

The **CS300** can be powered from a DC-to-AC inverter if the DC source and the inverter meet the specifications defined in the CS300 “Operating Instructions” on page 5-4. The DC source and inverter should be checked for proper operation by qualified maintenance personnel prior to emergency use. The message **Battery in Use** will not be displayed during proper AC inverter Operation.

TRANSPORT CONSIDERATIONS

Portable Operation

Datascope recommends the following:

1. Battery fully charged prior to starting transport.
2. Back up battery pack available.
3. Altitude changes are compensated for automatically in the **Autofill** mode or manually in the **Manual Fill** mode.
4. The system must be properly secured when used in an ambulance, helicopter, or fixed wing aircraft.

The Universal Transport System (UTS) is specifically designed for air and vehicular transport. The UTS version mechanically attaches to a docking station for high strength mounting. Refer to additional detail on the UTS on page 5-9 of the CS300 Operating Instructions.

WARNING: The user should continually rely on visual alarm messages during high noise transport situations.

CAUTION: Prior to transport, ensure that the Helium cylinder yoke handle is tight and the Helium pressure gauge is a least 25% full. Approximately every 30 minutes during transport verify that the yoke handle is tight and that a noticeable pressure drop has not occurred.

NOTE: Prior to using the system in any other position except vertical, consult with Technical Service.

NOTE: For information on outfitting an aircraft for IABP transport contact your local Datascope sales representative. See "Accessories" on page 10-8 of the CS300 Operating Instructions for information on the Transport Docking Station.

EFFECTS OF ALTITUDE CHANGES DURING AIR TRANSPORTATION

NOTE: Before using the system in air transportation, check for sufficient supply of Helium since the balloon will be filled several times.

For proper Operation during air transport, the IABP balloon pressure must adapt to local atmospheric pressure. In the **Auto Fill** mode the system will automatically purge and fill the IAB when local atmospheric pressure decreases or increases by 25 or 50 mmHg, respectively. These pressure changes occur approximately every 1,000 feet of rise or 2,000 feet of drop in altitude.

WARNING: The Auto Fill mode should be used during air transport. If the Auto Fill mode cannot be used and the Manual Fill mode is required, ensure that a manual fill is performed at each interval and altitude that an Auto Fill would occur.

REMOVING PUMP CONSOLE FROM THE CART

The console can be removed from the cart with or without the battery pack attached. When removing the pump console or the monitor from the cart or returning them to the cart, ensure that the wheels of the cart are in the locked position.

To remove the console with the battery pack attached:

Unlock the console by pressing the tab to the right of the console release handle and pull the handle straight out (fig. 1). Lift the pump console straight up and off the cart.

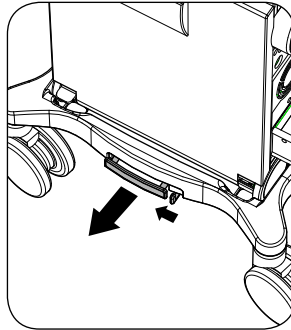


fig. 1

To remove the console by detaching the battery pack:

With the console on the cart, lift the battery release levers to the unlock position (fig. 2). Lift the console straight up and off the cart. To release the battery from the cart, unlock the battery pack by pressing the tab to the right of the console release handle and pull the release handle straight out. Lift the battery pack off the cart. With the release levers in the unlocked position, lift the pump console and lower it straight down onto the battery pack. Return the release levers to the locked position (fig. 3).

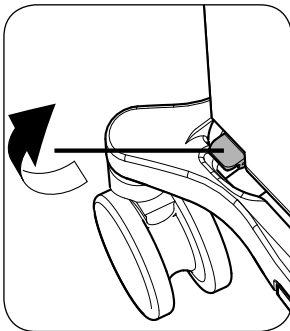


fig. 2

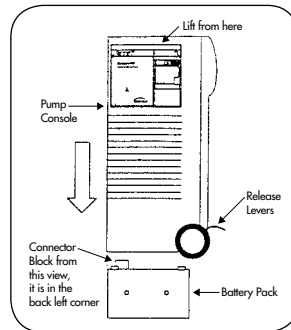


fig. 3

To attach the monitor to the pump console:

Detach the monitor from the cart handle by pressing the button on the rear of the monitor (fig. 4). Attach the monitor to the top of the pump console. Make sure the monitor is securely attached before moving the system. Extend the console handle until it locks into position, tilt the System, and pull to transport. (fig. 5).

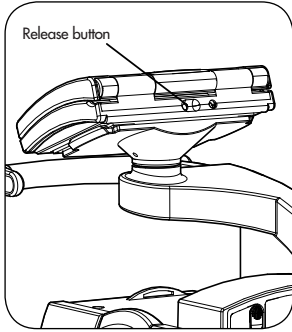


fig. 4

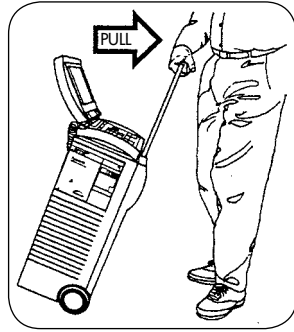


fig. 5

 *Caution: Federal (U.S.A.) Law restricts this device to sale, distribution and use by or on the order of a physician. Refer to package insert and CS300 Operating Instructions (p/n 0070-10-0654-01) for current indications, warnings, contraindications, precautions and complete instructions for use.*

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