Cogent™

Hemodynamic Monitoring System (HMS)

User Wireless Guide

Wireless Configuration Setup

1. Display unit may be mounted to an IV pole, up to 50 feet or 15.24 meters from the base unit.
2. Plug in the display charger cable to the connector on the display unit and an electrical outlet.
3. When the battery icon displays all green bars the UIM can be used in wireless mode for up to four hours.

Initializing the System

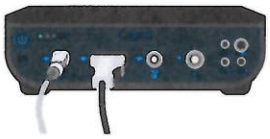
1. Connect the AC power supply cable to the DC connector on the base unit and plug the cable into an electrical outlet. The base unit will automatically power on.
2. Press the Power button on top right corner of display module.

New Patient Setup

1. Select the New Patient button.
2. On the Patient Information screen, enter Patient ID, Gender, Height, Weight, and Age. Optional values (Hgb, PaO_2, PvO_2, MPAP, and PAOP) can be added now or at a later time.
3. Save each entry by selecting the check mark.

Thermodilution CCO Setup

1. Connect the Thermal Coil cable to the front panel of the base unit.
2. Connect the Cardiac Output cable to the front panel of base unit.
3. Select the check mark button on the Technology Selection screen to accept Thermodilution CO.
4. Select the CCO button CCO to activate CCO.



PulseCO™ CCO Arterial Setup

1. Connect the CardioFlo™ cable to the front panel of the base unit.
2. Connect the primed CardioFlo sensor to the catheter lumen.
3. A pressure waveform appears on the PulseCO Arterial Setup screen, accessed via the Main Menu button. If no waveform appears, check cable and sensor connections.
4. When a pressure waveform is present, select the CCO button CCO. Confirm the CardioFlo is aligned with the phlebostatic axis, then open the stopcock located on the CardioFlo sensor to eliminate effects of atmospheric pressure.
5. When the pressure waveform reaches the baseline on the PulseCO screen, select the Zero button.
6. Close the stopcock on the sensor to restore the pressure waveform. The CCO button changes to a green color CCO to indicate activation of PulseCO.

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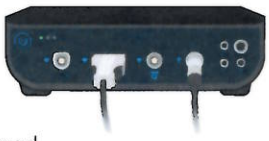
SvO_2/$ScvO_2$ Setup



1. Select the SvO_2 primary parameter box.
2. Activate the Audible Alarm by selecting the Yes button.
3. Select Upper Alarm Limits.
4. Enter a value within the default range using the on-screen keypad.
5. Select the check mark button to save.
6. Enter values for Lower Alarm Limits, Upper Scale Limits, and Lower Scale Limits as described in steps 4 and 5. Save after each entry by selecting the check mark button.
7. Attach the OpMod cable to the optical connector O_2 on the front of the base unit. OpMod warming process may take up to fifteen minutes.
8. Select either Pre-Insertion Calibration or In-Vivo Calibration process on the Venous O_2 Calibration screen.

Pre-Insertion Calibration Method

1. Once Pre-Insertion is selected, the Calibration Checklist is displayed on the screen and Cogent starts an internal check.
2. Once the OpMod is warmed up, select the Start Calibration. If calibration is not successful, select either Retry or Skip Calibration. If Skip Calibration is selected, an In-Vivo Calibration must be initiated (establishing a Light Intensity Baseline).
3. From the Main Menu button select Venous O_2 Calibration, then select Light Intensity Baseline.
4. If the current light intensity signal resembles either an optimal or acceptable signal on the scale, select the check mark button on the Light Intensity Baseline screen to confirm. Calibration will then proceed.
5. If calibration fails, options to Retry (with/without repositioning the catheter) or Skip Calibration are presented again.
6. If calibration is successful, select the Continue button and return to the Venous O_2 Calibration Menu.

In-Vivo Calibration Method

1. Select In-Vivo Calibration on the Venous O_2 Calibration screen.
2. Select the Start Blood Draw button to initiate the process.

Powering Off

1. Select the Main Menu button.
2. Then select the Power Off button.
3. Select the check mark on the Confirm screen to power off the system.

FCC Notes

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. The Device wireless operation is safe and complies to RF Exposure requirements

ISED Notes

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's liscense-exempt RSS(s). Operation is subject to the following two conditions:

(1) This device may not cause interference.

(2) This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

(1) L'appareil ne doit pas produire de brouillage;

(2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Warning: When monitoring in Wireless (undocked) configuration, the Patient Interface Module (PIM) or base unit should be placed > 20cm from user or patient.

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Integration Instructions

General:
Enli Inc. RF Module FCC ID: 2AWKZ-QCNFA324; IC: 26176-QCNFA324 integration instruction into the ICU Medical Cogent HMS User Interface Module (UIM)

List of applicable FCC rules:
The RF Module complies to the following FCC and ISED rules:

- FCC Part 2.1093 / RSS-102;
- FCC 15.247 / RSS-247;

Operational use conditions:
The operating band of the wireless operation is 2.4GHz, technology of 802.11n & frequency range of 2412-2462MHz.

Limited module procedures:
The RF Module integrated into the UIM Host Device is used in portable operation. Therefore, The RF Module was installed in the Host Device for SAR testing.

Trace antenna designs:

Not applicable.

RF exposure considerations:
The RF Module installed in the UIM Host Device was SAR tested with 0mm separation distance from nearby persons.

Antennas:
The RF Module integrated into the UIM uses two TE Connectivity antenna's part numbers 2108857-6 and 2108857-8; the peak antenna gain is 2.5dBi at 2400-2500MHz frequency range.

Label and compliance information:

- Contains FCC ID: 2AWKZ-QCNFA324
- Contains IC: 26176-QCNFA324

Information on test modes and additional testing requirements:
The RF Module installed in the UIM Host Device was tested per KDB Publication 996369 D04 Module Integration Guide.

Additional testing, Part 15 Subpart B / ICES-003:
The End Product with integrated RF Module was tested for compliance to FCC Part 15 Subpart B / ISED ICES-003

Note EMI Considerations:
The End Product with integrated RF Module is considered a Medical Device and is the subject for applicable EMI/EMC testing.

How to make changes:
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
The RF Module Grantee Holder is ENLI Incorporation.
The Host Device (UIM) manufacturer is ICU Medical Inc.

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human connections