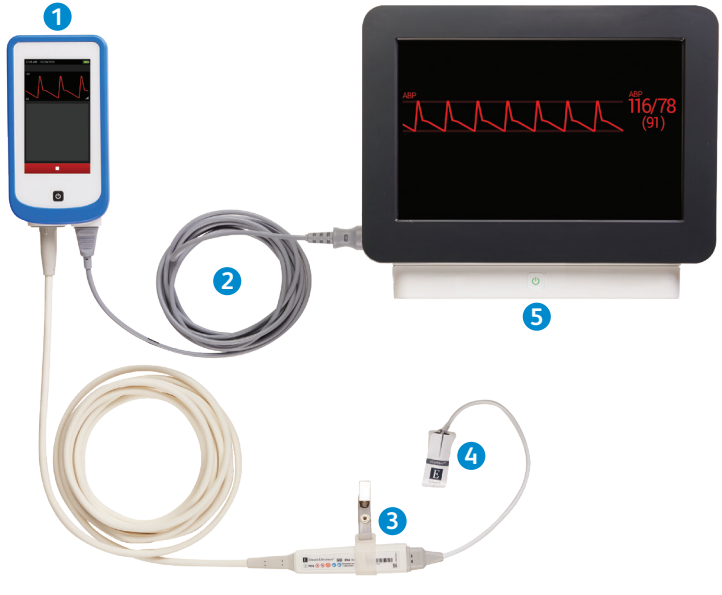
HemoSphere Stream™ Module with VitaWave Plus Cuff

Setup Guide

Experience noninvasive arterial pressure waveform monitoring with the HemoSphere Stream™ Module, designed for seamless integration with compatible bedside patient monitors. Utilizing the Smart Pressure Controller and VitaWave Plus™ Finger Cuff, the compact module provides real-time waveform data without the need for invasive catheters. This setup guide provides step-by-step instructions for configuring the system and placing the VitaWave™ Plus Cuff.



1. HemoSphere Stream™ Module
2. Compatible pressure-out to patient monitor
3. Smart pressure controller (PC1Q)
4. VitaWave Plus™ Finger Cuff
5. Patient monitor

BD

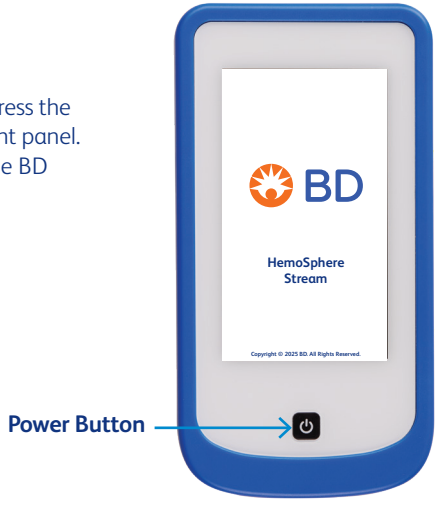
HemoSphere Stream™ Module Initial Setup

Step 1: Mounting
Securely mount the module on an IV pole or rail using the included clip according to your institution's practices. The operator should be positioned in front of the module and at close proximity during use.

Step 2: Power
Ensure the power supply is securely plugged into the bottom panel of the modules USB-C Port.

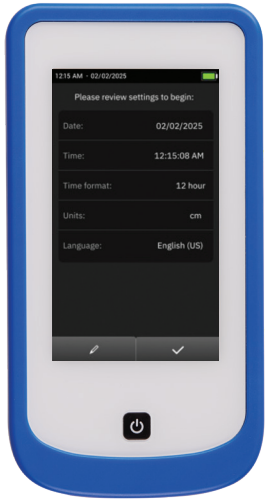
NOTE: The module contains a rechargeable battery. The battery is intended as a backup power source during power-loss and can only support waveform transmission for a limited time. Connect the power supply to a medical-grade AC outlet during use whenever possible.

Step 3: Start Up Procedure
To turn on and off the module, press the power button located on the front panel. After turning on the module, the BD screen is displayed.



Step 4: Initial Settings

Upon initial startup, setting options are offered which affect the displayed language, time and date formats, and units of measurement. The Review Settings screen appears after the initial boot-up process is complete. This occurs after the first time the module is powered on. Review the displayed settings for Date, Time, Time format, Units and Language.



Touch the edit icon to change any of the displayed settings.

Touch the check icon to accept the displayed settings. Each of the display-related settings can be changed later in the Settings menu by touching the settings icon.

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HemoSphere Stream™ Module Screen Appearance

All functions are initiated by touching the appropriate area on the touch screen. The main components of the HemoSphere Stream™ Module screen are shown in figure below. The main window displays the current Instructions, Status, Menu, or Settings Screen.

Information Bar

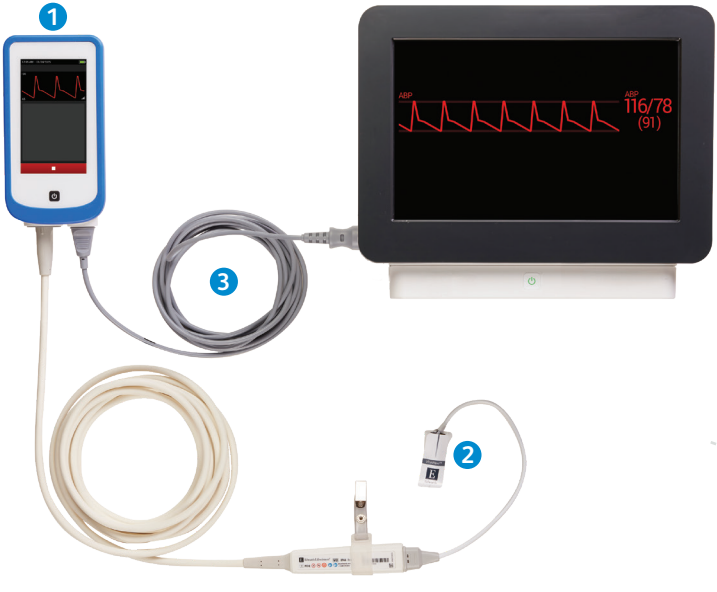
Main Window

- Instructions
- Status
- Settings

Start Monitoring Button

Step 5: Measurement Setup

After the module is powered on, the following instructional steps are provided on the module screen and are needed to begin a noninvasive measurement of the waveform and its transmission.



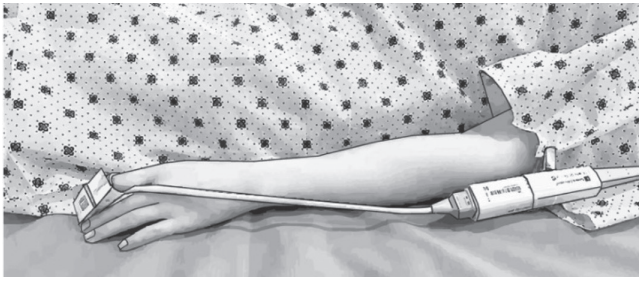
1 Connect Smart Pressure Controller

Connect the Smart pressure controller to the HemoSphere Stream™ Module Smart pressure controller port.

NOTE: Once complete, a green check icon ✓ will appear next to Step 1, "Connect cuff cable."

Next, use the Smart pressure controller cable clip(s) to place the Smart pressure controller near the patient's forearm.

Smart pressure controller port



2 Apply and Connect Finger Cuff to Smart Pressure Controller

For detailed instructions, please review section "Applying the Finger Cuff."

NOTE: Once complete, a green check icon ✓ will appear next to Step 2, "Apply and connect finger cuff."

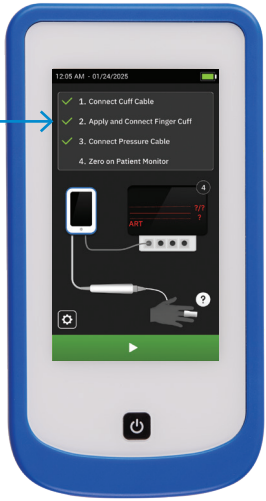
3 Connect Pressure Cable

Connect the compatible DPT pressure-out cable from the HemoSphere Stream™ Module to the patient monitor.

NOTE: Once complete, a green check icon ✓ will appear next to Step 3, "Connect Pressure Cable."

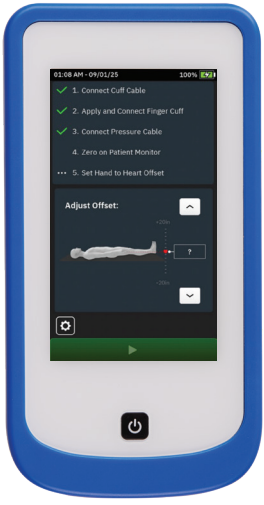
Step 6: Zero on Patient Monitor
Zero the patient monitors arterial blood pressure and confirm 0 mmHg is displayed. Refer to the patient monitor instructions for use.

NOTE: Once complete, a green check icon will not appear next to step 4, "Zero on patient monitor."



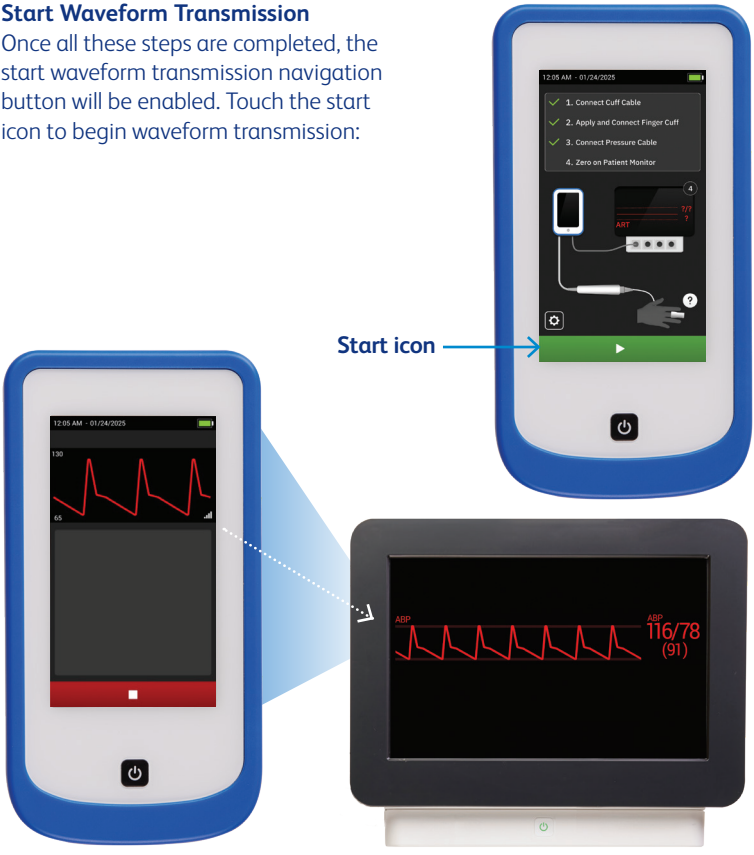
Step 7: Set Hand to Heart Offset *(if enabled)*
Manual hand offset is a feature that can be enabled. When this feature is enabled through advanced settings, an additional step must be performed before transmitting the noninvasive arterial blood pressure waveform. The pressure controller software must account for differences in pressure due to the change in vertical level of the monitored finger relative to the heart.

Use the arrows to indicate this height difference. The allowable entered offset can be between -20 inches and 20 inches in 1-inch increments (-50 cm to 50 cm, in 1 cm increments). The entered offset can be updated during active waveform transmission.



Start Waveform Transmission

Once all these steps are completed, the start waveform transmission navigation button will be enabled. Touch the start icon to begin waveform transmission:



Active Waveform Transmission

During active waveform transmission, the arterial waveform appears at the top of the module screen along with a stop icon. If there are any errors in transmission, they will appear on the screen. Please refer to the HemoSphere Stream Ops manual for more information on the system error messages.

Touch the stop icon to end waveform transmission.

Waveform Transmission Considerations

SQI: A signal quality indicator (SQI) is present on the blood pressure waveform display. SQI level is calculated every 20 seconds. The SQI symbol appears next to the waveform on the waveform transmission screen. SQI levels of one and two are typically associated with alert conditions. A SQI level of zero is shown when waveform transmission is initializing (starting or resuming). A zero SQI value can also be associated with an error condition.

Cuff Pressure Release

During waveform transmission, the HemoSphere Stream™ Module will automatically release pressure from the finger for five minutes at regular four-hour intervals. When ≤5 minutes remain until a cuff pressure release, a notification popup will indicate that the countdown clock has been initiated along with the time remaining until pressure release.

Touch the snooze icon to postpone the cuff pressure release. The cuff pressure release can be postponed up to two times for five-minute increments each. Continuous waveform transmission will not be extended beyond the 8-hour cumulative monitoring limit on a single finger.

Once the countdown timer ends, pressure will be released from the cuff and waveform transmission will be temporarily suspended. A notification will appear on the screen to indicate that finger cuff pressure has been released. A five-minute timer will be initiated and display time until the cuff is reinflated and waveform transmission is automatically resumed.

Power Save Mode

After 2 minutes of user inactivity (no screen touches), the module will enter power save mode. Waveform transmission will continue to the patient monitor. To wake the module up from power save mode, touch anywhere on the screen.

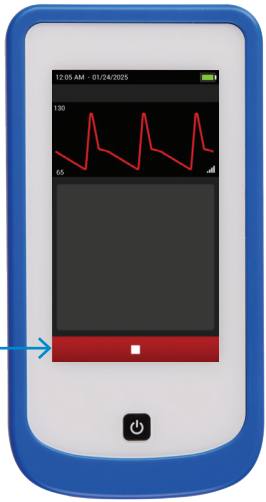
Stop Transmission: Wake up the HemoSphere Stream™ module by touching anywhere on the screen. Then, click the red button on the bottom to stop Transmission. Please note that Transmission must be stopped prior to removing the finger cuff to avoid damage to the finger cuff.

Battery

The HemoSphere Stream™ Module allows for uninterrupted waveform transmission during power loss. Battery life is indicated on the information bar by the symbols (figure 1). The approximate run time of the system, when using a fully charged battery, is 30 minutes.

Figure 1.

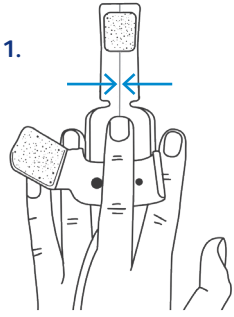
Battery symbol	Indication
	The battery is fully charged.
	The battery has greater than 50% charge remaining.
	The battery has less than 50% charge remaining.
	The battery has less than 20% charge remaining.
	The battery is low.
	The battery is charging.



Applying the Finger Cuff

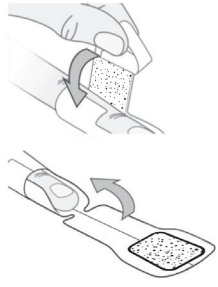
1 Open the cuff and place the finger on the gray line (Figure 1), with the cuff centered between the second and third knuckles; the cuff is not intended to be placed on the thumb, small finger, or previously fractured fingers.

Figure 1.



2 Allow the finger cuff to close around the finger. Ensure that the finger cuff does not rotate. Secure the finger cuff using its attached fastener. Then, fasten the distal end of the alignment tab to the top of the cuff (Figure 2).

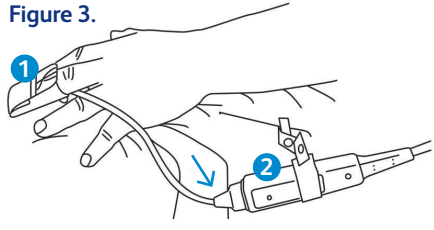
Figure 2.



3 Gently lead the finger cuff cable between the two fingers to the back side of the hand (Figure 3).

4 Connect the finger cuff cable (1) to the Smart Pressure Controller (Figure 3). (2) Once connected, a green light will become visible near the cuff connection.

Figure 3.



5 Touch the **Green Icon** to begin waveform transmission ▶.

6 Touch the **Red Icon** to stop waveform transmission ■.

Medical device for professional use. See instructions for use. CE marked medical device. CE 0123

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