



DIRECTIONS FOR USE

MODEL FM

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Regulatory Information

Use statement: The VitalsBridge FM™ is for use in the United States, Canada and in CE marking countries.

Federal Communications Commission Statement: This device complies with part 15 Subpart B of the FCC rules.



Caution: Only use cables supplied with the VitalsBridge FM and accessories approved for use with the VitalsBridge FM. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.



Disposal/Recycling: Recycle and dispose of in accordance with all governing requirements and regulations. The VitalsBridge FM contains a Li-ion battery, which should be recycled.



The VitalsBridge FM instrumentation and its associated cables are latex free.

Support

For technical assistance, contact VitalsBridge customer support:

support@vitalsbridge.com, 1-435-200-3402 or 1-801-484-3820

Disclaimer

Use of the VitalsBridge FM should be conducted under supervision of suitably trained medical personnel with an understanding of clinical monitoring, patient simulation educational principles, and recognized medical protocols. As with all simulation training devices, there may be approximations, variations, and inaccuracies in the information being presented.

Global Warranty

The VitalsBridge FM has a 1 year limited warranty; see www.vitalsbridge.com or contact support@vitalsbridge.com for additional details and warranty options.

VitalsBridge FM Directions for Use





Manufacturer

The VitalsBridge FM™ is made in the USA and is manufactured by:

Dynasthetics, LLC
3487 W. 2100 S. #300
Salt Lake City, Utah, 84119
USA

Warnings and Caution

The VitalsBridge FM is intended solely for use during patient simulation. It is not a medical device.




-  *Warning:* Never connect the VitalsBridge FM to a patient.
-  *Warning:* Never connect the VitalsBridge FM to a patient vital signs monitor that is connected to or in use by a patient.
-  *Warning:* The VitalsBridge FM is not waterproof. Protect the VitalsBridge FM in damp conditions and keep away from liquids.
-  *Warning:* The VitalsBridge FM contains a lithium ion battery, which if damaged, could cause risk of fire or explosion.

Follow all cautions and warnings outlined with your patient simulator's Directions for Use.


Compressed Gases and Regulators

Only use compressed CO₂ cartridges with the VitalsBridge FM. Adequate training and expertise is required to work with compressed gases. Cartridges may be purchased from a number of sources contact us at support@vitalsbridge.com for additional guidance.

The VitalsBridge FM is supplied with a portable gas regulator that uses compressed CO₂ cartridges. Take care when handling these cartridges as they pose a potential risk of injury if used improperly. Cartridges should be stored and operated at temperatures below 120° F (49° C) and punctures should be prevented. They should not be heated. Do not inhale the gas.


-  *Warning:* Do not use compressed oxygen (fire hazard) or any other flammable substance with or near the VitalsBridge FM.
-  *Warning:* CO₂ cartridges may become extremely cold when discharging. Protect eyes and hands when installing and handling VitalsGas cartridges.
-  *Warning:* Mishandled CO₂ cartridges may become projectiles.


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 *Caution:* CO₂ cartridges may **not** be transported by air.

Defibrillation Hazards:

When providing defibrillation on a patient simulator, the defibrillator and VitalsBridge FM may present a shock hazard. All standard safety precautions must be taken when using a defibrillator with a patient simulator and VitalsBridge FM.

 *Warning:* Defibrillation on the ECG connectors of the VitalsBridge FM will damage the internal electronics and may cause personal injury.

 *Warning:* Never connect any cables from the VitalsBridge FM to the designated defibrillator connectors on your patient simulator.

VitalsBridge FM Directions for Use

Requirements Checklists

Cables and Accessories

Please verify the following has been included in your shipment. If you are missing any of these items, have damaged items, or need extras, please contact VitalsBridge FM™ customer support for replacements.

1. VitalsBridge FM power supply, 9V, with wall plug
2. Non-Invasive Blood Pressure (NBP) parts kit (array of adapters to connect VitalsBridge FM to NBP cable on patient monitor)
3. SpO₂ Adapter and probe kit
4. Fetal Heart Rate and Uterine Activity (Toco) connector cable
5. USB cable for optional serial (RS-232) communication with the VitalsBridge FM
6. Ethernet cable for optional hard-wire network communication with the VitalsBridge FM
7. CO₂ regulator and mounting bracket

Computer and Software Requirements

1. VitalsBridge Connector Application: Windows 8, 8.1, or 10 operating system (see www.vitalsbridge.com/downloads/)
2. VitalsBridge Connector Mobile App: Android operating system (5.0 or Higher)
3. Software used to control your patient simulator or to simulate a standardized patient (optional)
4. Ethernet (LAN), wireless network (WLAN), Bluetooth or serial (RS-232) communication capability

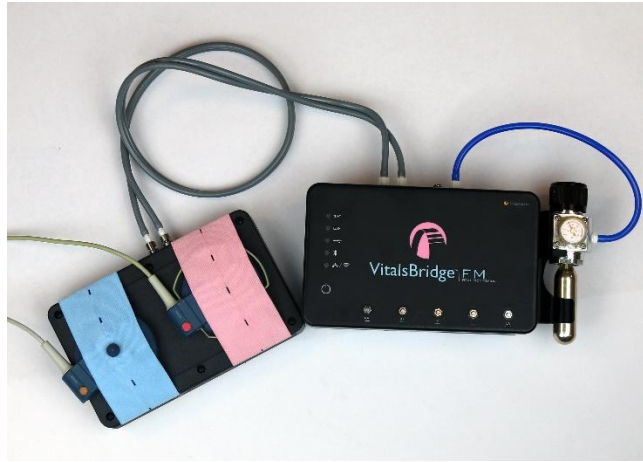
Additional Requirements

1. VitalsBridge FM instrumentation
2. VitalsBridge FM adapter
3. Commercially available fetal/maternal vital signs monitor and all associated cables
4. AC power source (i.e. a wall outlet)
5. Source of compressed gas (the supplied VitalsGas portable regulator and cartridges, or another external CO₂ or other compressed air source, regulated to 10-15PSI)

VitalsBridge FM Directions for Use

VitalsBridge FM™ Overview

The VitalsBridge FM™ is a device that allows simulated or digitized vital signs to be presented on real clinical fetal/maternal vital signs monitors. It is intended to increase the realism and effectiveness of simulations for users by enabling them to view, interact with, and control real patient monitors used in clinical practice.



Vital signs can be easily controlled from the VitalsBridge FM Connector Software. The VitalsBridge FM can also be connected to your patient simulator software allowing for vital sign changes made in the software to seamlessly update on your patient monitor. The VitalsBridge FM is able to run on a battery for increased portability.

Whether you are using a low-fidelity simulator, a high-fidelity simulator, or a standardized patient, the VitalsBridge FM presents increased opportunities for enhanced simulation experiences, heightened training and education on clinical monitoring, and improved patient information systems testing, just to name a few.



The VitalsBridge FM is compatible with modern fetal/maternal patient monitors and can be used with patient simulators or with a standardized patient. Some software applications for patient simulators feature direct integration with the VitalsBridge FM.

VitalsBridge FM Directions for Use

The VitalsBridge FM supports different vital signs and device connection options.

VitalsBridge FM Supported Signals:

- Uterine Activity (Toco)
- Fetal Heart Rate (Doppler Ultrasound)
- Maternal SpO₂
- Maternal Non-Invasive Blood Pressure (NBP)
- Maternal ECG

VitalsBridge FM Communication Options:

- Bluetooth
- USB cable
- WiFi
- Ethernet

Additional features include:

- High-fidelity patient simulator software compatibility (e.g. Laerdal's LLEAP)
- VitalsBridge FM Connector Software used to manually control vital signs
- Internal battery

Overview of Setting Up the VitalsBridge FM

Setup of the VitalsBridge FM is completed in three stages. Each of these are described in detail in subsequent pages.

Establishing VitalsBridge FM to Patient Monitor Connection (see p. 10)

- Set up your fetal/maternal vital signs monitor and cables and power it on
- Connect power to your VitalsBridge FM and power it on
- Connect your VitalsBridge FM to your monitor using the cable and sensor kit that was included with your VitalsBridge FM
- Turn on gas supply by turning the knob of the CO₂ regulator

VitalsBridge FM Connector Software Installation (see p. 25)

- Install the software that sends simulated vital signs from a Windows PC to the VitalsBridge FM (this software is also needed to use the VitalsBridge FM with Laerdal patient simulators)

Establishing VitalsBridge FM Communication (see p. 26)

- Connect to the VitalsBridge FM using a Windows PC
- Establish a connection and communicate with the VitalsBridge FM over Bluetooth, USB, WiFi, or Ethernet

Depending on your simulation equipment and scenario, some additional information may be helpful:

Using the VitalsBridge FM with a Patient Simulator (see p. 35)

- Communication between the VitalsBridge and Laerdal simulators is available through the VitalsBridge Connector software
- The VitalsBridge FM can be used with a Standardized Patient

Establishing VitalsBridge FM to Patient Monitor Connection

Setting Up your Fetal/Maternal Vital Signs Monitor

Begin the connection process by setting up your fetal/maternal patient monitor so that it would function normally if all sensors were connected to a real patient. Connect all appropriate sensor cables to the patient monitor and ensure it is powered on.

Preparing your VitalsBridge FM for Patient Monitor Connection

Configuration of Compressed CO₂ Source


 Video Link Install: <https://tinyurl.com/VBCO2install>


 Video Link Gas Shutoff: <https://tinyurl.com/VBCO2uninstall>


Compressed air is required to simulate the fetal heart rate and uterine activity vital signs. The VitalsGas, a regulated source of compressed CO₂, fulfills this need. A 16g threaded CO₂ cylinder may be used with the supplied portable regulator.

Note: compressed air or compressed CO₂ from another external source may be available at your facility (wall source, a tank, etc). Consult your facility's engineering department regarding external compressed air sources and the appropriate regulators and adapters for correct and safe connection.

Using the Portable CO₂ Regulator: The portable CO₂regulator uses 16g threaded disposable cylinders. The regulator may be detached by moving the regulator out of its bracket on the side of the VitalsBridge. The regulator's tubing has a luer lock fitting that will connect into the VitalsBridge and regulator knob to control the flow of gas. The regulator should be turned to the off position when it is not connected to the VitalsBridge via the luer connection. Only turn the regulator on when a tight and secure connection to the VitalsBridge has been verified.

 **Caution:** The regulator should be kept horizontal to upright when the VitalsGas cylinder is attached. The cylinder is pressurized. Sudden release of pressure may cause injury. Turn regulator to **OFF** when not in use.

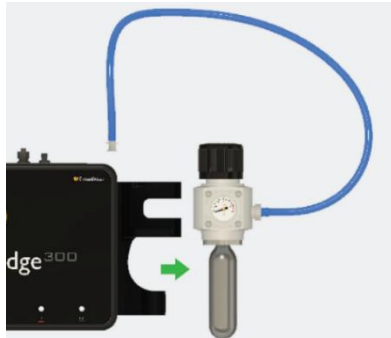
 **Warning:** VitalsGas cartridges may become extremely cold when discharging. Protect eyes and hands when installing and handling VitalsGas cartridges.

 **Warning:** Mishandled VitalsGas cartridges may become projectiles.

VitalsBridge FM Directions for Use

Installing Compressed CO₂ Cartridge:

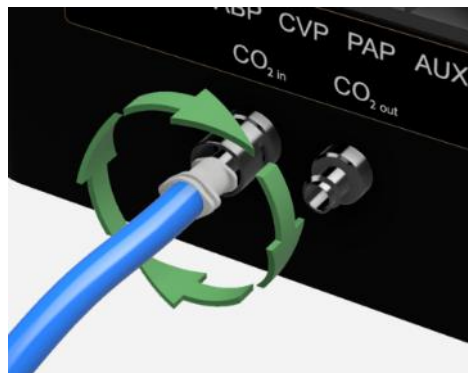
1. If replacing a cartridge, temporarily remove the regulator from its bracket on the VitalsBridge FM instrumentation and remove the empty cartridge from the regulator by turning it counterclockwise. *(If this is the first time installing a cartridge, the regulator should already be separated from its bracket and there should be no cartridge attached to it, unlike the figure below.)*



2. Adjust the regulator knob to the “OFF” position by rotating it counterclockwise.



3. Attach the blue tubing to the blue luer lock (CO₂_{in}) to the VitalsBridge FM. To ensure a secure connection between the regulator and the VitalsBridge FM, twist the luer fitting at least 180 degrees to the left before inserting the luer into the metal port on the VitalsBridge FM. Then twist to the right until it is tight.



VitalsBridge FM Directions for Use

4. Orient the VitalsBridge FM so the threaded connection on the regulator can be seen. Hold the regulator in one hand, align the cartridge under the housing, and quickly turn it clockwise into the regulator. Do not stop until tight. Do not over tighten; the cartridge only needs to be hand tight. It is normal for a small burst of gas to leak out during cartridge installation.



5. Replace the regulator back on the bracket that is attached to the VitalsBridge FM instrumentation.
6. SLOWLY turn the regulator knob clockwise until the pressure on the gauge reads 10-15 PSI. Do not set the regulator to a reading higher than 20 PSI.



- ⚠ Caution:** Ensure CO₂ cartridge has been fully released prior to disposing of the cartridge. This may be accomplished by: (i) turning the regulator to “OFF”, (ii) detaching the female luer fitting from the blue luer lock ring on the VitalsBridge, (iii) **slowly** turning the regulator knob clockwise (towards “HI”), and (iv) allowing the remaining compressed gas to expel in a controlled manner. The cartridge may be very cold. Point the outlet of the cartridge away from yourself and others. Wear eye protection. **Ensure that the knob is turned to the off position before a new cartridge is installed.**
- ⚠ Caution:** When not in use turn the regulator to the off position and disconnect the regulator tubing from the VitalsBridge.
- ⚠ Caution:** CO₂ cartridges may **NOT** be transported by air.

VitalsBridge FM Directions for Use

Connecting Power to the VitalsBridge FM

External Power

To power the VitalsBridge FM via wall power, simply connect the external power adapter and plug into any standard wall outlet.

- ⚠ *Warning:* Use only the included 9V power supply. Prior VitalsBridge models used a different voltage for their power supply. Using an incorrect power supply may damage the VitalsBridge FM and void the warranty.



Internal Battery

The VitalsBridge FM contains an internal, non-replaceable Lithium-Ion battery to allow for unplugged operation of the unit. When fully charged, this will allow for at least 1 hour of use (2 – 5 hours typical). To charge the battery, connect the external power supply. The power supply will charge a fully depleted battery in 6-12 hours. When the unit is switched on, the battery indicator on the top panel will flash when there is less than 15% of battery life remaining; if you need to continue using the VitalsBridge FM, connect the external power.

When plugged in and powered off, the VitalsBridge FM battery will be charged. When plugged in and powered on, the VitalsBridge FM battery will also be charged (at a slower rate).

VitalsBridge FM Directions for Use

Turning on the VitalsBridge FM

Power on your VitalsBridge FM. It is turned on by pressing the power button in the lower left corner of the top surface of the device. Once powered on, the VitalsBridge FM takes approximately 30 seconds to initialize. The LED below the battery will flash as the VitalsBridge FM is initializing.



Check the status indicator lights on top of the VitalsBridge FM instrumentation to determine power and connectivity.

The VitalsBridge FM instrumentation has 5 LEDs: Power, battery/charge, USB/Serial, Bluetooth and LAN/WiFi.

- Power indicator:
 - No light: switched off, or switched on and the VitalsBridge FM is not plugged into an outlet
 - Solid: switched on and power available to the VitalsBridge FM
- Battery/charge indicator:
 - No light: VitalsBridge FM is not running
 - Solid: VitalsBridge FM is on, battery charge > 15%
 - Flashing every 1 second: unit is running on low battery charge < 15%
- USB/Serial
 - No light: USB is not ready
 - Solid: USB is ready
- Bluetooth
 - No light: Bluetooth is not ready
 - Solid: Bluetooth is ready
- WLAN or LAN:
 - No light: not connected to router
 - Solid: the VitalsBridge FM is connected to the manikin's internal router or to an external router

Note: If you have just reconfigured your VitalsBridge FM to connect to WiFi, the light will *not* turn on until you have first closed out of the VitalsBridge FM Connector software.

Now that both your patient monitor and the VitalsBridge FM are turned on, as each connection is made it will be possible to verify that each piece is connected and working properly.

VitalsBridge FM Directions for Use

Connecting the VitalsBridge FM to the Patient Monitor

This section will describe how to connect the cables and sensors between the VitalsBridge FM and the vital signs fetal/maternal monitor. The cable and sensor kit provided with the VitalsBridge FM is intended to be preconfigured with the vital signs monitor brand and model you plan to use. If more than one vital signs monitor will be used, visit www.vitalsbridge.com to purchase additional cable and sensor kits.

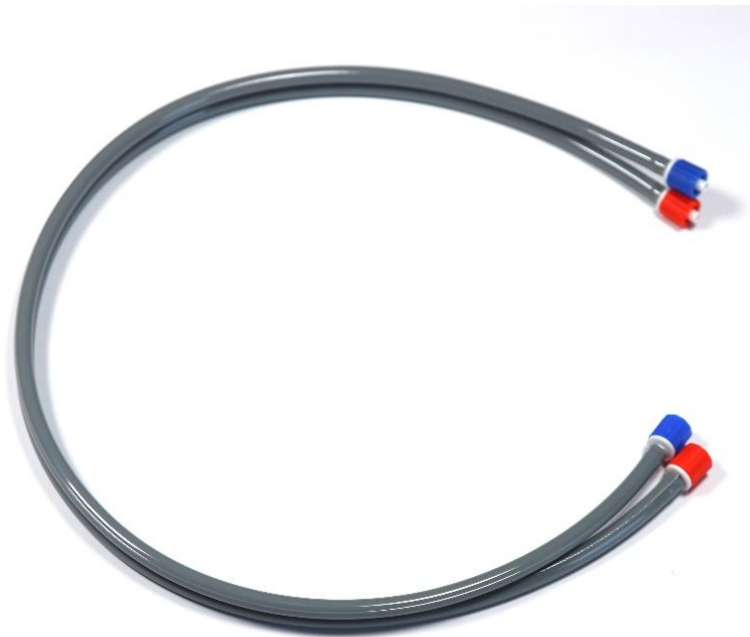
Fetal Heart Rate (FHR) and Uterine Activity (UA)

FHR measures the heart rate of the fetus. FHR is an indicator of the baby's health, particularly during labor. The VitalsBridge FM simulates external FHR, allowing an ultrasound probe to be attached to a specially constructed adapter that is attached to the VitalsBridge FM instrumentation.

UA (i.e. Toco) is a signal that measures the strength and duration of uterine contractions during labor. The VitalsBridge FM uses a specially constructed adapter that simulates a pressure level that UA sensor can measure and display on the vital signs monitor.

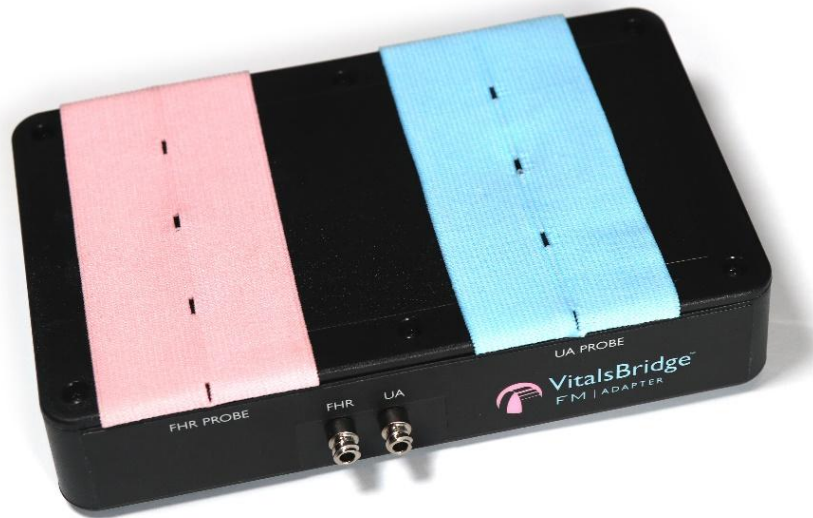
Configuring FHR and UA

1. Locate the FHR and UA connector cable. This is a grey cable with two tubes and two connectors at each end – one red and one blue.

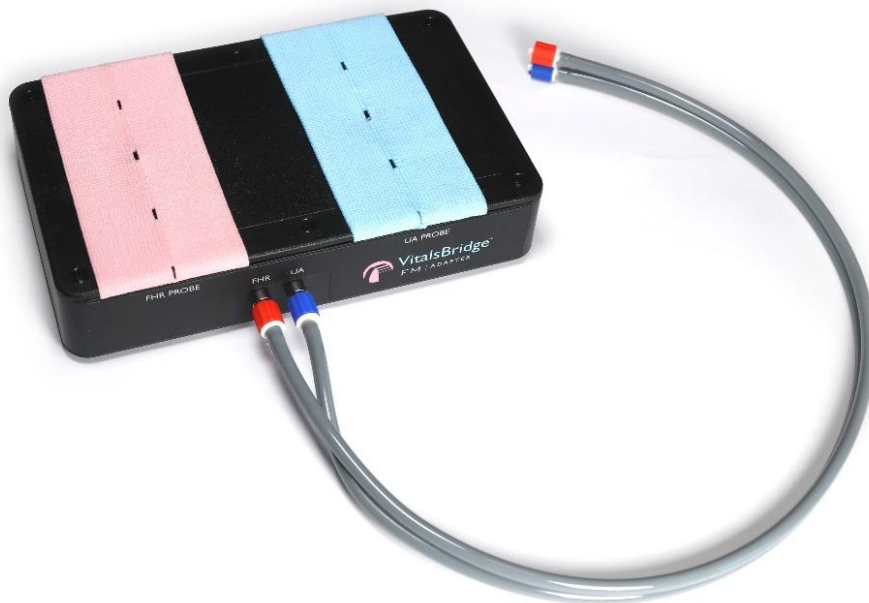


VitalsBridge FM Directions for Use

2. Locate the VitalsBridge FM Adapter that came with your VitalsBridge FM.

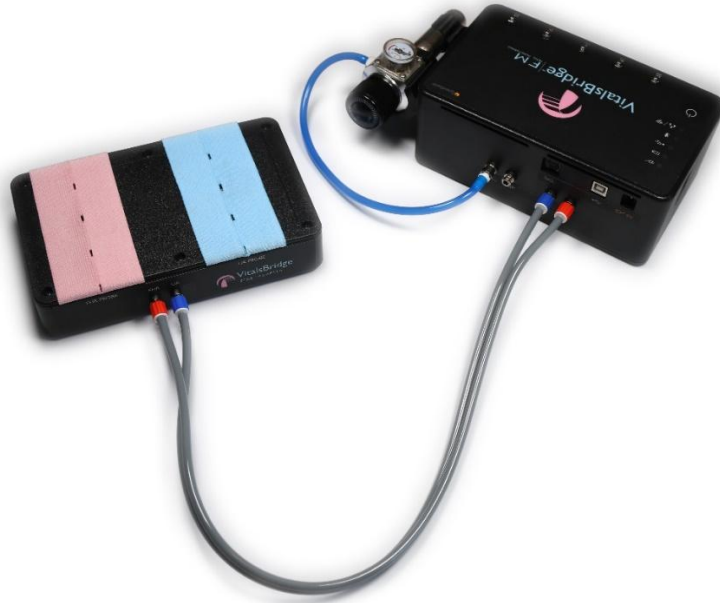


3. Connect the FHR and UA connector cable to the VitalsBridge FM Adapter. The red connector links to the FHR port and the blue connector links to the UA port. Twist the colored connectors to the right to ensure a secure connection.



VitalsBridge FM Directions for Use

4. Connect the FHR and UA connector cable to the VitalsBridge FM. Similarly, the red connector links to the FHR port and the blue connector links to the UA port. Note that the FHR port is on the *right* and the UA port is on the *left*, opposite of the ports on the VitalsBridge FM Adapter. Twist the colored connectors to the right to ensure a secure connection.



5. Connect the VitalsBridge FM Adapter to the fetal/maternal monitor.
 - a. Locate your FHR and UA probes that go with the patient monitor.
 - b. Slide the UA probe under the blue elastic belt on the VitalsBridge FM Adapter.
 - i. If the probe has a plastic or metal post, push it through the center hole in the belt to help it stay in place.
 - ii. Adjust the position of the probe so that it is centered over the hole under the belt on the VitalsBridge FM Adapter.

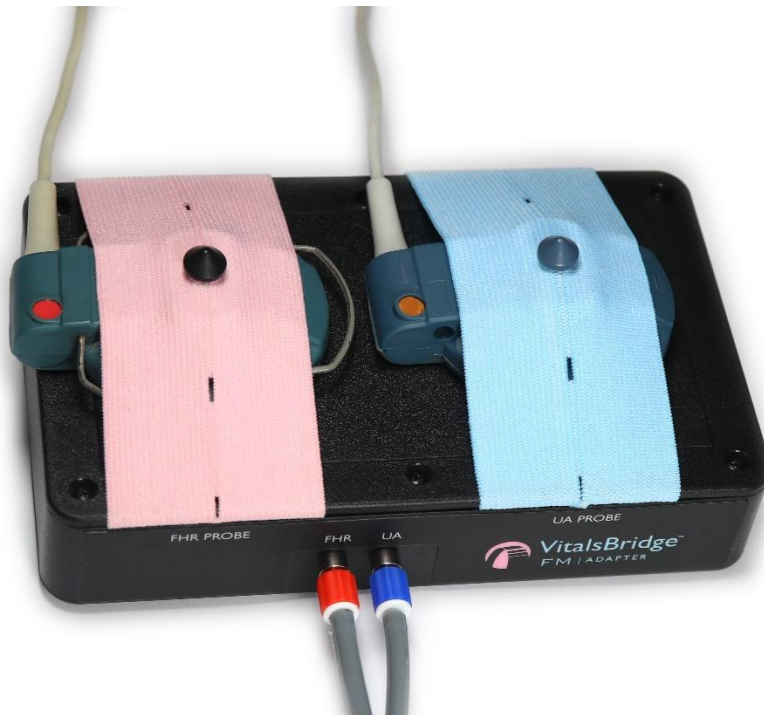


VitalsBridge FM Directions for Use

- c. Apply a pea-sized amount of ultrasound transmission gel to the FHR probe. Spread it slightly so that it covers an area about the size of a penny.

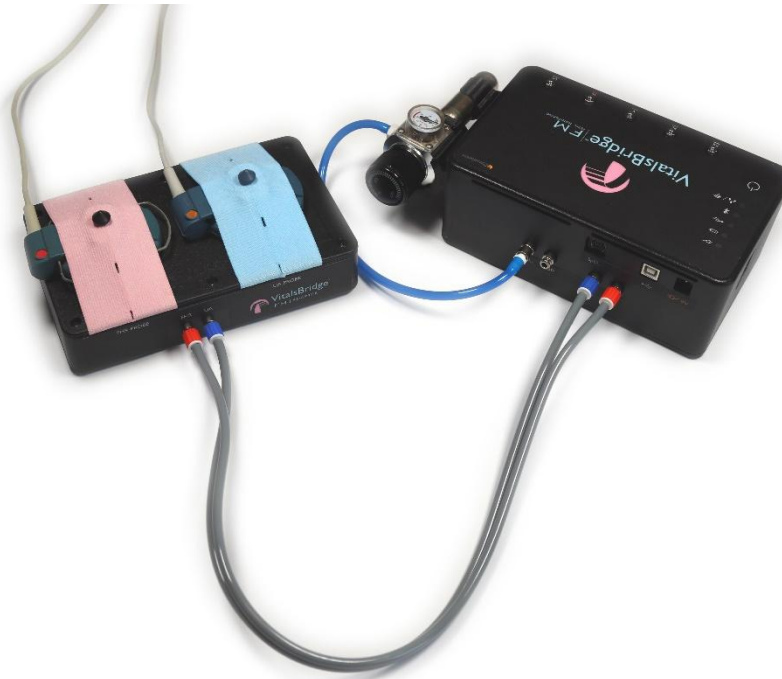


- a. Slide the FHR probe under the pink elastic belt on the VitalsBridge FM Adapter.
 - i. If the probe has a plastic or metal post, push it through the center hole in the belt to help it stay in place.
 - ii. Adjust the position of the probe so that it is centered over the hole under the belt on the VitalsBridge FM Adapter.



VitalsBridge FM Directions for Use

6. Your setup for these vitals should now look like the image below. If everything has been connected correctly, both readings should appear on the fetal/maternal monitor after a few moments.



NOTE: Due to the nature of simulating Toco signals, the VitalsBridge FM Adapter is highly sensitive to movement and vibrations. Jostling of the Adapter unit and attached probes may affect the readings on the patient monitor. The VitalsBridge FM Adapter unit should be carefully placed in your simulations to avoid disturbance.

To further avoid these disturbances, take the Velcro strap that was included with your VitalsBridge and wrap it tightly around the UA probe as shown in the image below.



NOTE: To increase realism for the learners, additional mock FHR and UA probes can be placed on a manikin or standardized patient that appear to run to the vital signs monitor.

VitalsBridge FM Directions for Use

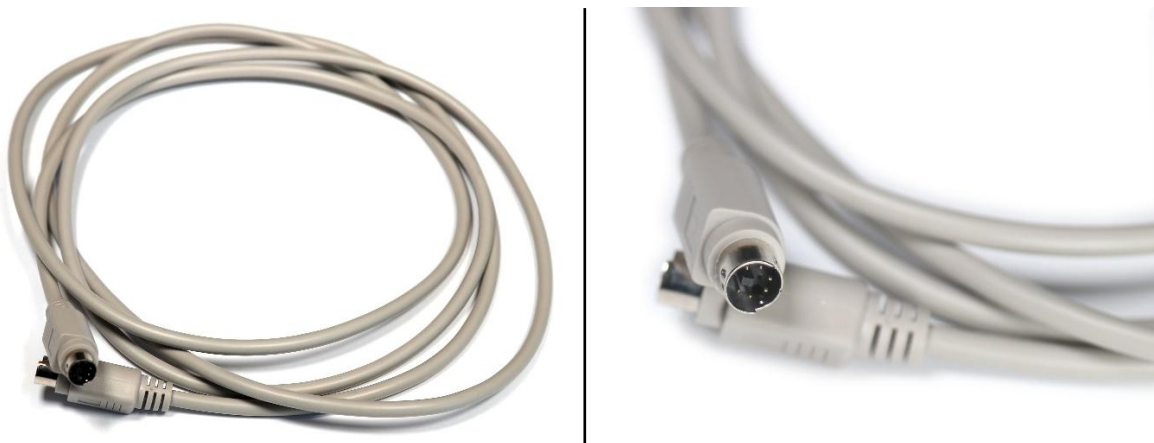
Maternal Pulse Oximetry (SpO₂)

 Video Link: <https://tinyurl.com/VBSpO2instruction>

Pulse oximetry, or SpO₂, is used to determine the oxygen saturation of a patient's blood. It also will provide a pulse measurement. SpO₂ simulation by the VitalsBridge FM uses special circuitry in a custom SpO₂ adapter and cable and sensor kit which provides expected levels to simulate the SpO₂ probe according to the maternal SpO₂ value set for your simulation. The custom SpO₂ adapter has labeled cable connections to both the VitalsBridge FM and the fetal/maternal monitor.

Configuring SpO₂

1. Locate the SpO₂ cable and probe connected to your monitor and the SpO₂ Adapter kit that came with the VitalsBridge FM.
2. In the SpO₂ Adapter kit, locate the grey cable with circular ends and seven pins.



3. Connect the grey cable to the SpO₂ port on the VitalsBridge FM.

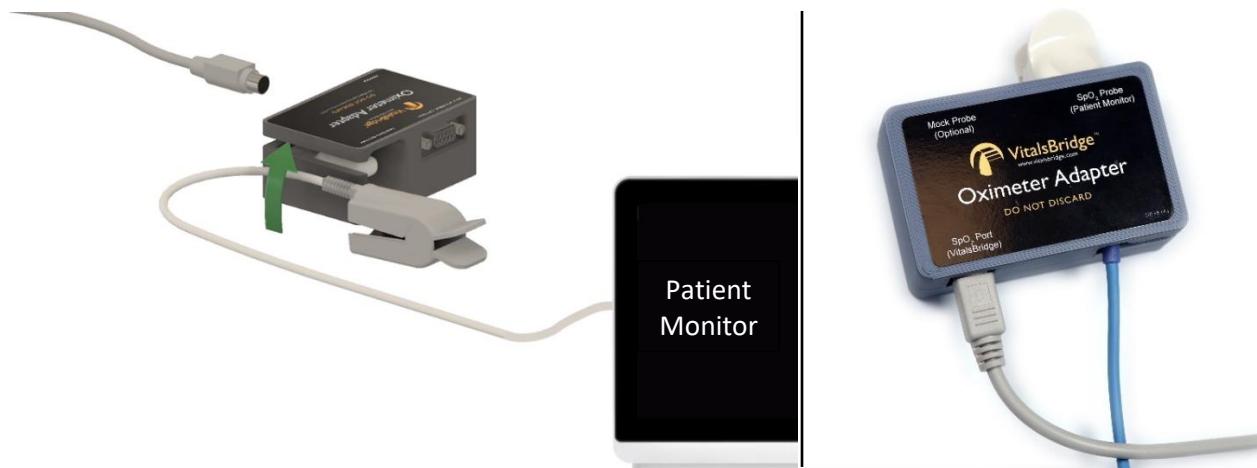


VitalsBridge FM Directions for Use

4. Connect the other end of the grey cable to the appropriate port on the Oximeter Adapter box.



5. Place the SpO₂ probe coming from the patient monitor in the Oximeter Adapter box. Below are written instructions and a diagram to help you complete this step.
 - a. Hold the probe parallel with the ground. The half of the probe with the cable attached should be on top. The half of the probe without a cable attached should be underneath, closest to the ground.
 - b. Locate the slot on the Oximeter Adapter box intended for the SpO₂ probe. You should see a white post that simulates a patient finger inside the slot.
 - c. Slide the cable attached to the SpO₂ probe through the slot on the side of the Oximeter Adapter box.
 - d. Open the probe slightly and push the probe firmly into the slot onto the white "finger," then release.



6. If everything has been connected correctly, a reading should appear on the fetal/maternal monitor after a few moments.
 - a. **NOTE:** You will see a port on the Oximeter Adapter box for a mock SpO₂ probe. If the mock probe included in the kit is connected to the Oximeter Adapter box, a reading will not appear on your patient monitor unless the mock probe is placed on a patient simulator's finger. We do not recommend connecting the mock probe until you ensure that the connection is working properly and are ready to run a simulation with a patient simulator. For more information on the mock probe, see the section on "Increasing Realism."

VitalsBridge FM Directions for Use

Maternal Non-invasive Blood Pressure (NBP)

 Video Link: <https://tinyurl.com/VBNBPinstruction>

The VitalsBridge FM simulates non-invasive blood pressure by mimicking the pulsing of an artery. The NBP tubing from the patient monitor is connected to the VitalsBridge, and when the patient monitor initiates an NBP reading, the VitalsBridge FM simulates an appropriate magnitude of pulsing.

Configuring NBP

1. Locate your NBP cable that goes with the patient monitor.
 - a. If a blood pressure cuff is still attached to the cable, carefully remove it.
2. Determine if your NBP cable needs configuring in order to connect to the VitalsBridge FM.
 - a. Compare the fitting at the end of your NBP cable to the NBP port on the VitalsBridge. If they will fit together, skip down to step 3. If not, continue to part 2.b.
 - b. Locate the NBP adapter bag. It contains tubing adapters and connectors for appropriate fitting(s) to connect the luer fitting on the VitalsBridge with the patient monitor's NBP tubing.



- i. Determine which connectors your cable will need to connect to the VitalsBridge NBP port. If the NBP tubing coming from your monitor has 2 connectors, a 2-tube to 1-tube adapter fitting has been provided.

VitalsBridge FM Directions for Use

- ii. Follow the instructions with the images below.



Select the appropriate tube and luer fittings



Affix the tube and luer fittings to each other to provide an ending that can be attached to the monitor NBP tubing


- c. Connect the appropriate adapters and connectors to the NBP cable from the patient monitor if necessary.
3. Connect the NBP cable to the NBP port on the VitalsBridge FM.



4. Run a blood pressure cycle on the fetal/maternal monitor. If everything has been connected correctly, a reading should appear on the fetal/maternal monitor once the cycle is complete.

VitalsBridge FM Directions for Use

Maternal Electrocardiogram (ECG) and Respiration

 Video Link: <https://tinyurl.com/VBECGinstruction>

The VitalsBridge FM has connections for up to 5 ECG leads (RA, RL, V, LL, and LA). In addition, a respiration by impedance signal is also produced by the VitalsBridge.

Configuring ECG

1. Using the ECG harness from the patient monitor, connect each lead to the VitalsBridge FM. Match the corresponding colors or labels on the leads to the snaps on the VitalsBridge FM.



2. If everything has been connected correctly, a reading should appear on the fetal/maternal monitor after a few moments.

VitalsBridge FM Connector Software Installation

Overview:

1. Software Requirements:
 - Windows 8, 8.1, and 10 operating system (see www.vitalsbridge.com/downloads/)
 - Ethernet (LAN), wireless network (WLAN), Bluetooth or USB/serial (RS-232) communication capability
2. Software Download Link:
 - www.vitalsbridge.com/downloads/

Installation of the VitalsBridge FM Connector Software on a Windows PC

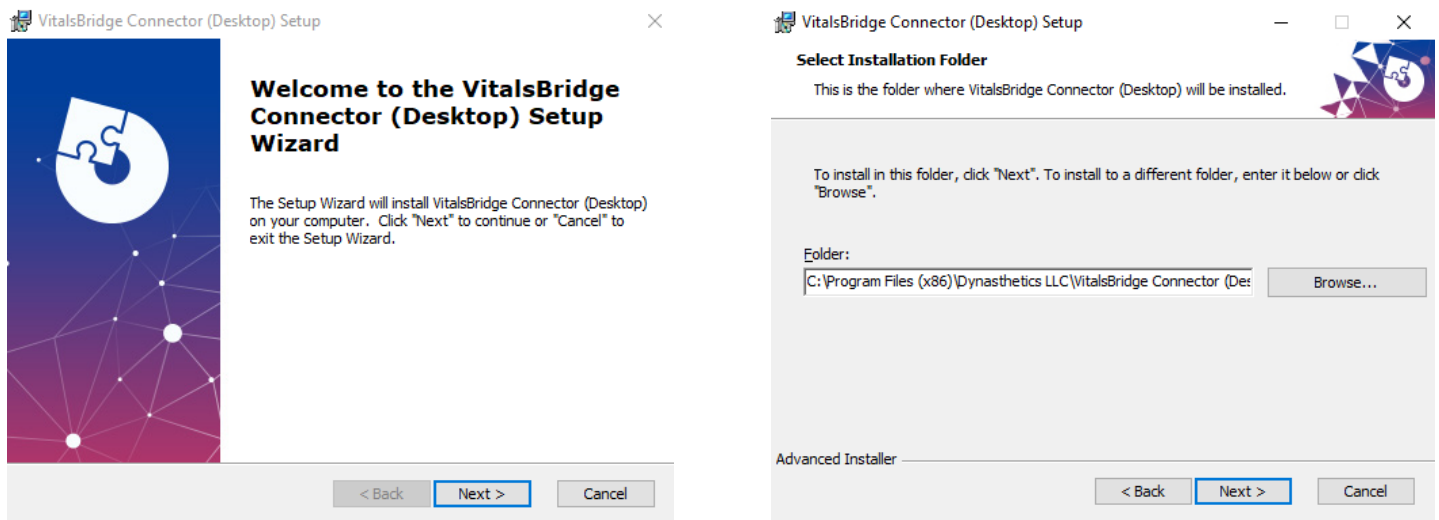
 Video Link: <https://tinyurl.com/VBSoftwareinstruction>

Download the appropriate VitalsBridge FM Connector installation software from www.vitalsbridge.com/downloads/. If necessary, copy the software to the computer on which it will be installed.

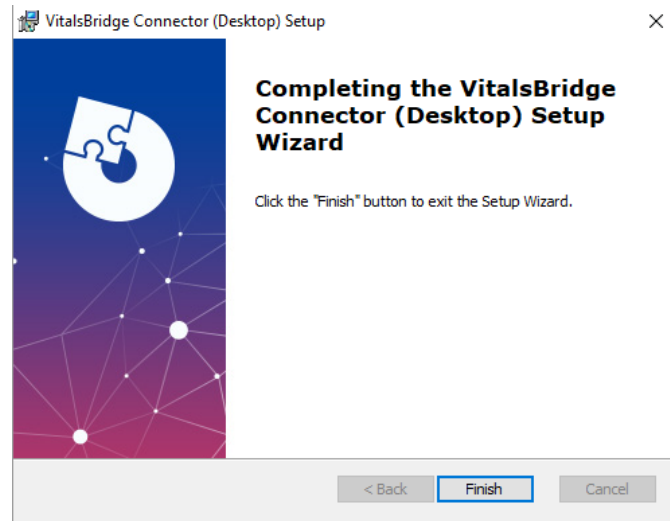
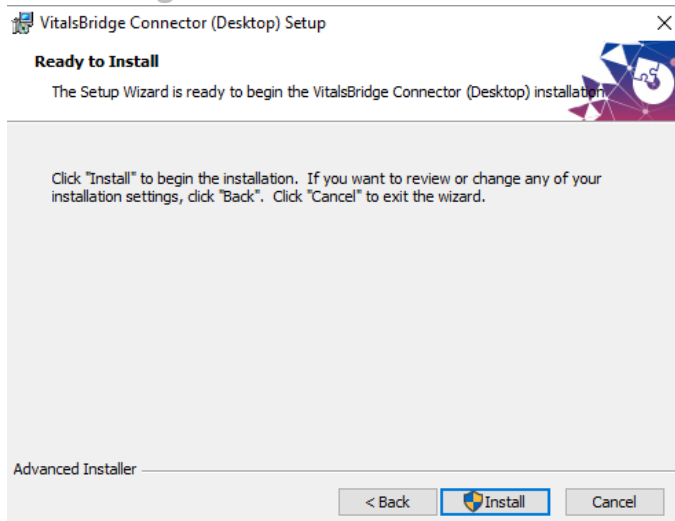
Note: If it is intended for the VitalsBridge FM to be used in conjunction with Laerdal LLEAP patient simulator software, download the VitalsBridge FM connector software to the computer where Laerdal's LLEAP is installed. Otherwise simply download the connector software to the computer the VitalsBridge FM will be controlled from.

Once downloaded, navigate to the installation software file and open it. Follow the on-screen installation instructions. Upon successful installation, a VitalsBridge FM icon will be created on the PC's desktop.

NOTE: Choose the appropriate VitalsBridge FM installation software carefully. There may be specific installation software that is compatible with a particular version of a patient simulator (e.g. a particular version of Laerdal's LLEAP) software.



VitalsBridge FM Directions for Use



Establishing VitalsBridge FM Communication

Overview:

When connecting to a PC, the connection options are:

1. USB (RS-232)
2. Bluetooth
3. Ethernet
4. WiFi

*Note: The WiFi connection option *cannot* be used for initial set-up. Please select one of the other connection methods for the first connection.

Please select the connection method that best suits your needs.

Note: only *one* connection is needed. The directions for set-up of each method can be found below.

Establishing the VitalsBridge FM – PC Connection

Bluetooth

Video Link: <https://tinyurl.com/VBBluetoothinstruction>

1. To communicate with the VitalsBridge FM over Bluetooth, the VitalsBridge FM must first be paired with the Windows-based computer or Android mobile device that has the VitalsBridge FM Connector application.
2. Refer to your computer's instructions on how to pair.
3. The VitalsBridge FM will provide a 6-digit pin, which may need to be confirmed/acknowledged during the pairing process. If this is the case, simply select "confirm" when the appropriate screen appears (the number shown has no significant meaning associated with the VitalsBridge FM and does not need to be compared to another number).
4. Once paired, the VitalsBridge FM will be available for connection in the VitalsBridge FM Connector Application.

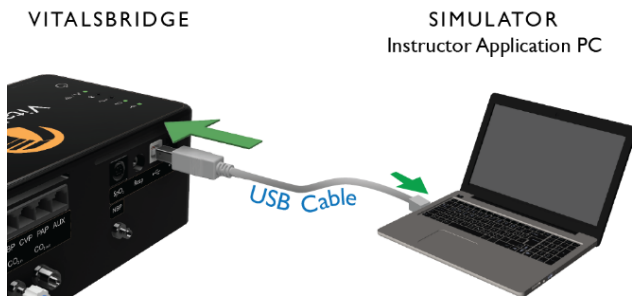
VitalsBridge FM Directions for Use

Note: When first connecting, the name of the device will be a randomly generated name followed by a random string of characters or numbers. The “name” of your VitalsBridge FM will be unique but may be something like, “Uter-FBB3,” “Todd-03E0,” or “Wendell-1411.” (This can be changed as explained on page 42.)

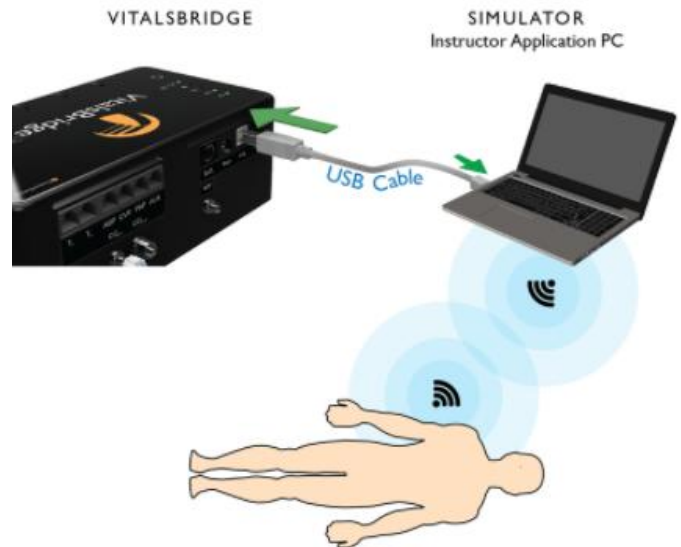
Note: You may have difficulties with your Bluetooth connection if it is 1) selected that the VitalsBridge FM be “forgotten” from by the device connected to and then 2) asked to be re-paired to that same device. To avoid this problem, if it is desired that the VitalsBridge FM not be connected with a device for a short time, turn off Bluetooth on the device, turn off the VitalsBridge, connect the VitalsBridge to a different device, or connect your device to another Bluetooth device rather than “forgetting” the VitalsBridge FM.

USB cable

1. With the supplied USB cable, connect the VitalsBridge FM to the Windows-based computer.
2. Windows will automatically install the appropriate drivers for RS-232 communication over USB. Please wait approximately two minutes for the appropriate drivers to be installed.
3. Consider restarting the computer prior to launching the VitalsBridge FM Connector application. (This step is optional but recommended for first-time connections.) Then launch the software.



Standardized Patient Setup



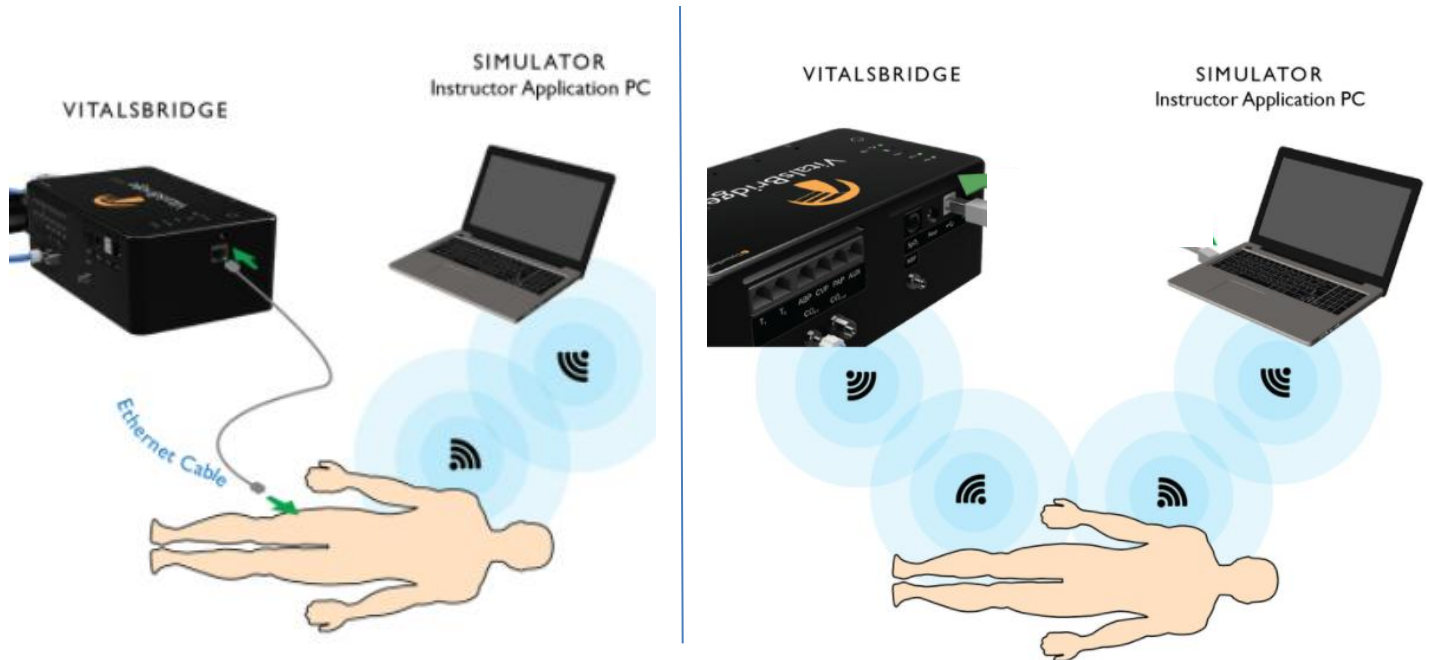
Running the VitalsBridge FM using a Serial Cable
With a patient simulator

VitalsBridge FM Directions for Use

Ethernet/WiFi

The VitalsBridge FM may be connected to a router by an Ethernet cable or by WiFi (2.4 GHz 802.11b/g/n). The VitalsBridge FM Connector software can run on a PC that is on the same network as the VitalsBridge FM and patient simulator (if applicable).

For details about connecting via these methods, see below.



Ethernet

When connecting the VitalsBridge FM to a patient simulator using an Ethernet cable, ensure the cable is functional and is securely connected between the Ethernet ports of the VitalsBridge FM and the manikin.

It is also possible for the VitalsBridge FM to be directly connected to a Windows PC that controls a patient simulator with an Ethernet cable. The VitalsBridge FM is assigned one of the link-local addresses in the range 169.254.1.1 - 169.254.254.254. Some additional network configuration may be necessary for this to work.

WiFi

WiFi communication for the VitalsBridge is possible *only* after it has been configured using the VitalsBridge FM Connector software. WiFi configuration is completed with a Bluetooth or USB connection to the VitalsBridge FM. WiFi communication *cannot* be used during the initial set-up.

WiFi SSID and Password

Video Link: <https://tinyurl.com/VBWiFiinstruction>

Note: Before completing the process outlined below, you *must* have already 1) downloaded the VitalsBridge FM Connector Software, 2) successfully established a connection between your PC and the VitalsBridge FM via USB or Bluetooth, and 3) connected the VitalsBridge FM to the connector software.

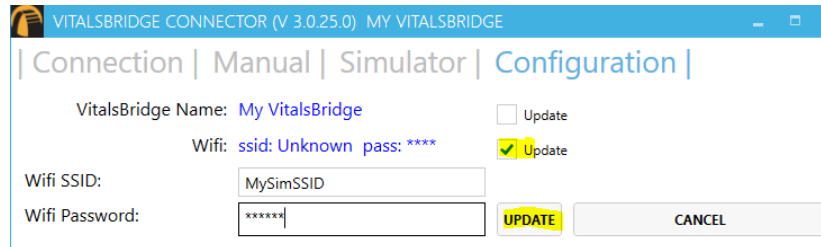
The WiFi SSID and Password may be set for the VitalsBridge FM in the Configuration tab of the VitalsBridge FM Connector Software. This will allow for a connection via WiFi.

VitalsBridge FM Directions for Use

Note: In order to configure the VitalsBridge FM WiFi, ensure that you are connected via USB or Bluetooth.

WiFi may be set-up to connect via an access point (i.e.: a router within a manakin) or via a typical wireless router.

1. Check the Update checkbox adjacent to the WiFi field.
2. Enter the name of the SSID and password of the wireless router or access point (note that both the SSID and password fields ARE case-sensitive).



Note: If the VitalsBridge FM has just been reconfigured to connect to WiFi, the indicator light will *not* turn on until you have first restarted the VitalsBridge FM connection software. The VitalsBridge FM will then connect to the router and you will be able to connect your PC to the VitalsBridge FM over WiFi when the VitalsBridge FM connection software is reopened.

Windows Network Settings

Discovery of the VitalsBridge FM instrumentation uses the UDP network protocol on port 14998, while TCP/IP communication occurs over port 14997. When running for the first time, please ensure you allow application access through the Windows Firewall on both the public and private profiles.

VitalsBridge FM Directions for Use

Calibrations

It may be necessary to calibrate the vital signs to your specific monitor. For instructions on how to complete the calibrations from the VitalsBridge FM Connector Software see below.

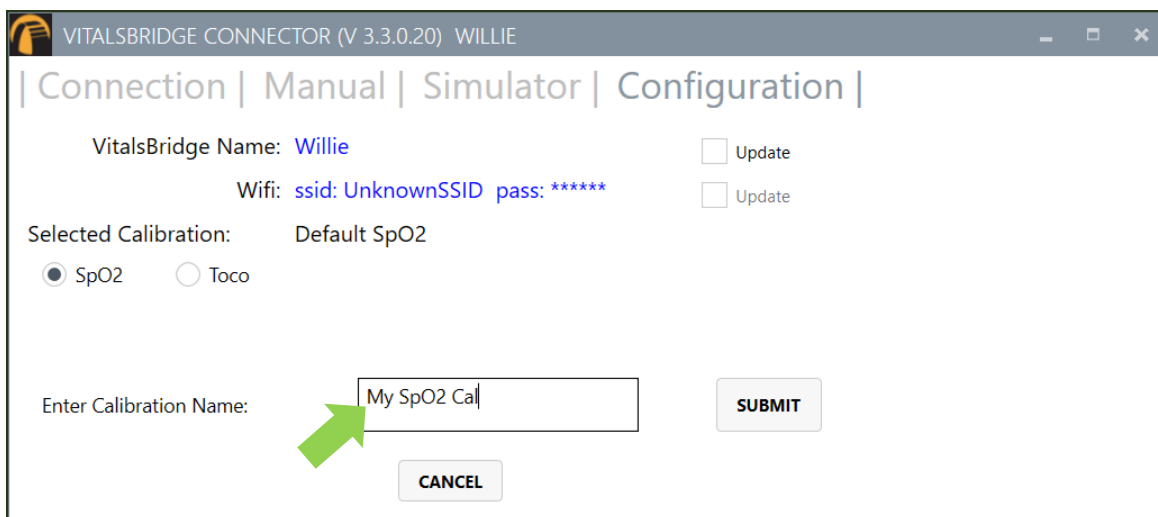
SpO₂ Calibration

The VitalsBridge FM is pre-calibrated with factory settings for a Nellcor standard probe. SpO₂ calibrations are stored on the VitalsBridge FM. If the set SpO₂ value significantly deviates from the value on the vitals sign monitor, then it is possible to use your own calibration. To perform a new calibration, first ensure the adapter is configured correctly. Next, under the Configuration Tab, Choose SpO₂ under “Selected Calibration” and press the NEW button.



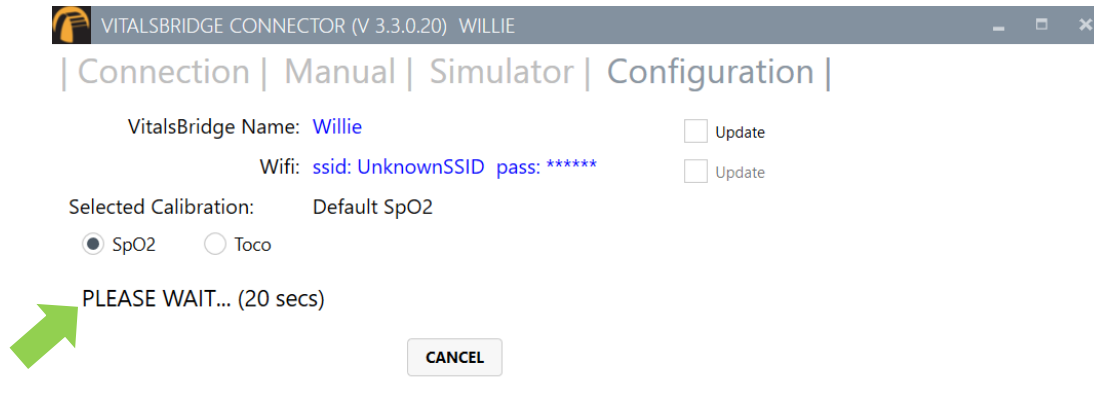
Note: When performing a calibration, it works best if the disposable SpO₂ probe (the “mock probe”) supplied is **NOT** connected to the adapter box. If the disposable SpO₂ probe is connected, it needs to be *on* a finger or something of the like. While it does not take an SpO₂ reading of the thing it is surrounding (finger, manikin, etc...), a light sensor indicates that it is in use. If the light sensor is not activated it will cause problems with the calibration.

Choose a name for the calibration:

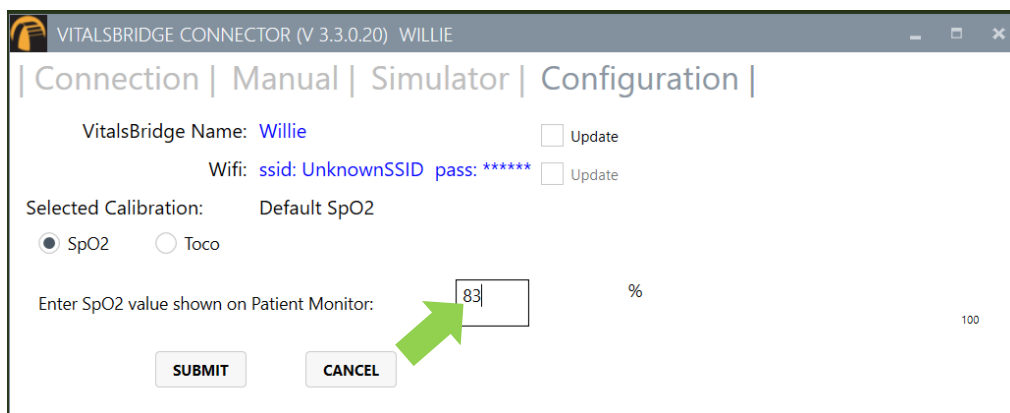


VitalsBridge FM Directions for Use

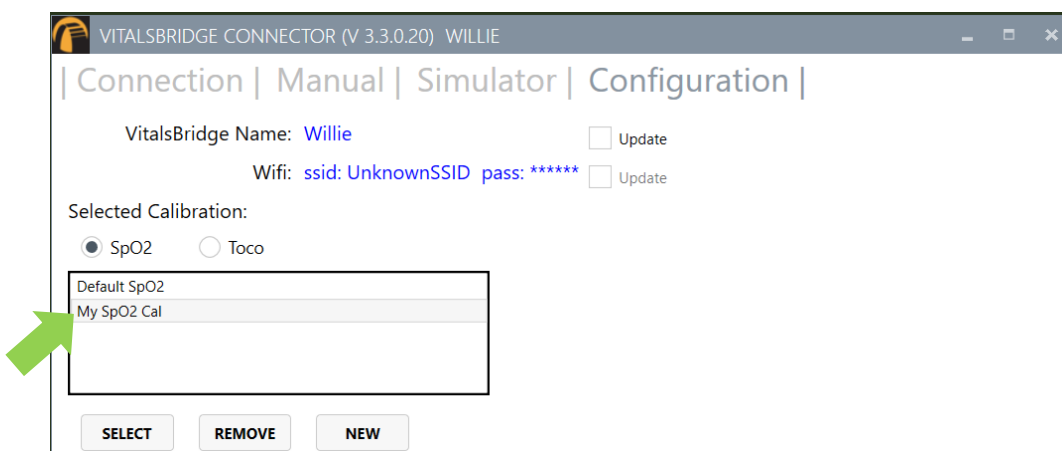
The user interface will instruct you to wait for a period of time and then to enter the SpO₂ reading shown on the patient monitor.



Note: Wait until the SpO₂ reading has stabilized on the monitor before entering the value. Some vital signs monitors will filter and average the SpO₂ value, and there may be a several second delay before the reading changes and stabilizes.



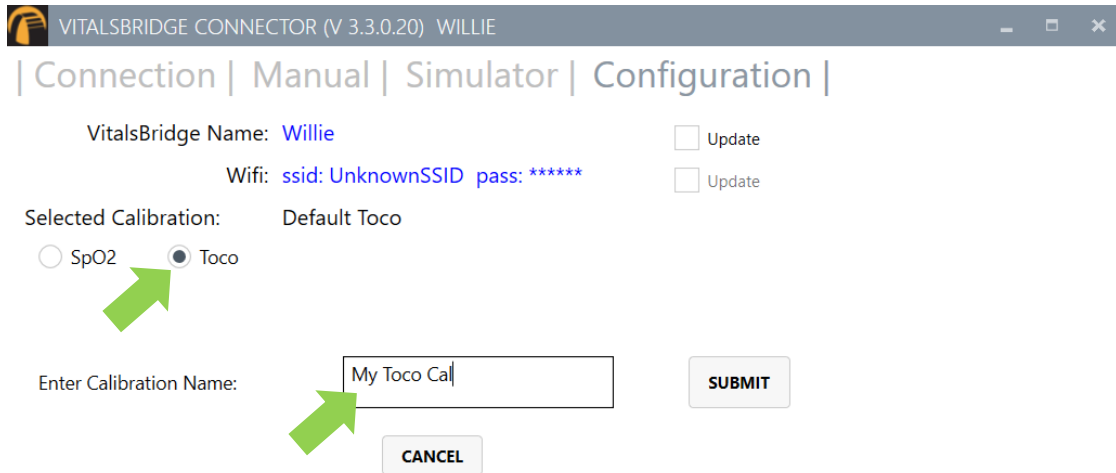
Additional calibration entries are shown and the process of entering in a SpO₂ value is repeated until enough points are found for an accurate calibration reading. Once enough points are found, the calibration is automatically saved and selected.



Unused custom calibrations may be removed by highlighting the desired calibration to remove and pressing the REMOVE button.

VitalsBridge FM Directions for Use Uterine Activity (Toco) Calibration

To begin a new calibration, go to the Configuration tab, choose Toco under “Selected Calibration” and press the NEW button. Then enter a calibration name.



VITALSBRIDGE CONNECTOR (V 3.3.0.20) WILLIE

| Connection | Manual | Simulator | Configuration |

VitalsBridge Name: **Willie** Update

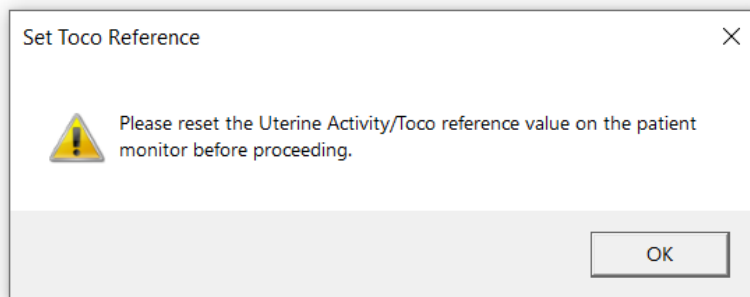
Wifi: ssid: **UnknownSSID** pass: ********* Update

Selected Calibration: Default Toco


SpO2 Toco

Enter Calibration Name:

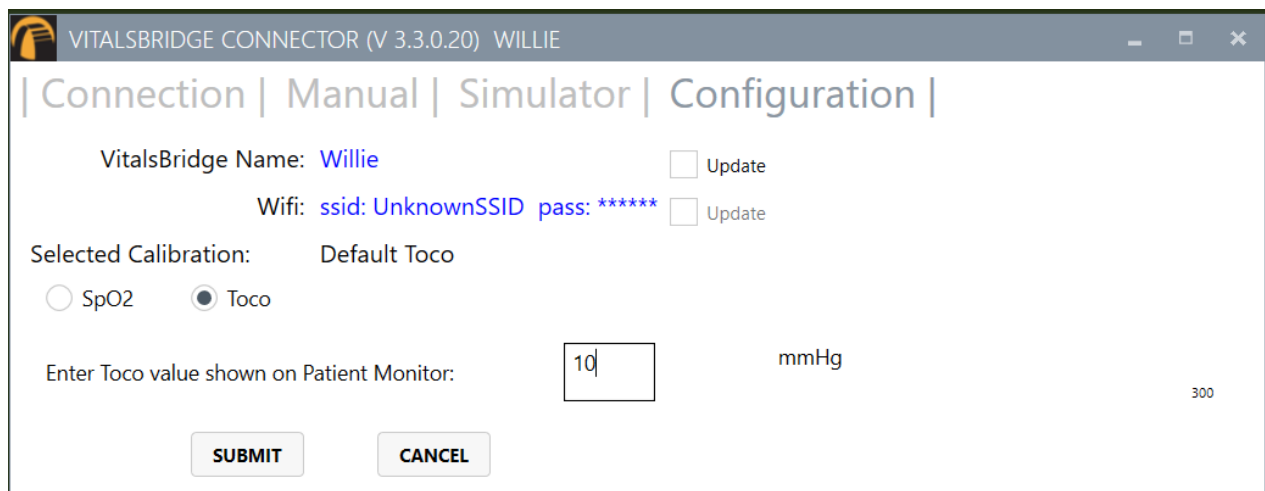
Follow the instructions on the screen. First, the software will prompt you to reset the UA/Toco reference value on the patient monitor.



Set Toco Reference

 Please reset the Uterine Activity/Toco reference value on the patient monitor before proceeding.

The user interface will instruct you to wait for a period of time and then to enter the Toco reading shown on the patient monitor.



VITALSBRIDGE CONNECTOR (V 3.3.0.20) WILLIE

| Connection | Manual | Simulator | Configuration |

VitalsBridge Name: **Willie** Update

Wifi: ssid: **UnknownSSID** pass: ********* Update

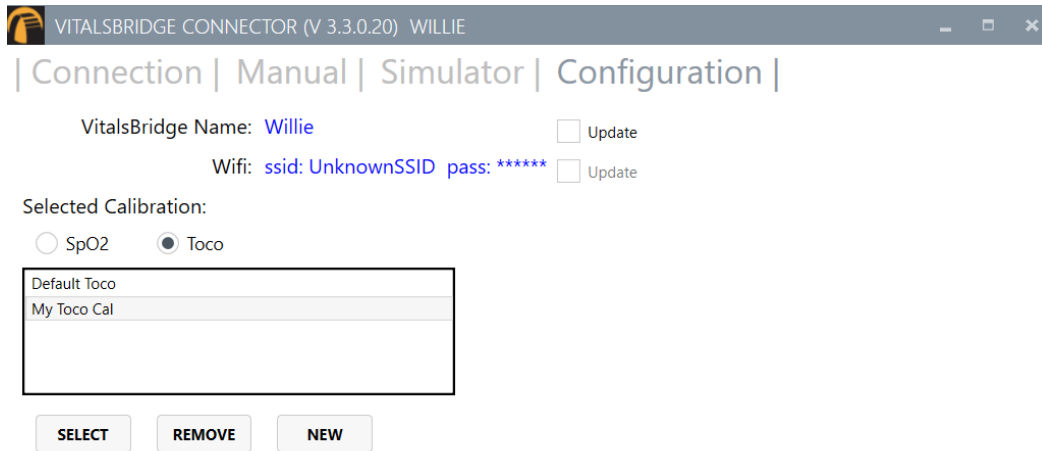
Selected Calibration: Default Toco

SpO2 Toco

Enter Toco value shown on Patient Monitor: mmHg

VitalsBridge FM Directions for Use

Additional calibration entries are shown and the process of entering in a Toco value is repeated until enough points are found for an accurate calibration reading. Once enough points are found, the calibration is automatically saved and selected.



VITALSBRIDGE CONNECTOR (V 3.3.0.20) WILLIE

| Connection | Manual | Simulator | Configuration |

VitalsBridge Name: [Willie](#) Update

Wifi: [ssid: UnknownSSID](#) [pass: *****](#) Update

Selected Calibration:

SpO2 Toco

Default Toco
My Toco Cal

VitalsBridge FM Directions for Use

Controlling Vital Signs with the VitalsBridge FM

There are two options to program your vitals for your simulation. Each of these methods are described in detail in subsequent pages.

1. Use the VitalsBridge FM Connector Software.
2. Use LLEAP while the VitalsBridge FM Connector Software runs in the background.

Using the VitalsBridge FM Connector Software

Before beginning this segment make sure the following have been completed:

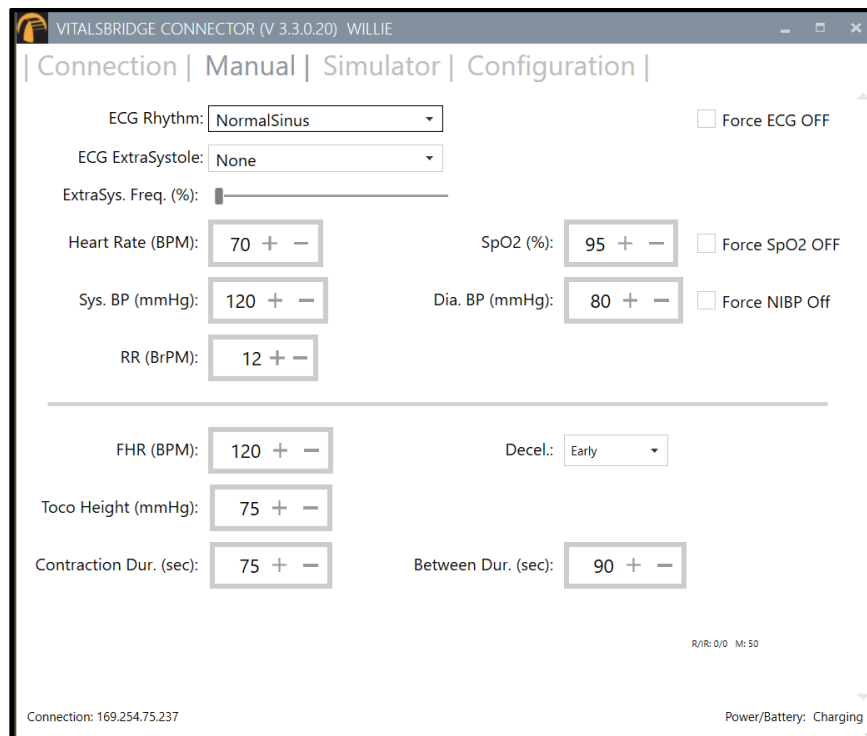
1. The VitalsBridge FM has been connected properly to the patient monitor.
2. The VitalsBridge FM has been connected properly to the device that will be used to control it.
3. The VitalsBridge FM Connector Software has been downloaded and installed on the PC that will be used to control the VitalsBridge FM.

Basic steps to run the VitalsBridge FM:

1. Power on the VitalsBridge FM.
2. Run the VitalsBridge FM Connector Software.
3. Connect the VitalsBridge FM to the connector software or app.
4. Manually control the desired vital signs via the connector software or app.

Manually Control Vital Signs

Once connected to the VitalsBridge FM, it is possible to manually control the vital signs. Touch the + / - to increase or decrease the value. One may also hold the + / - value to make rapid changes or type the desired value into the number box. Use the check boxes to completely turn off certain signals (ECG, SpO₂, NBP).



VitalsBridge FM Directions for Use

The top portion of the Manual screen shows the maternal vital signs:

- ECG Rhythm with extrasystole options
- Heart rate
- Pulse oximetry (SpO₂)
- NBP
- Respiratory rate (via ECG impedance)

The lower portion manually controls fetal heart rate and uterine activity (Toco):

- Fetal heart rate in beats per minute with options for when decelerations occur in comparison to uterine contractions
- Toco Height (peak height of a contraction in mmHg)
- Contraction duration and duration between contractions (i.e., each contraction period is Contraction Dur. + Between Dur.)

Using the VitalsBridge FM with a Patient Simulator

Overview:

- The VitalsBridge FM Connector Software is used to manually control vital signs. It also offers direct integration with Laerdal Patient Simulators through LLEAP. Other patient simulators will offer this feature in the future. This guide provides instruction on how to use the VitalsBridge FM Connector Software with Laerdal's LLEAP. Note that the VitalsBridge FM Connector Software is not compatible with SimPad. For a video tutorial, please see our YouTube channel: VitalsBridge. The instructions for this connection for the VitalsBridge FM are the same as the instructions for the VitalsBridge 300.
- Before beginning this segment with a Laerdal manikin, make sure the following have been completed:
 1. The VitalsBridge FM instrumentation has been set up properly and is connected to any desired monitors.
 2. The VitalsBridge FM has been connected properly to the computer that has the simulation software.
 3. Confirm that the appropriate version of Laerdal's LLEAP Software is downloaded and installed on the desired PC that you wish to control your Laerdal simulator.
 4. The VitalsBridge FM Connector Software has been downloaded and installed on the device that will be used to control the VitalsBridge FM.
 5. Verify that the version of the VitalsBridge FM Connector Application is compatible for the version of LLEAP software that controls your patient simulator.
 6. Ensure that LLEAP application and VitalsBridge FM Connector software are run on computers that are on the same network. If LLEAP is used to control a patient simulator, then the simulator must also be on the same network.
- Basic steps to run the VitalsBridge FM with a standardized patient:
 1. Power on the computer.
 2. Power on the VitalsBridge FM.
 3. Run the VitalsBridge FM Connector Software.

VitalsBridge FM Directions for Use

4. Connect the VitalsBridge FM to the connector software.
 5. Control the desired vitals via the VitalsBridge FM Connector software.
- Basic steps to run the VitalsBridge FM with a manikin:
 6. Power on the patient simulator.
 7. Power on the patient simulator's computer.
 8. Run the software that is used to control the patient simulator.
 9. Power on the VitalsBridge FM.
 10. Run the VitalsBridge FM Connector Software.
 11. Connect the VitalsBridge FM to the connector software.
 12. Connect the connector software to the patient simulator.
 13. Control the desired vitals via the patient simulator software.

Running the VitalsBridge FM

Power on the Patient Simulator

Power on the patient simulator and wait until it is fully initialized. Refer to the simulator's directions for use on how to run the manikin.

Power on the Patient Simulator's Computer

Power on the computer used to control the patient simulator. Refer to the simulator's directions for use on how to run the computer that is used to control the patient simulator.



Power on the VitalsBridge FM

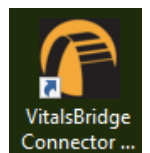
Press the on/off button to power on the VitalsBridge FM. Once powered on, the VitalsBridge FM takes approximately 30 seconds to initialize and, if communicating over a network, attempt to connect to the manikin's internal router. The LED below the battery will flash as the VitalsBridge FM is initializing.

Check the status indicator lights on top of the VitalsBridge FM instrumentation to determine power and connectivity.

Run the VitalsBridge FM Connector Software

On your PC, double click on the VitalsBridge Connector icon, located on the computer's desktop.

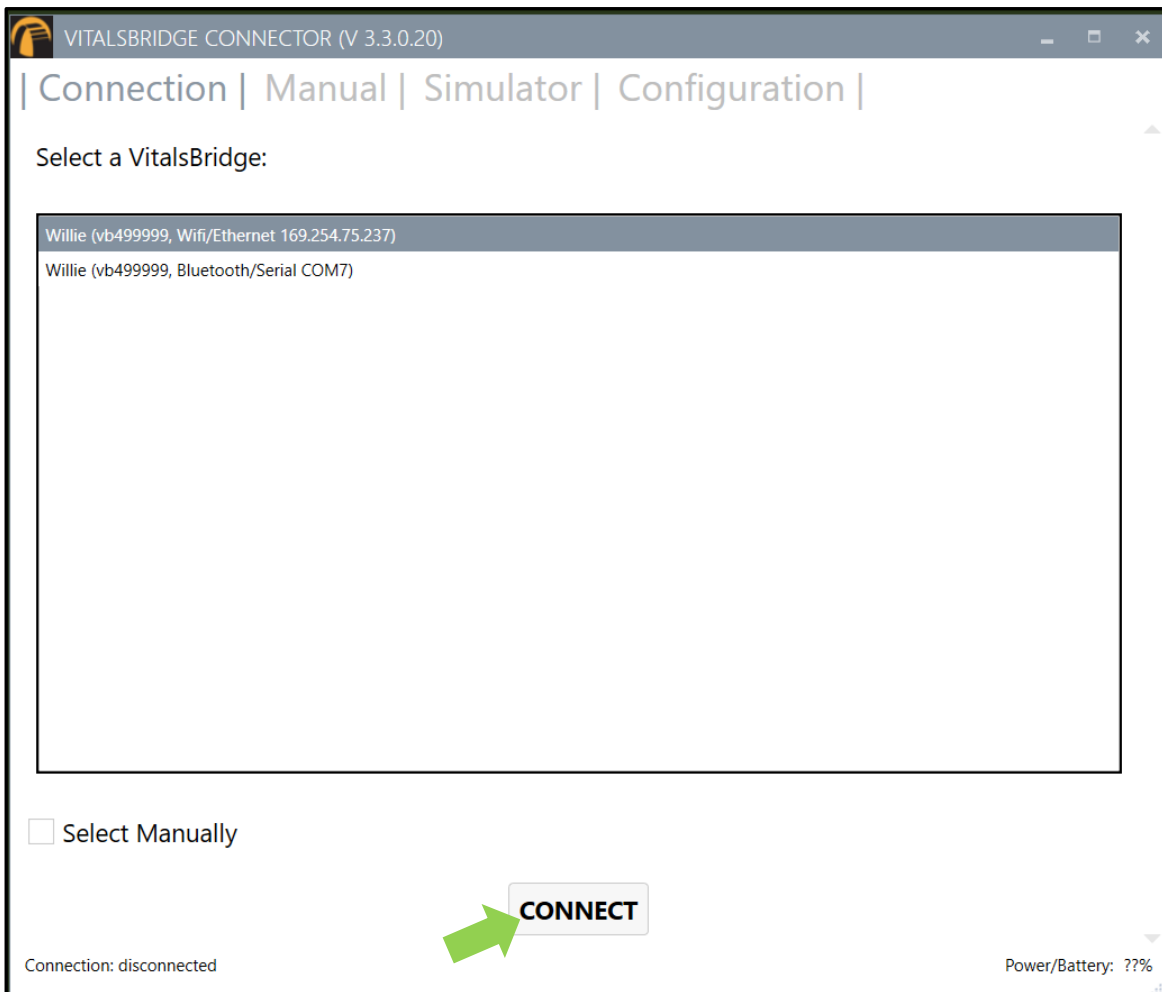
Alternatively, the software may be located by searching for "VitalsBridge" using the Windows search function (i.e., by pressing the  button in Windows 7 and typing in the search dialog or by pressing +S in Windows 8/10).



VitalsBridge FM Directions for Use

Connect the VitalsBridge FM to the Connector Software

Once the Connector Application is running, any available VitalsBridge FM units will appear in the Connection tab (any units connected via Bluetooth, Serial, or Ethernet/WiFi). Select the correct VitalsBridge FM unit and press the CONNECT



button.

Note: If your VitalsBridge FM does not appear in the list, close out of the program and reopen the software. Make sure the VitalsBridge FM unit is turned on and initialized *before* opening the software.

Note: If your VitalsBridge FM does not appear in the list and the VitalsBridge FM – PC connection has only just been made, it is possible that the automatic install of the appropriate drivers that run the VitalsBridge FM have not been completed. Close out of the connector software, wait a few minutes and then reopen the software.

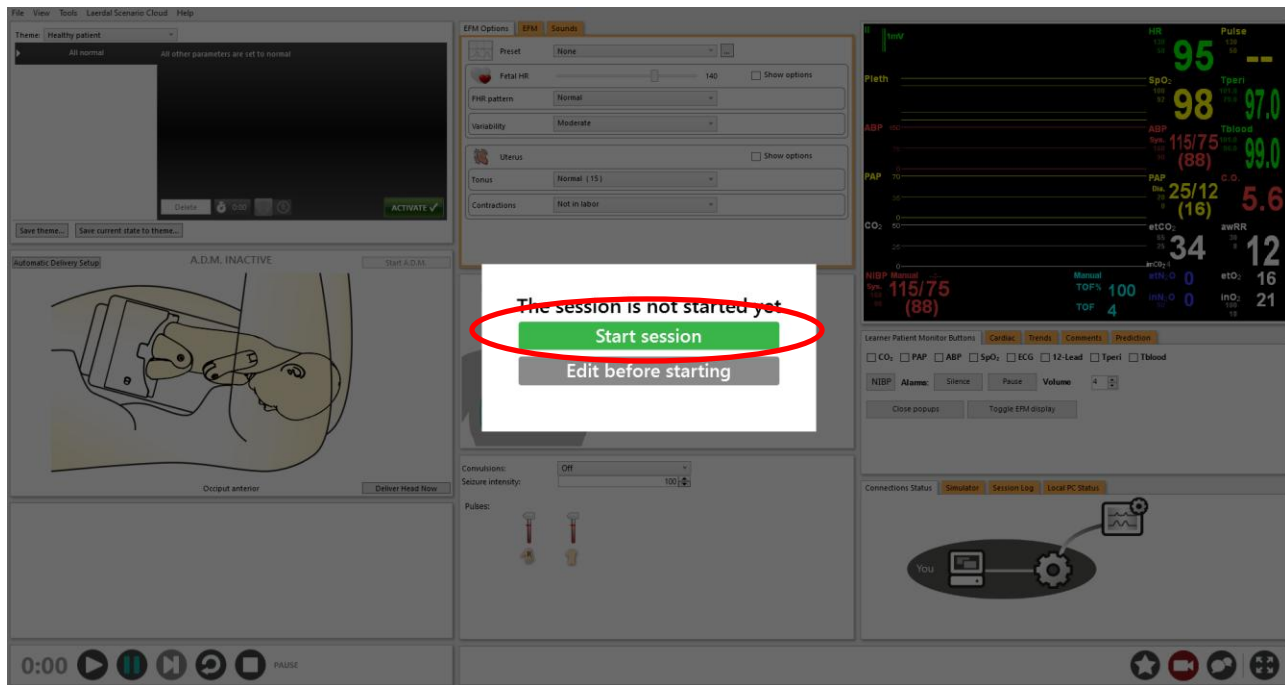
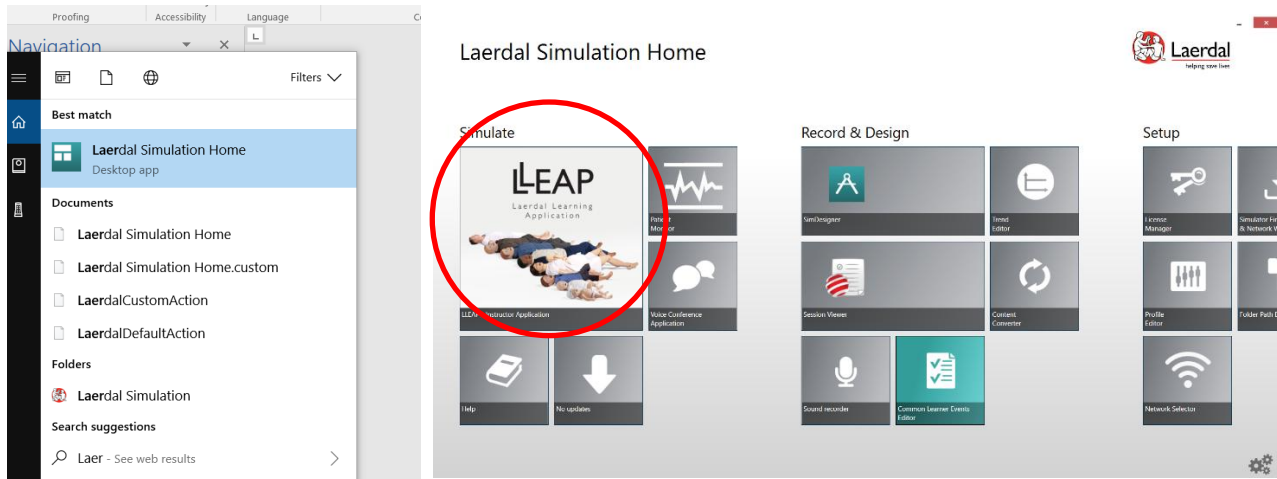
Run the Software Used to Control the Patient Simulator

Some patient simulator manufacturers supply software to connect their manikin with the VitalsBridge. Please refer to the specific simulator manufacturer's support information.

VitalsBridge FM Directions for Use

Connecting to a Laerdal Patient Simulator

To use the VitalsBridge with Laerdal’s manikins, open the ‘Laerdal Simulation Home’ software, select LLEAP and begin a new session. Refer to the simulator’s directions for use on how to appropriately run the software used to control the patient simulator.

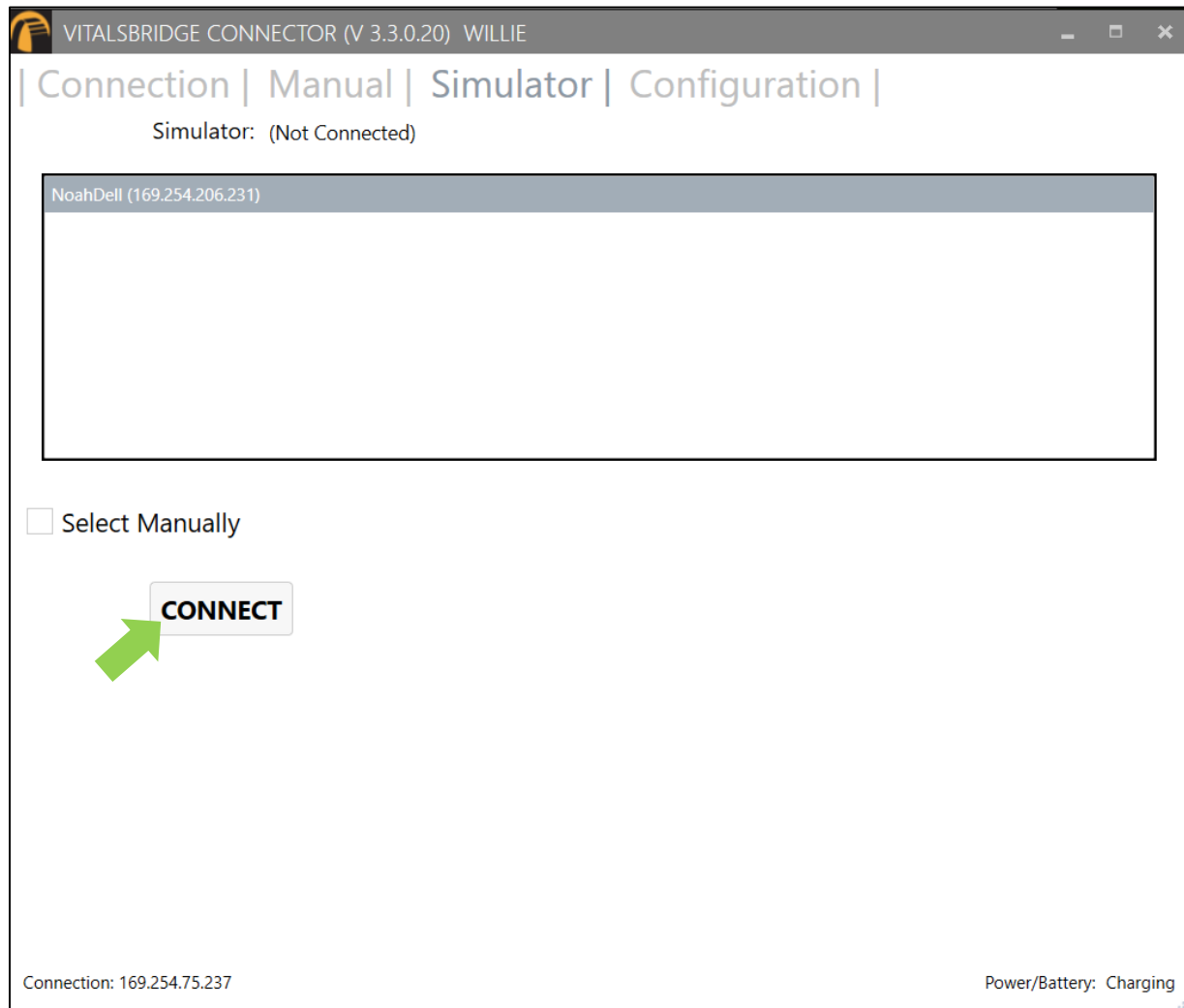


Ensure the computer can connect to a patient simulator over a network. Then, select the “Simulator” tab in the VitalsBridge Connector software.



VitalsBridge FM Directions for Use

Select the appropriate patient simulator that is reported in the dialog box and select CONNECT (if Laerdal's LLEAP software is running, it should automatically appear in the menu).

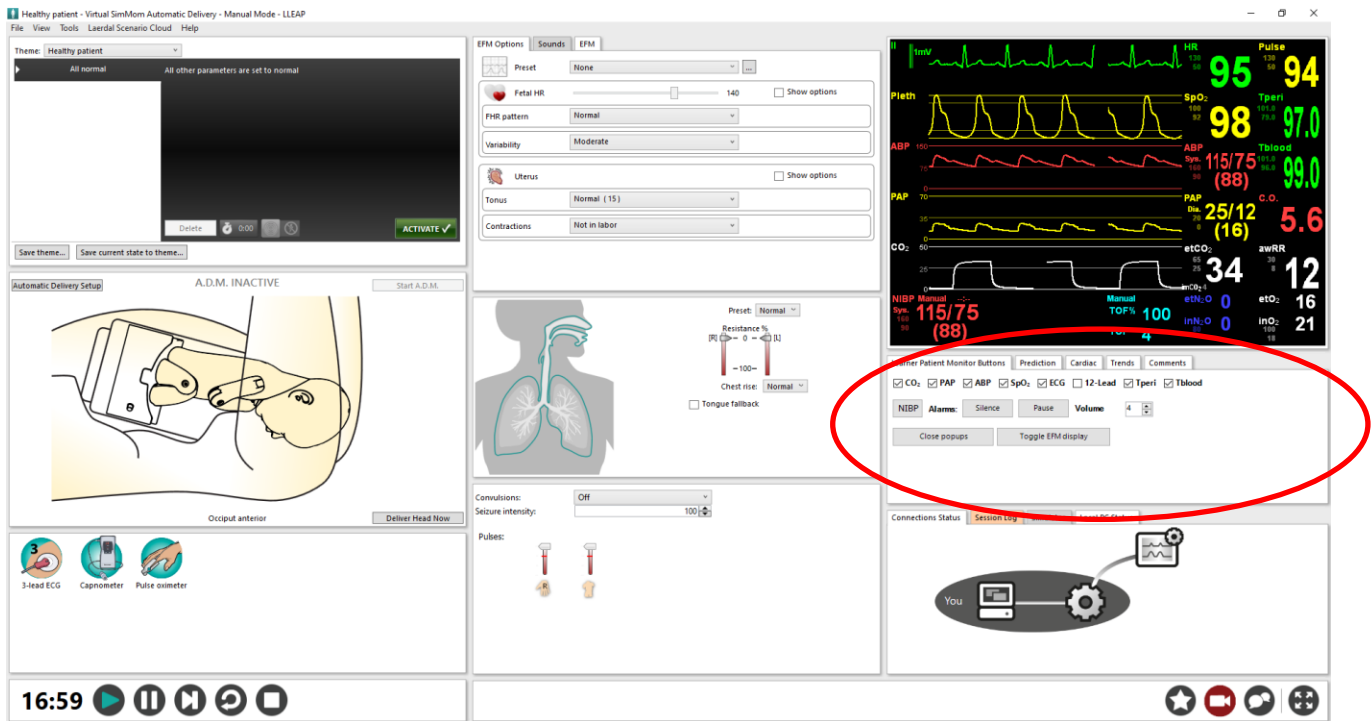


Note: A simulation must be running in order for it to be reported in the dialogue box.

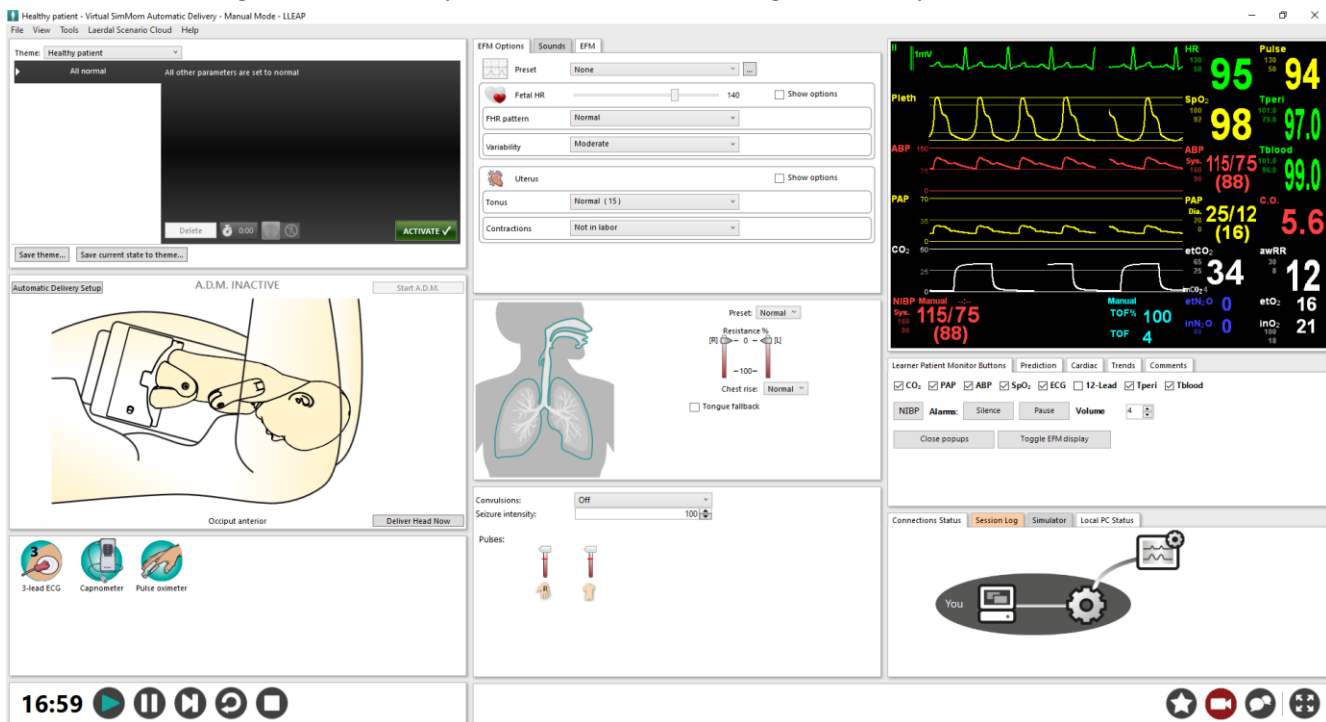
VitalsBridge FM Directions for Use

Control the Desired Vital signs Via the Patient Simulator Software

Use the patient simulator's application to control whether ECG leads are placed, Capnography is enabled, and whether the SpO₂ probe in place (if you are not using a mock probe) by checking the "Learner Patient Monitor Buttons" on the Laerdal control panel for the vital signs you would like to control.



Vital signs set in LLEAP will be communicated to the VitalsBridge FM Connector software. If the VitalsBridge FM is connected and configured with a real patient monitor, the vital signs will be updated.



Refer to the simulator's directions for use for more detailed instructions on how to control the vital signs.

Increasing Realism

Props

Various “props” can be used to enhance simulation experience when using the VitalsBridge. None of these props are necessary for the VitalsBridge to run.

Only one prop is included with your VitalsBridge FM. This is the mock SpO₂ probe that is described on page 21. This is also the only prop that is connected to the VitalsBridge FM. When connected to the SpO₂ adapter, the probe must be on a finger of some sort for an SpO₂ reading to be displayed on the patient monitor (simulating how a real SpO₂ probe would need to be on a patient finger for a reading to be displayed).

Additional props that may be used but that do not come with the VitalsBridge FM may include instruments used to measure NBP and Toco probes. While these props may be used, they should NOT be plugged into the VitalsBridge FM or the patient monitor.

Hiding the VitalsBridge FM

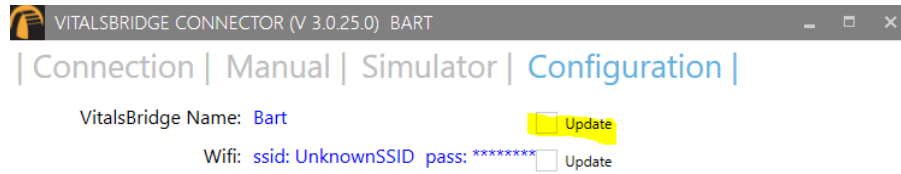
To make the experience more realistic for the learner, the VitalsBridge FM can be placed out of sight. While it will need to remain close to the patient monitor, it can be placed behind the monitor, underneath a manikin, or on a cart.

Additional Features

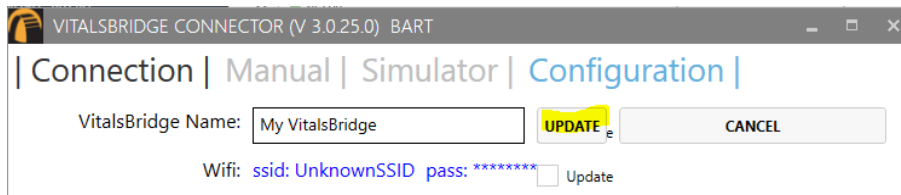
Additional Software Features

Setting the VitalsBridge FM Name

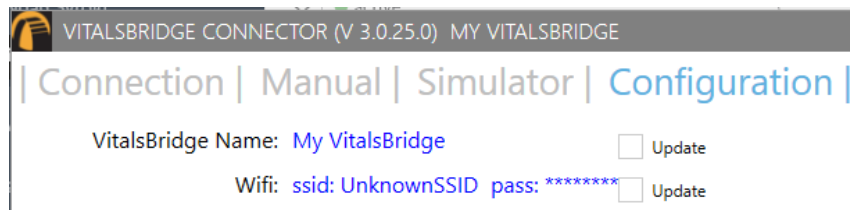
1. Navigate to the Configuration Tab of the VitalsBridge FM.
2. Check the Update checkbox adjacent to the VitalsBridge FM name.



3. Enter the new name of the VitalsBridge FM and press UPDATE.



4. The VitalsBridge FM will be updated with the new name.



VitalsBridge FM Frequently Asked Questions

General Use and Connectivity

Q: Who do I contact for customer support?

A: Please contact Dynasthetics LLC in the USA, phone: +1-435-200-3402 or +1-801-484-3820, email: support@vitalsbridge.com. Also see www.vitalsbridge.com.

Q: Is my monitor is compatible with the VitalsBridge FM?

A: There are many different brands and thousands of different configurations of vital signs monitors. The VitalsBridge FM is compatible with most brands and models of fetal/maternal monitors. The VitalsBridge FM requires some specific cables and configuration for a vital signs monitor's non-invasive blood pressure cuff and SpO₂. Refer to www.vitalsbridge.com for information on how to purchase VitalsBridge FM compatible patient monitor cables.

Q: Is the VitalsBridge FM compatible with Laerdal patient simulators that can run the LLEAP software?

A: Yes, the VitalsBridge FM is LLEAP compatible. However, when installing the VitalsBridge FM software, ensure that the correct version is chosen (i.e., choose the LLEAP compatible installer if running with LLEAP).

Q: Is the VitalsBridge FM compatible with Laerdal patient simulators that run on SimPad?

A: The VitalsBridge FM is **not** SimPad compatible. However, many Laerdal patient simulators that run on SimPad also run on LLEAP, which is compatible with the VitalsBridge FM. Contact Laerdal for additional details.

Q: How long will the VitalsBridge FM run on a fully charged battery?

A: Typical running times are 1 to 2+ hours, depending on how often non-invasive blood pressure measurements are made.

Q: What is the recommended sequence for starting the VitalsBridge FM?

A: If you have been running the manikin for more than 30 minutes prior to starting the VitalsBridge FM, it is recommended that you exit the Instructor Application software, and power off the manikin. Power on the patient simulator and wait for it to initialize fully, start the software that is used to control the patient simulator, power on the VitalsBridge FM, and start the VitalsBridge FM Connector application.

SpO₂

Q: My monitor is not giving a SpO₂ reading with the cable adapter kit that I received with my VitalsBridge.

A: You may have an incorrect SpO₂ cable kit. Please contact Dynasthetics support.

Q: There is a lot of noise/artifact on my SpO₂ waveform reading. What is wrong?

A: If you manikin has a RFID reader (e.g., for drug and airway management device recognition), try disabling the RFID through the application that is used to control the patient simulator.

Non-invasive Blood Pressure

Q: I am not getting a reading from my non-invasive blood pressure monitor. What should I check?

A: First check that the cable from the monitor is secure and not leaking at both the monitor's connector and at the VitalsBridge FM connector. Ensure that NBP tubing and connections are not leaking. Ensure that none of the cuff tubes are kinked. Ensure that the VitalsBridge is running.

VitalsBridge FM Directions for Use

Compressed CO₂ Cartridge

Q: How long will each VitalsGas cartridge last?

A: When the VitalsBridge FM is running, a CO₂ cartridge will last 20 minutes or longer, depending on the simulation. When the regulator is not in use, turn the regulator to off, disconnect the tubing connection from the luer fitting on the VitalsBridge FM and securely fit the cap on the end of the regulator tubing, without over tightening.

Q: My CO₂ regulator has a partially full cartridge that I wish to empty and dispose, what do I do?

A: Turn the regulator to off. Disconnect the regulator from the VitalsBridge FM by unscrewing the luer fitting. Hold the tubing approximate 3-5 cm away from the end of the tubing. *Slowly* turn the knob on the regulator to let the gas escape at a low flow rate from the outlet of the regulator until no more gas release is heard or felt. Take care when removing the empty cartridge. It may be very cold.

Respiration by ECG Impedance

Q: I am using a 5-lead ECG on my simulator, but my simulator does not have connections for 5 leads. Will respiration work?

A: You may use the 5 ECG posts on the VitalsBridge FM to simulate an ECG with respiration impedance.