



# PULSE OXIMETRY SIMULATOR



**FSX-1101**

**USER MANUAL**



**BC BIOMEDICAL  
FSX-1101 SERIES  
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**CALIBRATION INTERVAL**

**To ensure the accuracy of the FSX-1101, BC Group International, Inc. recommends that it be calibrated at least once every 12 months. Calibration must be done by BC Group International, Inc in order to maintain the LIFETIME warranty.**

## **WARNING - USE**

The FSX-1101 is intended for testing only and should never be used in diagnostics, treatment or any other capacity where it would come in contact with a patient.

## **WARNING - CONNECTIONS**

All connections to patients must be removed before connecting the DUT to the FSX-1101. A serious hazard may occur if the patient is connected when testing with the FSX-1101.

## **CAUTION - SERVICE**

The FSX-1101 is intended to be serviced only by authorized service personnel. Troubleshooting and service procedures should only be performed by qualified technical personnel.

## **CAUTION - ENVIRONMENT**

Exposure to environmental conditions outside the specifications can adversely affect the performance of the FSX-1101. Allow the FSX-1101 to acclimate to specified conditions for at least 30 minutes before attempting to operate it.

### **CAUTION - CLEANING**

**Do not immerse. The FSX-1101 should be cleaned by wiping gently with a damp, lint-free cloth. A mild detergent can be used if desired.**

### **CAUTION - INSPECTION**

**The FSX-1101 should be inspected before each use for obvious signs of abuse or wear. The FSX-1101 should not be used and should be serviced if any parts are in question.**



# EU DECLARATION OF CONFORMITY



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BC Group International, Inc. hereby declares under our sole responsibility that the product,

**Product:** FSX-1100 Series; may be followed by additional letters  
**Product Description:** Digital Pulse Oximetry Simulator  
**Year of CE marking:** 2020

is in accordance with the European Union harmonized legislation as described within the following Directive(s):

- 2014/30/EU ELECTROMAGNETIC COMPATIBILITY (EMC)
- 2014/35/EU LOW VOLTAGE (LVD)

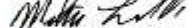
and in conformity with the following Harmonized Standard(s):

EN 61010-1:2010, 10 <sup>th</sup> Edition	SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE – GENERAL REQUIREMENTS
EN 61326-1:2013, 13 <sup>th</sup> Edition	ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE – EMC REQUIREMENTS – PART 1: GENERAL REQUIREMENTS
EN 61000-3-2:2014, 2014 Edition	ELECTROMAGNETIC COMPATIBILITY (EMC) - PART 3-2: LIMITS - LIMITS FOR HARMONIC CURRENT EMISSIONS (EQUIPMENT INPUT CURRENT LESS THAN OR EQUAL TO 16 A PER PHASE)
EN 61000-3-3:2013, 2013 Edition	ELECTROMAGNETIC COMPATIBILITY (EMC) - PART 3-3: LIMITS - LIMITATION OF VOLTAGE CHANGES, VOLTAGE FLUCTUATIONS AND FLICKER IN PUBLIC LOW-VOLTAGE SUPPLY SYSTEMS, FOR EQUIPMENT WITH RATED CURRENT LESS THAN OR EQUAL TO 16 A PER PHASE AND NOT SUBJECT TO CONDITIONAL CONNECTION

A Technical file is maintained at the above address and is available, in full or in part, when additional documentation is required to show compliance with the applicable Directive(s) and Regulations referenced above.

I, the undersigned, of BC Group International, Inc. do hereby declare that the product(s) specified above, in its intended use as described within the product's User Manual, is in compliance with the directive(s) and standard(s) referenced above.

**Place:** BC Group International Inc.  
 3801 Elm Point Industrial Dr.  
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**Signature:**   
 Mel Roche  
 President  
**Date:** 6/23/20

**Document No.:** 65-732841-10-00  
**Revision:** 00

Form: 65-700071-10 (00)

## NOTICE – SYMBOLS

<u>Symbol</u>	<u>Description</u>
---------------	--------------------



**Caution**

(Consult Manual for Further Information)



Per European Council Directive  
2002/95/EC, do not dispose of this  
product as unsorted municipal waste.

## NOTICE – DISCLAIMER

BC GROUP INTERNATIONAL, INC. WILL NOT BE RESPONSIBLE FOR ANY INJURIES SUSTAINED DUE TO UNAUTHORIZED EQUIPMENT MODIFICATIONS OR APPLICATION OF EQUIPMENT OUTSIDE OF THE PUBLISHED INTENDED USE AND SPECIFICATIONS.

## **NOTICE – DISCLAIMER**

BC GROUP INTERNATIONAL, INC. RESERVES THE RIGHT TO MAKE CHANGES TO ITS PRODUCTS OR SPECIFICATIONS AT ANY TIME, WITHOUT NOTICE, IN ORDER TO IMPROVE THE DESIGN OR PERFORMANCE AND TO SUPPLY THE BEST POSSIBLE PRODUCT. THE INFORMATION IN THIS MANUAL HAS BEEN CAREFULLY CHECKED AND IS BELIEVED TO BE ACCURATE. HOWEVER, NO RESPONSIBILITY IS ASSUMED FOR INACCURACIES.

## **NOTICE – CONTACT INFORMATION**

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**BC BIOMEDICAL  
FSX-1101 SERIES  
PULSE OXIMETER SIMULATOR**

The FSX-1101 is a microcontroller based pulse oximetry simulator. It uses BC Biomedical derived R-curves to simulate pulsatile blood pulses to correspond with multiple manufacturer's pulse oximetry modules. It incorporates a 2.4" color touchscreen to allow the user to cycle through multiple combinations of oxygen saturations, heart rates, perfusion indices, and pulse oximeter manufacturers.

The FSX-1101 has a built in preset mode with preconfigured combinations of simulation parameters. It allows users to cycle through these often used test parameters with a single button. The independent pulse oximeter manufacturer control in this preset mode allows these preset combinations to be used with any of the supported manufacturers.

In many test environments, there are common pulse oximeter device manufacturers. The FSX-1101 has built in memory to save the current selected manufacturer when the device is turned off and is automatically recalled when the device is turned back on.

The FSX-1101 has the ability to sync with other BC Biomedical products that output SpO<sub>2</sub> pulses with the included BC20-41376 sync cable. By connecting the FSX-1101 to a BC Biomedical PS-2100 series, PS-2200 series, or NIBP-1000 series device, the FSX-1101 will synchronize its pulsatile output with the heart rate setting on the connected BC Biomedical device.

The FSX-1101 has multiple options for powering the unit. Two AA alkaline batteries can power the unit for convenient on-the-go testing. The unit can also be powered with the included micro USB cable and AC adapter or from a connected BC Biomedical device connected with the sync cable. The ability to decrease screen brightness and audio volume can also be used to preserve battery life.

STANDARD ACCESSORIES:



BC20-41376 FSX Sync Cable



BC20-41377 Micro USB Cable



BC20-21121 AC Power Adapter



BC20-21122 INTL Adapter Set



BC20-30123 FSX Carrying Case

# SCREENS

**MAIN SCREEN** – The main screen of the unit loads immediately after splash screen.

From this screen, all options can be manually set to achieve any combination of simulation variables possible.

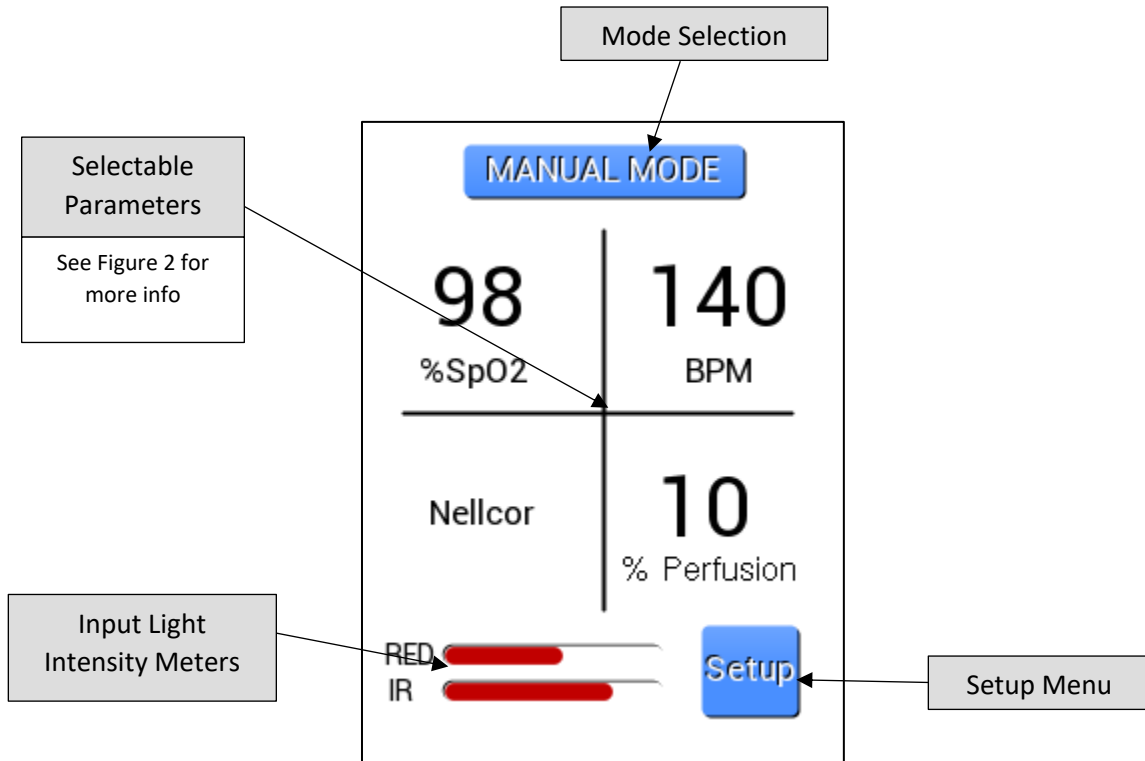
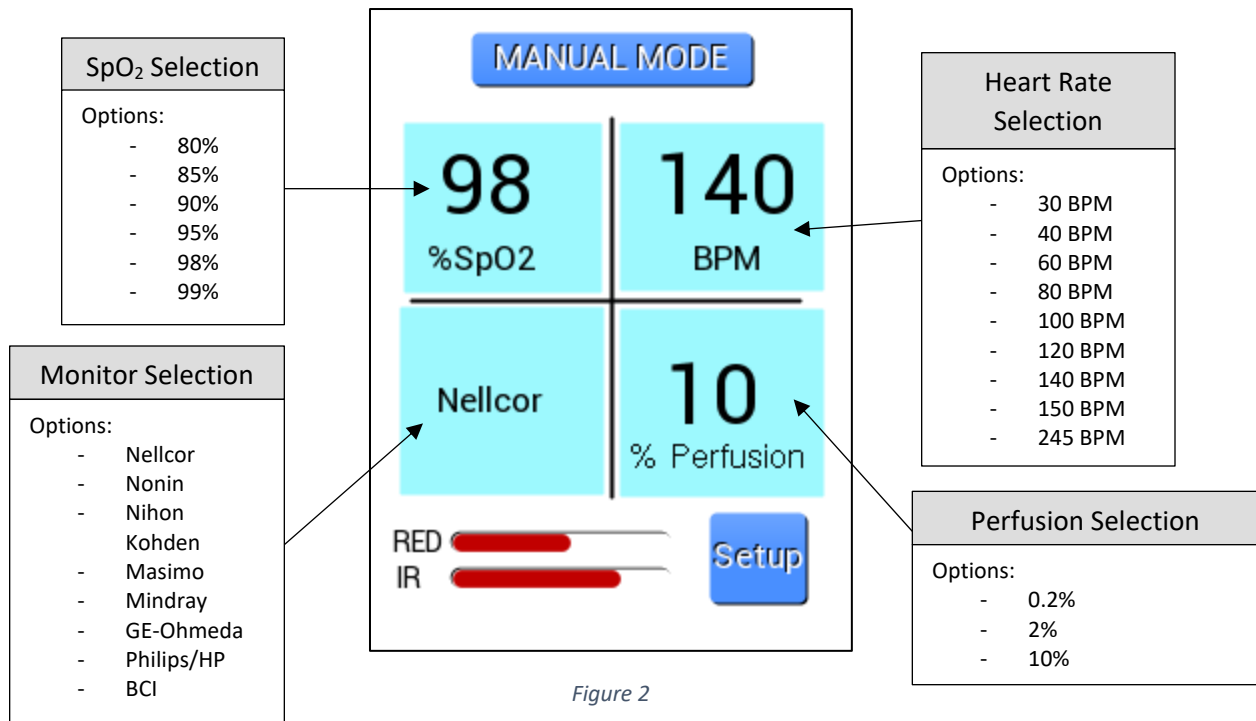


Figure 1

**MAIN SCREEN** – Figure 2 below shows the available settings for the main screen.



**NOTE** – The **BLUE** rectangles in Figure 2 represent the touch area corresponding to each selection. This is only an illustration for this document. They do **not** appear in the actual unit.

**PRESET SCREEN** – The preset screen is a convenient mode of operation. It allows the user to advance through 5 preset combinations of SpO<sub>2</sub>%, Heart Rate, and Perfusion Index. These are factory set and not customizable by the user.

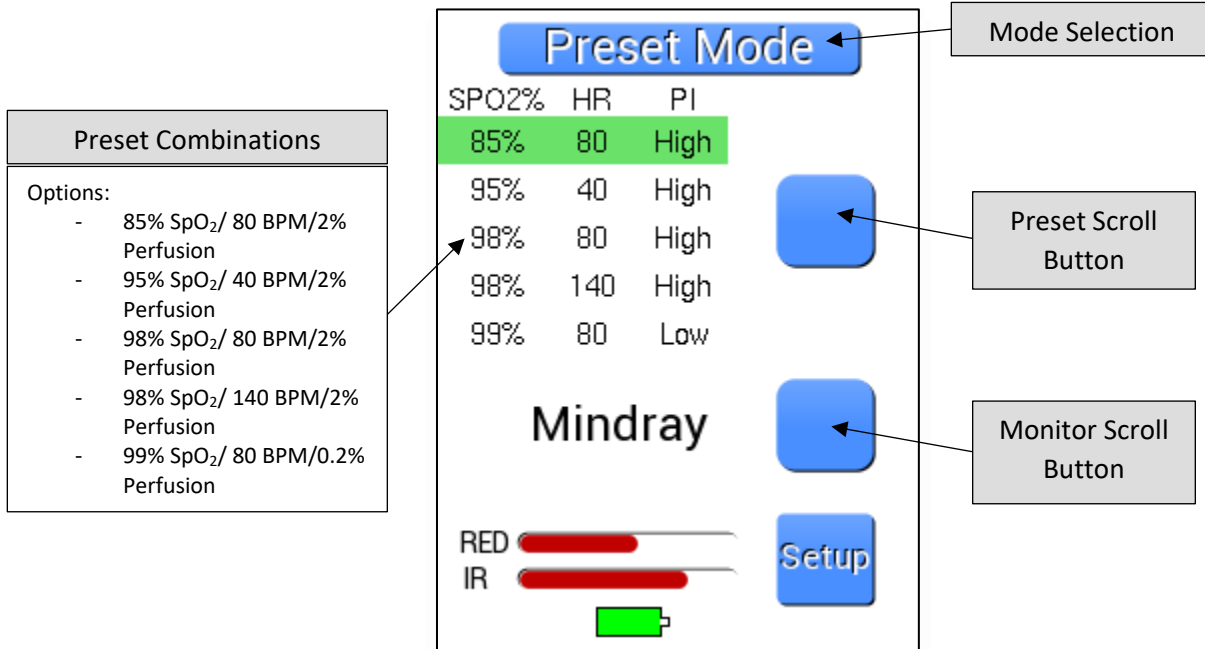



Figure 3

**SETUP SCREEN** – The Setup Screen is a scrollable list of user configurable options. Scroll the list by pressing the Up or Down arrows at the bottom of the screen. The Setup

screen can be accessed at any time by pressing the  key.

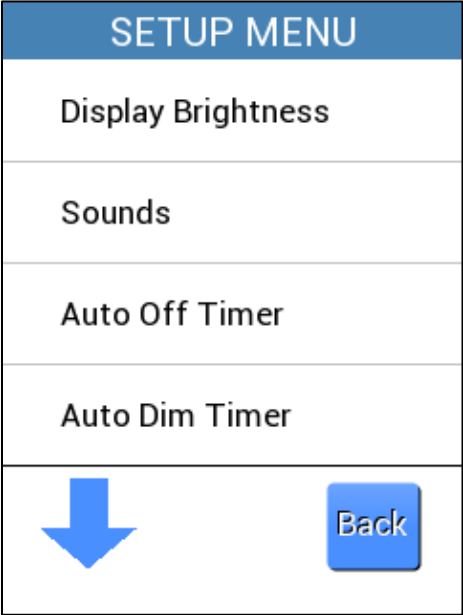


Figure 4

The following is a breakdown of the parameters available in the configuration of the unit and their available options:

<b>System Setup Configuration</b>		
<b>Parameter</b>	<b>Description</b>	<b>Range</b>
Display Brightness	Adjusts the brightness of the screen.	5%-100% in 5% increments.
Sounds	Adjusts the volume of all system sounds.	0%-100% in 5% increments.
Auto Off Timer	Adjusts the timeout that will turn the unit off after a period of inactivity. This is only applicable when the unit is running on battery power.	5-100 minutes in 5 minute increments. Turning this setting off will disable the auto off feature.
Auto Dim Timer	Adjust the timeout that will turn the display brightness down to 15% after a period of inactivity.	5-100 minutes in 5 minute increments. Turning this setting off will disable the auto dim feature.
Custom User Offset	Adjusts the derived R-curve value for SpO <sub>2</sub> setting to a user's preference.	+/- 100 Adjustment Increments. (Note: This is not a direct 1:1 correlation to the displayed SpO <sub>2</sub> value on the DUT)
Device Information	This displays the current version of the software and any other applicable information.	N/A
Update Firmware	This will erase the firmware from the unit in order for the user to update to a newer version of the firmware.	N/A



## OPERATION

The finger cuff is attached to the top of the FSX-1101. The cuff needs to be aligned in an orientation where the sensor's light pulses enter the back of the finger portion of the FSX-1101 as shown.

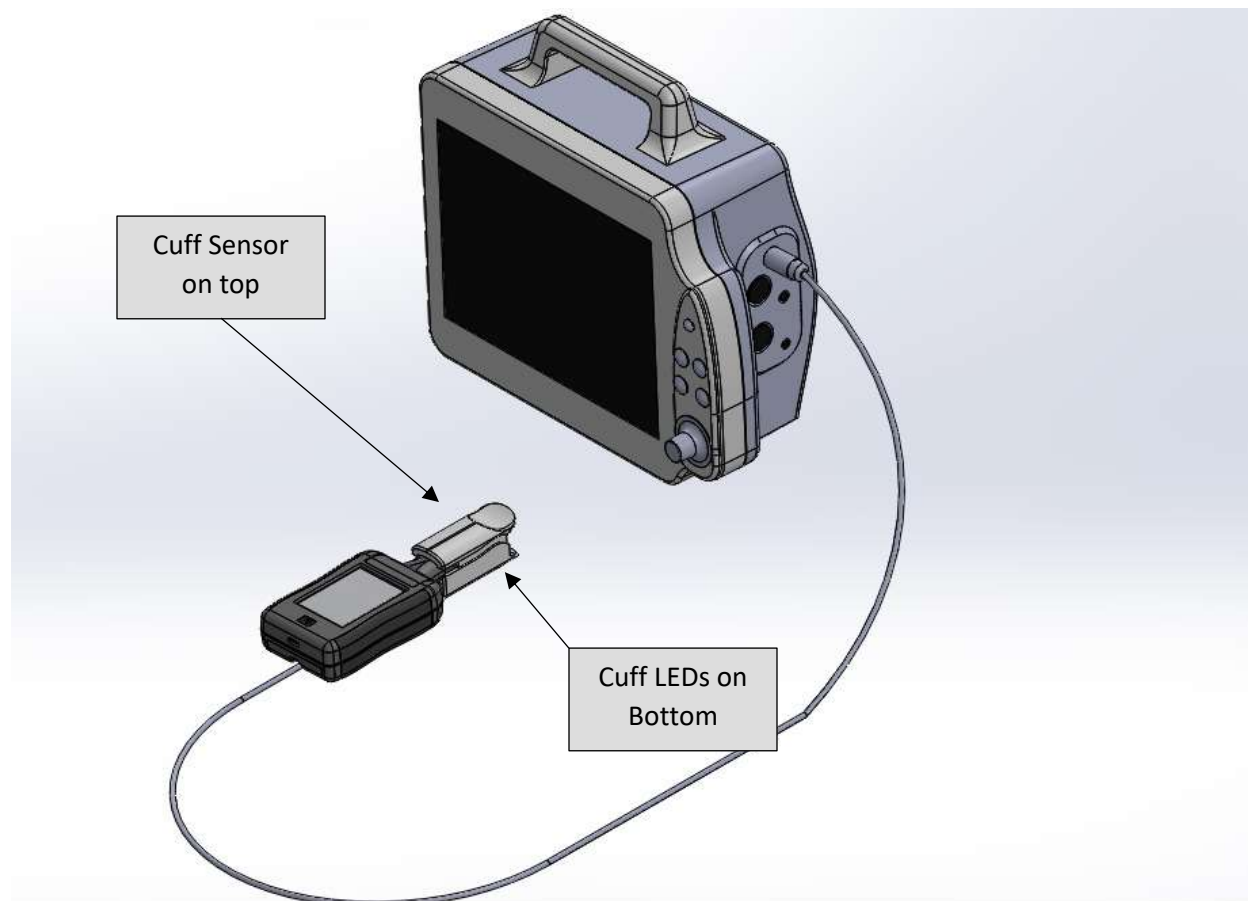


Figure 5

To adjust the simulation environment follow these steps:

### From the Main Screen –

According to *figure 2*, there are 4 quadrants associated with touch locations for changing parameters. Touching in these quadrants will cycle through the list of possible settings in a circular fashion.

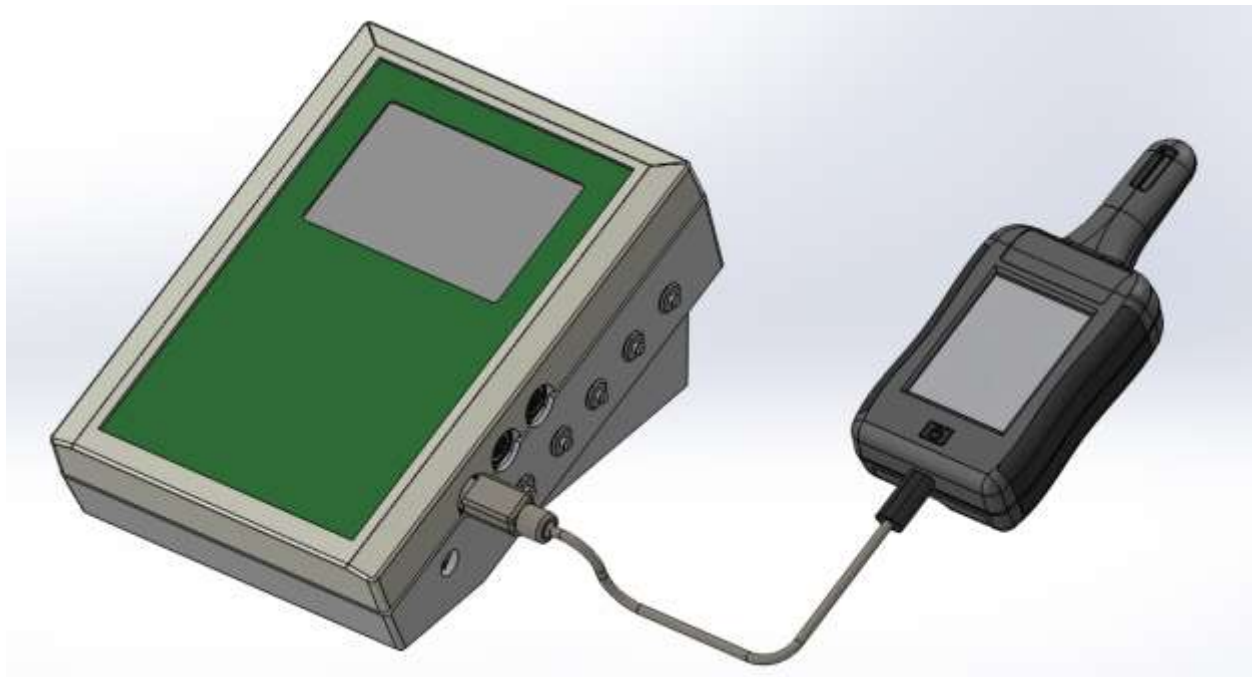
Pressing the Mode Selection button will alternate between **Manual Mode** and **Preset Mode**.

### From the Preset Screen –

Pressing the preset selection button will cycle through the list of preset combinations in a circular fashion. The monitor selection can be changed independently of the preset combination so that each preset can be used on any supported monitor manufacturer. Toggling back to **Manual Mode** from **Preset Mode** will preserve the current settings.

### Sync Mode –

Shown in *Figure 6* below is the connection for synchronization between a FSX-1101 and BC Biomedical device equipped with SpO<sub>2</sub> pulse output. In this configuration, the FSX-1101 can be powered from the connected device and synchronize its output pulsatile heart rate with the settings on the connected device. The SpO<sub>2</sub> output must be enabled and the connected device for this configuration to be active.



*Figure 6*

### Battery Indicator

Located at the bottom of simulation screens is a battery life indicator. Once the batteries reach ~20% of life remaining, the battery indicator turns red to alert you of depleted batteries.

## Custom User Offset

In the setup menu, the FSX-1101 is equipped with the option to modify the factory programmed R-curves for each manufacturer and for each SpO<sub>2</sub> setting. There are no absolute standards for pulse oximetry and each manufacturer has established its own proprietary R-curve. Due to these varying values, some oximeters may display readings outside of an acceptable range. After the factory R-curve has been modified, the operational screens will display the SpO<sub>2</sub> setting in Red text on the main screen and with a Red highlight bar in the preset screen.

**CAUTION**

**These adjustments must be used with caution as they will allow the user to adjust the output results to invalid values.**

**These adjustments should only be used to aid in the simplification of testing and with documented controls.**

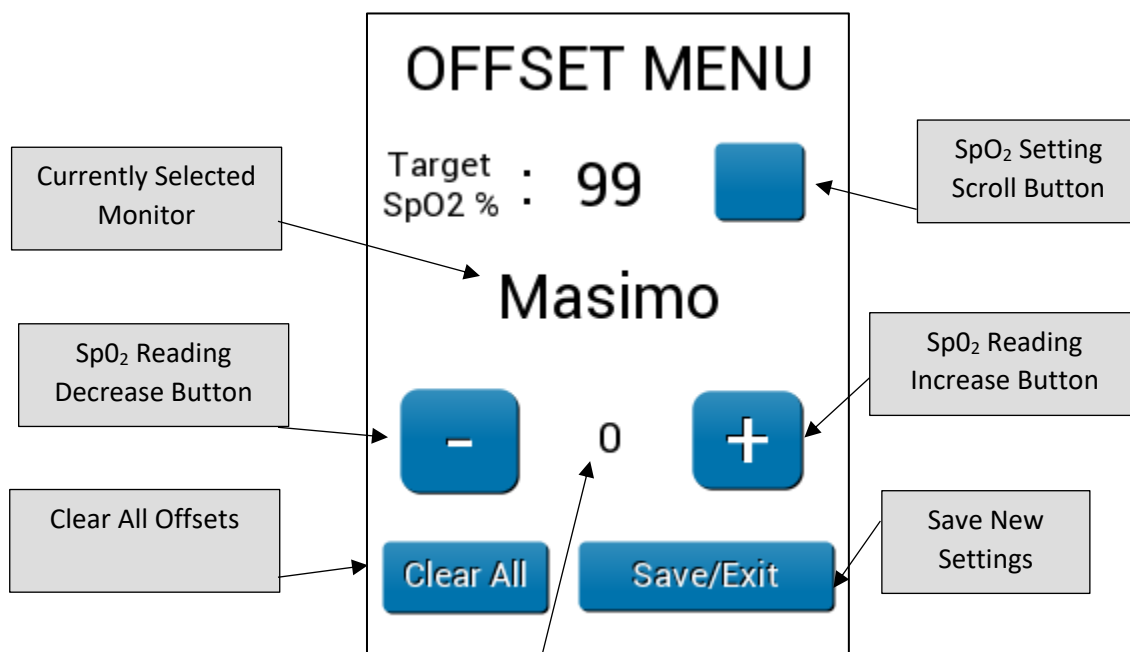



Figure 7

Current Adjustment Value.  
(THIS IS NOT A DIRECT CORRELATION TO THE DISPLAYED SpO<sub>2</sub> VALUE ON THE DUT)

## Clearing User Offsets

Each offset setting can be individually adjusted to back to zero to restore the factory programmed R-curve for each specific SpO<sub>2</sub> setting. In the case the user wants to reset all settings for an individual pulse oximeter manufacturer or reset all settings for every

manufacturer, the FSX is equipped with a method to do this. Pressing the  button on the Custom User Offset screen brings you to this screen which allows you to clear all offsets for the selected manufacturer or clear all offsets globally. The Exit button on this screen takes the user back to the Custom Offset Menu.

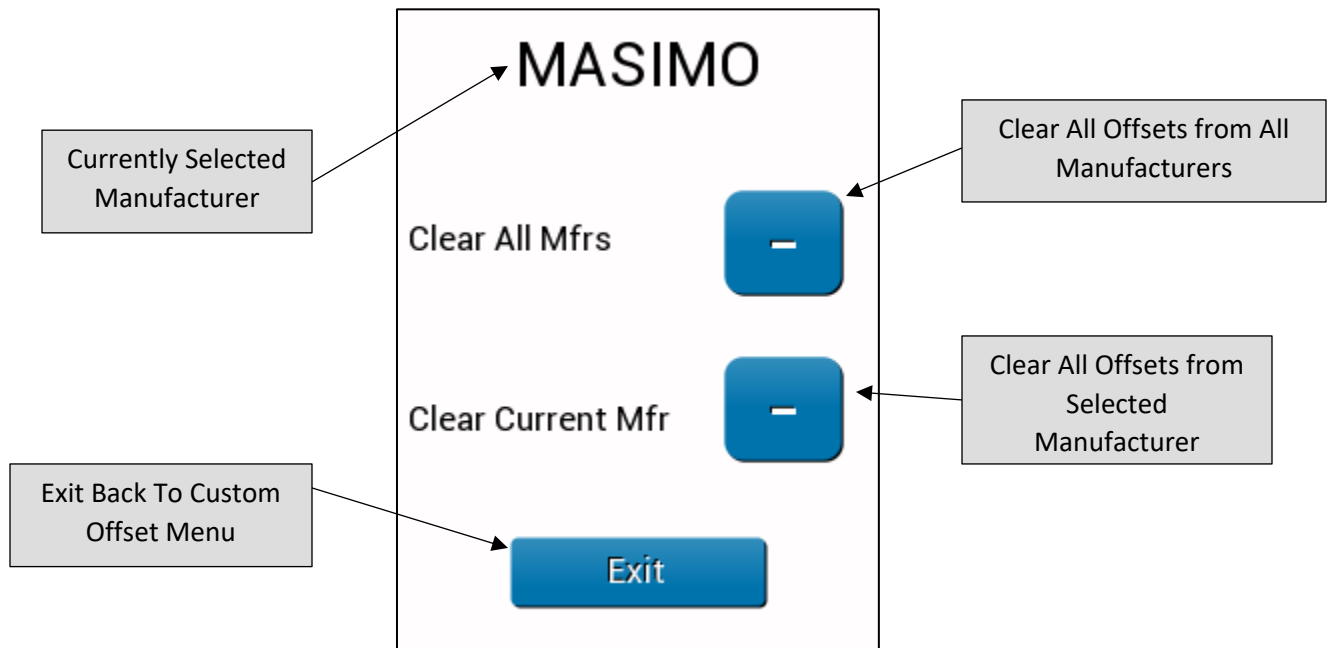


Figure 8

## Firmware Update

BC Group Intl. periodically makes firmware upgrades for continuous product improvements. These updates can be applied by the user manually. After entering the Update Firmware screen from the Setup Menu, this screen is visible.

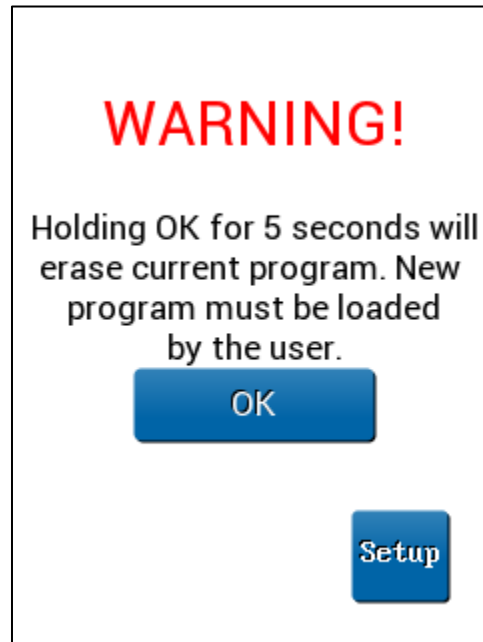


Figure 9

The latest version of firmware is available at:

<http://www.bcgroupestore.com/FSX-1101-Firmware-Update.aspx>

After holding the OK Button for five seconds, the unit will erase the current firmware. The unit can be updated by connecting the included Micro USB cable (BC20-41377) to a PC. The FSX will appear as a Mass Storage Device to the computer. Dragging the latest firmware file onto this drive will update the FSX. The unit will reboot automatically and be fully functional.

## MANUAL REVISIONS

<u>Revision #</u>	<u>Program #</u>	<u>Revisions Made</u>
Rev 01	DT7302CA	Origination
Rev 02	DT7302CD	Updated Screens/Operational sections

## LIMITED WARRANTY

**WARRANTY: BC GROUP INTERNATIONAL, INC.** WARRANTS THE FSX-1101 TO BE FREE FROM DEFECTS IN MATERIALS AND WORKMANSHIP UNDER THE SERVICE FOR WHICH THEY ARE INTENDED. THIS WARRANTY IS EFFECTIVE FOR THE LIFETIME OF THE PRODUCT, PROVIDED THAT IT IS RETURNED ANNUALLY FOR CALIBRATION TO BC GROUP INTERNATIONAL, INC. TO ACTIVATE THE LIFETIME WARRANTY, REGISTER YOUR FSX-1101 AT

[http://www.bcgroupestore.com/fsx\\_registration.aspx](http://www.bcgroupestore.com/fsx_registration.aspx)

**EXCLUSIONS:** THIS WARRANTY IS **IN LIEU OF** ANY OTHER WARRANTY EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO ANY IMPLIED WARRANTY OF **MERCHANTABILITY** OR FITNESS FOR A PARTICULAR PURPOSE.

**BC GROUP INTERNATIONAL, INC.** IS NOT LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

## SPECIFICATIONS

<b>FSX-1101 Specifications</b>	
SpO2	80, 85, 90, 95, 98, 99%
SpO2 Accuracy	2%
Heart Rate	30, 40, 60, 80, 100, 120, 140, 150, and 245 BPM
Rate Accuracy	1%
PI	0.2%, 2.0%, and 10%
Manufacturer Type	Nellcor, Masimo, Nonin, Nihon Kohden, Mindray, GE-Ohmeda, Philips/HP, and BCI
Test	Manual plus Factory Preset (5 steps)
Battery Type	2xAA Alkaline Batteries
Battery Life	10 Hours (Full Backlight)
Display	Color Touchscreen, 2.4 inch
Size	2.5 x 3.75 x 1 (inches) (without finger)
Weight	6 oz (with batteries)

**NOTES**



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