RIGEL

MEDICAL

RIGEL PatSim200

Patient Simulator

Instruction Manual
404A920 Revision 1.1

Rigel Medical 5 year Warranty Statement

To activate your 5 year warranty register your product at the below link. Terms and conditions apply.

www.rigelmedical.com/5years

Calibration Statement

The PatSim200 Patient Simulator is fully calibrated and found to be within the specified performance and accuracy at the time of production. The Seaward Group provides its products through a variety of channels; therefore it may be possible that the calibration date on the provided certificate may not represent the actual date of first use.

Experience has indicated that the calibration of this instrument in not effected by storage prior to receipt by the user. We therefore recommend that the recalibration period be based on a 12 month interval from the first date the unit is placed in to service.

For information on service or calibration please go to the below link.

www.rigelmedical.com/calibration

Date received into service;   /   /

Disposal of old product

The PatSim200 Patient Simulator has been designed and manufactured with high quality materials and components, which can be recycled and reused.

Please familiarise yourself with the appropriate local separate collection system for electrical and electronic products or contact your local supplier for further information.

Please dispose of this product according to local regulations. Do not dispose of this product along with normal waste material. By offering your old products for recycling, you will help prevent potential negative consequences for the environment and human health.

User Notes

These operating instructions are intended for the use of adequately trained personnel.

⚠ **Important, follow the documentation! This symbol indicates that the operating instructions must be adhered to in order to avoid danger.**

If the PatSim200 is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

This product contains a lithium ion battery:

Do not disassemble, crush, or puncture a battery
Do not short the external contacts on a battery
Do not dispose of a battery in fire or water
Do not expose a battery to temperatures above 60 °C (140 °F)
Keep the battery away from children
Avoid exposing the battery to excessive shock or vibration
Do not use a damaged battery
If a battery pack has leaking fluids, do not touch any fluids.
Dispose of a leaking battery pack

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1 Introduction

The PatSim200 from Rigel was designed to make every patient simulation quicker.

Unlike other Patient Simulators, the PatSim200 uses a home and recall function to easily move between tests and store your most used sequences, no more clicking and scrolling through 'tree style' hierarchy to perform each test.

The handheld PatSim200 is capable of the below simulations:

- ECG
  - ECG wave forms
  - Arrhythmia's
  - Performance Waveform
  - Pacer Waveforms
  - Fetal Maternal
- Respiration
- Temperature
- Invasive blood pressure (2 channel)

The PatSim200 forms part of a comprehensive range of high performance specialist biomedical test equipment supplied by Rigel Medical, part of the Seaward Group.

For further information go to www.rigelmedical.com

1.1 Getting to know your PatSim200

1- Charging LED status
2- Function keys F1-5
3- Navigation keys
4- Rigel key - on/off
5- Home screen button
6- Temperature output
7- IBP1 output
8- IBP2 output
9- Micro USB power input
10- Universal ECG connections x10
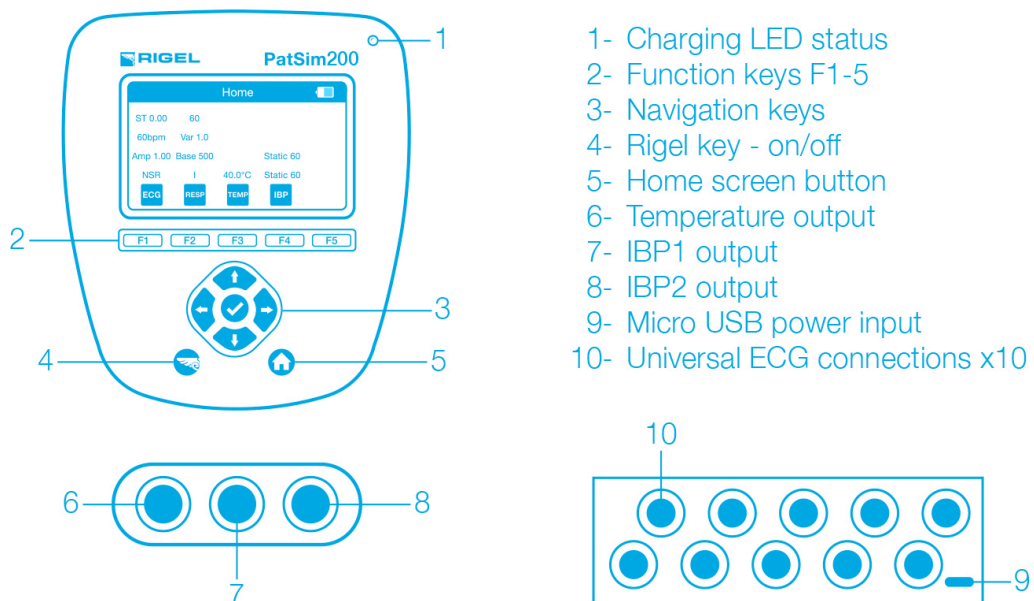
1.2 In the box
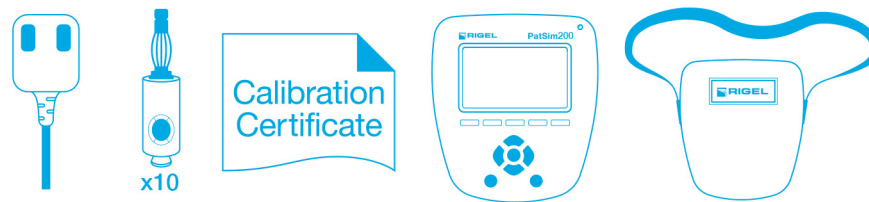
- Quick start guide
- Universal USB Power Supply
- 10 x Applied Part Adaptors
- Calibration Certificate
- PatSim 200 Simulator
- PatSim 200 carry case

1.3 Additional & Optional Accessories

Replacement Battery   404A954
Temperature Cable (unterminated)   404A955
IBP Cable (unterminated)   404A956
Replacement Carry Case   404A950
Applied Part Adaptors   404A951
Universal USB Power Supply   404A952

1.4 Charging

The PatSim200 is supplied with a universal USB charger. You should only use the supplied charger with your PatSim200.

Whilst the charger is connected to the unit and energised, the LED light on the top right of the top fascia will be illuminated.

Note: The LED does not indicate the charging status.

Whilst the PatSim200 is powered on you will also see the below symbols on the display.

 Bulk Charging

 Trickle charging

The PatSim200 may be used whilst charging however displayed signal quality may be reduced on some monitor types.

1.5 Battery Status

During normal use, the PatSim200 automatically checks the battery status and shows the closest representation using the symbols below.

 Fully charged

 Battery empty

When the battery is completely empty the unit will warn the user that it is about to turn off before shutting down.
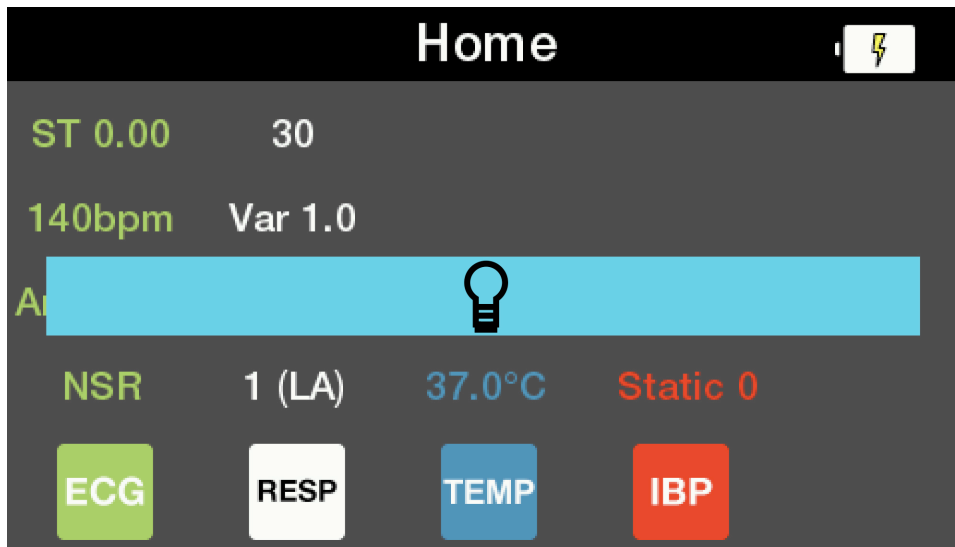
1.6 Powering On/Off

Turn your PatSim200 on or off by pressing and holding the 'Rigel' button for 3 seconds.

1.7 Screen Brightness

You can change the screen brightness on the PatSim200 to make it suitable for different environments. To change the screen brightness press the left or right arrow keys in the home screen.

2 Getting Started

2.1 Setup

In the PatSim200 you have the option to change the language, temperature units and auto off time of the unit.

Pressing the Rigel key in any menu will take you to the Settings screen.
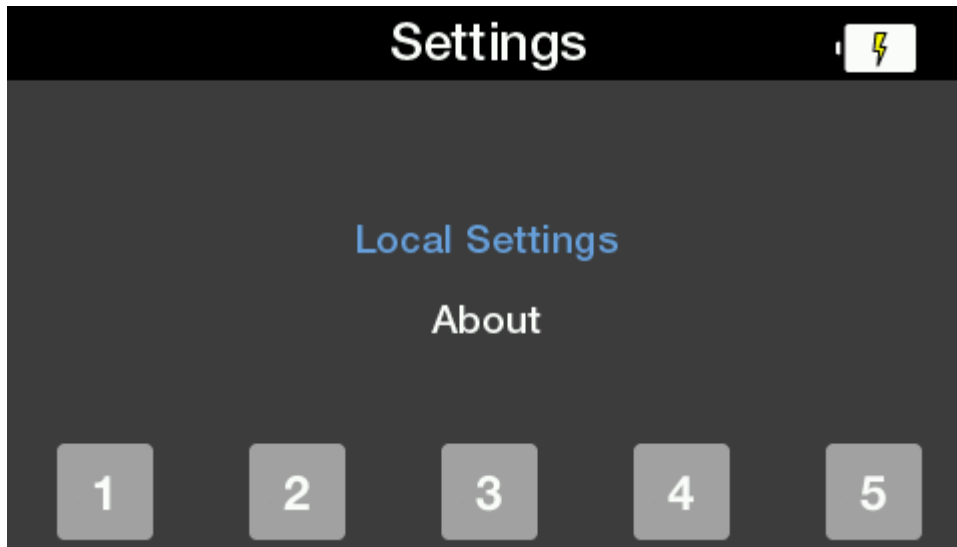
Here you can use the up & down arrow keys to highlight Local Settings and press the select (tick) button.
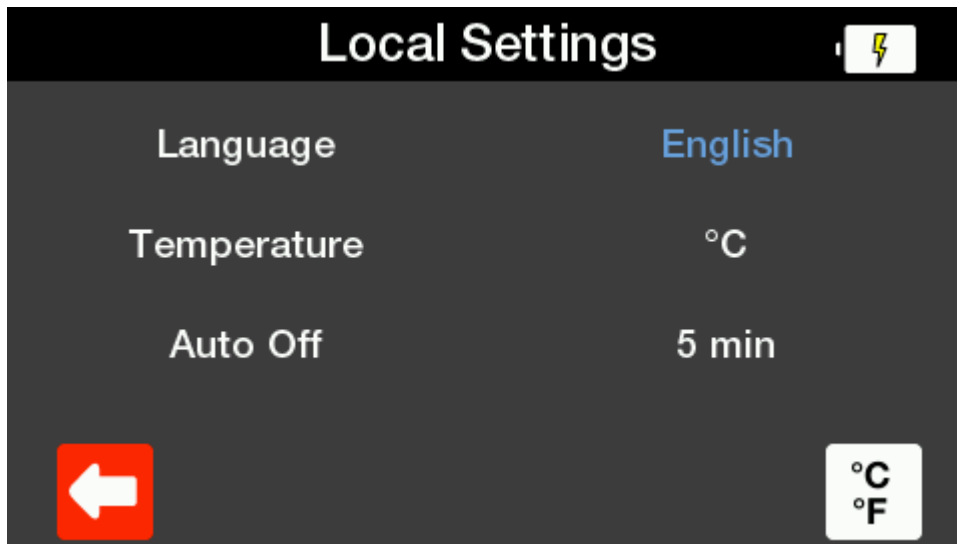
You can then use the up & down arrow keys to highlight the parameter you wish to change and then use the left & right arrow keys to select your preferred setting. There is a fast key on F5 to switch between °C & °F.
Pressing Home or Back will automatically save these settings. The settings will remain even when the unit is powered down and back on.

Available Settings

Language	English German French Spanish Polish Simplified Chinese
Temperature	°C °F
Auto Off	Off 2 min 5 min 10 min 30 min 60 min

2.2 About

From the Settings screen you can view information about the tester. Highlight About using the up and down arrow keys and press the select (tick) button.
This will show you information on when the unit was last calibrated, the serial number, hardware and firmware versions.
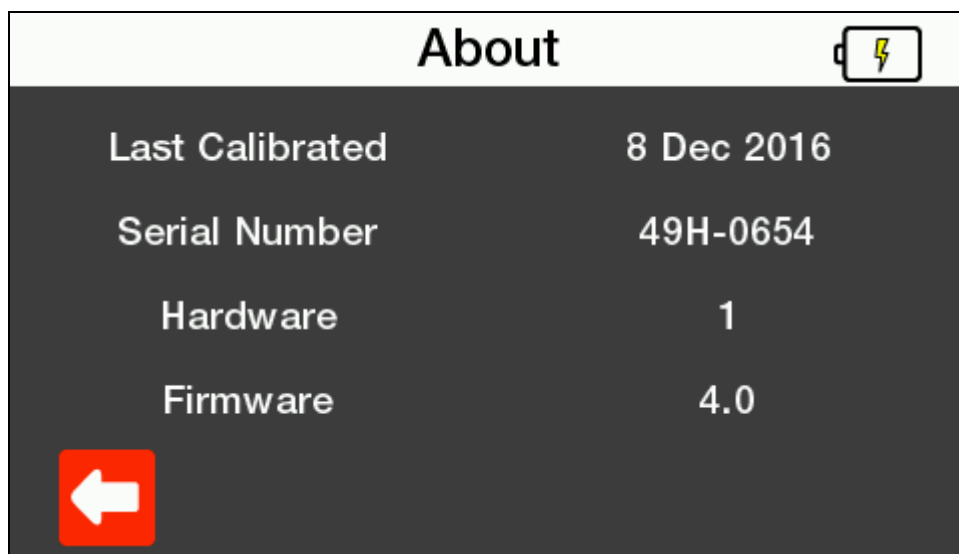
To leave this screen you can press the back button to go back to the settings menu or the Home button to go back to the Home screen.

2.3 Favourite Simulations

You can save up to 5 of your most used simulation settings for recall at any time.

2.3.1 Default settings

The unit will be delivered with 5 default settings as detailed below.

2.3.2 Adding a new favourite setting

Pressing the Rigel key in any menu will take you to the Settings screen.
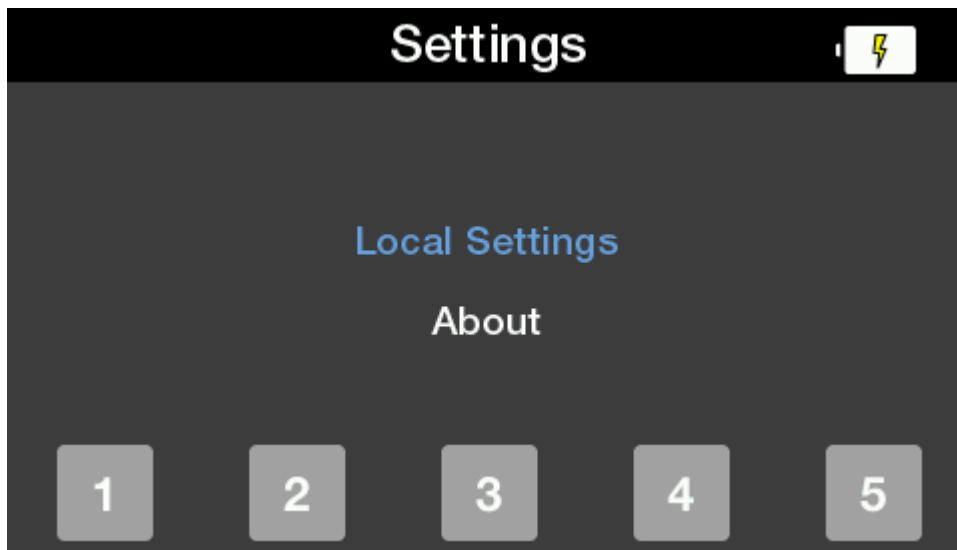
Here you can hold down one of the function keys for 3 seconds to save the current settings to that memory location. You will see a messaging asking if you are sure.
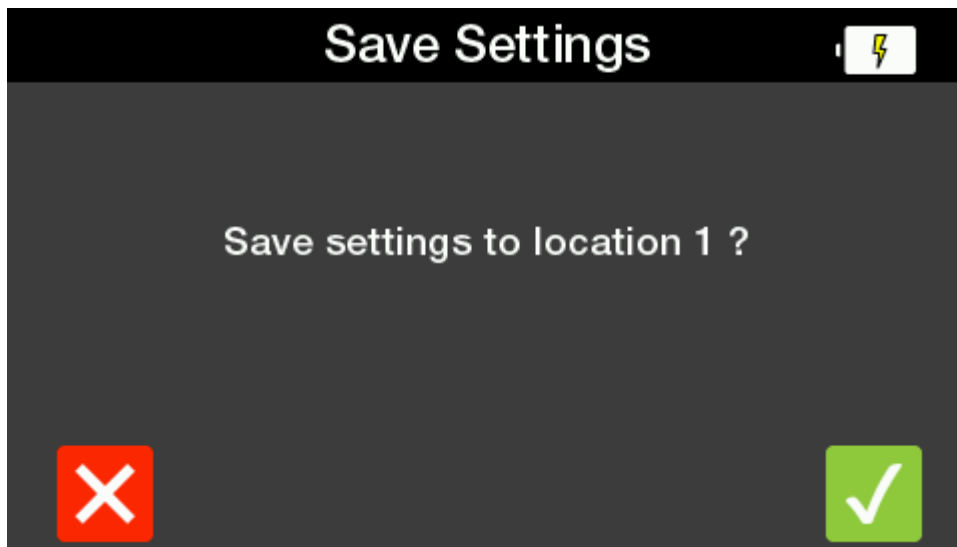
Press the cross on F1 to go back to the settings screen. Press the tick on F5 for yes and the tester will display a message of Saving Settings and then Settings Saved before returning to the home screen.

2.3.3 Recalling a favourite setting

Pressing the Rigel key in any menu will take you to the Settings screen.
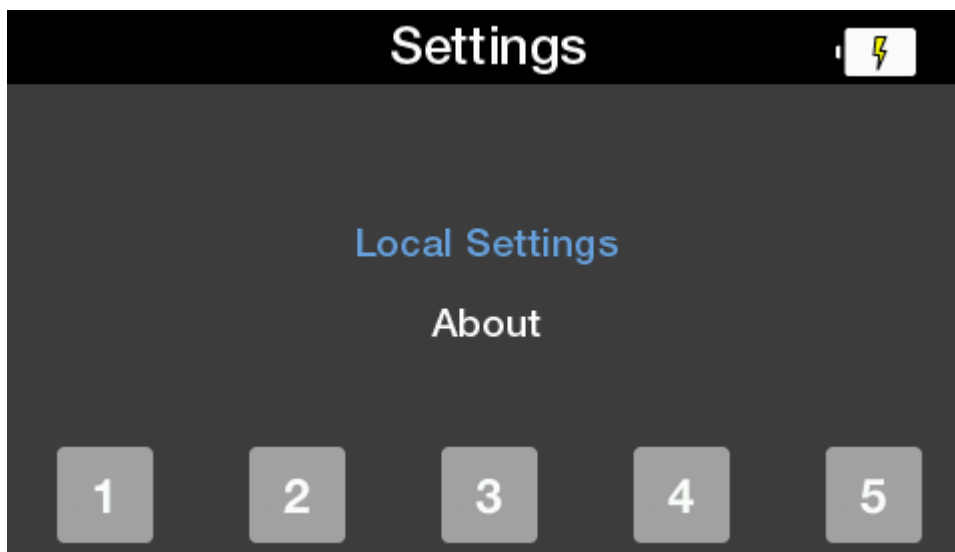
Here you can press one of the 5 function keys to access the corresponding settings.

You will see a messaging asking if you are sure.
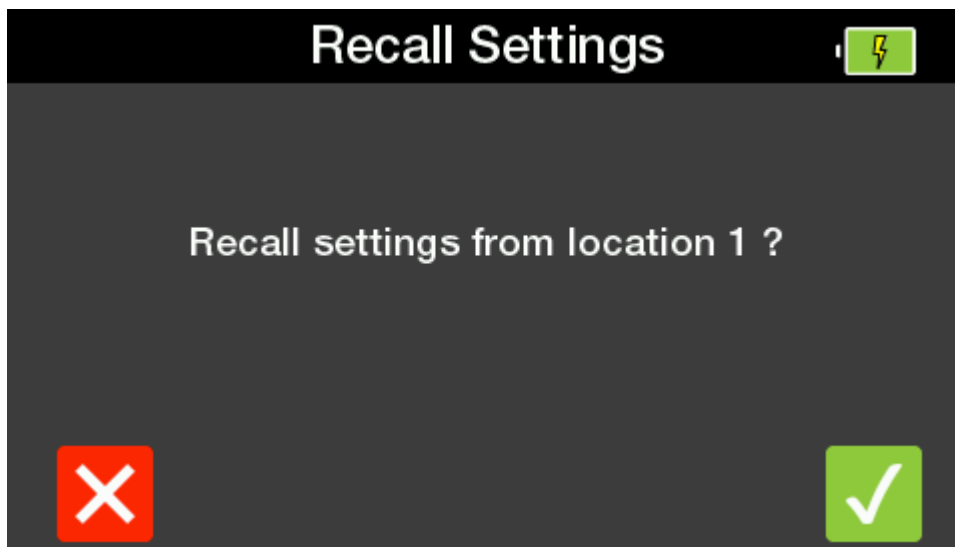
Press the cross on F1 to go back to the settings screen. Press the tick on F5 for yes and the tester will go to the home screen with the relevant settings selected.

3 Simulation Settings

The PatSim200 is capable of the below simulations:

- ECG
    - ○ ECG wave forms
    - ○ Arrhythmia's
    - ○ Performance Waveform
    - ○ Pacer Waveforms
    - ○ Fetal Maternal
- Respiration
- Temperature
- Invasive blood pressure (2 channel)

A list of the full settings available for each simulation is available at the end of each section.

Upon power-up, the user is presented with the Home screen which shows the Simulation Menu on F keys 1-4 and a summary of the settings saved on memory location 1.

3.1 ECG Settings

Pressing F1 from the home screen takes you to the ECG menu. The screen shows the current settings.
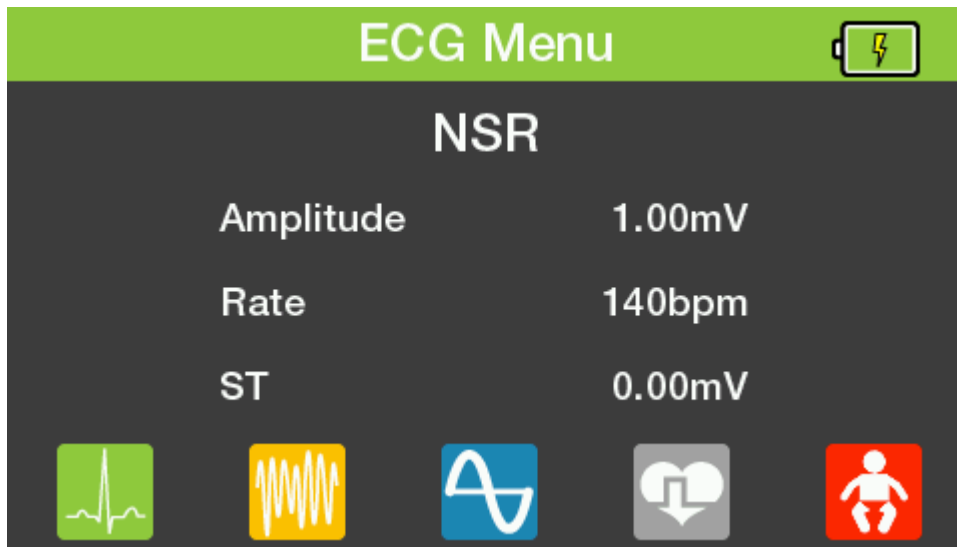
Note: All ECG waveform images are representations specifically for Lead II

3.1.1   Normal Sinus Rhythm

Pressing F1 in the ECG menu takes you to the Normal Sinus Rhythm screen. The screen will show the current settings. You can then use the up & down arrow keys to highlight the parameter you wish to change and then use the left & right arrow keys to select your required setting.
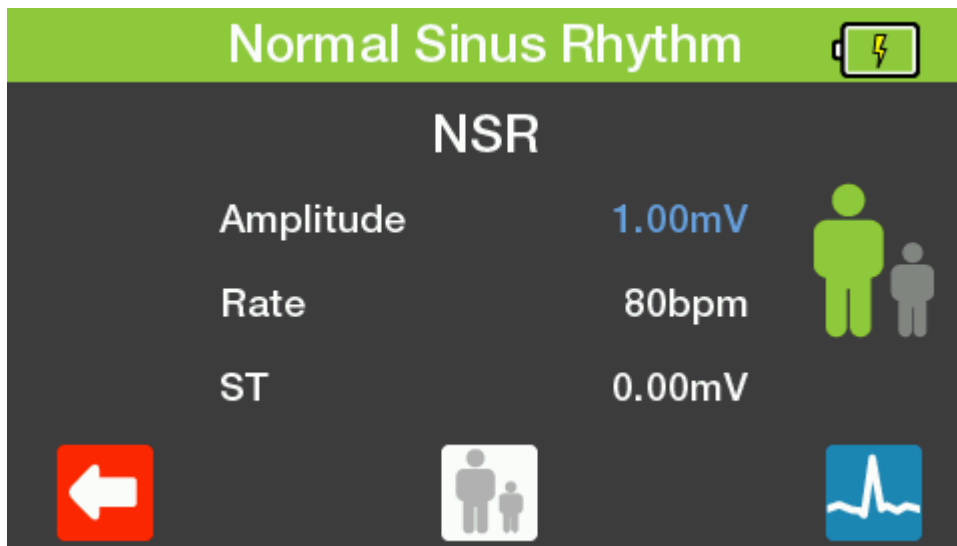
Pressing F3 changes between adult and neonatal settings.

You can see which is currently selected by which figure is in green on the right hand of the screen.
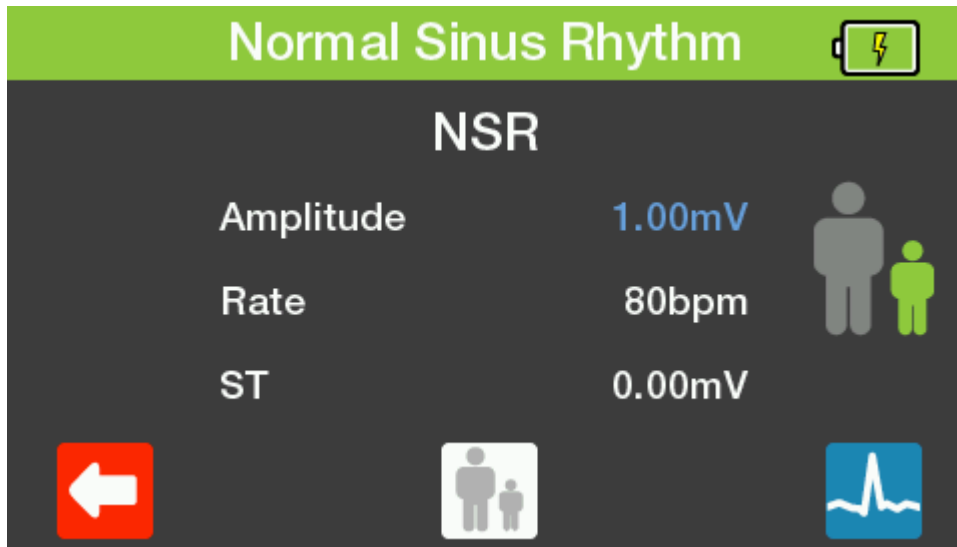
Pressing F5 shows a visual representation of the waveform you should expect to see on the monitor with the current settings.
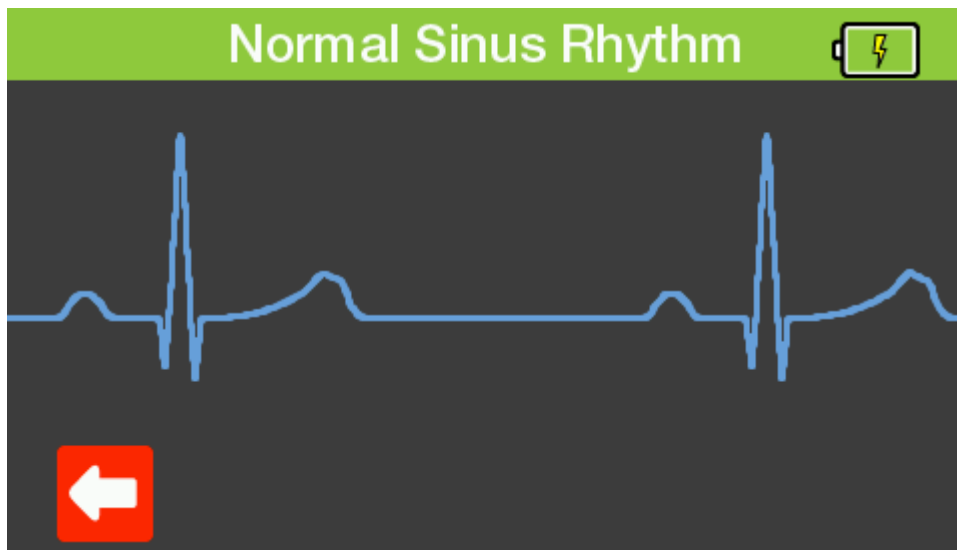
To leave any of these screens you can press the back button to go back to the previous menu or the Home button to go back to the Home screen.

Available Normal Sinus Rhythm Simulations

Rates	30, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200, 220, 240, 260, 280, 300 BPM
Amplitude (lead II)	0.05 mV to 0.45 mV (0.05 mV steps) 0.5 mV to 5.5 mV (0.5 mV steps)
ST Segments	-0.8 mV to +0.8 mV in 0.1 mV steps and +0.05mV and -0.05mV on Lead II

3.1.2 Arrhythmias

Pressing F2 in the ECG menu takes you to the Arrhythmias screen. You can then use the up & down arrow keys to highlight the type of arrythmia you wish to simulate and the select (tick) key to select. Alternatively you can use the function keys as fast keys to select the corrosponding arrythmia type.
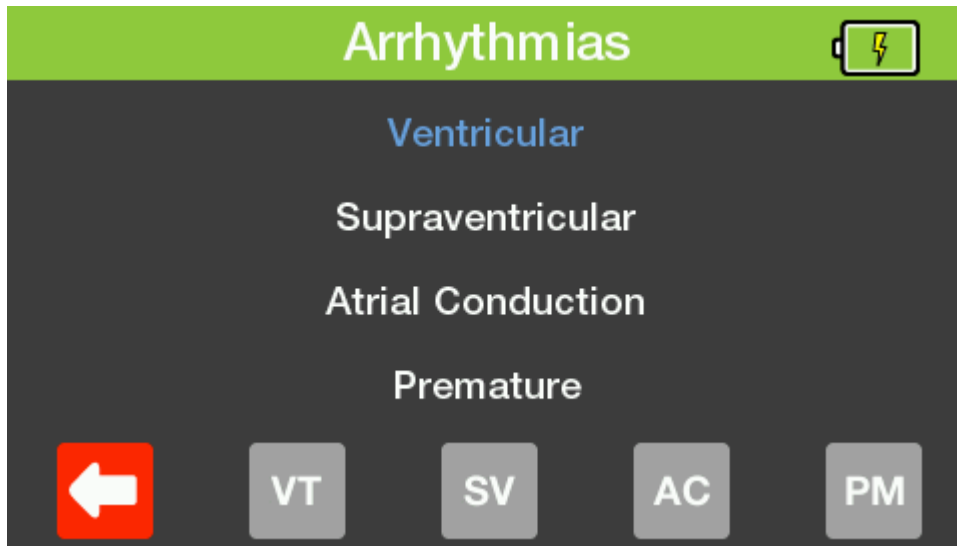
You can then use the left and right arrow keys to highlight the specific arrythmia you wish to simulate. Press down to hilight the amplitude and the left and right arrows to select the setting you wish to use.
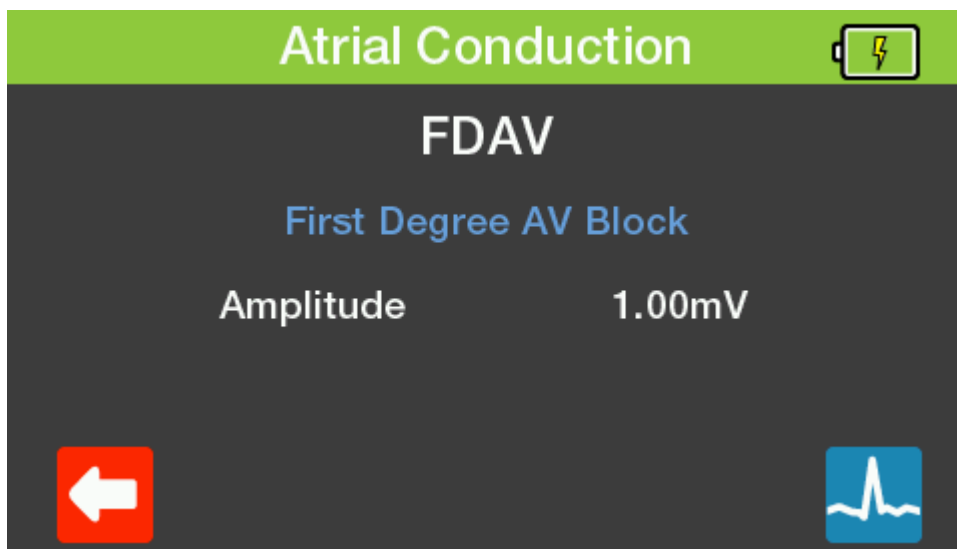
Pressing F5 shows a visual representation of the waveform you should expect to see on the monitor with the current settings.
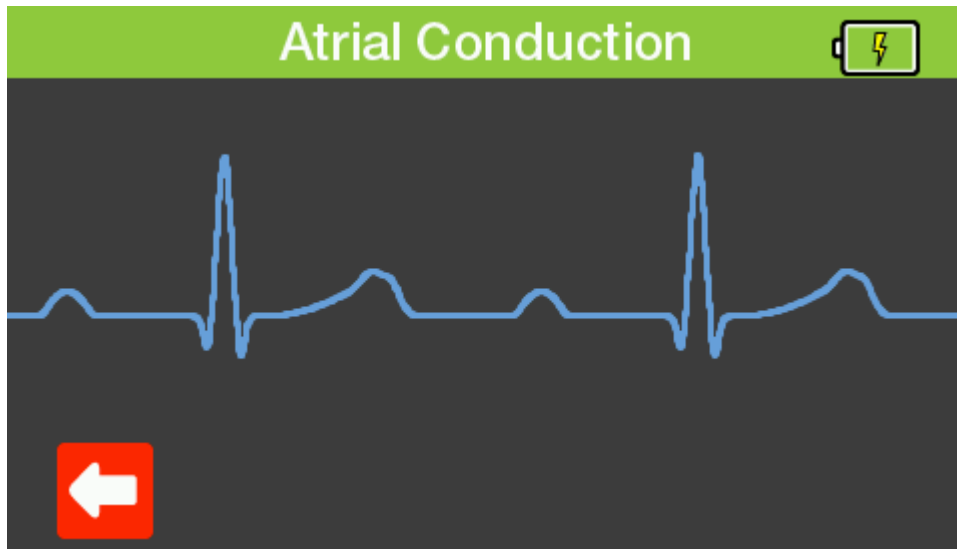
To leave any of these screens you can press the back button to go back to the previous menu or the Home button to go back to the Home screen.

Available Arrhythmia Settings

VENTRICULAR	Asystole Bigeminy Trigeminy Ventricular Fibrillation (coarse) Ventricular Fibrillation (fine) Ventricular Tachycardia
SUPRAVENTRICULAR	Atrial Fibrillation coarse Atrial Fibrillation fine Atrial Flutter Atrial Tachycardia Missing beat Nodal rhythm Paroxysmal Atrial Tachycardia Sinus Arrhythmia Supraventricular Tachycardia
ATRIAL CONDUCTION	First Degree AV Block Left Bundle Branch Block Right Bundle Branch Block Second Degree AV Block - Mobitz I Second Degree AV Block - Mobitz II Third Degree AV Block
PREMATURE	Premature Atrial Contraction Premature Nodal Contraction Premature Left Ventricle Contraction Premature Left Ventricle Contraction - early Premature Left Ventricle Contraction - R on T Premature Right Ventricle Contraction Premature Right Ventricle Contraction - early

	Premature Right Ventricle Contraction - R on T
	Premature Ventricular Contraction - 6 / min
	Premature Ventricular Contraction – 12 / min
	Premature Ventricular Contraction - 24 / min
	Premature Ventricular Contraction – frequent multifocal
Amplitude (lead II)	0.05 mV to 0.45 mV (0.05 mV steps)
	0.5 mV to 5.5 mV (0.5 mV steps)

3.1.3   Performance Waveform

Pressing F3 in the ECG menu takes you to the Performance Waveform screen. The screen will show the current settings. You can then use the up & down arrow keys to highlight the parameter you wish to change and then use the left & right arrow keys to select your required setting.
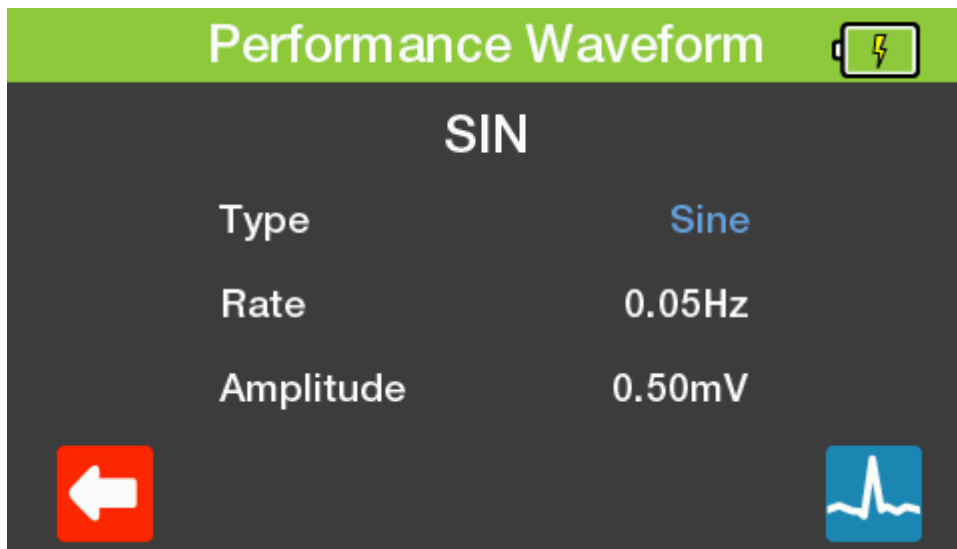
Pressing F5 shows a visual representation of the waveform you should expect to see on the monitor with the current settings.
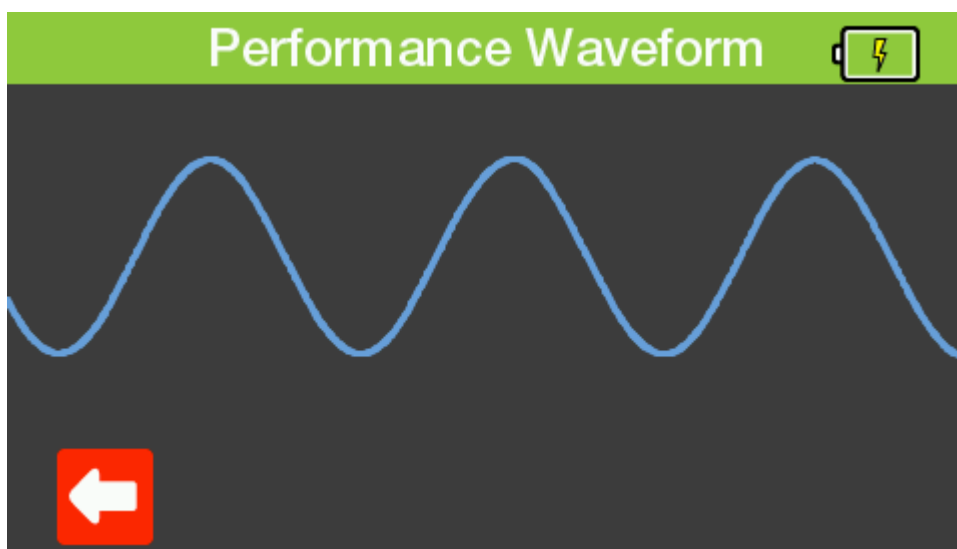
To leave any of these screens you can press the back button to go back to the previous menu or the Home button to go back to the Home screen.

Available Performance Waveforms

Sine Waves	0.05, 0.5, 1, 10, 25, 30, 40, 50, 60, and 100 Hz
Square Waves	0.125, 2 Hz
Pulse	60bpm or 240bpm
Triangle Wave	2 Hz
Performance amplitude	0.5 to 5.0 mV in 0.5 mV steps

3.1.4   Pacer Waveforms

Pressing F4 in the ECG menu takes you to the Pacer Waveforms screen. The screen will show the current settings. You can then use the up & down arrow keys to highlight the parameter you wish to change and then use the left & right arrow keys to select your required setting.

Pressing F3 takes you to the R-Wave Detection menu. You can then use the up & down arrow keys to highlight the parameter you wish to change and then use the left & right arrow keys to select your required setting.
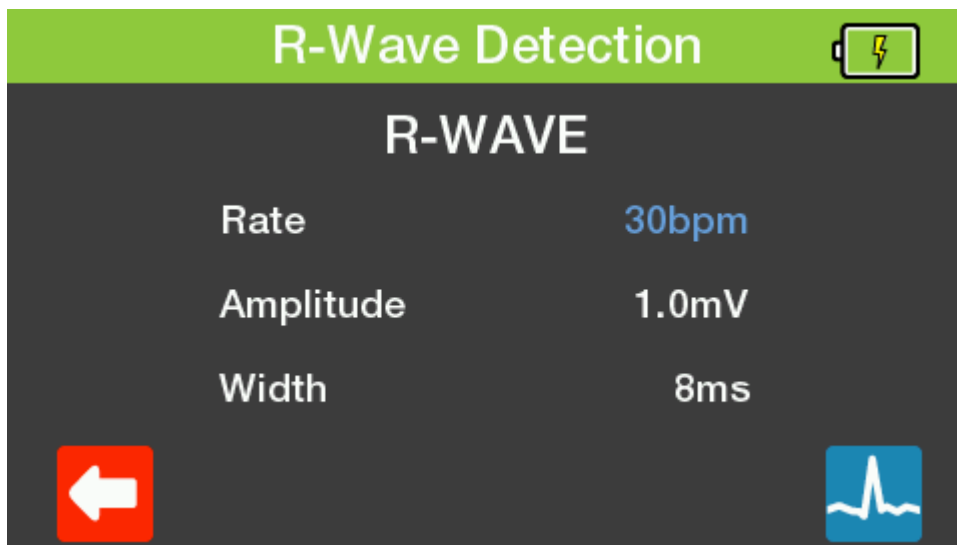
Pressing F5 in either screen shows a visual representation of the waveform you should expect to see on the monitor with the current settings.
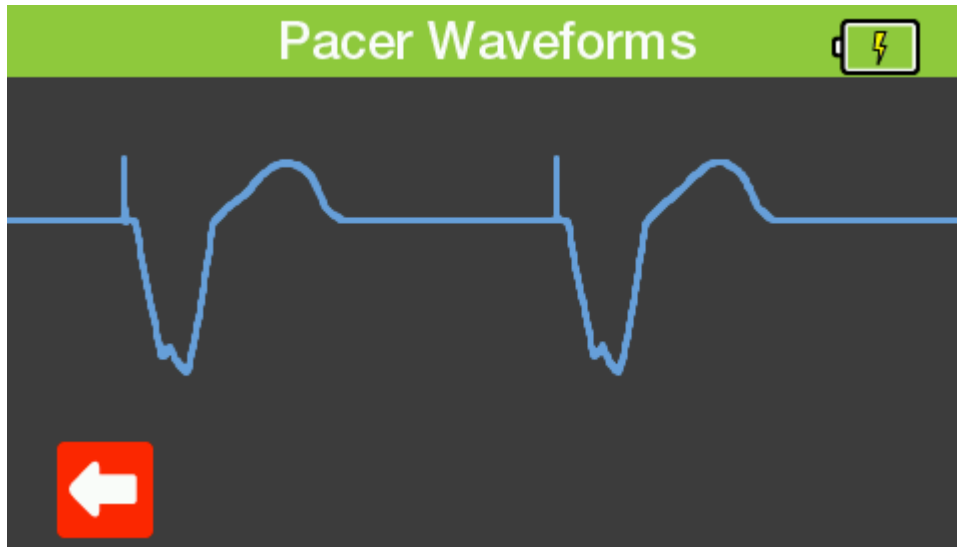
To leave any of these screens you can press the back button to go back to the previous menu or the Home button to go back to the Home screen.

Available Pacer Waveforms

Simulated Rhythms	Asynchronous at 75 BPM
	Demand with frequent sinus beat
	Demand with occasional sinus beat
	A-V sequential
	Non-capture
	Non-function
Pulse amplitude	1.0, 2.0, 5.0, 10.0 mV
Width	0.1, 0.2, 0.5, 1.0, 2.0 ms.
R-Wave Detector Test	60 BPM haver-triangle wave
R-Wave amplitude	0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0 mV
Haver-triangle Width	8, 10, 12, 20, 40, 60, 80, 100, 120, 140, 160, 180, 200 ms

3.1.5   Fetal Maternal

Pressing F5 in the ECG menu takes you to the Fetal Maternal screen. The screen will show the current settings. You can then use the up & down arrow keys to highlight the parameter you wish to change and then use the left & right arrow keys to select your preferred setting.
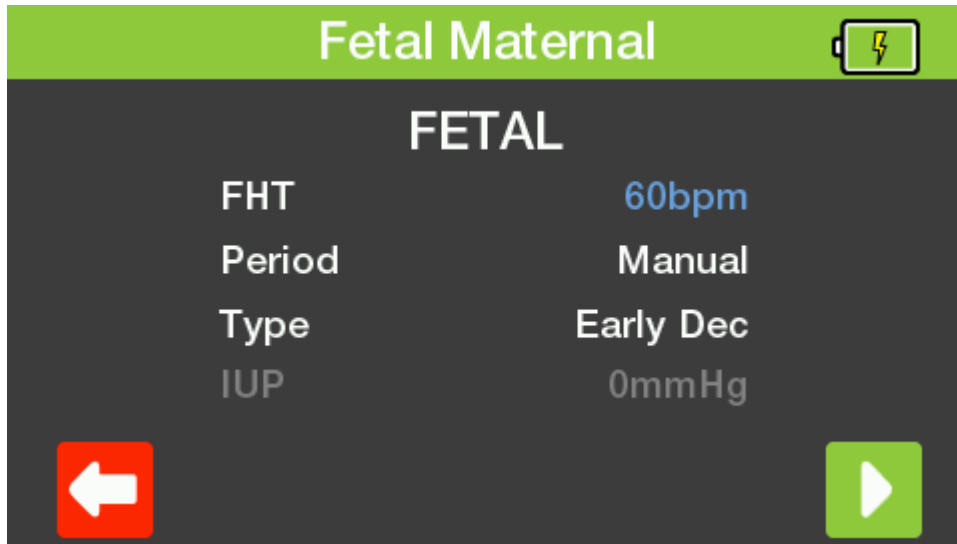
Pressing F5 starts the timer. Pressing F5 again stops the timer.
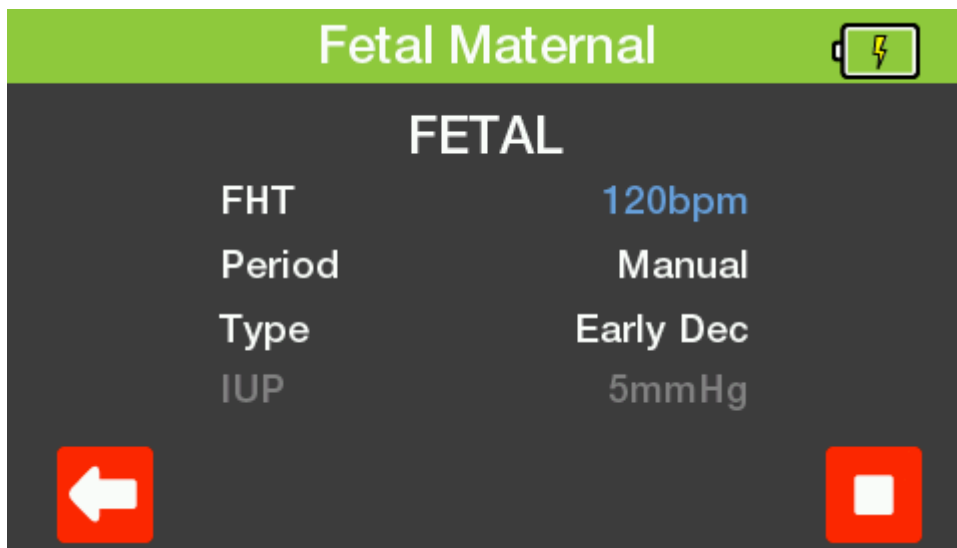
Note: IUP is displayed for information only during the Fetal Simulation.

To leave any of these screens you can press the back button to go back to the previous menu or the Home button to go back to the Home screen.
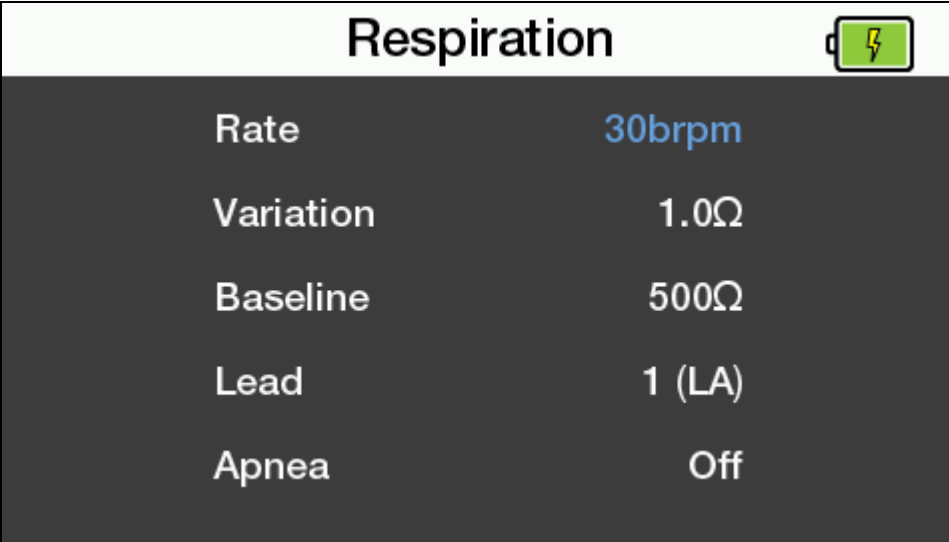
Note: The Fetal simulation is output on IBP1.

Available Fetal Simulation Settings

Maternal heart rate (fixed)	80 BPM
Fetal heart rate (selectable)	60, 90, 120, 140, 150, 210 and 240 BPM
Fetal heart rate (IUP)	140 BPM at beginning, then varying with pressure
Intrauterine-pressure waveforms (IBP1)	Early deceleration, late deceleration, and uniform acceleration
Simulation period	Manual or 2, 3, or 5 minutes

3.2 Respiration Settings

Pressing F2 from the home screen takes you to the Respiration menu. The screen shows the settings on memory location 1. You can then use the up & down arrow keys to highlight the parameter you wish to change and then use the left & right arrow keys to select your preferred setting.

To leave this screen you can press the Home button to go back to the Home screen.

Available Respiration Settings

Rate	0, 5, 10, 15, 30, 40, 60, 80, 120, 180 brpm
Resistance Variations	0.2, 0.5, 1.0, 3.0 Ω
Base Resistances	500, 1000, 1500 and 2000 Ω
Lead selection	Lead 1 (LA) and 2 (LL), user selectable
Apnoea Simulation	ON / OFF

3.3 Temperature Settings

Pressing F3 from the home screen takes you to the Temperature menu. The screen shows the settings on memory location 1. You can then use the left & right arrow keys to select your preferred setting. Alternatively you can use the function keys as fast keys to select the corresponding temperature.
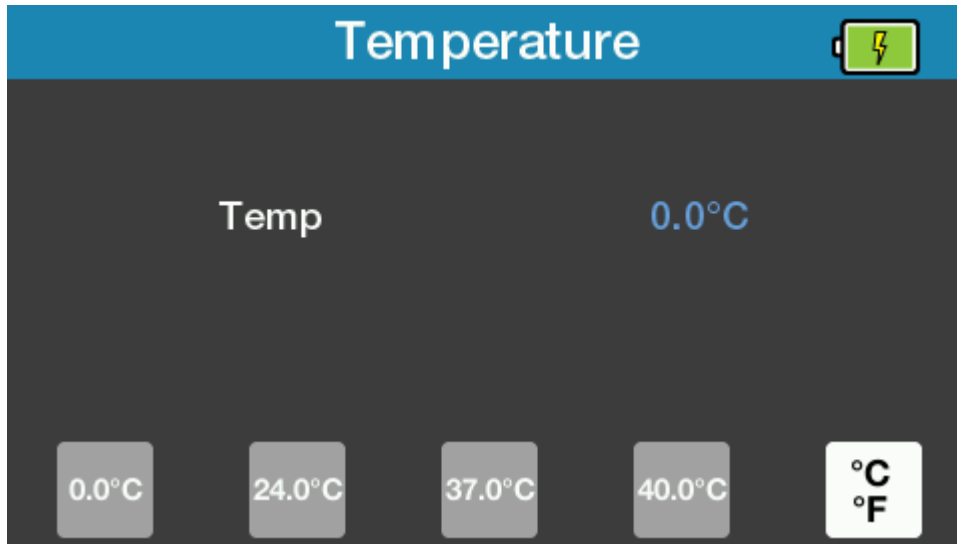
There is a fast key on F5 to switch between °C & °F.
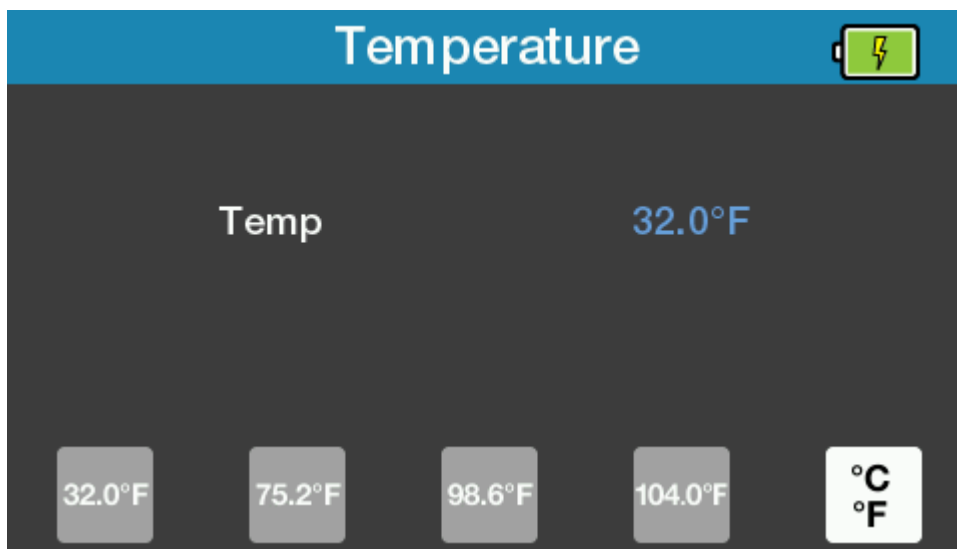
To leave this screen you can press the Home button to go back to the Home screen.

Available Temperature Settings

Simulation	YSI 400 / 700A / 700B Static
Temperature unit	°C or °F, user selectable
Range	pre-set 4 values at 0.0, 24.0, 37.0, and 40.0°C pre-set 4 values at 32.0, 75.2, 98.6, 104.0°F
Accuracy	± 0.1 °C / °F
Connector	mini DIN style

3.4 Invasive blood pressure settings

Pressing F4 from the home screen takes you to the Invasive Blood Pressure menu. The screen shows the settings.
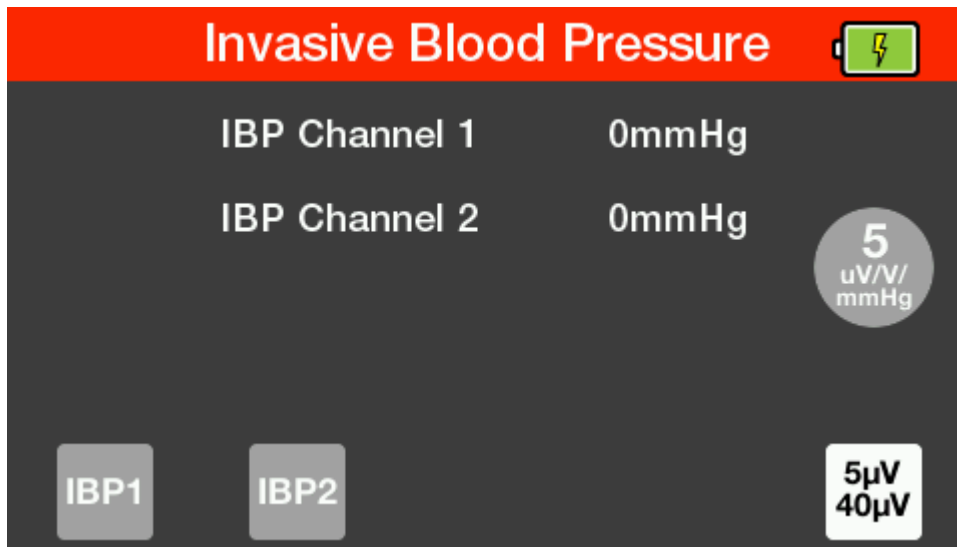
Press F1 or F2 to select the required channel. You can then use the up & down arrow keys to highlight the parameter you wish to change and then use the left & right arrow keys to select your preferred setting.
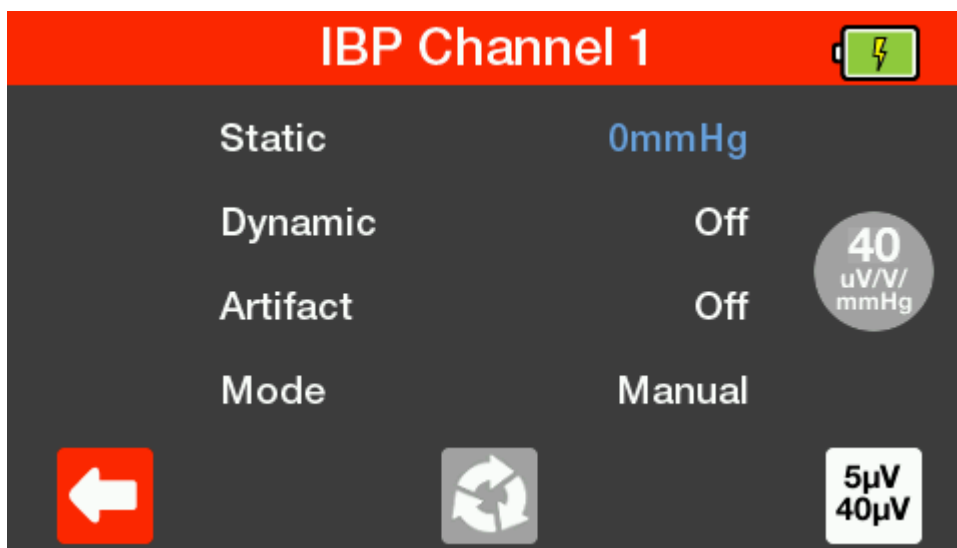
Setting Mode to Auto will cycle through all of the Dynamic settings one by one for 15 seconds each.

Note: Auto mode is only available on channel 1.

Pressing F3 resets all values back to zero.

There is a fast key on F5 to switch between 5µV and 40µV available in all of these screens.
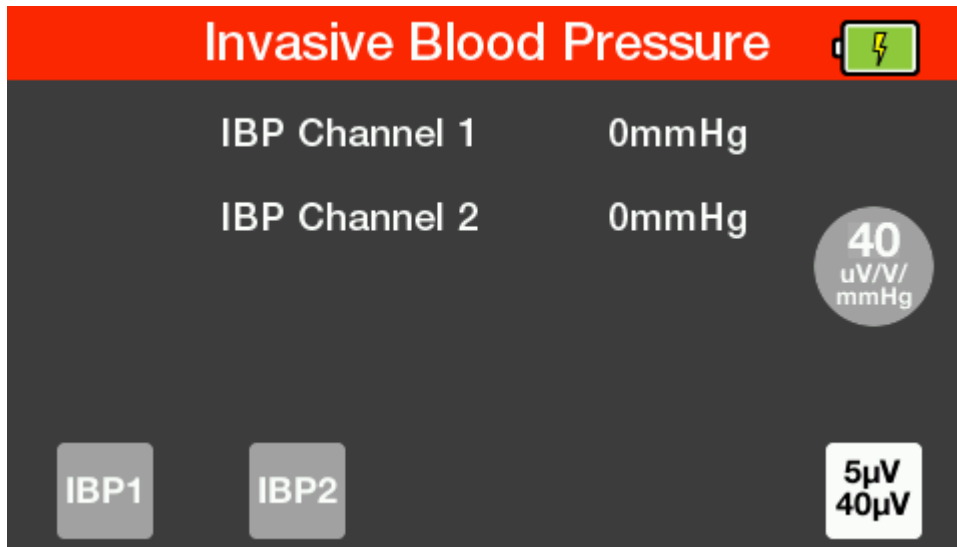
To leave this screen you can press the Home button to go back to the Home screen.

Available IBP Settings

Channels	2
Static Pressure	-10,-5,0,20,40,50,60,80,100,150,160,200,240,320,400mmHg
Dynamic Simulation	Arterial [ART] 120/80
	Radial Artery [RA] 120/80
	Left Ventricle [LV] 120/00
	Right Ventricle [RV] 25/00
	Right Atrium (central venous) [CVP] 15/10
	Pulmonary Artery [PA] 25/10
	Pulmonary Artery Wedge [PAW] 10/2
	Left Atrium [LA] 14/4
Auto sequence (Channel 1 only)	Cycle through simulations with 15 second step duration: - Arterial [ART] 120/80 - Radial Artery [RA] 120/80 - Left Ventricle [LV] 120/00 - Right Ventricle [RV] 25/00 - Pulmonary Artery Wedge [PAW] 10/2 - Pulmonary Artery [PA] 25/10 - Right Atrium (central venous) [CVP] 15/10
Simulated sensitivity	5µV/V/mmHg or 40µV/V/mmHg (user selectable)

4   Maintaining the PatSim200

4.1   Cleaning the PatSim200

The PATSIM 200 case can be cleaned with a damp cloth with, if necessary, a small amount of mild detergent. Prevent excessive moisture around the socket panel or in the lead storage area.

Do not allow liquid inside the PATSIM 200 or near the sockets. Do not use abrasives, solvents or alcohol.

If any liquid is spilt into the PATSIM 200 case, the simulator should be returned for repair, stating the cause of the defect.

4.2   User Maintenance

The PatSim200 is a rugged quality instrument. However, care should always be taken when using, transporting and storing this type of equipment. Failure to treat the product with care will reduce both the life of the instrument and its reliability.
If the PatSim200 is subject to condensation, allow the tester to completely dry before use.

- Always check the PatSim200 and supplied accessories for signs of damage and wear before use.
- Do not open the PatSim200 under any circumstances.
- Keep the instrument clean and dry.
- Avoid testing in conditions of high electrostatic or electromagnetic fields.
- Maintenance should only be performed by authorised personnel.
- There are no user replaceable parts in the PatSim200.
- The unit should be regularly calibrated (at least annually).

5 Technical Specifications

General ECG

Simulation		Full 12 lead ECG with independent outputs for each signal lead

Lead I	70%
Lead II	100%
Lead III	30%
Lead V1	24%
Lead V2	48%
Lead V3	100%
Lead V4	120%
Lead V5	112%
Lead V6	80%

ECG Normal Sinus Rhythm

Simulation	Full 12 lead ECG with independent outputs for each signal lead
Heart rate	18 selectable values 30-300 BPM
Accuracy	±1BPM or 1%
Amplitude (lead II)	0.05 mV to 0.45 mV (0.05 mV steps) 0.5 mV to 5.5 mV (0.5 mV steps)
Amplitude Accuracy	± 2%
ST Segments	18 selectable values, 8 elevated & 8 depressed
Neonatal Mode	ECG R wave width is reduced to 40ms

Arrhythmia Waveforms (Atrial)

Amplitude (lead II)	0.05 mV to 0.45 mV (0.05 mV steps) 0.5 mV to 5.5 mV (0.5 mV steps)
Amplitude Accuracy	± 2%
Ventricular Waveforms	Asystole Bigeminy Trigeminy Ventricular Fibrillation (coarse) Ventricular Fibrillation (fine) Ventricular Tachycardia
Supraventricular Waveforms	Atrial Fibrillation coarse Atrial Fibrillation fine Atrial Flutter Atrial Tachycardia Missing beat Nodal rhythm Paroxysmal Atrial Tachycardia Sinus Arrhythmia

	Supraventricular Tachycardia
Atrial Conduction Waveforms	First Degree AV Block
	Left Bundle Branch Block
	Right Bundle Branch Block
	Second Degree AV Block - Mobitz I
	Second Degree AV Block - Mobitz II
	Third Degree AV Block
Premature Waveforms	Premature Atrial Contraction
	Premature Nodal Contraction
	Premature Left Ventricle Contraction
	Premature Left Ventricle Contraction - early
	Premature Left Ventricle Contraction - R on T
	Premature Right Ventricle Contraction
	Premature Right Ventricle Contraction - early
	Premature Right Ventricle Contraction - R on T
	Premature Ventricular Contraction - 6 / min
	Premature Ventricular Contraction – 12 / min
	Premature Ventricular Contraction - 24 / min
	Premature Ventricular Contraction – frequent multifocal

Performance Waveforms

Square Waves	2 Hz, 0.125 Hz
Triangle Wave	2 Hz
Pulse	60bpm or 240bpm
Sine Waves	0.05, 0.5, 1, 10, 25, 30, 40, 50, 60, and 100 Hz
R-Wave Detector Test	60 BPM haver-triangle wave with selectable width and amplitude
Haver-triangle Width	12 selectable values between 8 and 200 msec
Performance amplitude	0.5 to 5.0 mV in 0.5 mV steps

Pacer Waveforms

Simulated Rhythms	Asynchronous at 75 BPM
	Demand with frequent sinus beat
	Demand with occasional sinus beat
	A-V sequential
	Non-capture
	Non-function
Pulse amplitude	1.0, 2.0, 5.0, 10.0 mV
Accuracy	±10%
Width	5 selectable values 0.1-2.0 ms.
Accuracy	± 5%.

R Wave Detection

Heart Rate	6 selectable values 30-250 BPM
Amplitude	0.05 mV to 0.50 mV (0.05 mV steps)
R wave width	13 selectable values 8-200ms

Respiration Simulation

Rates	0, 5, 10, 15, 30, 40, 60, 80, 120, 180 BRPM
Resistance Variations	0.2, 0.5, 1.0, 3.0 Ω
Accuracy	±10%
Base resistances	500, 1000, 1500 and 2000 Ω
Accuracy	±5%
Lead selection	1 (LA), 2(LL) user selectable
Apnoea Simulation	Manual on/off

Temperature Simulation

Simulation	YSI 400 / 700A / 700B Static
Temperature unit	°C or °F, user selectable
Range	pre-set 4 values at 0.0, 24.0, 37.0, and 40.0°C
	pre-set 4 values at 32.0, 75.2, 98.6, 104.0°F
Accuracy	± 0.1 °C / °F
Connector	mini DIN style

Invasive Blood Pressure Simulation

Channels	2 channels
Static Pressure	-10,-5,0,20,40,50,60,80,100,150,160,200,240,320, 400mmHg
Dynamic Simulation	Arterial [ART] 120/80
	Radial Artery [RA] 120/80
	Left Ventricle [LV] 120/00
	Right Ventricle [RV] 25/00
	Right Atrium (central venous) [CVP] 15/10
	Pulmonary Artery [PA] 25/10
	Pulmonary Artery Wedge [PAW] 10/2
	Left Atrium [LA] 14/4
Auto sequence (C1 only)	Cycle through simulations with 15 second step duration:
	Arterial [ART] 120/80
	Radial Artery [RA] 120/80
	Left Ventricle [LV] 120/00
	Right Ventricle [RV] 25/00
	Pulmonary Artery Wedge [PAW] 10/2
	Pulmonary Artery [PA] 25/10
	Right Atrium (central venous) [CVP] 15/10
Accuracy	± 1mmHg
Excitation voltage	2V to 16V
Impedance	350Ω Nominal
Simulated sensitivity	5µV/V/mmHg or 40µV/V/mmHg (user selectable)
Connector	mini DIN style

General Specifications

Mains power/Battery info	3.7V 3900mAh 14.4WH Li-Ion battery
	5V 1A USB micro-B power supply
	100-240V ~ 50/60Hz 0.18A max.
Charge time (new battery)	Up to 6 hours
Battery life	Up to 8 hours (depending on simulation and screen brightness)

Weight	0.70 Kg / 1.5 lbs
Dimensions	180 x 150 x 55 mm, 7.1 x 5.9 x 2.2 inch

Serviceability

|	
Warranty:	5 years [terms and conditions apply]
Calibration:	1 year

Environmental

Operating conditions	10 - 40°C (50 - 104°F) 0-90% RH - NC
Storage environment	-15 - 60°C (5 - 140°F) 0-90% RH – NC
Environmental protection	IP40
Impact Rating	IK08

Electrical Interfaces

ECG (&respiration) via 10 x 4 mm sockets
BP 1 – 4: 6 pin mini DIN
TEMP 8 pin mini DIN
USB Port micro

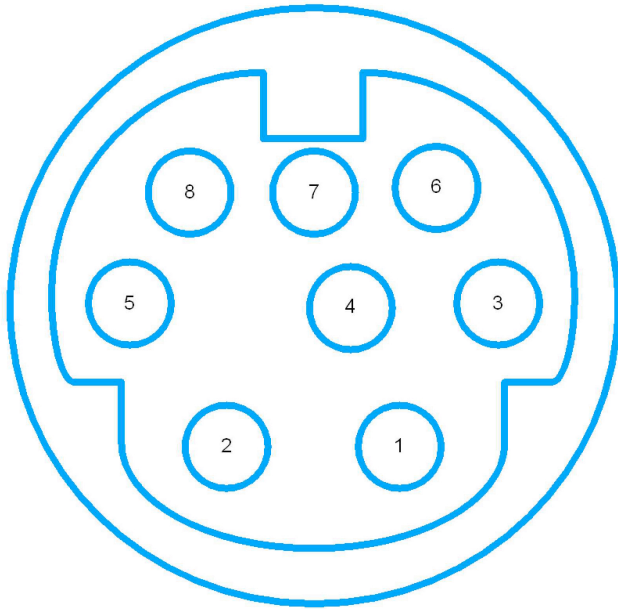# Appendix A - IBP cable wiring diagram
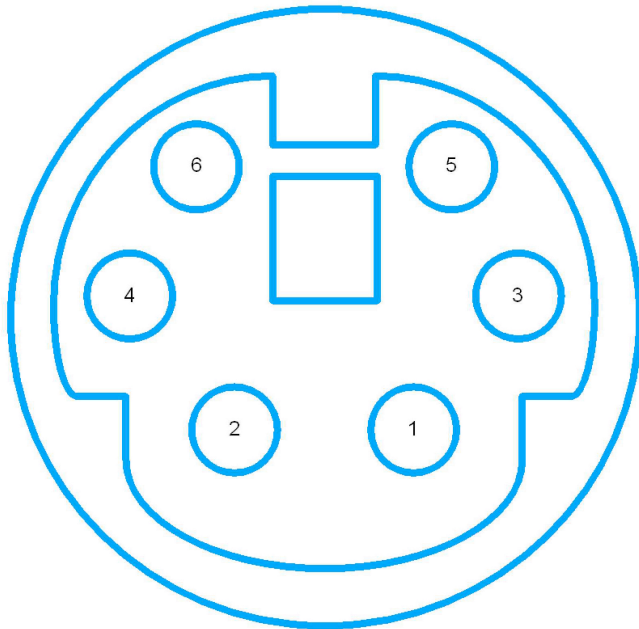
NOTES:
1. PINOUT:
    1   +VE Excitation
    2   NC
    3   +VE Output
    4   -VE Excitation
    5   NC
    6   -VE Output

2. "NC" is Not Connected

3. IBP 1, 2, 3 & 4 pinouts
   are identical

4. Pinout is with respect
   looking at the PATSIM

Appendix B - Temperature cable wiring diagram

NOTES:
1. PINOUT:
   1   NC
   2   YSI400
   3   NC
   4   NC
   5   YSI700B
   6   NC
   7   TEMP COMMON
   8   YSI700A

2. "NC" is Not Connected

4. Pinout is with respect
   looking at the PATSIM