Cardell® Insight Veterinary Monitor

For Models:

8014
Blood Pressure

8015
Blood Pressure, Pulse Oximetry

User Guide

003-2981-00 Rev. C (6/5/20)
Software Version 1.2V

Product Information

Dealer:	***Date of Purchase:***
Model / Serial Number:	***Midmark Authorized Service Company:***

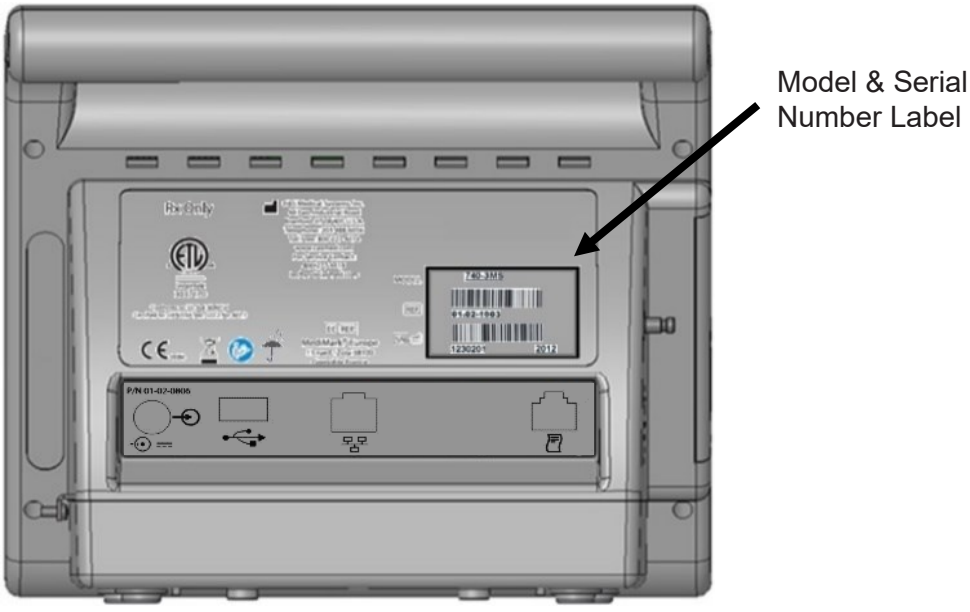


Table of Contents

Product Information i

1. Important Information 4

1.1 Operating Environment 4
1.2 Electromagnetic Interference 4
1.3 Disposal of Equipment 4

2. Introduction 5

2.1 Indications for Use 5
2.2 Contraindications 5
2.3 Brief Description 5
2.4 Patient Environment 7

3. Unpacking the Monitor 8

3.1 Initial Inspection 8
3.2 Monitor Checklist 8
3.3 Optional Mounting Accessories 9

4. Symbols 10

4.1 Safety Symbols 10
4.2 Symbols on the Monitor 10
4.2.1 Symbols near Patient Connection 12
4.2.2 Symbols on Front Panel 12
4.3 Symbols on Packaging 12
4.4 Touchscreen Keys on Display 13
4.5 Alarms/Audio State Icons 13
4.6 Patient Mode Icons 14
4.7 Workflow Icons 14
4.8 Touchscreen Controls on Display 14

5. Monitor Safety Measures 18

5.1 Overview – Dangers 18
5.2 Overview – Warnings 18
5.3 Overview – Cautions 21
5.4 Overview – Notes 22
5.5 Installation and Functional Verification 23

6. Monitor Overview 24

6.1 Front Panel 24
6.1.1 Front Panel Controls 24
6.2 Rear Panel 25
6.2.1 Rear Panel Ports & Connections: 25
6.3 Left Side View 26
6.4 Right Side View 27
6.5 Patient Connections 27
6.5.1 NIBP Cuff Hose Connection 27
6.5.2 SpO_2 Patient Connection 27
6.5.3 Speaker 28
6.6 Battery 28

7. Monitor Operation 30

7.1 Operating Modes 30
7.2 Turning the Monitor “On” 30
7.3 Turning the Monitor “Off” 32
7.4 Power Up Screen 32
7.5 Workflow 33
7.6 Monitor ID Selection 35
7.7 Main Screen Display 36
7.7.1 Date and Time 37
7.7.2 Screen Lock Icon 37
7.7.3 Patient Mode (Type) 38
7.7.4 Patient Information Button 40
7.7.5 Clinician Information 41
7.7.6 NIBP Numeric Field 42
7.7.7 SpO_2 Fields 43
7.7.8 Waveforms 43
7.8 Alarms and Messages 46
7.8.1 Message Area (Alarms) 47
7.8.2 Numeric Area (Alarms) 48
7.8.3 Alarm Log 48
7.8.4 Audio Silence 49
7.8.5 Alarm Pause 49
7.8.6 Alarm Limits and Settings 50
7.8.7 Audible and Visual Indicators 53
7.9 Error Messages on the Display 54

8. Menu Setup 58

8.1 Entering the Setup Menu 58
8.2 Alarm Pause 58
8.3 Audio 59
8.4 Save Trends 60
8.5 Patient Setup 60
8.5.1 Patient Information 60
8.5.2 Clinician Information 62
8.6 Restore User Defaults 63
8.7 Clear Trends 64
8.8 Administrator 64
8.8.1 Alarms 64
8.8.2 System 66
8.8.3 Service 73

8.8.4 Configuration 73
8.8.5 Factory 73
8.8.6 Display 74
9. Blood Pressure Monitoring 75
9.1 General Information 75
9.2 Safety Measures 75
9.3 Tips 77
9.4 Cuff Selection and Application 78
9.4.1 Cuff Placement for Cats 79
9.4.2 Cuff Placement for Dogs 80
9.4.3 Cuff Placement for Large Animals ..80
9.5 NIBP Measurement 81
9.5.1 NIBP Alarm Limits 82
9.5.2 Manual Mode 83
9.5.3 Automatic (AUTO) Mode 83
9.5.4 STAT Mode 83
10. Pulse Oximetry Monitoring 85
10.1 Safety Measures 85
10.2 Alarm Limit Values 90
10.3 SpO_2 Measurement 91
10.3.1 Attachment Procedure 91
10.3.2 Removing the Interface Cable 92
10.4 Plethysmograph 93
10.5 SpO_2 Messages 94
11. Trends 95
12. Cleaning 96
12.1 Overview 96
12.2 Display 96
12.3 Monitor 96
12.4 Blood Pressure Cuffs 97
12.5 Pneumatic Tubing 98
12.6 SpO_2 Interconnect Cable 98
12.7 SpO_2 Sensors (Reusable) 98
13. Maintenance 99
13.1 Maintenance Intervals 99
13.1.1 Preventative Maintenance 99
13.1.2 Painted Metal / Plastic Surfaces 99
13.2 Oximetry Calibration Check 99
13.3 NIBP Calibration Check 100
13.4 Monitor Battery 101
13.4.1 Replacing the Monitor Battery 101
14. Accessories 104
15. Specifications 106
15.1 Monitor Configuration Examples 106
15.2 NIBP Measurement 106
15.3 Oximetry 107
15.4 Patient Alarms 108
15.5 Control Panel 109
15.6 Power 109
15.7 Storage/Transport Environment 109
15.8 Physical Dimensions & Weight 110
15.9 Settings and Defaults 110
15.9.1 Initial Inflation Pressure 110
15.9.2 Main Screen 111
15.9.3 Setup Screen 111
15.9.4 Administrator Screen 112
15.10 Standards 113
16. Electromagnetic Compatibility 114
17. Warranty Information 117
18. After-sale Service and Support 120

1. Important Information

1.1 Operating Environment

Characteristic	Specification
Temperature:	-20°C to 60°C (-4°F to 140°F)
Humidity:	15 to 95% RH, non-condensing
Altitude:	0 to 40,000 ft (101 to 19 kPa)

WARNING

The monitor may not meet performance specifications if stored or used outside temperature and humidity ranges. When moving the monitor from a storage location, wait at least one-hour or more prior to use to allow the monitor to adjust to room temperature.

1.2 Electromagnetic Interference

This product is designed and built to minimize electromagnetic interference with other devices. However, if interference is noticed between another device and this product:

- Remove interfering device from room
- Increase separation between monitor and interfering device
- Contact Midmark if interference persists

1.3 Disposal of Equipment

At the end of product life, the monitor, accessories, and other consumable goods may become contaminated from normal use. Consult local codes and ordinances for proper disposal of equipment, accessories, and other consumable goods. EU distributors and treatment facility personnel may contact the manufacturer to obtain relevant information concerning WEEE Selective Treatment and Recycling.

2. Introduction

The Cardell Insight is a multi-parameter monitor measuring Blood Pressure and Oxygen Saturation. Non-invasive Blood Pressure is measured using the oscillometric step-deflation technique determining systolic, diastolic, mean arterial pressure (MAP) and pulse rate. The Pulse Oximeter function continuously monitors and displays values for functional arterial hemoglobin saturation and a pulse rate.

2.1 Indications for Use

The Cardell Insight monitor is indicated for use on animals as a portable, multi-parameter, variable acuity device for use by qualified veterinarians and technicians in a variety of veterinary centers, for non-invasive spot checking, and/or continuous monitoring and/or recording of:

- Blood pressure and pulse rate.
- Functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate

2.2 Contraindications

- Do not use on a limb with a vascular shunt
- Do not use in a hyperbaric chamber
- Do not use near an MRI machine
- Do not use near flammable anesthetics
- Do not place SpO_2 sensors near electro-cauterization
- Do not use on patients connected to a cardiopulmonary bypass device
- Do not use on patients connected to intra-aortic balloon pump device
- Do not use on patients with peripheral convulsions, tremors, or seizures
- Not intended for use with severe arrhythmia
- For contraindications of SpO_2 sensors, consult the manufacturer's directions for use
- No other contraindications are known at this time

2.3 Brief Description

The Cardell Insight multi-parameter monitor is compact, lightweight, and portable, allowing it to be easily carried and used in a variety of clinical settings. The monitor is powered by AC Line Power or by an internal Lithium Ion (Li-ion) rechargeable battery pack. The internal battery pack charges when the monitor is plugged into an AC Line power source. The monitor is equipped with a touchscreen interface. The touchscreen presents touch targets allowing the monitor to be configured for various type patients and clinical settings. The LCD screen displays various system alarm messages (physiologic

and equipment). These messages direct the user to check conditions such as limit violations, sensor attachment, battery state, air leaks and measurement problems.

The non-invasive Cardell blood pressure technology (NIBP) parameter automatically inflates an occluding cuff and, using the oscillometric measurement technique, determines systolic, diastolic, and mean arterial pressure and pulse rate. Measurement results along with user prompts and error messages are displayed on the front panel. The frequency of NIBP determination can be selected by the user in varied times between one and ninety minutes. The Auto and Manual operating modes cover a variety of clinical uses. The Start BP Options feature provides the user with a selection of inflation pressures for use while in Spot-Check workflow mode or adaptive blood pressure typically used during continuous patient monitoring. The Signal Quality Status (SQS) indicator provides an assessment of signal quality and level of motion artifact present during the NIBP measurement.

The Cardell Insight monitor provides the option of Covidien OxiMax pulse oximetry technology. The pulse oximeter parameter (%SpO_2) determines arterial oxyhemoglobin saturation by measuring the absorption of red and infrared light passing through the tissue. Changes in absorption caused by pulsations of blood in the vascular bed are used to determine arterial saturation and pulse rate. The oximeter requires no routine calibration or maintenance.

Oxygen saturation and heart rate are displayed on the LCD screen. A bar graph gives the user a relative signal quality indication. An audio “beep” can be enabled that is generated each time the SpO_2 module detects a pulse. The display screen can be configured to display the SpO_2 Plethysmograph.

The Cardell Insight monitor provides the flexibility to easily configure the monitor for use in various clinical workflows. The monitor can be specifically configured to operate in either Spot-Check or Continuous Monitoring Mode.

The monitor configuration can be saved as user Defaults (institutional settings) and subsequently copied to a USB flash drive for cloning additional Cardell Insight monitors to the same configuration.

Safety features include the ability for clinicians to lock (and un-lock) the main screen to prevent an unauthorized user from accessing and changing monitor settings. Higher level administration screens typically used to establish institutional and hospital settings are password protected.

Upper and lower alarm limits are provided for all parameters: NIBP, SpO_2, PR. Active alarms can be managed using Audio Silence and Alarm Pause features. Active alarms are easily distinguished on the display screen by the flashing parameter field.

The Cardell Insight monitor provides an extensive list of high-end features in a highly compact and portable design. Features specifically designed to enhance workflow, efficiency, and patient safety include:

- Standby Mode for enhanced patient workflow and alarm management
- Alarm Log for recall and display of patient and equipment alarms, alarm limit settings changes
- Screen Lock/Unlock to prevent unauthorized users from accessing the monitor
- SpO_2 alarm acknowledgement for management of equipment alarms (e.g., SpO_2 check sensor placement)
- Auto Dim display screen for enhanced nighttime operation

- Save Snapshots available in Spot-Check and Continuous Monitoring workflow modes

Caution
If the monitor has been configured for use in Spot-Check workflow mode, selecting OK from the "Save snapshot? Screen" will automatically clear patient information, and restore the monitor to user established default settings

- Start BP Options allow the Clinician to select the appropriate Initial Inflation Pressure from a list while operating in Spot-Check workflow mode
- Automatic trend capture – 1-minute average of continuously monitored physiologic parameters as well as interval capture of non-continuously monitored parameters (e.g. NIBP)
- Second speaker tone to inform the clinician an alarm has persisted for an extended period of time and provide back-up to the primary speaker
- Li-ion battery for extended operational use and transport
- Light weight for ease of use during transport
- Rugged design: Rated for use during professional transport

2.4 Patient Environment

The Cardell Insight monitor has been tested with specific parts of the "system" used within the Patient Environment (refer to Figure 1). The parts of the "system" that can be used in the Patient Environment are defined in Table 1:

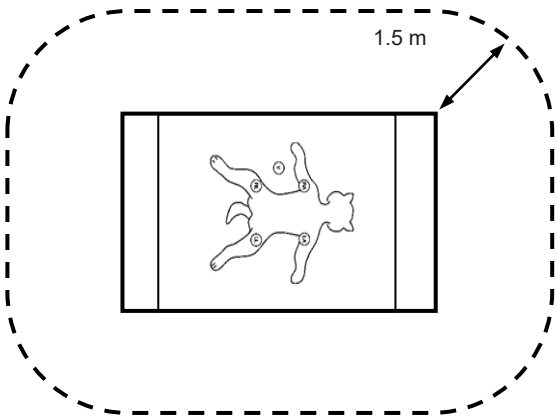


Figure 1: Patient Environment

Table 1: Parts of the System

Cardell Insight multi-parameter monitor
Appropriate Accessories, Refer to Section 14: Accessories
Power Supply and AC Line Cord

3. Unpacking the Monitor

3.1 Initial Inspection

Before unpacking the monitor, inspect the packaging for damage. If there are any signs of damage to the package, a claim should be filed immediately with the shipping agent. It is the receiver's responsibility to notify the carrier's local office to arrange for the pickup of the damaged items. Save the damaged shipping carton as evidence.

Contact Midmark to report external damage and to arrange for repair or replacement of damaged equipment.

The shipping carton should contain the items listed below. Unpack the monitor and account for each item. Inspect each item for signs of external damage, dents, cracks, scratches, etc. If an item is missing or damaged, contact Midmark within 15 days of delivery.

Record the monitor model, serial number, and date of purchase at the front of this Manual.

3.2 Monitor Checklist

Note
Actual shipping carton contents will vary depending on monitor configuration, accessories and software options ordered

Qty.	Description
1	Cardell Insight monitor w/Lithium-ion battery (installed)
1	Power Supply
1	AC Power Cord (*)
1	Cardell Insight User Manual
1	Veterinary Blood Pressure Start Up Kit Includes: 2m Hose, Vet Blood Pressure Cuffs and Cuff Selector Guide- Applied Part

For models with SpO_2 (Nellcor OxiMax) option installed:

1	SpO_2 Interconnect Cable
1	Vet SpO_2 Sensor - Applied Part

(*) The monitor is shipped with the appropriate line cord for the country and or voltage being used.

Caution
Do not use any other power supply other than the one supplied by Midmark. Refer to Section 14: Accessories for power supply part number information

3.3 Optional Mounting Accessories

Several mounting configurations are available to fit your needs. Refer to Section 14: Accessories for part number information. Contact Midmark for further information.

4. Symbols

The following is a summary of all symbols used on the monitor and accessories. Symbols may occur on the product or on its packaging.

4.1 Safety Symbols

DANGER
Indicates an imminently hazardous situation which will result in serious or fatal injury. This symbol is used only in the most extreme conditions.

WARNING
Indicates a potentially hazardous situation which could result in serious injury.

Caution
Indicates a potentially hazardous situation which may result in minor or moderate injury. It may also be used to alert against unsafe practices.

Note
Directions that make it easier to use the monitor.

Equipment Alert
Indicates a potentially hazardous situation which could result in equipment damage.

4.2 Symbols on the Monitor


Caution


Input


Indicates the polarity of the DC power input

⎓	Direct Current
CE	European CE Mark according to Council Directives 2014/30/EU and 2014/35/EU
	Indicates this monitor is subject to the Waste Electrical and Electronic Equipment Directive in the European Union
	Keep dry
IPX1	Protected against dripping water (refer to IEC 60529)
	Connection for USB Memory stick
	Ethernet connection (future use)
IOIOI / 	Two-way Communication and/or Cardell Insight Printer Port (Future Use)
Rx only	Federal law restricts this device to sale by or on the order of a veterinarian or licensed practitioner
	Follow instructions for use
	Product has been independently evaluated and certified by a Nationally Recognized Testing Laboratory (NRTL)
REF	Part Number Reference
	Manufacturer
	Manufacture Date

4.2.1 Symbols near Patient Connection

	Indicates protection against the effects of the discharge of a cardiac defibrillator. Patient connections are Type BF and protected against defibrillation
NIBP	NIBP Hose and Blood Pressure Cuff Connector
SpO_2	Pulse Oximeter Input Connector, accompanied by one of the following:
	Nellcor SpO_2 Technology

4.2.2 Symbols on Front Panel

	ON/Off – Turns the monitor On or Off

4.3 Symbols on Packaging

	Symbol used to indicate the minimum and maximum storage and transport Temperatures. Refer to Section 1.1:Operating Environment .
	Symbol used to indicate the minimum and maximum relative humidity for storage and transport. Refer to Section 1.1:Operating Environment .
	Symbol used to indicate the minimum and maximum atmospheric pressure for storage and transport. Refer to Section 1.1: Operating Environment .
	Fragile, handle with care
	This end up

4.4 Touchscreen Keys on Display

The monitor uses touchscreen keys to facilitate monitoring functions. Touch keys are located on the far right-hand side of the display screen in a vertical fashion. The keys are fixed and cannot be changed or reconfigured.

Silence	Alarm Silence touch area - Pauses Audio for 1, 1.5, or 2 minutes
Standby	Standby touch area - Places the monitor into standby mode; touching the screen will return the monitor to full operation (NO alarms are generated while in Standby)
Save	Save touch area - Saves snapshot of patient values to trend storage
Trends	Trends touch area - Display a record of trends and Saved Snapshots in tabular form
Setup	Setup touch area - Enter the Setup screens to configure the monitor
Home	Home touch area - Returns the monitor's display to the Main screen

Note

Standby is used to enhance clinical workflows:

- *Allows attachment of patient interface cables to the monitor in advance of patient*
- *The monitor automatically reverts to active monitoring when patient data is detected*
- *Provides the user with the option to suspend all patient monitoring*

4.5 Alarms/Audio State Icons

Alarms Pause - Indicates the generation of all Alarms has been temporarily paused (by pressing "Alarm Pause" in the Setup menu).

Audio Pause - Indicates the audio associated with current Alarms has been temporarily paused by pressing "Silence"

4.6 Patient Mode Icons

Horse: Sets the Cardell Insight alarm defaults to horse.

Dog: Sets the Cardell Insight alarm defaults to dog.

Cat: Sets the Cardell Insight alarm defaults to cat.

4.7 Workflow Icons

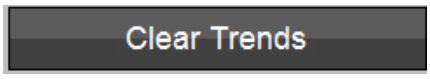
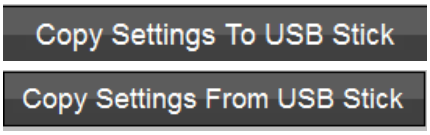
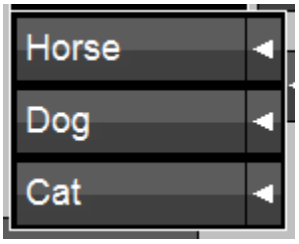
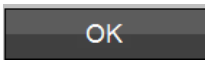
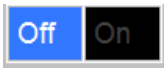
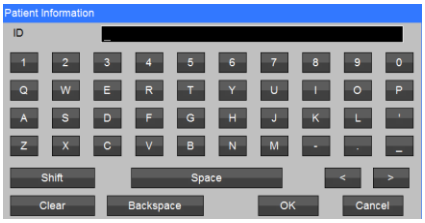
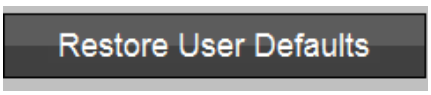
CONT **CONT** - Continuous mode

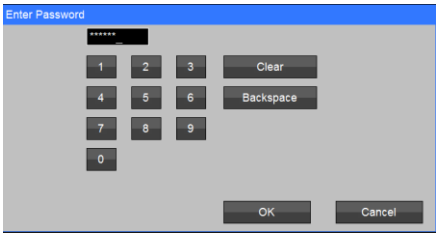
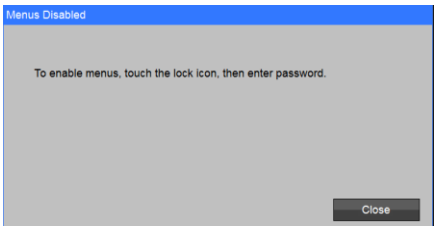
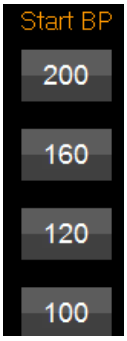
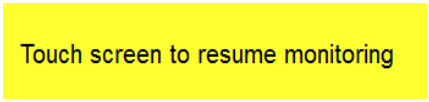
SPOT **SPOT** - Spot Check mode

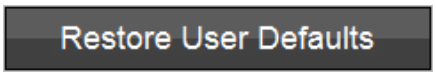
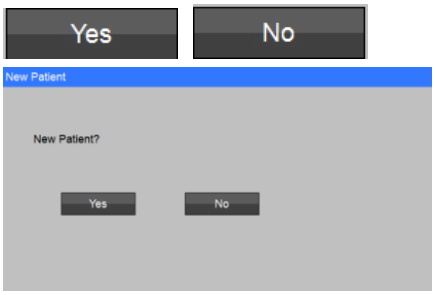
4.8 Touchscreen Controls on Display

Provides the user with interactive touchscreen monitor controls and activity buttons used to configure monitor settings, limits etc.

Touchscreen Control:	Example:	Description:
Alarm Log Arrows (right or left)	< >	Allows user to navigate to the right or left to view the entire table/log.
Alarms Log Review	Top Bottom	Allows user to navigate to the beginning or end of the Alarm log.
Backspace	Backspace	Used to move the cursor back one space or more.
Cancel	Cancel	Located in all Setup screens. Used to exit a screen without making a change.
Clear	Clear	Used to remove current entry in a data field.

Clear Trends		Located in the Setup menu. Allows the user the ability to remove all current Trends stored on the monitor.
Close		Select to exit the screen being viewed.
Copy Settings to and from USB Flash Drive		Allows user to copy settings/defaults from one monitor to another or to retain a copy of the current monitor default settings for future reference.
Demo Mode		Indicates the monitor has been placed into Demonstration Mode from a password protected screen. No active monitoring while in Demo Mode.
Drop-down		Selection keys typically appearing in the Setup menu.
Numeric Keypad		Used to enter information (passwords, patient weight, etc.).
OK		Located in all Setup screens. Used to confirm a setting and return to prior screen.
On/Off		Used to turn a feature or setting On or Off.
Patient Identification		Used to enter the current patient ID. When selected opens a screen allowing patient specific information to be entered using an on-screen QWERTY keyboard.
Restore user Defaults		Allows the user to reset the monitor to the previously saved user Defaults.

Screen Lock Screen Unlock	  	Used to limit access to menus by unauthorized users. When padlock icon is selected (upper right-hand corner of display screen) the Enter password screen is opened. User is required to enter a password to lock access to menus or unlock access to menus. Password is the current date displayed on the main menu (MM/DD/YY). Example: Current date: 12/10/2016 Enter: 12102016
SpO_2 Alarm Acknowledge		Selecting this button silences the audible SpO_2 equipment alarm and clears the alarm messages (e.g., SpO_2 check sensor placement)
Start BP		* Typically used for Spot-Check workflow mode Start BP Options provide workflow flexibility (Spot-Check, Continuous Monitoring workflow modes – adaptive measurements).
Start/Stop NIBP		* Typically used during continuous monitoring Used to start or stop an NIBP measurement (Start changes to Stop when selected).
Touch screen to resume monitoring		When the monitor is in Standby Mode, allows user the option to initiate patient monitoring at any time by touching the monitor display screen.
Up and Down Arrow		Typically used for setting adjustment or navigation (e.g. increase audio volume or scroll through Trends log)

User Defaults		Located in the password protected Setup System menu. Allows the institution to establish and save settings and monitor features (profile) as user Defaults.
Yes / No		Yes - Used to express agreement with a posed question. (e.g., “New Patient?”). No - Used to express disagreement of a posed question. (e.g., “New Patient?”).

5. Monitor Safety Measures

5.1 Overview – Dangers

DANGER
The Li-Ion battery should not be incinerated.

5.2 Overview – Warnings

WARNING

- ⇨ *The monitor needs special precautions regarding EMC and needs to be installed and put to service according to the EMC information provided in the Electromagnetic Compliance section.*
- ⇨ *Portable and mobile RF communications equipment may affect the monitor and should be used no closer to any part of the monitor, including cables, than the recommended separation distance calculated in the Electromagnetic Compliance Section.*
- ⇨ *The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.*
- ⇨ *The monitor Alarm Volume should be verified suitable for the area in which they are used.*
- ⇨ *Do not use this instrument for any purpose other than specified in this Manual. Doing so will invalidate the monitor's warranty.*
- ⇨ *Do not connect more than one (1) patient to the monitor.*
- ⇨ *To remove all power from the monitor, the AC plug must be disconnected from the wall outlet or the power cord must be removed from the rear of the monitor and the battery pack must be removed.*
- ⇨ *Do not plug the monitor into an outlet controlled by a wall switch.*
- ⇨ *Before each use, verify that the alarm limits are appropriate for the patient being monitored.*
- ⇨ *Before each use, make sure that the monitor default alarm settings are appropriate for the specific patient being monitored.*
- ⇨ *The position of patient, physiological condition, and other factors affect the readings.*

WARNING

- ⇨ *Occasionally, electrical signals at the heart do not produce a peripheral pulse*
- ⇨ *If a patient's beat-to-beat pulse amplitude varies significantly (for example, pulsus alternans, atrial fibrillation, rapid-cycling artificial ventilator), blood pressure and pulse rate readings can be erratic and an alternate measuring method should be used for confirmation.*
- ⇨ *Where the integrity of the external protective conductor in the installation or its arrangement is in doubt, EQUIPMENT shall be operated from its INTERNAL ELECTRICAL POWER SOURCE.*
- ⇨ *Do not, under any circumstances, perform any testing or maintenance on the monitor, power supply or power cords while the unit is being used to monitor a patient. Unplug the power cords before cleaning or servicing the monitor. The user should not perform any servicing except as specifically stated in this Manual.*
- ⇨ *Do not touch part of non-medical electrical equipment in the patient environment after removal of covers, connectors, etc. without the use of a tool which operate at voltages not exceeding 25 VAC or 60 VDC and the patient at the same time.*
- ⇨ *Do not use a frayed or damaged power cords, or any accessory if you notice any sign of damage. Contact Midmark for assistance.*
- ⇨ *Equipment is not suitable for use in the presence of FLAMMABLE ANESTHETICS.*
- ⇨ *Equipment is not intended to be used in Oxygen Enriched Atmospheres.*
- ⇨ *Do not gas sterilize or autoclave the monitor.*
- ⇨ *The use of Accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include: 1) Use of the accessory in the Patient Environment; and 2) Evidence that the safety certification of the accessory has been performed in accordance with the appropriate IEC 60601-1 collateral and particular harmonized national standard.*
- ⇨ *Do not use the monitor in the presence of Magnetic Resonance Imaging (MRI) equipment.*
- ⇨ *Do not place liquids on top of the monitor. Do not immerse the monitor, power supply or power cords in water or any liquid. If unit is accidentally wetted it should be thoroughly dried. The rear and bottom cover can be removed by a qualified service technician to verify absence of water.*
- ⇨ *ELECTRICAL SHOCK – To reduce the risk of electrical shock, do not remove the back or bottom cover. Refer all servicing to qualified personnel.*

WARNING

- ⇨ *ELECTROMAGNETIC COMPATIBILITY (EMC) – The equipment needs special precautions regarding EMC. Refer to the Electromagnetic Compliance section for additional information regarding EMC. Be aware that strong electromagnetic fields may interfere with monitor operation. Interference prevents the clear reception of signals by the monitor. If the hospital is close to a strong transmitter such as TV, AM, or FM radio, police or fire stations, a HAM radio, an airport, or cellular phone, their signals could be picked up as signals by the monitor.*

- ⇨ *ACCURACY – If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by alternate means and then check the monitor for proper functioning.*

- ⇨ *CABLES - Route all cables away from patient's throat to avoid strangulation.*

- ⇨ *ACCESSORIES – The use of accessories and cables other than those specified, except for the accessories and cables sold by Midmark as replacement parts, may result in increased emissions or decreased immunity of the monitor.*

- ⇨ *ACCESSORIES – It is the responsibility of the organization and/or user to verify the compatibility of the monitor, probes, and cables before use, otherwise patient injury can result.*

- ⇨ *DEFIBRILLATION – Do not come in contact with patients during defibrillation. Serious injury or death could result.*

- ⇨ *DISPOSAL – Dispose of the packaging material, observing the applicable waste control regulations.*

- ⇨ *SITE REQUIREMENTS – For safety reasons, all connectors for patient cables and sensor leads are designed to prevent inadvertent disconnection, should someone pull on them. Do not route cables in a way that they may present a stumbling hazard. For devices installed above the patient, adequate precautions must be taken to prevent them from dropping on the patient.*

- ⇨ *STACKING – Where a monitor is used adjacent to or stacked with other equipment, the monitor should be observed to verify normal operation in the configuration in which it will be used.*

- ⇨ *Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin, may affect the accuracy of the measurement.*

- ⇨ *For data accuracy and consistency, as well as patient comfort, adhere to the guidance in Section 9.3: Tips.*

- ⇨ *Cardiogreen and other intravascular dyes, depending on the concentration, may affect the accuracy of the oximeter measurement.*

WARNING

- ⇨ *A NIBP monitor does not operate effectively if a patient is having seizure activity, convulsions, or tremors. When a patient is experiencing arrhythmias during a NIBP measurement, the accuracy of the pulse determination may be affected, or the time needed to complete a measurement may be extended. The monitor will not resolve beyond 120 seconds.*

- ⇨ *Setting the Upper Alarm limit to the extreme high value can render the Upper Alarm Limit detection ineffective.*

- ⇨ *Setting the Lower Alarm limit to the extreme low value can render the Lower Alarm Limit detection ineffective.*

5.3 Overview – Cautions

Caution

- ⇨ *Pressing the touchscreen with a sharp or pointed instrument may permanently damage the touchscreen. Press the touchscreen using only your finger.*

- ⇨ *Inspect the monitor, air hose, and sensors for any damage prior to operation. If any damage is noted, the monitor should not be used until it has been serviced. The monitor should be repaired only by authorized personnel*

- ⇨ *Use only Midmark approved accessories and sensors to preserve the integrity, accuracy, and the electromagnetic compatibility of the monitor.*

- ⇨ *The oximeter is factory calibrated to determine the percentage of arterial oxygen saturation of functional hemoglobin.*

- ⇨ *Some sensors may not be appropriate for in certain cases. If at least ten (10) seconds of adequate height pulse on the Plethysmograph waveform cannot be observed for a given sensor, change sensor location or sensor type until this condition is achieved.*

- ⇨ *If the monitor fails to respond (including the display and touchscreen), do not use it until the situation has been corrected by qualified personnel.*

- ⇨ *ACCIDENTAL SPILLS – In the event fluids are accidentally spilled on the monitor, take the monitor out of operation, and inspect for damage.*

- ⇨ *ELECTROSURGERY – Measurements may be affected in the presence of strong electromagnetic sources such as electro surgery equipment.*

Caution

- ⇨ *GROUNDING – Do not defeat the three-wire grounding feature of the AC power cord by means of adaptors, plug modifications, or other methods. Do not use extension cords of any type. Do not connect the monitor to an electrical outlet controlled by a wall switch or dimmer.*
- ⇨ *INTERFACING OTHER EQUIPMENT – Monitoring equipment must be interfaced with other types of medical equipment by qualified biomedical engineering personnel. Be certain to consult manufacturers' specifications to maintain safe operation.*
- ⇨ *The monitor may not meet performance specifications if stored or used outside temperature and humidity ranges. When moving a monitor from a storage location, wait at least one hour prior to use to allow it to adjust to room temperature.*
- ⇨ *Remove the battery if the monitor is not likely to be used for some time.*
- ⇨ *Under certain conditions, the monitor provides "DRIP-PROOF" level of protection from ingress to moisture. Do not expose the monitor to extreme moisture levels such as direct exposure to rain. Exposure to extreme moisture levels may cause incorrect or inaccurate performance or monitor failure during or after exposure.*

5.4 Overview – Notes

Notes

- ⇨ *There are no known risks with common disposal of equipment or accessories; however, the disposing of accessories should follow in accordance with local hospital policies. The user should ensure these policies do not conflict with any local, state, or federal guidelines.*
- ⇨ *The monitor is suitable to be connected to public AC mains power.*
- ⇨ *The monitor is not "Category AP or APG Equipment".*
- ⇨ *The monitor is for "Continuous Operation".*
- ⇨ *The applied parts are "Type BF Defibrillation Proof".*

5.5 Installation and Functional Verification

The user should be positioned in front of the monitor, within arm's length to allow operation of the touchscreen as well as connection/disconnection of cables. The user should be positioned to allow hearing of audible alarm tones generated by the monitor.

Perform the following steps to set up the monitor.

Table Top

1) Position the monitor on a flat surface, away for the any edge.
2) Route the patient cables so that if pulled the monitor will not fall.

Perform the following steps to power on the monitor and assess the Alarm Operation:

1) Connect the supplied AC power cord to the power supply.
2) Connect the AC power cord plug to a wall outlet. The wall outlet should not be controlled by a switch.
3) Connect the power supply's DC power cord into the DC Connection in the rear of the monitor
4) Power on the monitor.
5) Verify the monitor is configured for the proper type patient: Horse, Dog or Cat

User-initiated Testing of Alarm Signal Generation

Once the monitor is on, verify the unit is functioning properly by performing the following functions:

1) Set the NIBPs Lower Alarm Limit to Off, and the NIBPs Upper Alarm Limit to 40 mmHg.
2) Attach the NIBP Cuff to a NIBP Simulator or your finger.
3) Start a NIBP Measurement and allow it to complete.
4) Verify a NIBPs Upper Alarm Limit violation is created; Visual and Audio annunciation.
5) Remove and Silence the NIBPs Upper Alarm Limit violation.

Caution

Testing of the Alarm operation should be done at least once every 6 months. The recommended functional verification may be completed by a qualified user.

6. Monitor Overview

6.1 Front Panel

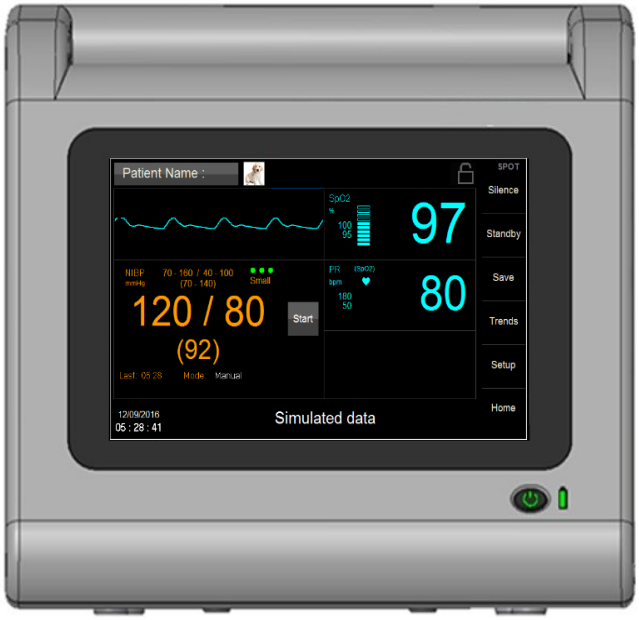
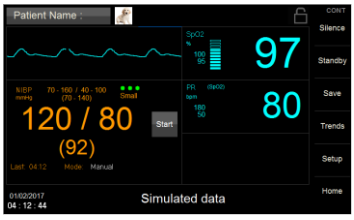


Figure 2: Front Panel View

6.1.1 Front Panel Controls

	On/Off: Press once, to turn “ON” (if it was Off). The button is illuminated when power is on. To turn “Off”, press and hold for two (2) seconds.
	POWER LED: Indicates External A/C Power is connected.
	TOUCHSCREEN: Provides Graphical user Interface (GUI) for controlling and configuring the monitor.

6.2 Rear Panel

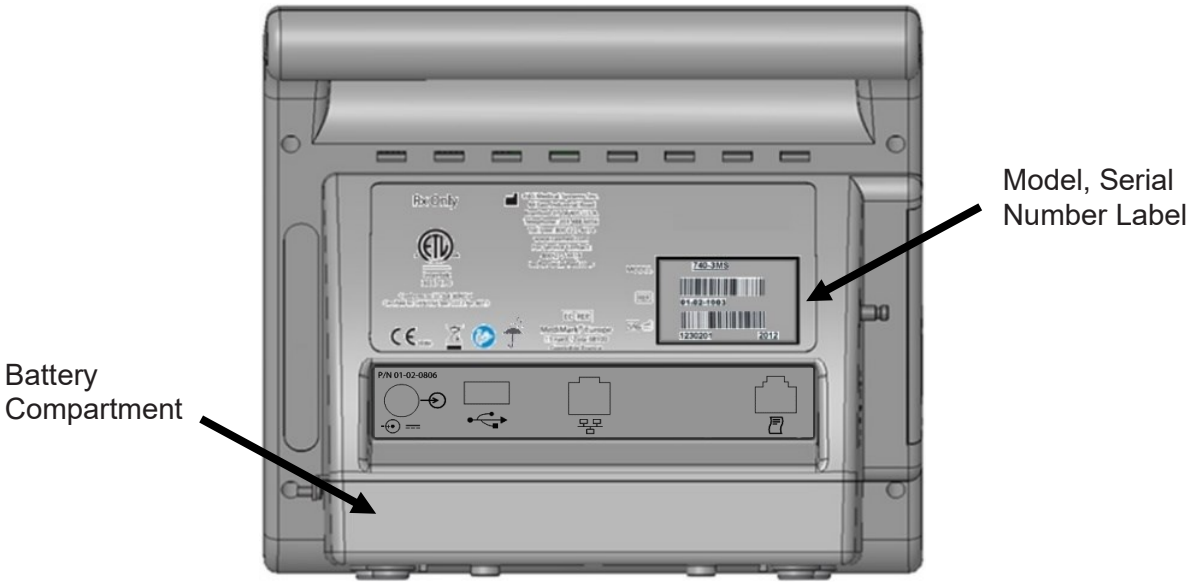


Figure 3: Rear Panel View

> ***Note***
> *The serial number label is located on the back side of the monitor, next to the SN symbol.*

6.2.1 Rear Panel Ports & Connections:

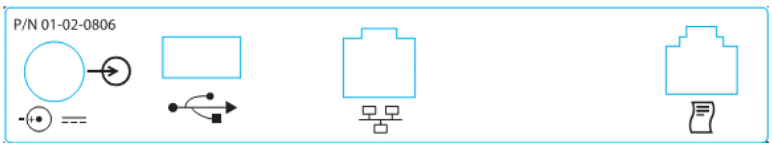


Figure 4: Rear Input Panel

DC Connection

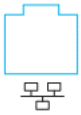
Receptacle for the DC power supply is located on the rear panel. Use only PN 015-3604-00 Power Supply.

USB Connection

Note: Not all flash drives are supported.

The USB connection allows for the following:

- Perform software upgrades via USB Flash Drive
- Copy monitor Settings to or from USB Flash Drive
- Copy monitor Logs to USB Flash Drive
- Download Trend Data



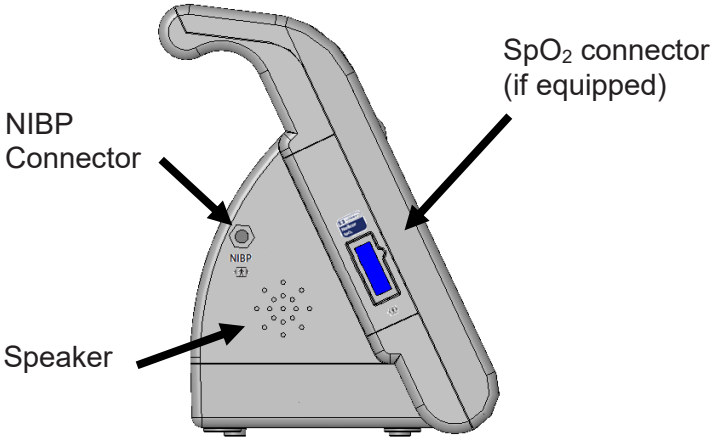
Ethernet Connection (Future)

Receptacle for Ethernet connectivity.

External Device Interface (Future)

Receptacle for serial communication.

6.3 *Left Side View*



SpO_2 Connector (if equipped) NIBP Connector

Figure 5: Left Side Panel View and Connectors

6.4 Right Side View

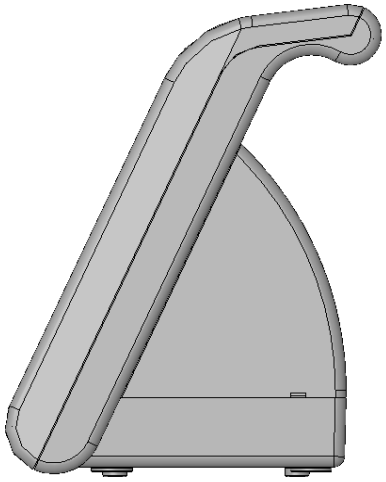


Figure 6: Right Side Panel View

6.5 Patient Connections

6.5.1 NIBP Cuff Hose Connection

The NIBP inflation hose is connected to the monitor. (Refer to Figure 5). An appropriately sized cuff for the patient's limb must be connected to the hose prior to use. Pull on the connector sleeve at the end of the hose to release hose from monitor.

6.5.2 SpO_2 Patient Connection

***For Monitors equipped with SpO_2:**

The SpO_2 Patient cable is connected to the monitor where the SpO_2 logo is located (refer to Figure 5). The SpO_2 Sensor is then connected to the SpO_2 Patient cable.

> ***Note***
> *The SpO_2 Patient cable is keyed and can only be inserted one way.*

6.5.3 Speaker

The monitor is equipped with an internal speaker to indicate the presence of alarm conditions.

> ***WARNING***
> *Do not place the monitor left side speaker grill against a solid surface. This will cause the alarm tones to be muffled.*

6.6 Battery

> ***DANGER***
> *Risk of fire, explosion, or burns. Do not short circuit, crush or expose battery to high temperature, incinerate or disassemble the battery.*

> ***Caution***
> *This product contains a rechargeable Li-ion battery that is recyclable. Under various state and local laws, it may be illegal to dispose of this battery into the municipal waste stream. Check with your local authorities for instructions on recycling options in your area.*

> ***Note***
> *Charge battery fully before initial use.*

> ***Equipment Alert***
> *Dispose of battery per the manufacturer's instructions.*

The monitor is equipped with an internal rechargeable battery. The battery is charging whenever the monitor is plugged into a power source. A green Battery Charging Visual Indicator (located to the right of the On/Off button) on the front panel is lit when the battery is charging.

Batteries will self-discharge when they are not used. It is recommended that the battery be maintained at full charge by leaving the monitor connected to a power source whenever possible.

The standard 10.8 Volt 7800 mAh battery pack, when new, fully charged, is capable of close to 10 hours of operation when the monitor is set in the 5-minute Automatic Mode (Continuous SpO_2 measurements).

The battery icon  appears when the monitor is disconnected from the mains power. The icon provides an indication of relative battery change level remaining.

When the message “Low Battery” message and 

icon appears on the main screen, approximately (30) minutes of battery operation remain. Three (3) audio “beeps” are heard every twenty-five (25) seconds.

WARNING
Upon the detection of a Low Battery condition and if the battery is not charged by the user, the monitor may no longer function as intended. The monitor should be plugged into a power source as soon as possible and allow the battery to charge for five (5) hours.

WARNING
Upon the detection of a Battery Nearly Depleted condition and if the monitor is not turned off by the user, the monitor shuts down and turns off within sixty (60) seconds of operations.

When the “Battery Nearly Depleted” message appears, the battery is no longer able to power a measurement. The message “Battery Nearly Depleted” is displayed on the main screen and a continuous audio tone is generated until the power is turned off.

When either of these messages appears, it is necessary to recharge the battery. A depleted battery may be fully recharged in five (5) hours. The monitor can be used to obtain measurements while the battery is charging.

If the monitor needs repair, it must be referred to the appropriate service personnel. Service performed by unauthorized personnel could be detrimental to the monitor and will void the warranty. For service, contact Midmark.

Note
Using the monitor while charging will lengthen the time to restore battery charge.

Note
During charging of the battery, the case may feel warm to the touch.

7. Monitor Operation

7.1 Operating Modes

> ***Caution***
> *Prior to patient monitoring, ensure the monitor is configured to the appropriate patient mode – Horse, Dog or Cat. Refer to Section 9.4: Cuff Selection and Application, for more information.*

NIBP function is affected by changing operating modes. Once power has been applied, a visual indicator on the display shall indicate the current operating mode. The monitor will operate in the mode selected until it is manually changed.

7.2 Turning the Monitor "On"

- Press the ON/Off switch on the front panel to turn the monitor "ON" (refer to Figure 7).
- The ON/Off switch illuminates when the monitor is turned on.

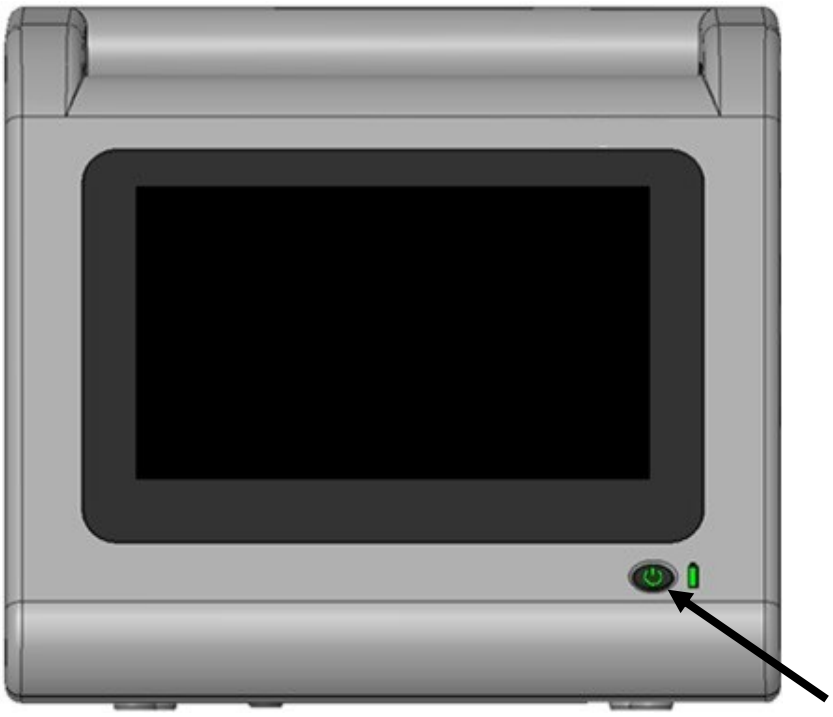


Figure 7: On/Off switch location

Each time the monitor is turned “ON”, a Configuration Setup Test and electronic Power On Self-Test (POST) is conducted to ensure that its internal circuits are functioning properly.

Completion of the Setup Test and POST is confirmed by a two-beep audio alert. Once the Power On Self-Test is completed, the monitor is ready for use.

> ***Caution***
> *The user should use the Power On Self-Test as a verification tool that all front panel visual indicators and the audio are functioning properly.*

Boot-Up Sequence (approx. 25-30 seconds):

- Power On – switch illuminated green
- Midmark splash screen appears
- Screen turns blank for approx. 5 seconds
- Audio beep to confirm POST completed
- **New Patient**? screen appears (default setting), refer to Figure 8

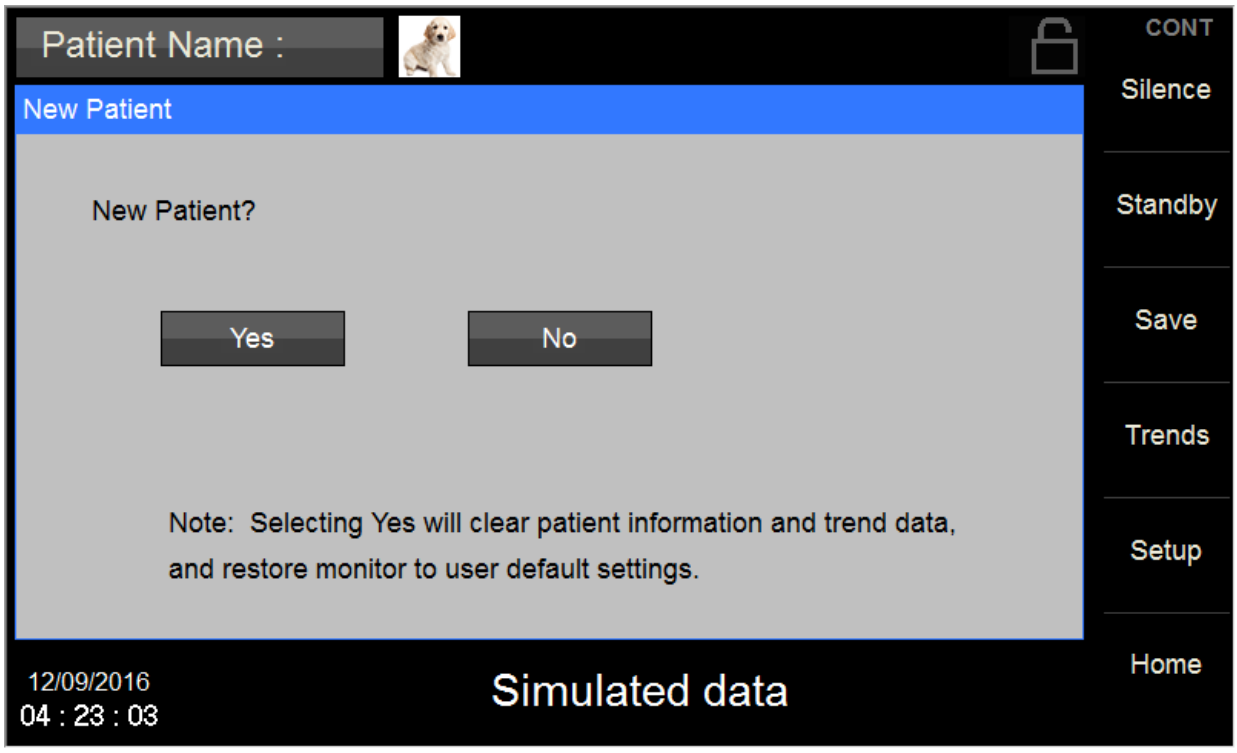


Figure 8: New Patient Question

7.3 Turning the Monitor "Off"

- Press and hold the ON/Off switch on the front panel for two (2) seconds to turn the monitor "Off" (refer to Figure 7).
- The switch is not illuminated when the monitor is turned off.

7.4 Power Up Screen

The *New Patient* Question will appear each time the monitor is power cycled (if configured). This feature is designed to help manage the monitor start-up behavior based on the clinical setting (e.g., Surgical Settings).

To configure the start-up behavior, perform the following to select the **On Power up** choice:

1) Press the **Setup** button
2) Press the **Administrator** button
3) Press the **System** button
4) Enter the required password **986**
5) Set **On Power up** selection to desired choice (refer to Figure 9)

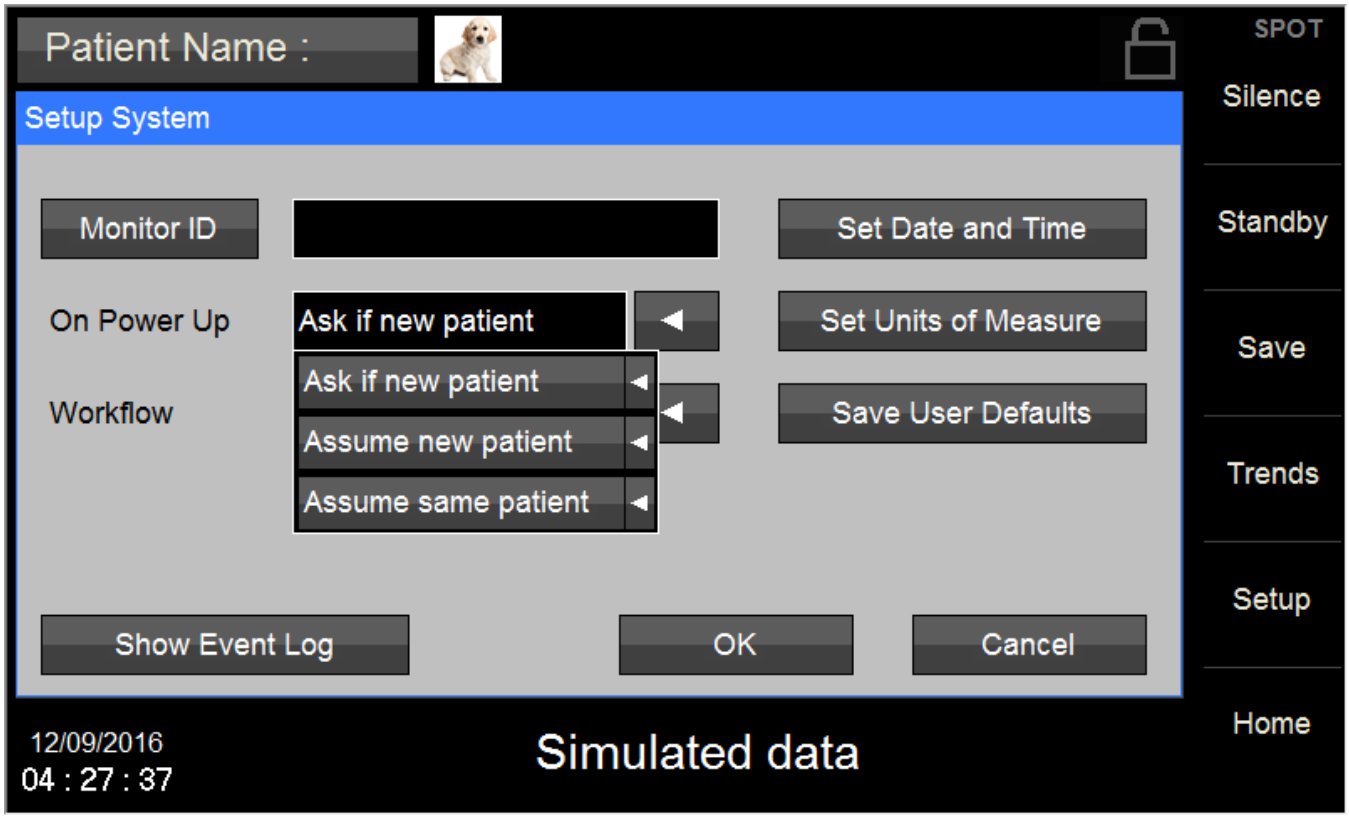


Figure 9: Setup System Menu: On Power Up selection

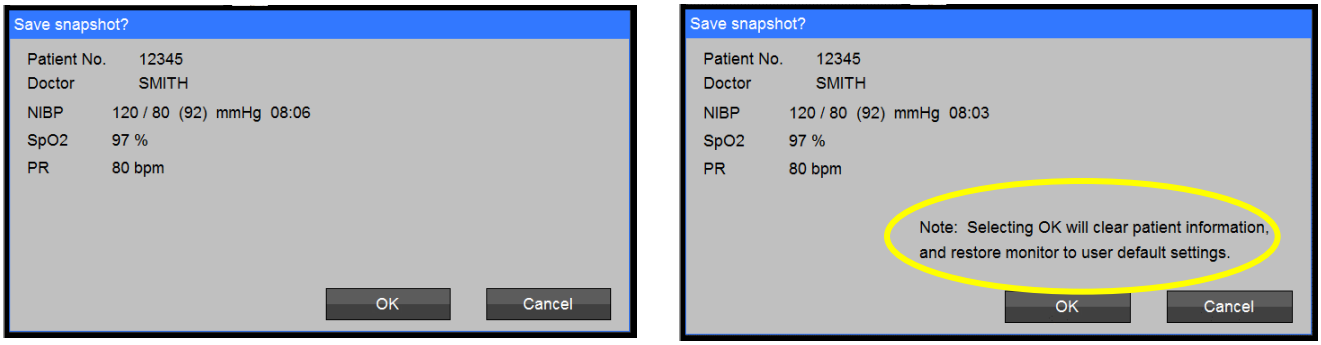
The On Power Up selection has the following choices:

- **Ask if new patient** - Upon power cycle, the user will be prompted with the question New Patient, Yes or No.
    - Selecting **Yes** (New Patient) will clear patient information and trend data and restore the monitor to user default settings
    - Selecting **No** (Same Patient) will maintain settings and limits established prior to turning the monitor Off.
- **Assume new patient** - Upon power cycle, the user will **NOT** be prompted with the question New Patient, Yes or No. This will clear patient information and trend data and restore the monitor to institutional user default settings.
- **Assume same patient** - Upon power cycle, the user will **NOT** be prompted with the question New Patient, Yes or No. The previous patient case shall continue. Data and information regarding that patient data shall be retained and case shall continue.

7.5 Workflow

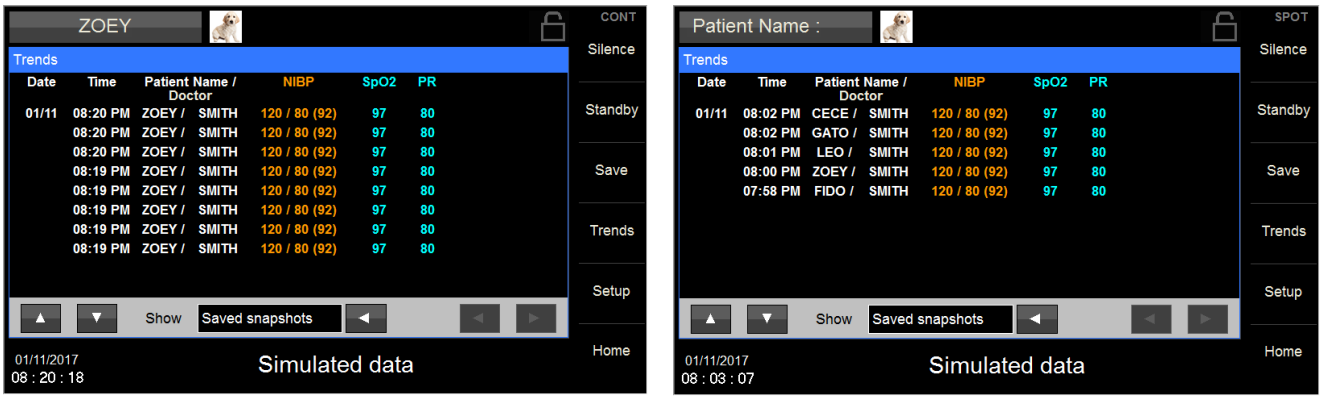
The monitor provides two options for clinical workflow:

- Continuous Monitoring
    - Typically used for taking multiple measurements over time for a single patient
    - If the monitor has been configured for use in Continuous Monitor workflow mode, selecting OK from the “Save Snapshot?” screen will retain all data stored in Trends (Save snapshots and Intervals) (refer to Figure 10).
        - The monitor will retain current settings and alarm limits.
        - A New patient can be entered at any time while in Continuous Monitor workflow mode. The previous patient information will be retained in the Trends with the unique Patient No. (if previously entered) (refer to Figure 11).
- Spot-Check
    - Typically used when operated with numerous patients.
    - If the monitor has been configured for use in Spot-Check workflow mode, selecting OK from the “Save Snapshot?” screen will automatically clear the patient information (including trend data stored as intervals) and restore the monitor to the user established default settings (refer to Figure 10).
        - Individual patient information (No. and physiologic measurements) will be stored in Trends and can be viewed at any time by selecting “Saved snapshot” in the Trends screen (refer to Figure 11)



Continuous Monitoring Mode Spot Check Mode

Figure 10:Save Snapshot Warning Screens



Continuous Monitoring Mode Spot Check Mode

Figure 11:Trend Logs with Patient Information Examples

To configure the workflow mode:

- Press the **Setup** button
- Press the **Administrator** button
- Press the **System** button
- Enter the required password **986**
- Select the desired **Workflow** option (refer to Figure 12)

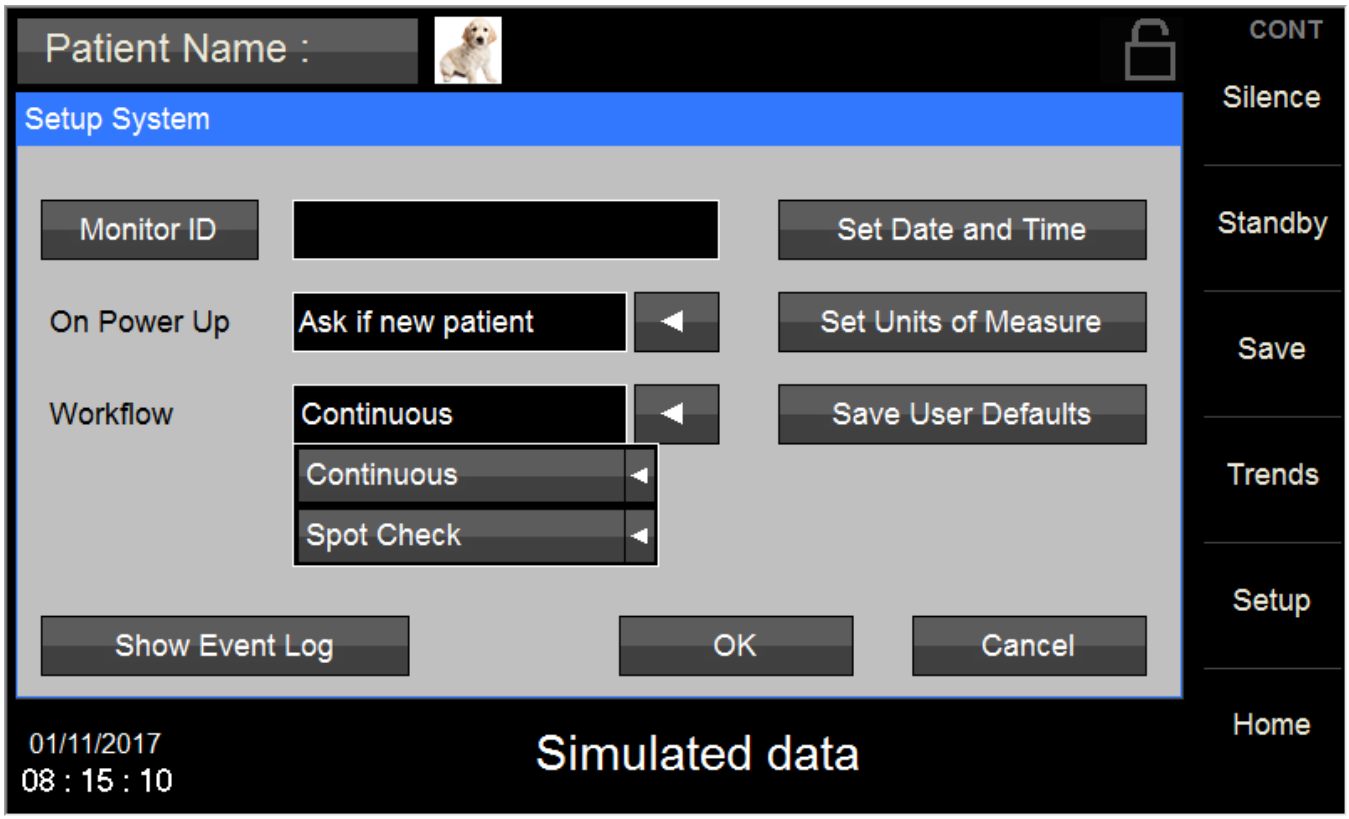


Figure 12: Setup System Menu: Workflow selection location

7.6 Monitor ID Selection

Text entered in this field is used to provide a unique and user-friendly identifying tag for each monitor. This text can optionally be displayed in the area that is reserved for showing either the Clinician ID or the Monitor ID.

7.7 Main Screen Display

The monitor has a large and easy to read numerals, 7” color LCD touchscreen display, one-touch access to parameter alarms, settings and Setup menu, and dedicated parameter fields (refer to Figure 13 below). For monitors equipped with Pulse Oximetry (SpO_2), the display is configurable with or without Plethysmograph (refer to Figure 14).

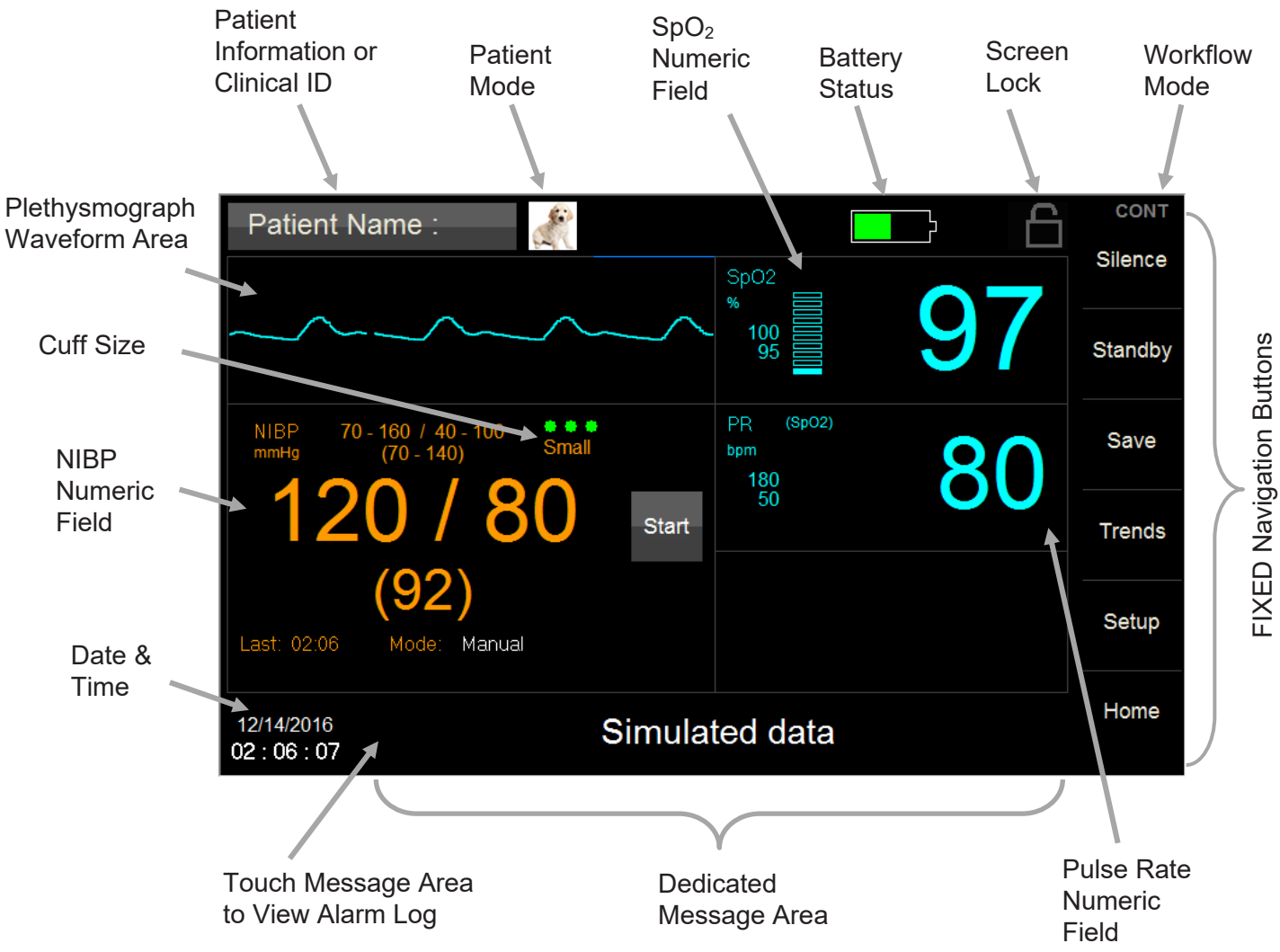


Figure 13: Home Screen Features

User Configurable Main Screen Options

(1) No Plethysmograph

(2) With Plethysmograph

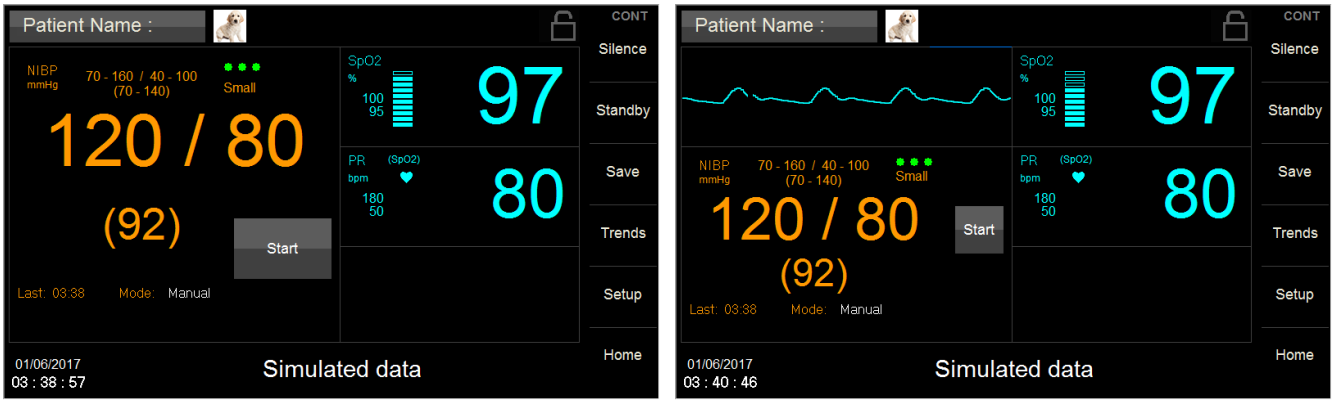


Figure 14: Home Screen Plethysmograph Options

7.7.1 Date and Time

Dedicated area for the display of the current time and date (refer to Figure 15).

Figure 15: Date & Time Example

7.7.2 Screen Lock Icon

Touch the Screen Lock icon to enable or disable the screen lock function.

> ***Note***
> *The Screen Lock password is the date shown on the monitor, e.g. 12102016 (December 10, 2016)*

7.7.3 Patient Mode (Type)

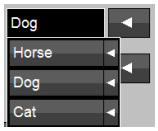
The monitor can accept a range of patient sizes, characterized as modes: *Horse, Dog* and *Cat*. The current patient mode selection is noted on the main screen by a Patient Type image (horse, dog, or cat).

Patient mode selection/changes can be made from either the main screen by touching the Patient Type Icon (as described below) or from the Patient Setup menu found under Setup [Setup/Patient Setup] (refer to Figure 16).

1) Touch Patient Type Icon 

2) With the Patient Setup menu open, press the arrow adjacent to Patient Species to open the drop-down menu.

3) To change the patient type, select the appropriate patient from the drop-down list provided. The selected patient type will appear in the dialog box.



4) Select OK to confirm the selection and close the window. Select Cancel at any time to exit without making a change.

5) When a different patient type is selected a Confirm Patient Type Change window will automatically appear. Determine appropriate action to be taken from the list provided.

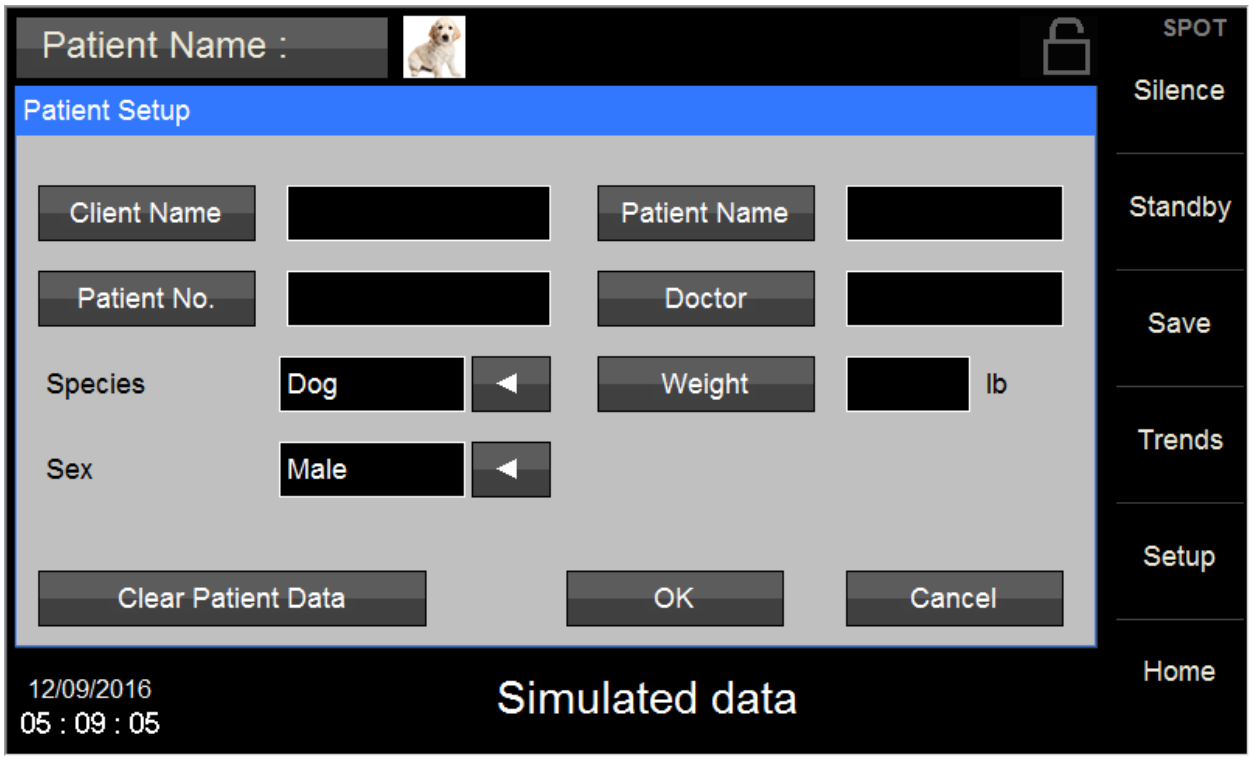


Figure 16: Patient Setup Screen

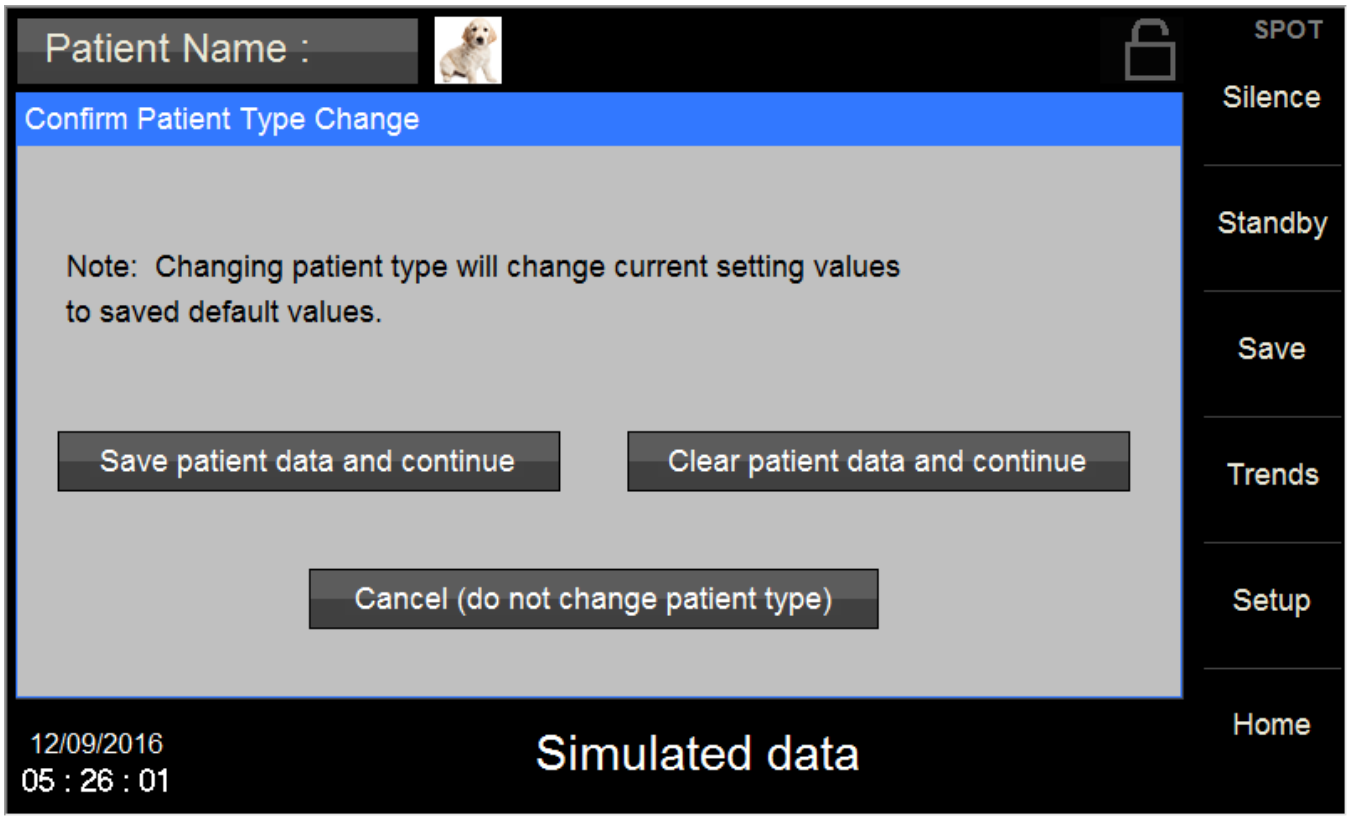


Figure 17: Confirm Patient Mode Change Screen

Caution

Switching modes from Horse, Dog or Cat to any other patient mode, shall recall the last saved values for the patient alarm limits.

Caution

Alarm limits are automatically set based on the patient mode selected.

7.7.4 Patient Information Button

Display of patient information is user configurable. User options may be selected from the Setup / Administrator / Display menu. Options available for the Patient Button Label are outlined in Figure 18.

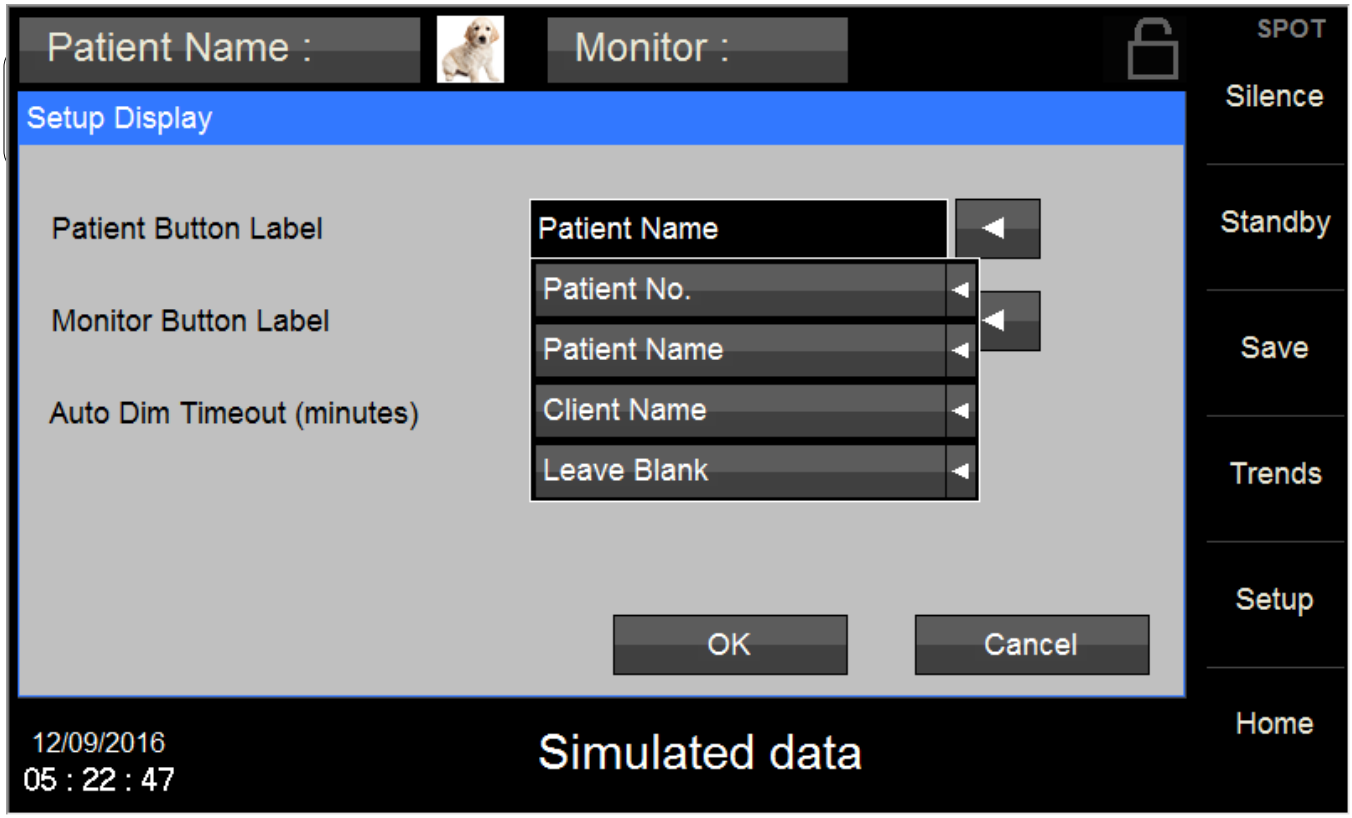


Figure 18: Patient Information Display Options

7.7.5 Clinician Information

Display of clinician information is user configurable. User options may be selected from the Setup / Administrator / Display menu. Display options available for the Monitor Button Label are outlined in Figure 19.

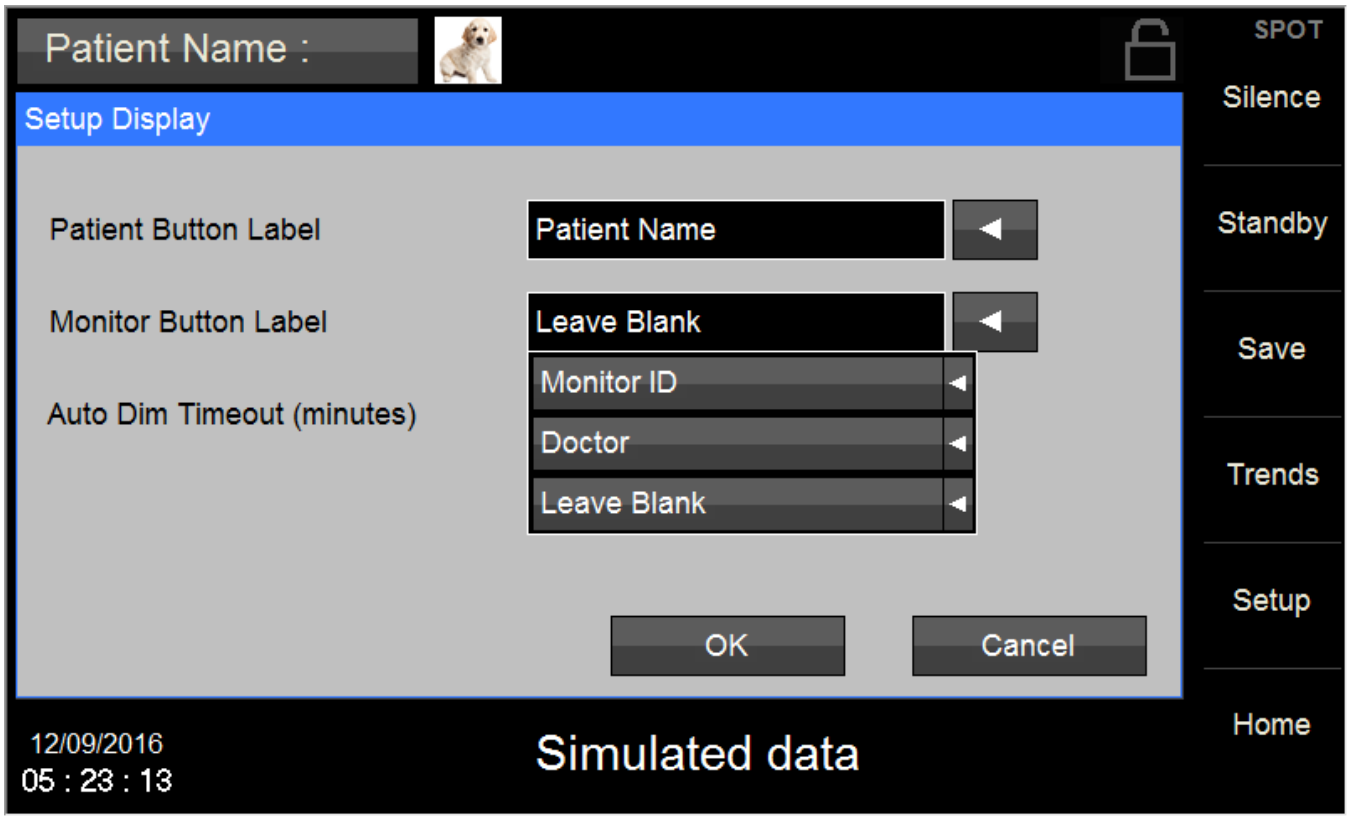


Figure 19: Clinical Information Display Options

7.7.6 NIBP Numeric Field

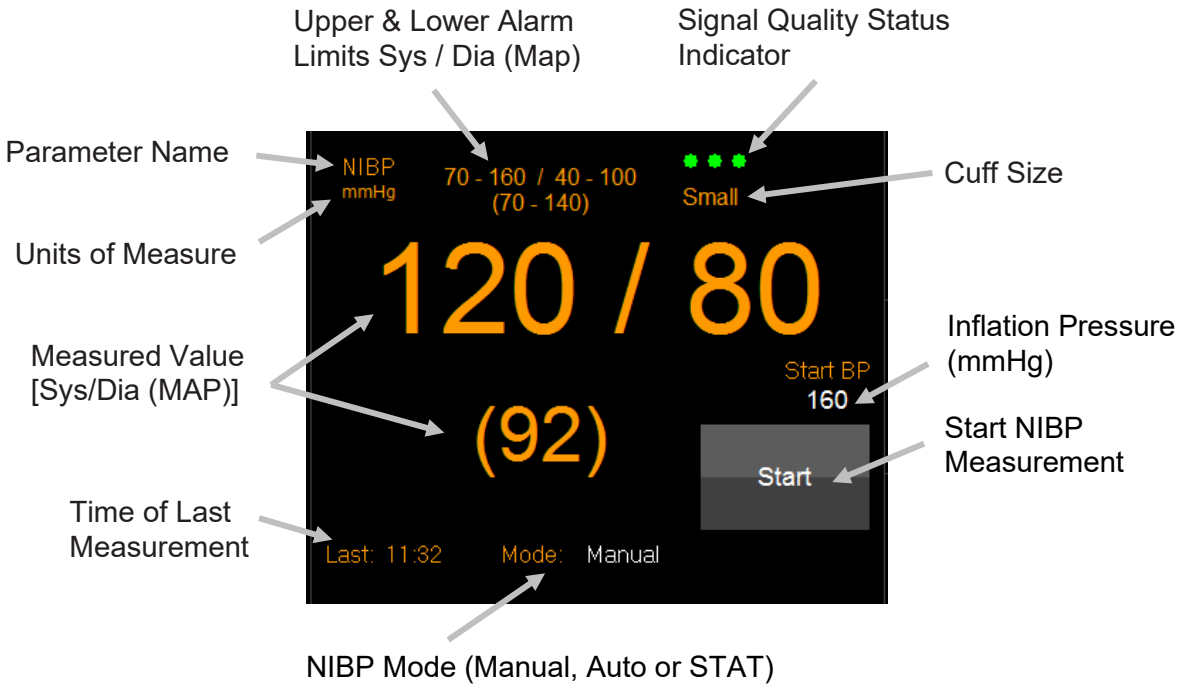


Figure 20: NIBP Numeric Field

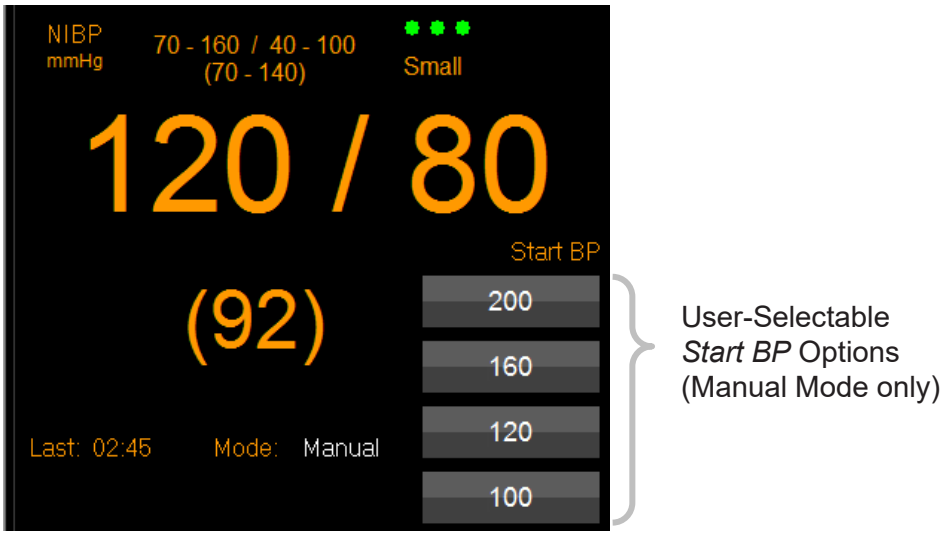


Figure 21: NIBP Numeric Field showing START BP Options

7.7.7 SpO_2 Fields

***For Monitors equipped with SpO_2:**

The appearance of the SpO_2 Numeric field will change depending upon SpO_2 parameter features and options enabled (refer to Figure 22).

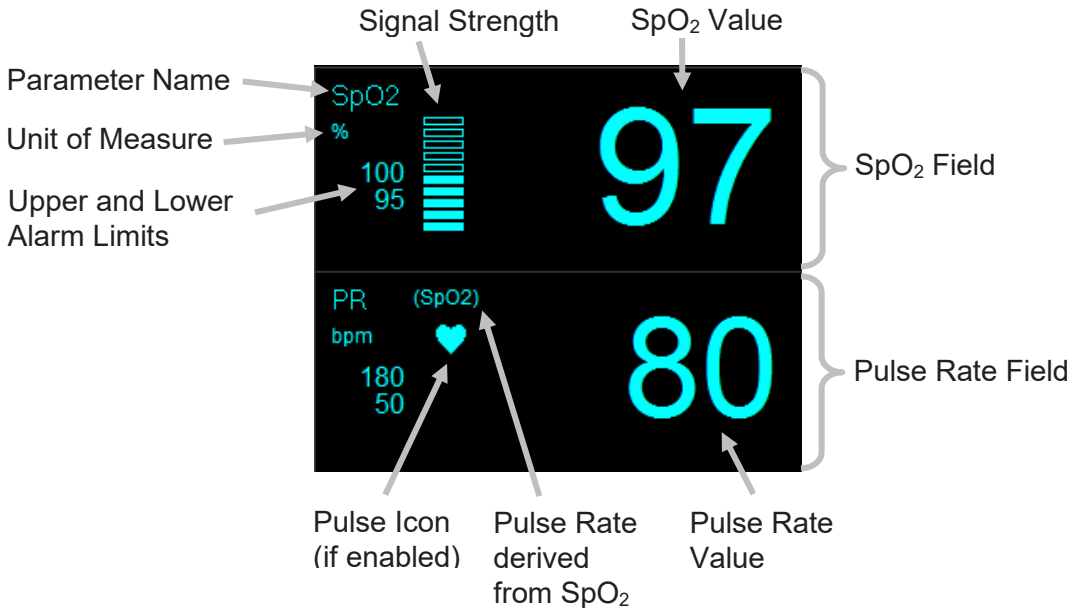


Figure 22: SpO_2 & Pulse Numeric Field Features

7.7.8 Waveforms

***For Monitors equipped with SpO_2:**

Display of the SpO2 / Plethysmograph waveform (Figure 23) is user configurable and may be found under the Setup Home Screen menu (refer to Figure 24). Waveform Sweep Speed can also be configured. In the Setup Waveform menu, use the drop down menu to select the Sweep Speed of Waveform to be displayed on the main screen (refer to Figure 25).

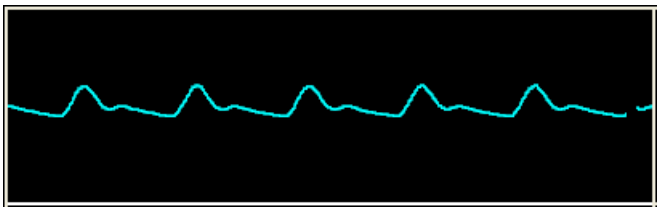


Figure 23: Plethysmograph Waveform

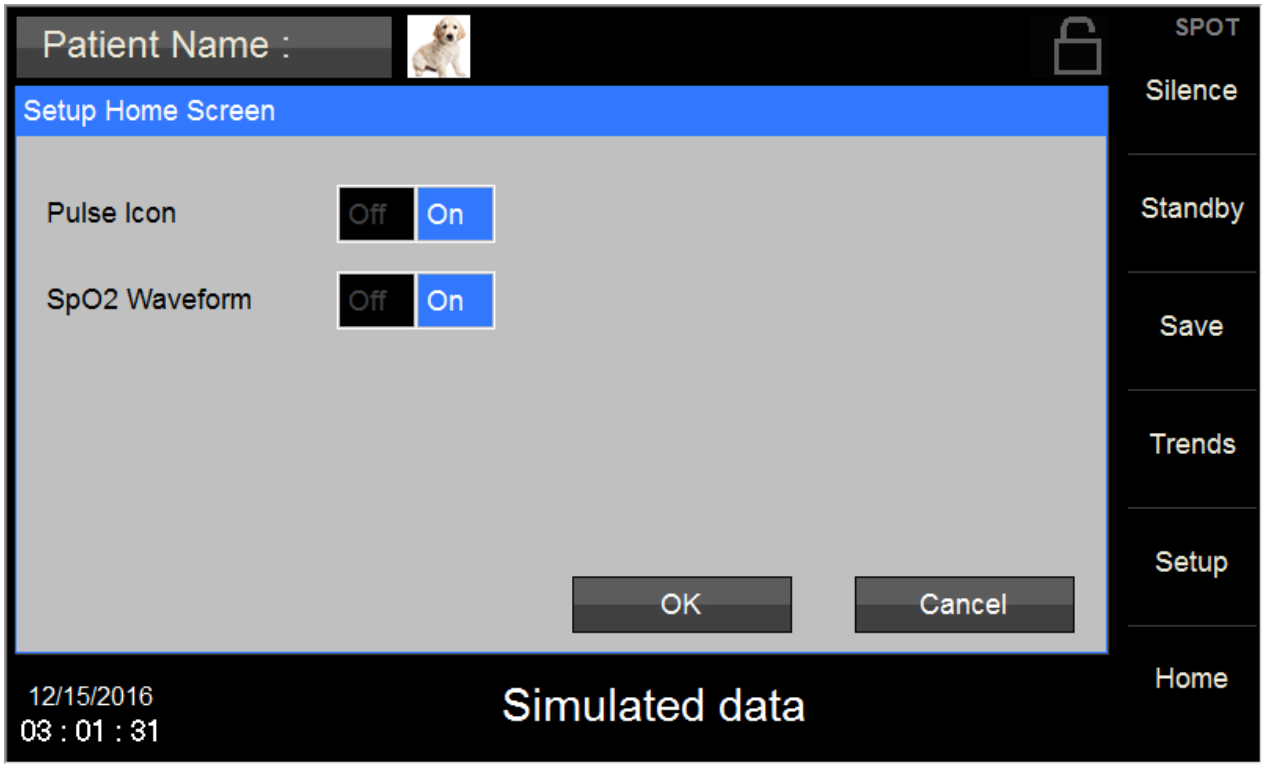


Figure 24: Plethysmograph Display Option

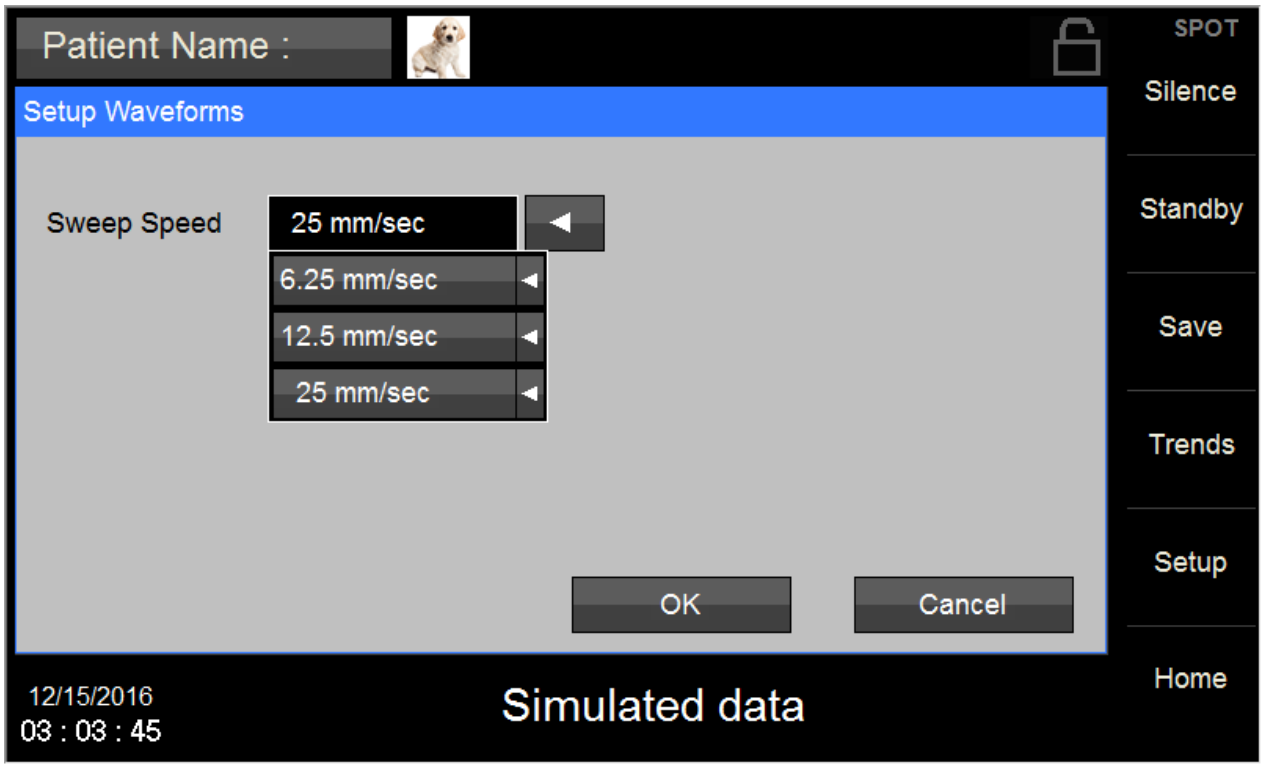


Figure 25: Setup Waveform screen

7.7.8.1 Freezing Waveforms

In some clinical environments, the user may want to freeze the displayed waveforms.

Touching the right side of the waveform area (under the blue line) will cause all displayed waveform to be frozen (refer to Figure 26 - SpO2 waveform frozen).

Only the waveforms are frozen. Numeric values will continue to be updated, and alarm conditions continue to be generated as they occur.

To unfreeze the displayed waveform, perform one of the following:

- Touch the right side of the waveform area again.

OR

- Touch anywhere on the screen that will open a menu (e.g., most buttons, numerals, left side of waveform area)

Touching **Alarm Silence** or **Home** button **will not unfreeze** displayed waveforms

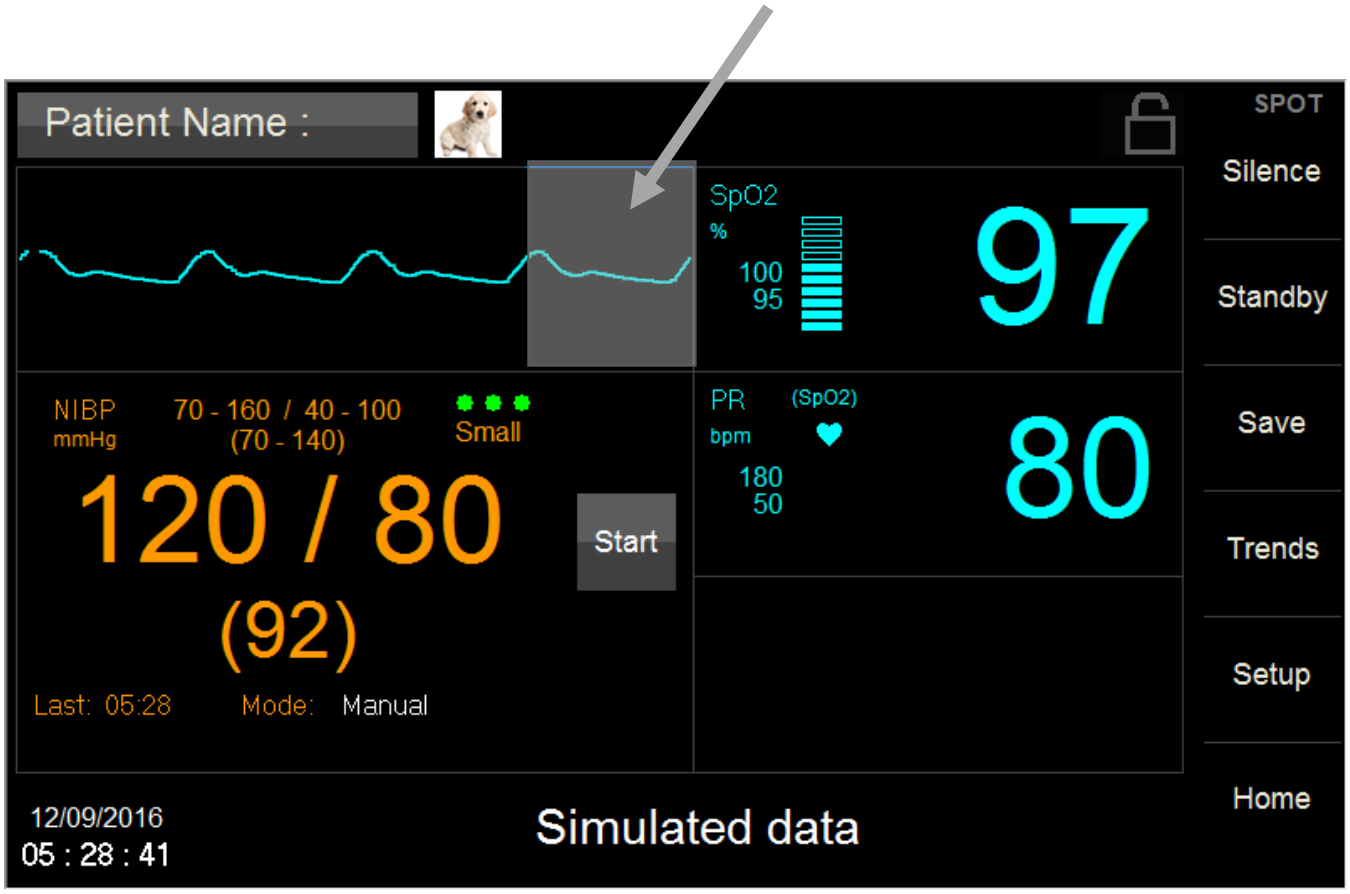


Figure 26: Waveform Frozen - Touch Area is under the blue line

7.8 Alarms and Messages

Alarms are annunciated in the following manner (refer to Figure 27):

- The background of the parameter field changes color and flashes from bright to dim.
- Alarm text is displayed in the dedicated message area.
- The background color of the message area changes and flashes from bright to dim co-incident with the parameter field.
- Touching Silence will pause the audio associated with that alarm (refer to Figure 28).

When a parameter alarm is active, the corresponding text message will be displayed in the monitors message area located at the bottom of the display screen.

If more than one alarm condition of equal priority is active at a given time, the message for each condition alternates within the dedicated message area. Individual alarm messages will appear for 2 to 3 seconds before the next alarm message will appear.

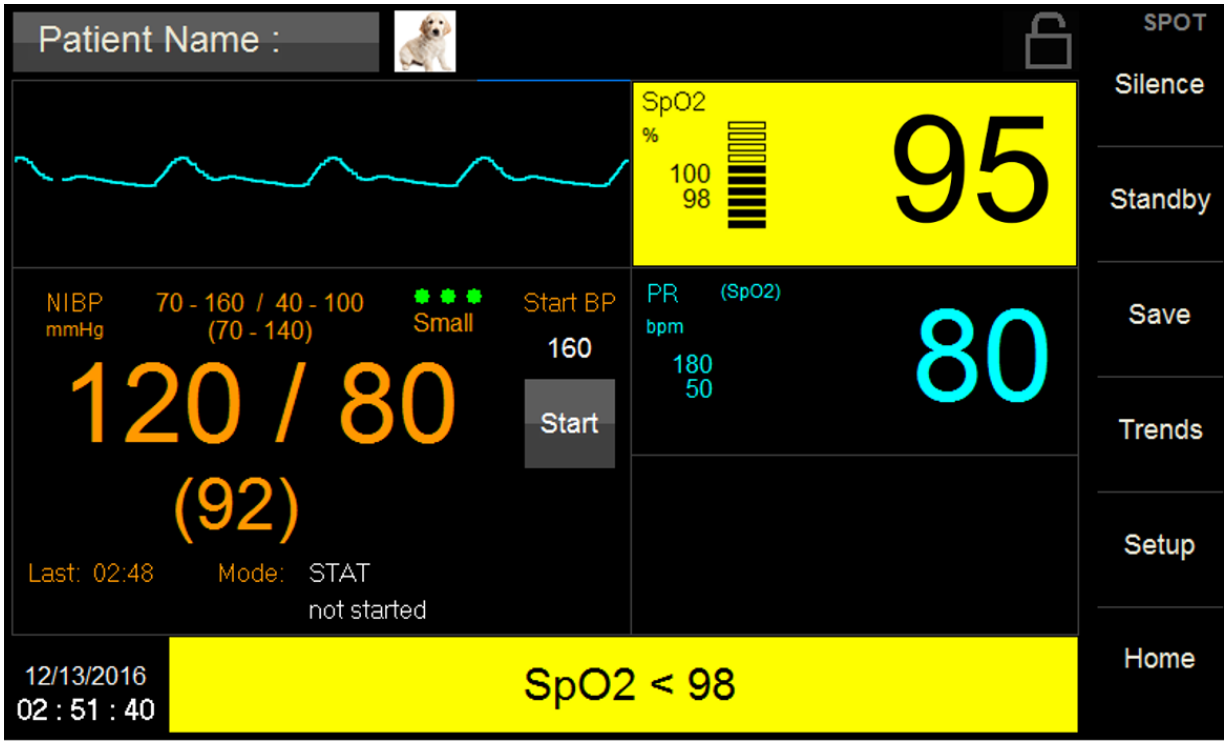


Figure 27: SpO_2 Alarm Example

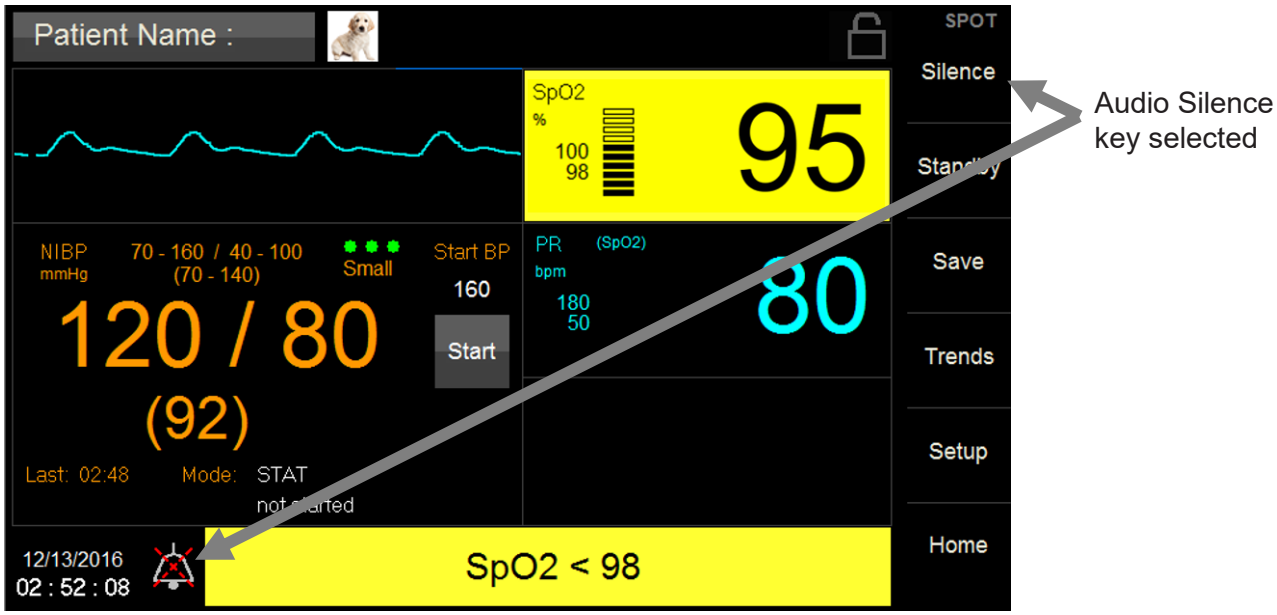


Figure 28: SpO_2 in Alarm, Audio paused

7.8.1 Message Area (Alarms)

The dedicated area for display of patient alarm and system messages will change background colors based on alarm priority.

- Medium Priority Alarm:
  - Medium Priority Alarm ("SpO2 < limit" Example - SpO2 parameter):

SpO2 < 98

- Low Priority Alarm
  - Low Priority Alarm ("Battery low" Example - Equipment):

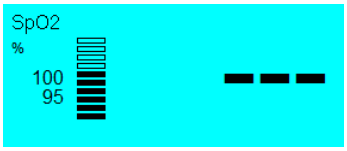
Battery low

> ***Note***
> *During the alarm condition for Medium Priority alarms, the background of the message areas shall alternate in the intensity of their colors: yellow with dark yellow.*

7.8.2 Numeric Area (Alarms)

The Numeric area will change background colors for display of patient alarm.

- Medium Priority Alarm
  - "SpO2 < limit" Example - SpO2 Numeric: The current value is displayed
  - 

- Low Priority Alarm
  - "SpO2 check sensor placement" Example - SpO2 Numeric: The text "---" (3 dashes) shall be displayed
  - 

> **Note**
> *During the alarm condition for Medium Priority alarms, the background of the Numeric areas shall alternate in the intensity of their colors: yellow with dark yellow.*

7.8.3 Alarm Log

The Alarm Log records and displays alarm limit setting changes, Medium priority physiologic alarms, and equipment alarms. The Alarm Log can be viewed at any time by touching the message area located at the bottom of the display screen (refer to Figure 29).

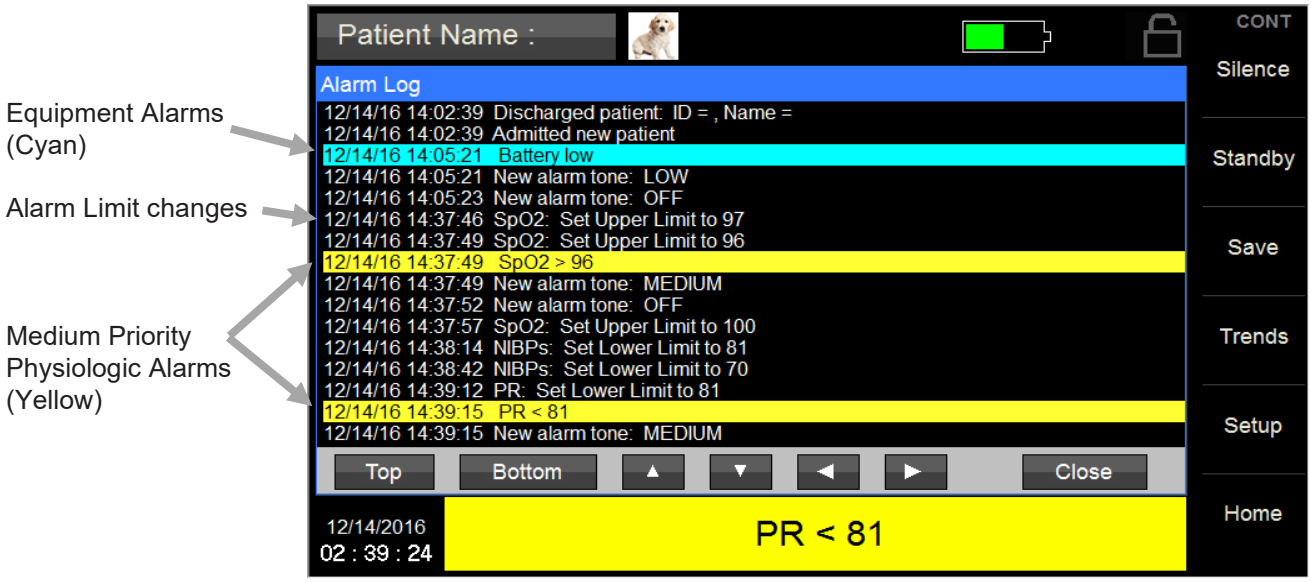


Figure 29: Alarm Log Examples

7.8.4 Audio Silence

When the Audio Silence key is selected, the system will pause the audio and visual alert associated with current alarms for the duration specified under Setup-Administrator-Alarms.

During this period, the background color for the alarming parameter(s) changes to a solid background (indicates Audio Silence has been selected). The audio silenced icon appears in the message area.

When the Audio Silence time period expires, both the audio alert and flashing background will resume if the alarm/condition persists.

7.8.5 Alarm Pause

When the Audio Pause is enabled, all Medium and Low Priority alarms are silenced for the pre-determined time period (set in the Administrator Setup menu). The display is cleared of any flashing parameter fields and the audio is silenced during this period.

- Alarms can be resumed at any time by selecting Alarm Resume found in the Setup window
- When the Audio Paused time period expires, the audio and visual associated with the current alarm will resume

The Alarms Paused feature is typically used to configure the monitor for Spot-Check workflow mode when workflow and patient care does not require continuous alarm management.

Caution
Always follow facility protocols when setting alarms.

7.8.6 Alarm Limits and Settings

Touching an individual parameter field will open a Setup screen to enable the setting of alarm limits or settings specific to that parameter. Setup screens are available for each installed parameter.

7.8.6.1 Setup NIBP Alarms

To access the Setup NIBP screen, touch anywhere within the NIBP numeric area to open the Setup NIBP window.

From the NIBP Setup screen you may set the following:

- Lower and Upper Alarm Limits for Systolic, Diastolic and MAP
- NIBP Mode (Manual, Auto, STAT)
- NIBP Interval (1, 2, 3, 4, 5, 10, 15, 30, 60, or 90 min)
- Cuff Size (Small (SV1-SV5], Large [SV8-SV10])
    - Refer to Section 9.4: Cuff Selection and Application for selecting cuff size and placement
- Start BP Options (No, Yes) determines the Initial Inflation Pressure(s) to start a blood pressure measurement (refer to Figure 30);
    - (Start BP Options) = No. Initial Inflation Pressure, patient mode dependent, next NIBP adaptive, typically used for continuous monitoring
    - (Start BP Options) = Yes. Select from list of Inflation pressures, patient mode dependent, typically used for Spot-Check workflow mode

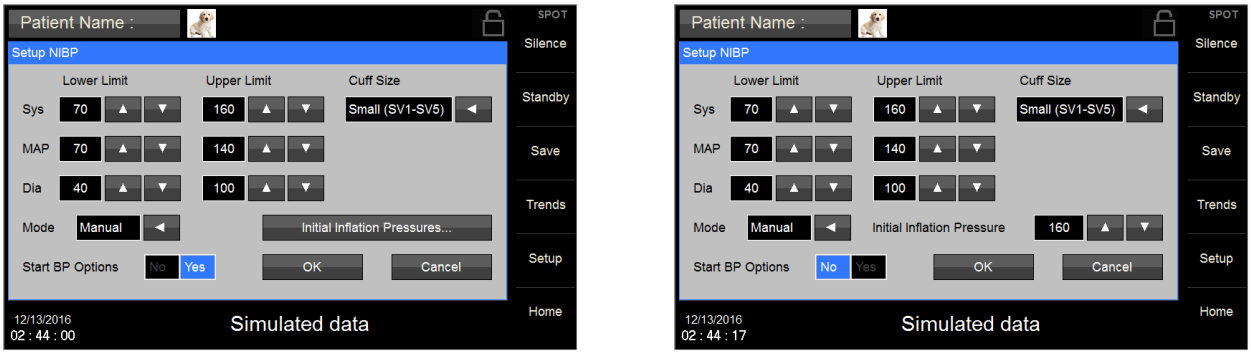


Figure 30: NIBP Setup Screen Options

To change NIBP alarm limits or the Initial Inflation Pressure, use the Up/Down arrows. The adjacent dialog box adjacent will note your current selection.

To change the NIBP Interval from the NIBP Interval drop down menu, select the NIBP Interval. The dialog box will note your current selection.

Select OK to confirm your selection(s) and close the Setup NIBP window and return to the main display screen. Current selections (as applicable) will now appear within the NIBP field. Select Cancel anytime to return to the main display without making any changes.

7.8.6.2 Setup SpO_2 Alarms

To access the Setup SpO_2 screen, touch anywhere within the SpO_2 field to open the Setup SpO_2 window (refer to Figure 31).

From the SpO_2 Setup screen you may set the following:

- Lower and Upper SpO_2 alarm limits
- Response Mode
- SatSeconds

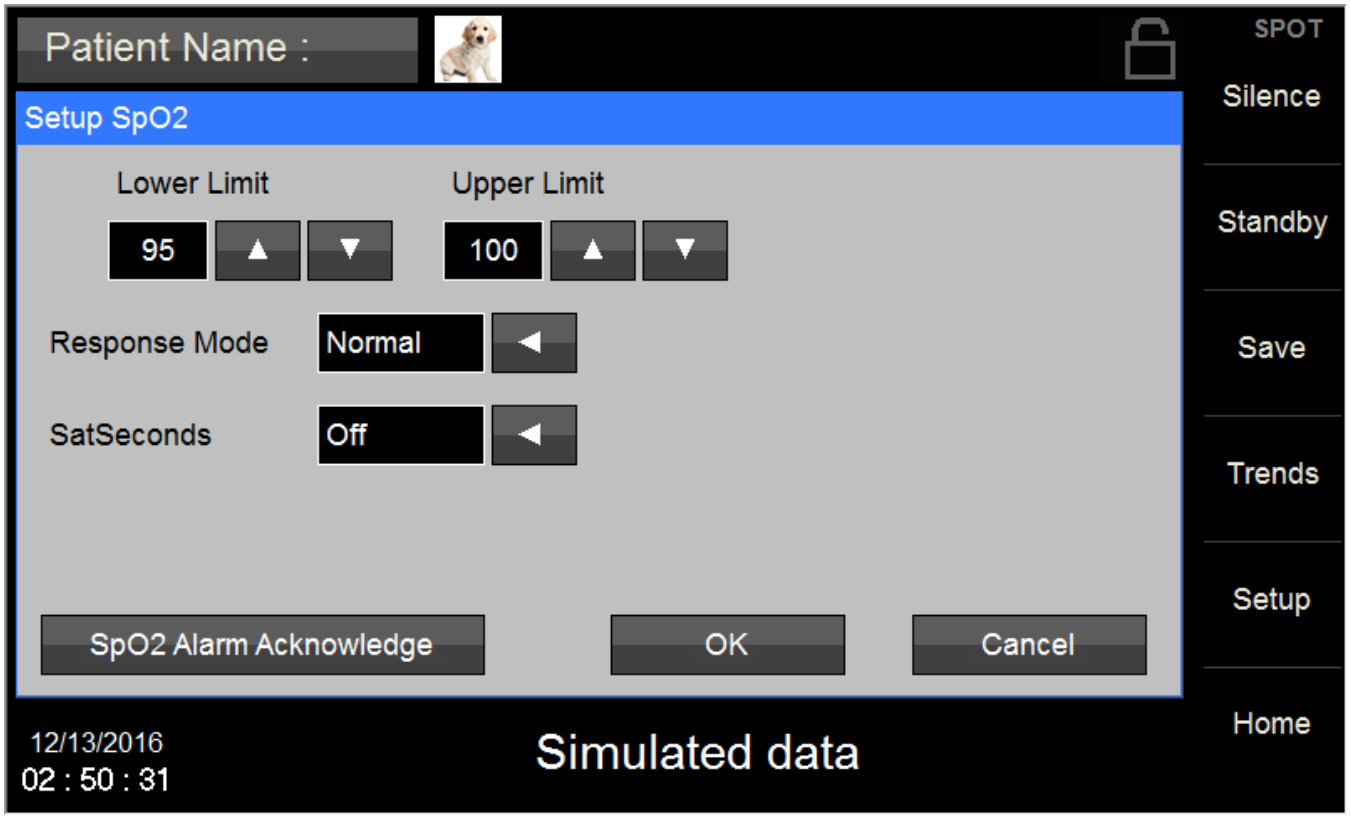


Figure 31: SpO_2 Setup Screen

To change alarm limits, use the Up/Down arrows. The adjacent dialog box adjacent will note your current selection.

Select OK to confirm your selection(s) and close the Setup SpO_2 window and return to the main display screen. Current selections (as applicable) will appear within the SpO_2 field. Select Cancel anytime to return to the main display without making any changes.

Caution

SpO2 Alarm Acknowledge *Selecting this button silences the audible SpO_2 equipment alarm and clears the displayed message (e.g., SpO_2 check sensor placement). It places the SpO_2 in a standby mode (e.g. no further alarms) when the probe is no longer applied to the patient.*

7.8.6.3 Setup PR (Pulse Rate) Alarms

To access the Setup PR screen, touch anywhere within the PR field to open the Setup PR window (refer to Figure 32).

From the PR Setup screen, you may set the following:

- Lower and Upper PR alarm limits
- Beat Volume (1-10)
- Beat Sound
- Pulse Icon

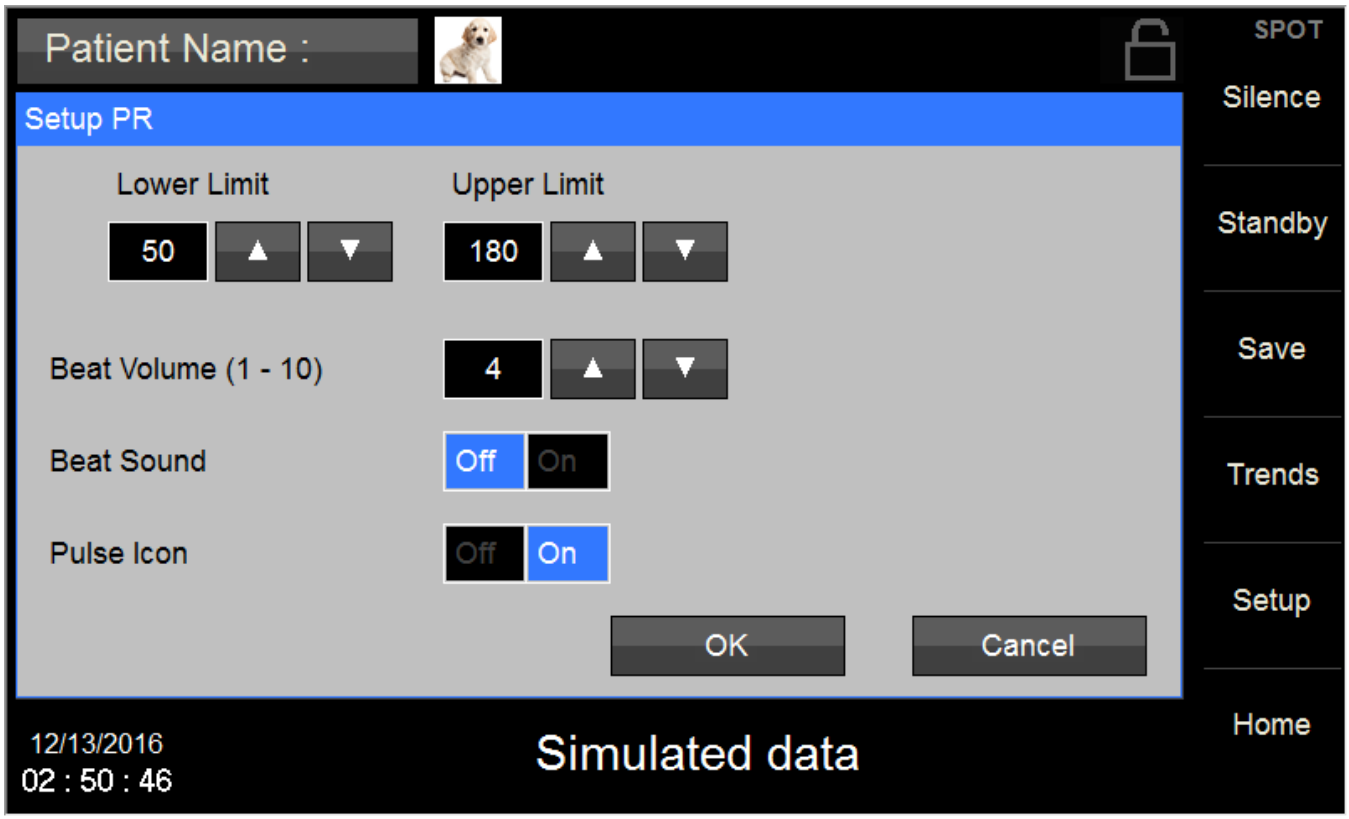


Figure 32: PR Setup Screen

To change alarm limits, use the Up/Down arrows. The adjacent dialog box adjacent will note your current selection.

Select OK to confirm your selection(s) and close the Setup PR window and return to the main display screen. Current selections (as applicable) will now appear within the PR field. Select Cancel anytime to return to the main display without making any changes.

7.8.7 Audible and Visual Indicators

The monitor can produce both an audible and a visual indicator for a variety of monitor conditions. Table 2 provides a cross reference for audible and visual indications.

Table 2: Audible and Visual Indicators

Audible Indication	**Priority Level**	**Alarm Condition**
Three, high-pitch, chime tones separated by approx. 15 second intervals	Medium	Physiological parameter limit violation
A single tone, lower pitch, chime tone separated by approx. 20 second interval	Low	Technical condition that prevents monitoring (e.g., check sensor placement)
Continuous tone	Battery Nearly Depleted	
Visual Indicator Color	**Priority Level**	**Alarm Condition**
Yellow Flashing background (physiologic parameter)	Medium	Alarm is active and has not been acknowledged
Yellow Solid Background (physiologic parameter)	Medium	Alarm is currently active and has been "Silenced"
Cyan Non-Flashing	Low	Alarm is currently active and has not been acknowledged
Black background (parameter field and message window)	No Active Alarm	Normal - No alarm

Equipment Alert

Refer to Table 3 for messages that may be displayed in the Numeric fields.

7.9 Error Messages on the Display

Table 3: Error Messages on the Display

Message	Parameter Value	Possible Cause	Suggested Action
System Messages			
Battery Low	N/A	Battery is running low (5 minutes left)	Connect monitor to mains power
Battery Nearly Depleted	N/A	Battery is almost depleted and will shut down in 60 seconds if not connected to mains	Connect monitor to mains power
Monitor problem detected	N/A	Internal problem has been detected	Turn the monitor off, then on. If message persists, contact Midmark.
NIBP Messages			
NIBP weak signal	---	Poor limb perfusion Improper cuff placement Cuff size too large for the patient	Check the patient and provide any necessary clinical care Check to make sure the cuff is wrapped properly Check the limb circumference against the recommended range as printed on the cuff, to ensure the cuff is not too big
NIBP artifact	---	Persistent patient movement (e.g. trembling or panting) Hemodynamic interference (varying pulse amplitudes due to breathing or valvular problem) Hose is clogged or leaking	Check the patient and provide any necessary clinical care Calm the patient Move the cuff to another limb with less movement If no obvious patient motion, switching to the other limb may still help in the case of hemodynamic interference Check the cuff and hose for signs of damage
NIBP cuff leak	---	Leaky cuff or hose Cuff not applied to patient	Check for leaks in the cuff or hose and replace if necessary Check that cuff and hose are connected to the monitor Check that cuff is applied to patient
NIBP blocked hose -- check patient	---	Pinched Hose	Check the patient and ensure that the cuff is deflated Check for kinks or obstructions in the hose Replace hose if necessary

Message	Parameter Value	Possible Cause	Suggested Action
NIBP measurement time exceeded	---	The measurement time limit was exceeded, usually due to motion artifact – 120 seconds	Refer to suggestions for “NIBP artifact” Repeat the measurement
NIBP problem detected	---	A hardware problem has been detected	Check the patient and ensure that the cuff is deflated Turn the monitor off, then on If message persists, contact Midmark.
NIBP cannot measure	---	Initial inflation pressure may not have been high enough (if patient’s systolic pressure is above 200 mmHg) Patient movement	Repeat the measurement (monitor will automatically adjust to using a higher initial inflation pressure if needed)
NIBPs < [lower limit]	[number]	The patient's systolic pressure has fallen below the current lower alarm limit	Check the patient and provide any necessary clinical care Change the alarm limit if it is no longer clinically appropriate
NIBPs > [upper limit]	[number]	The patient's systolic pressure has risen above the current upper alarm limit	Check the patient and provide any necessary clinical care Change the alarm limit if it is no longer clinically appropriate
NIBPd < [lower limit]	[number]	The patient's diastolic pressure has fallen below the current lower alarm limit	Check the patient and provide any necessary clinical care Change the alarm limit if it is no longer clinically appropriate
NIBPd > [upper limit]	[number]	The patient's diastolic pressure has risen above the current upper alarm limit	Check the patient and provide any necessary clinical care Change the alarm limit if it is no longer clinically appropriate
NIBPm < [lower limit]	[number]	The patient's mean pressure has fallen below the current lower alarm limit	Check the patient and provide any necessary clinical care Change the alarm limit if it is no longer clinically appropriate
NIBPm > [upper limit]	[number]	The patient's mean pressure has risen above the current upper alarm limit	Check the patient and provide any necessary clinical care Change the alarm limit if it is no longer clinically appropriate

Message	Parameter Value	Possible Cause	Suggested Action
Pulse Rate Messages			
PR < [lower limit]	[number]	The patient's pulse rate has fallen below the current lower alarm limit	Check the patient and provide any necessary clinical care Change the alarm limit if it is no longer clinically appropriate
PR > [upper limit]	[number]	The patient's pulse rate has risen above the current upper alarm limit	Check the patient and provide any necessary clinical care Change the alarm limit if it is no longer clinically appropriate
SpO_2 Messages			
SpO_2 check sensor	---	Bad SpO2 sensor Incorrect device configuration	Replace the SpO_2 sensor Contact Midmark
SpO_2 check sensor placement	---	Sensor has become detached from patient Sensor not fully inserted on patient's site Excessive ambient light Bad sensor (no red light coming from sensor)	Check to make sure the sensor is attached fully and securely to the patient Cover the sensor with opaque material, such as a towel, to reduce ambient light Reattach the sensor on a smaller or larger site Replace sensor if there is no red light coming from it
SpO_2 low perfusion	[number] or ---	Poor perfusion Large tissue mass Bad SpO_2 sensor	Check the patient and provide any necessary clinical care Warm the patient's extremities if needed Reattach the sensor on a smaller site Replace the SpO_2 sensor
SpO_2 unplugged	[blank]	SpO_2 sensor not connected to SpO_2 cable	Check to make sure the SpO_2 sensor is securely connected to the SpO_2 cable on the monitor
SpO_2 artifact	---	Patient movement Hemodynamic interference Small tissue mass	Calm the patient Reattach the sensor on another site with less movement Reattach the sensor on a larger site
SpO_2 problem detected	---	A hardware problem has been detected	Turn the monitor off, then on. If message persists, contact Midmark

Message	Parameter Value	Possible Cause	Suggested Action
SpO_2 < [lower limit]	[number]	The patient's oxygen saturation has fallen below the current lower alarm limit	Check the patient and provide any necessary clinical care Change the alarm limit if it is no longer clinically appropriate
SpO_2 > [upper limit]	[number]	The patient's oxygen saturation has risen above the current upper alarm limit	Check the patient and provide any necessary clinical care Change the alarm limit if it is no longer clinically appropriate
PR < [lower limit]	[number]	The patient's pulse rate has fallen below the current lower alarm limit	Check the patient and provide any necessary clinical care Change the alarm limit if it is no longer clinically appropriate
PR > [upper limit]	[number]	The patient's pulse rate has risen above the current upper alarm limit	Check the patient and provide any necessary clinical care Change the alarm limit if it is no longer clinically appropriate

8. Menu Setup

The Setup section allows you to review monitor information and configure it to your patient and institutional requirements.

8.1 Entering the Setup Menu

To enter the monitor's Setup Menu, press the **Setup** touch area located on the main screen (refer to Figure 33).

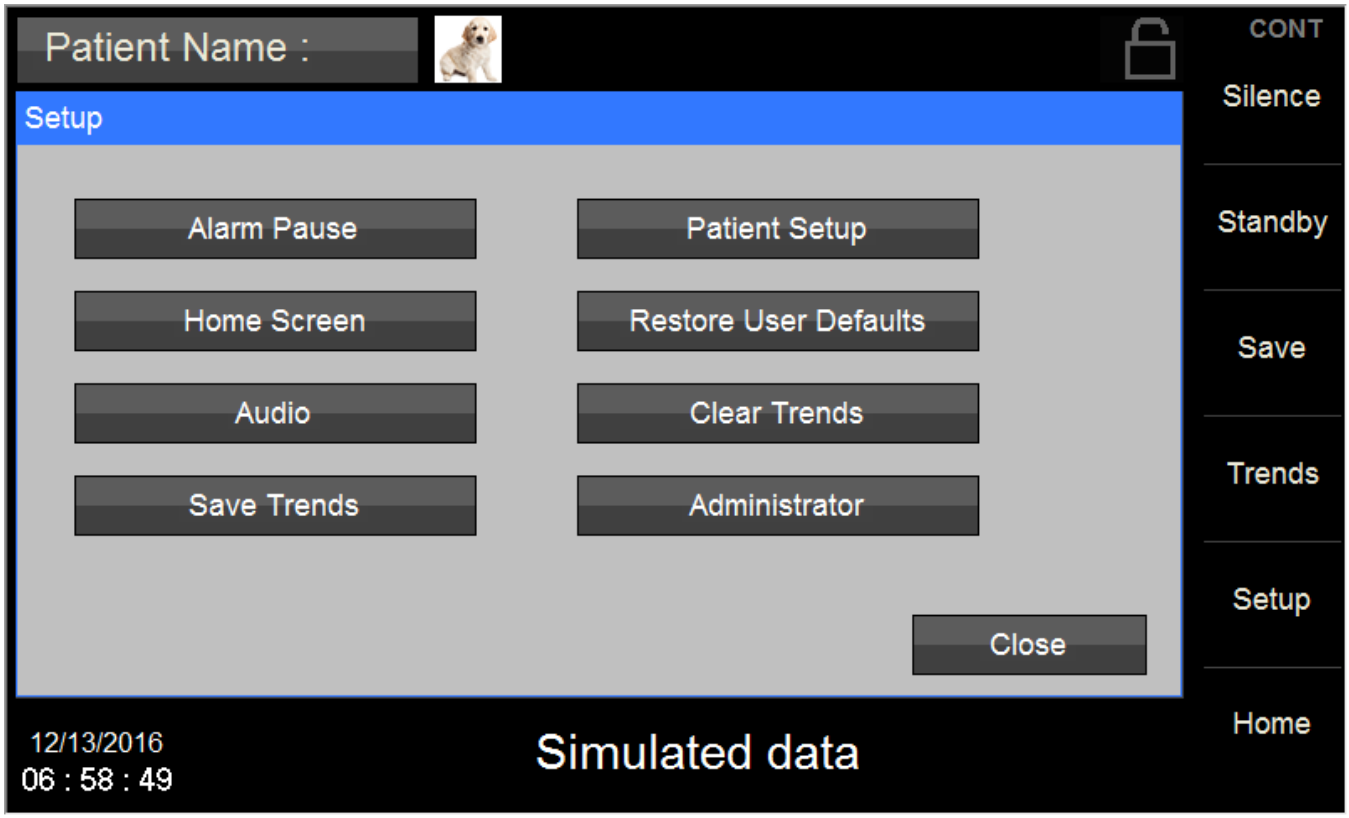


Figure 33: Setup Menu Screen (8015 shown)

8.2 Alarm Pause

- Press the Alarm Pause key to pause all Alarms (Global) (refer to Figure 34).
    - When Alarm Pause has been enabled, a countdown timer will be displayed along with the message Alarms Paused in a yellow background. The Alarms Paused Icon is adjacent to the monitor date/time.
- Press the Alarm Resume key at any time to quit and return to active monitoring.

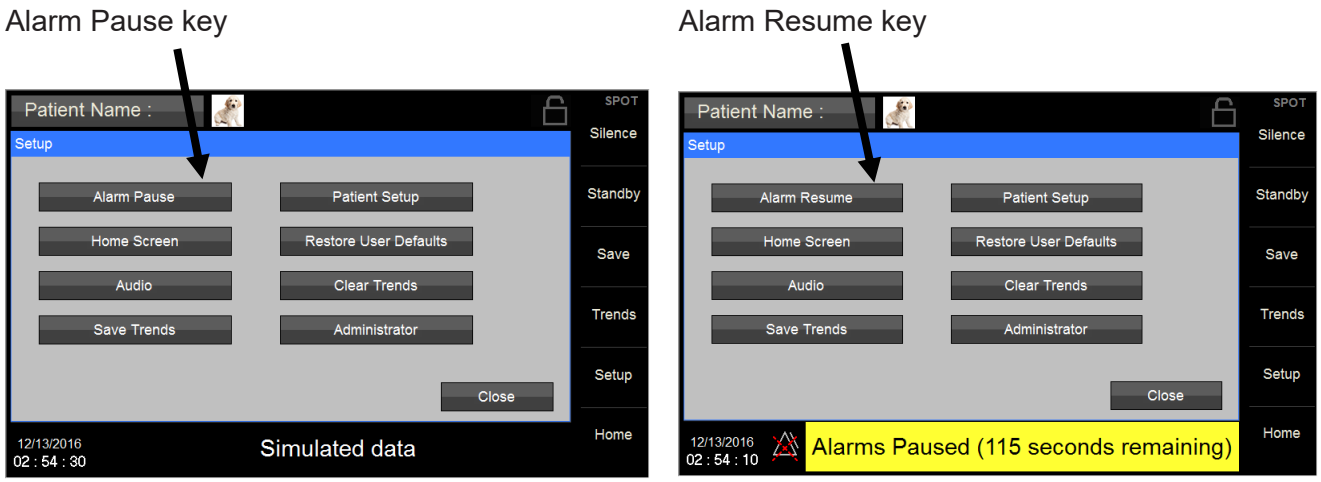


Figure 34: Alarm Pause / Alarm Resume Screens (8015 shown)

> ***Note***
> *The duration the Alarm Pause may be configured in Setup-Administrator-Alarms (refer to Section 8.8.1 Alarms).*

8.3 Audio

Provides the ability to manage loudness and touch screen navigation sounds (refer to Figure 35).

- Alarm Volume
  - Monitor alarm volume
  - Range 1-10, Default 6
- Beat Volume (8015 only)
  - SpO_2 pulse tone volume
  - Range 1-10, Default 4
- Beat Sound (8015 only)
  - Enable or disable SpO_2 pulse tone
  - Settings: Off, On; Default On
- Touch Click
  - Provides user with touch key audio feedback
  - When enabled, an audio response is generated when any active area, button, or key is selected on the monitor display
  - Settings: Off, On; Default Off

Figure 35: Setup Audio Screen (8015 model shown)

8.4 Save Trends

If a USB stick is inserted at the time this button is pressed, the monitor creates a file on the USB stick with the name *"PATIENT NAME(S)_Trend_YYYY_MMDD_HHMMSS.csv*" (where YYYYMMDD_HHMMSS represents the current date and time). You can then remove the USB stick and open the .csv file using Excel or a similar program.

8.5 Patient Setup

8.5.1 Patient Information

1) Enter the Patient Setup menu (refer to Figure 33) to enter Patient Information.
2) Client Name, Patient Name, Patient No., and Weight buttons will present a keyboard for data entry
3) Use the drop down menus to enter patient specific information (refer to Figure 36).
4) Use the keyboard (refer to Figure 37) to enter patient specific information.
5) Select OK to confirm and exit window.

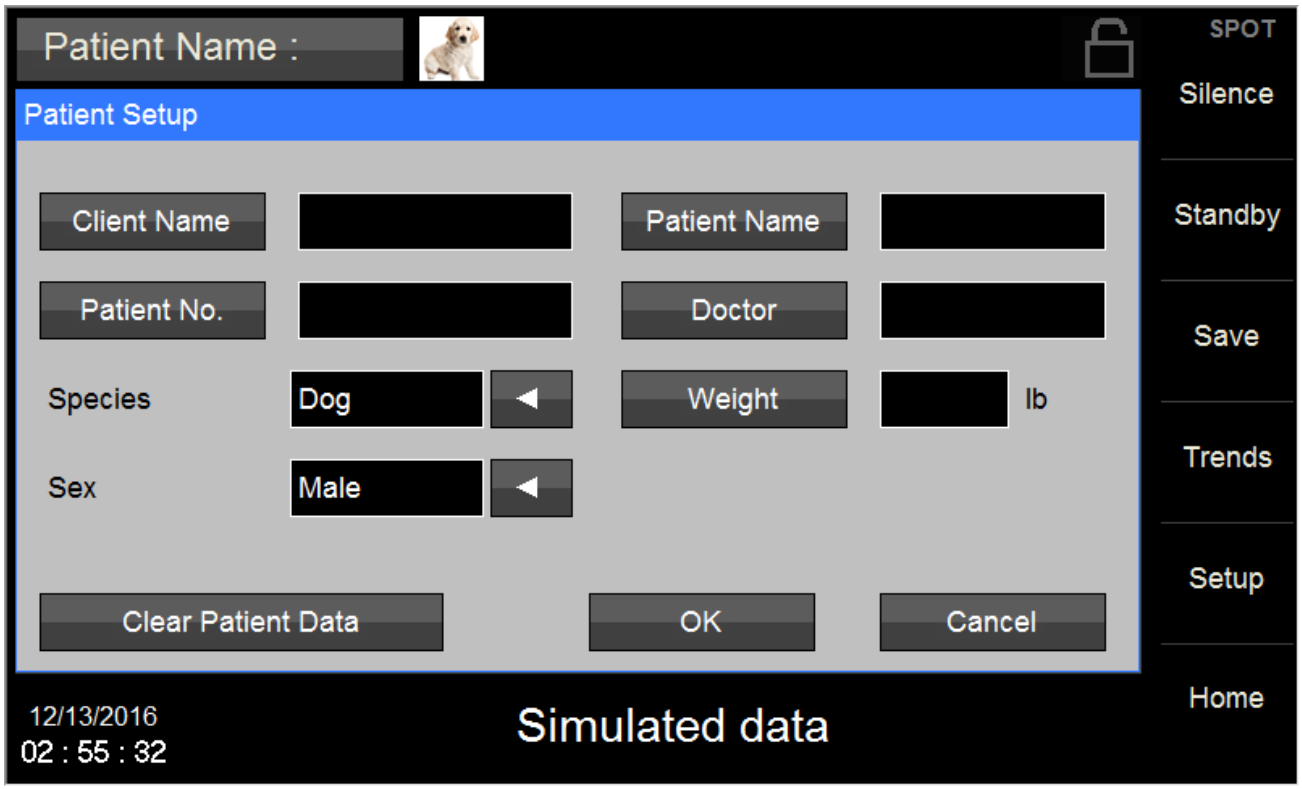


Figure 36: Patient Information Screen

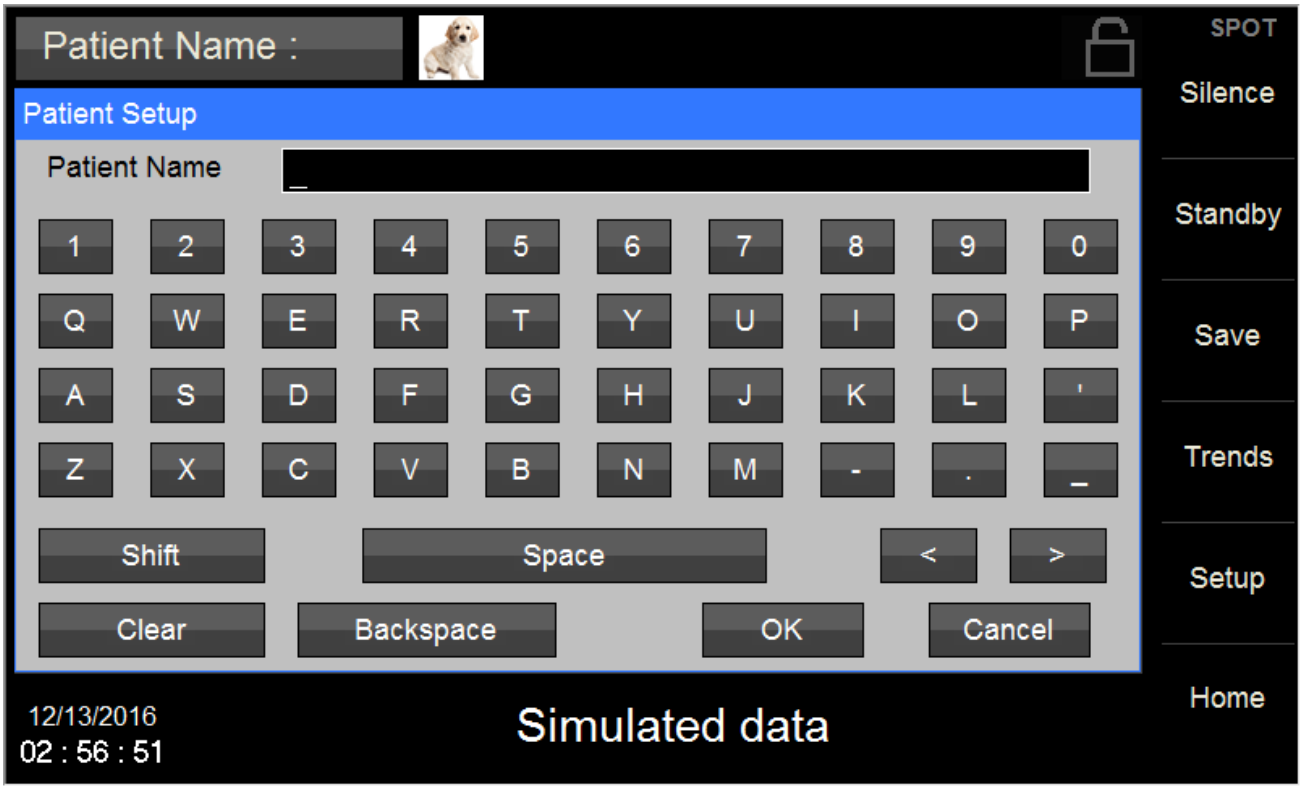


Figure 37: Keyboard for information entry

8.5.2 Clinician Information

1) Use the Patient Setup menu to enter clinician information (e.g. Doctor name) (refer to Figure 36).
2) Use the keyboard (refer to Figure 38) to enter Clinician specific information.
3) Select OK to confirm and exit window.

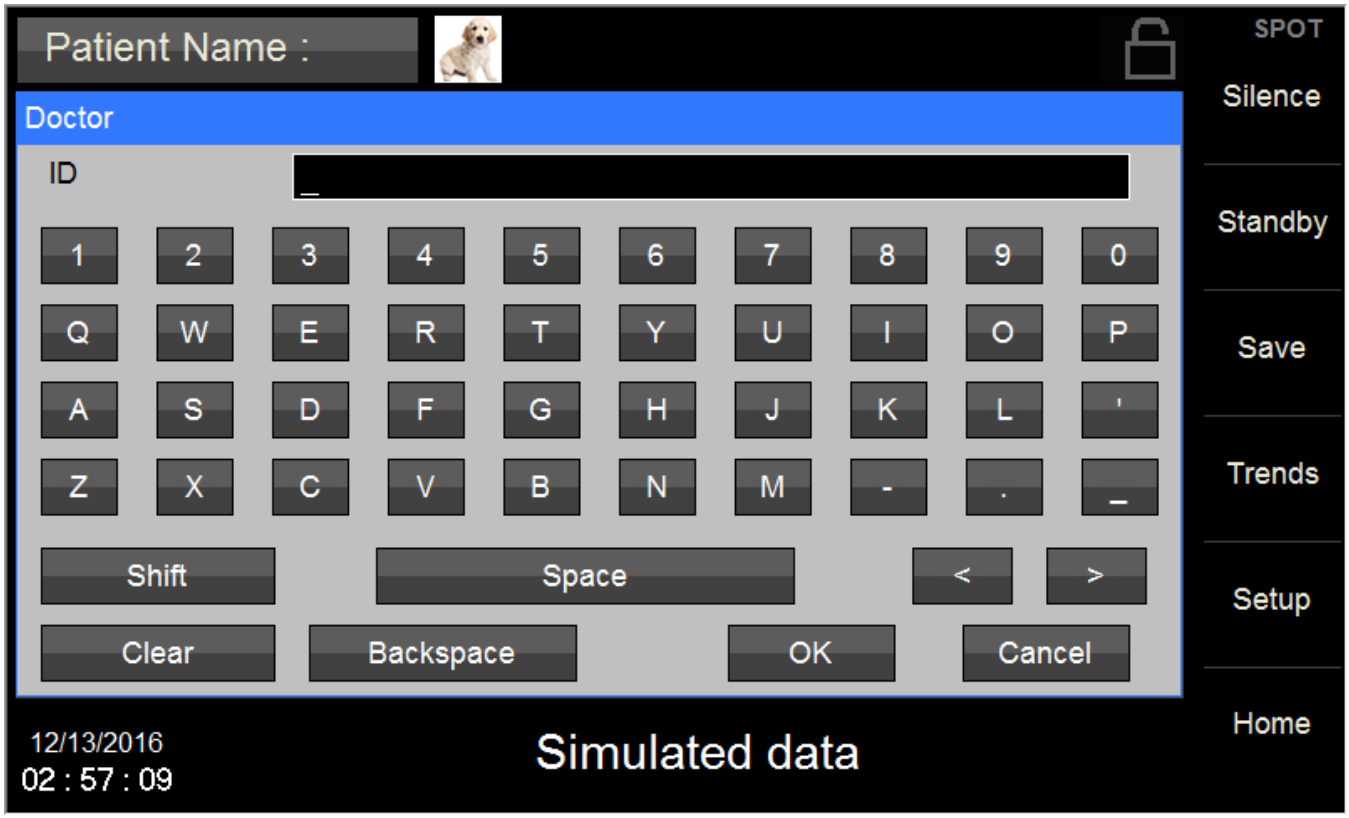


Figure 38: Enter Clinician Information Screen

8.6 Restore User Defaults

During clinical practice, the User Default may be changed to match patient monitoring needs; the monitor may be reverted (restored) to the previously Saved User Default at any time.

Follow these steps to Restore User Defaults:

1) Select Setup/Restore User Defaults.
2) Press Restore User Defaults to restore the default values (refer to Figure 39).
3) Select OK to Restore User Default Setup.
4) “Setup Restored” will appear in the message area of the monitor confirming the Defaults have been restored. Select Cancel to exit without making a change.

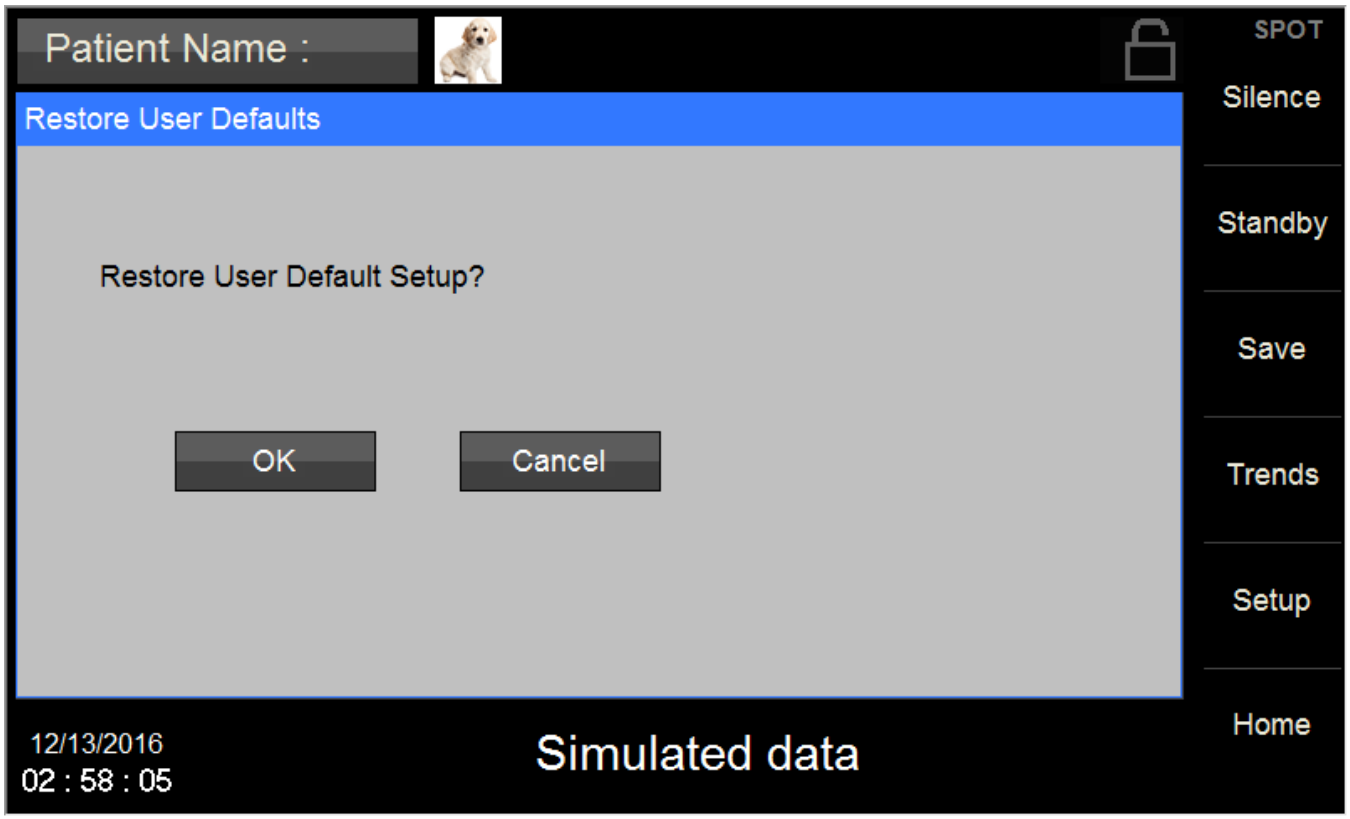


Figure 39: Restore User Defaults Screen

> ***Caution***
> *Restoring User Defaults automatically restores the default Alarm Volume.*

8.7 Clear Trends

Select Clear Trends to clear all the trend data stored in the device. The monitor will prompt you to confirm this selection, to avoid doing it accidentally.

8.8 Administrator

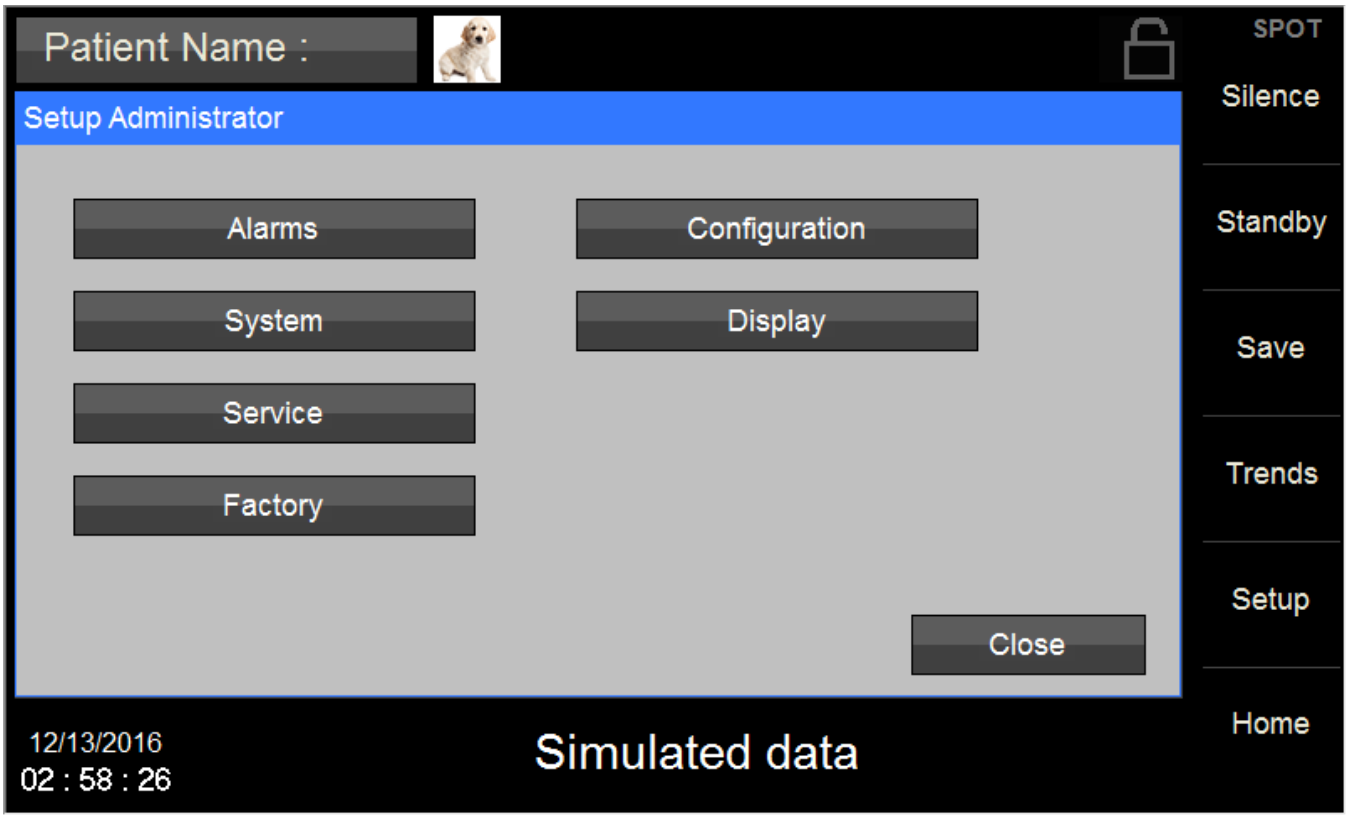


Figure 40: Setup Administrator Menu

8.8.1 Alarms

The Alarms menu is password protected. This menu is accessed to establish global/ and institutional type alarm settings and monitor features.

To enter the Setup Alarms screen, touch [Setup/Administrator/Alarms]. Use the keyboard to enter the password 986.

- Enter the Setup Alarms window (refer to Figure 41) to configure the following global alarms:
    - Alarm Silence Time, Alarm Pause Time, Second Speaker Time

Use the arrows and drop-down menus to make selections. Selection(s) will appear in the dialog box. Select OK to confirm your selection and return to the prior screen.

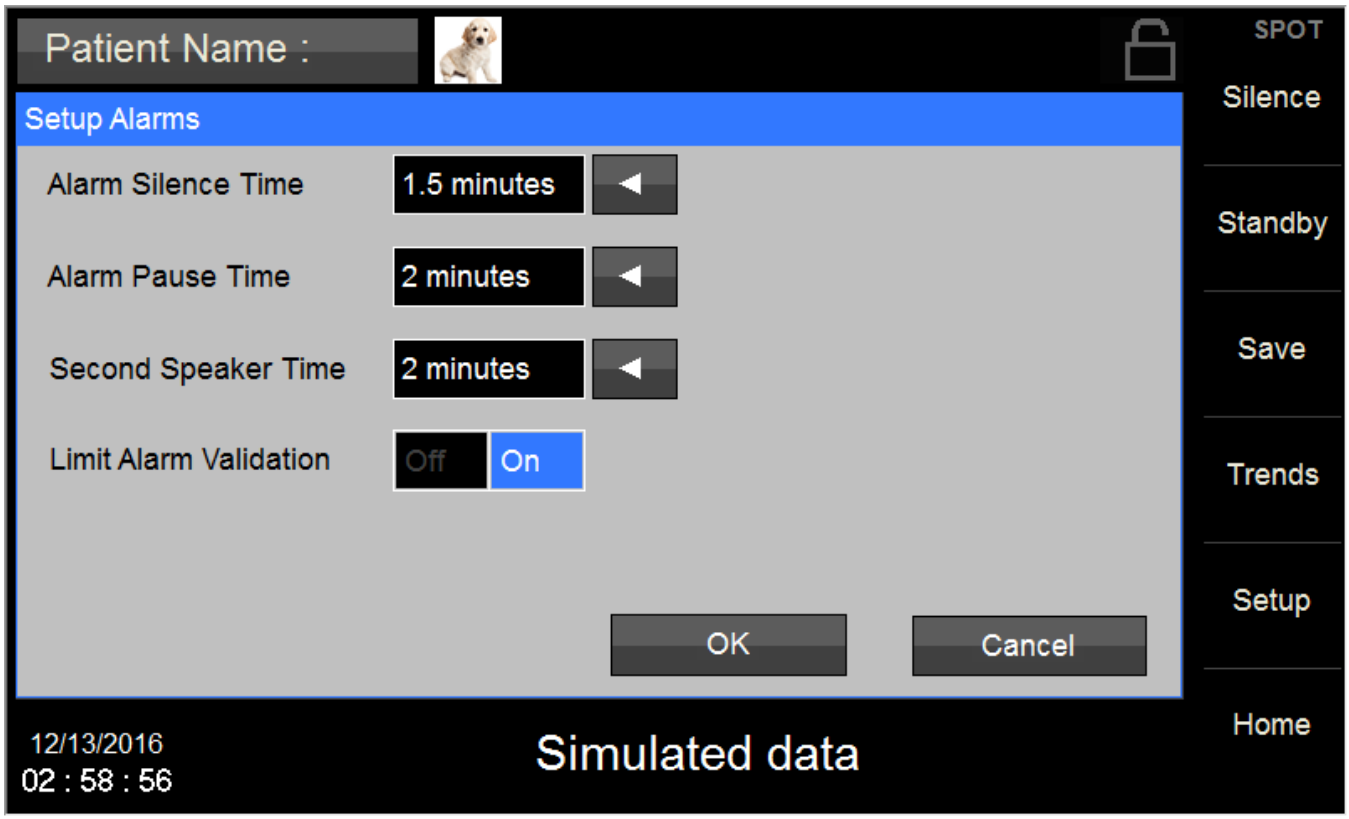


Figure 41: Setup Alarms Screens

- The Alarm (Audio) Silence Time is user selectable: 1, 1.5, and 2 minutes. The Factory Default Alarm Silence Time is 1.5 minutes.
- The Alarm Pause Time is user selectable: 1, 1.5, and 2 minutes. The Factory Default Alarm Suspend Time is 2 minutes.
- The Second Speaker Time is user selectable: 0, 1, 2, and 3 minutes. The Factory Default Second Speaker Time is 2 minutes.
- For the "Limit Alarm Validation" is user selectable: Off and On. The Factory default value is "On". Table 4 indicates the intervals for each listed parameter and Limit violation.

Table 4: Alarm Delay Intervals

Parameter	Lower Limit Violation	Upper Limit Violation
PR	3 seconds	3 seconds
SpO_2	10 seconds	10 seconds

8.8.2 System

The Setup System menu is password protected.

This menu is accessed to establish global and institutional type alarm settings and monitor features.

To enter the Setup System screen, touch [Setup/Administrator/System]. Use the keyboard to enter the password 986.

Enter the Setup System window (refer to Figure 42) to configure monitor Workflow (Spot-Check or Continuous Monitoring), Power-up Behavior, (Ask if new patient, Assume new patient, or Assume same patient), Set Monitor ID, Set Date and Time, Set Units of Measure, Save User Defaults, or Show Event Log.

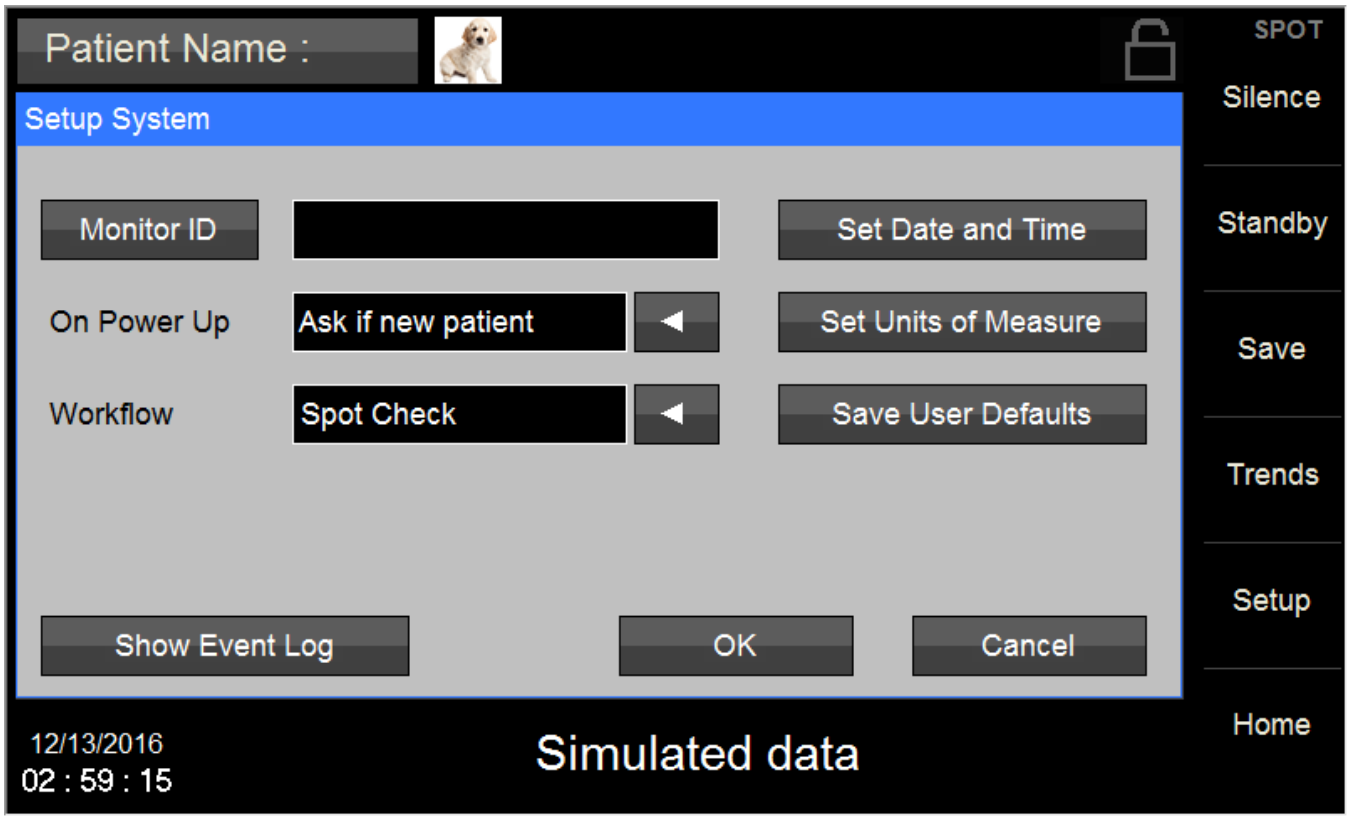


Figure 42: Setup System Screen

8.8.2.1 Workflow

Configure the monitor for the appropriate clinical workflow options:

1) Spot-Check
    a. If the monitor has been configured for use in Spot-Check workflow mode, selecting **OK** from the "**Save snapshot?**" screen will:
        i. Automatically clear patient information (including trend data stored as Intervals) and restore the monitor to the user established default settings.
        ii. Individual patient information (ID and physiologic measurements) will be stored in Trends and can be viewed at any time by selecting "Saved snapshots" in the Trend screen.
    b. Perform the following to enable Spot-Check workflow mode:
        i. Press the **Setup** button
        ii. Press the **Administrator** button
        iii. Press **System** button
        iv. Enter the required password **986**
        v. Set **Workflow** selection to **Spot Check**
2) Continuous Monitoring (Default Setting)
    a. If the monitor has been configured for use in the Continuous Monitoring workflow mode, selecting **OK** from the "**Save snapshot?**" screen retains all data stored in Trends (Saved snapshots and Intervals).
    b. The monitor retains the current settings and alarm limits.
    c. A new Patient can be entered at any time during Continuous Monitoring. The Previous patient information will be retained in Trends with the unique Patient No. (if previously entered).
    d. Perform the following to enable Continuous workflow mode:
        i. Press the **Setup** button
        ii. Press the **Administrator** button
        iii. Press **System** button
        iv. Enter the required password **986**
        v. Set **Workflow** selection to **Continuous**

8.8.2.2 On Power Up

The On Power Up selection can be configured to ask the New Patient question, Assume a new patient or Assume the same patient.

This feature is designed to help manage the monitor boot up behavior based on the clinical setting (e.g., Surgical Settings).

To configure the On Power Up selection complete the following steps:

1) Select Setup followed by the Administrator and System menu.
2) Enter the required password 986.
3) From the On Power Up drop down menu select the desired action (Ask New Patient question, Assume new patient or Assume same patient). The selection will appear in the dialog box.
    a. **Ask if new patient** is typically used in a hospital setting with Spot Check mode.
    b. **Assume new patient** is typically used in surgical settings. Monitor opens to the main screen and is ready for patient monitoring as quickly as possible.
    c. **Assume same patient** is typically used in a hospital setting when continuously monitoring the same patient.
4) Select OK to confirm the selection and close the window.

8.8.2.3 Monitor ID

Used to enter a unique monitor ID description.

To enter a description, complete the following steps:

1) Select Setup, followed by Administrator and System Menu
2) Enter the required password 986
3) Select the Monitor ID dialog box to open the Monitor ID keyboard.
4) Enter the Monitor ID using the keyboard and navigation keys.
5) Select OK to confirm the selection and close the window

8.8.2.4 Set Date and Time

The year, month, and day, as well as the hour and minute, are displayed on the Home screen. The Date & Time value is set at the factory. To change the date and time field:

1) From the Home screen, select the Date and Time field.
2) Set the date and time using the Up/Down arrows. The selection will appear in the dialog box.
3) Select OK to confirm the selection and close the window.

> ***Caution***
> *Before making a change to the date and time, clearing patient trends is recommended to avoid patient data appearing out of sequence. [Setup/Administrator/Clear Trends]*

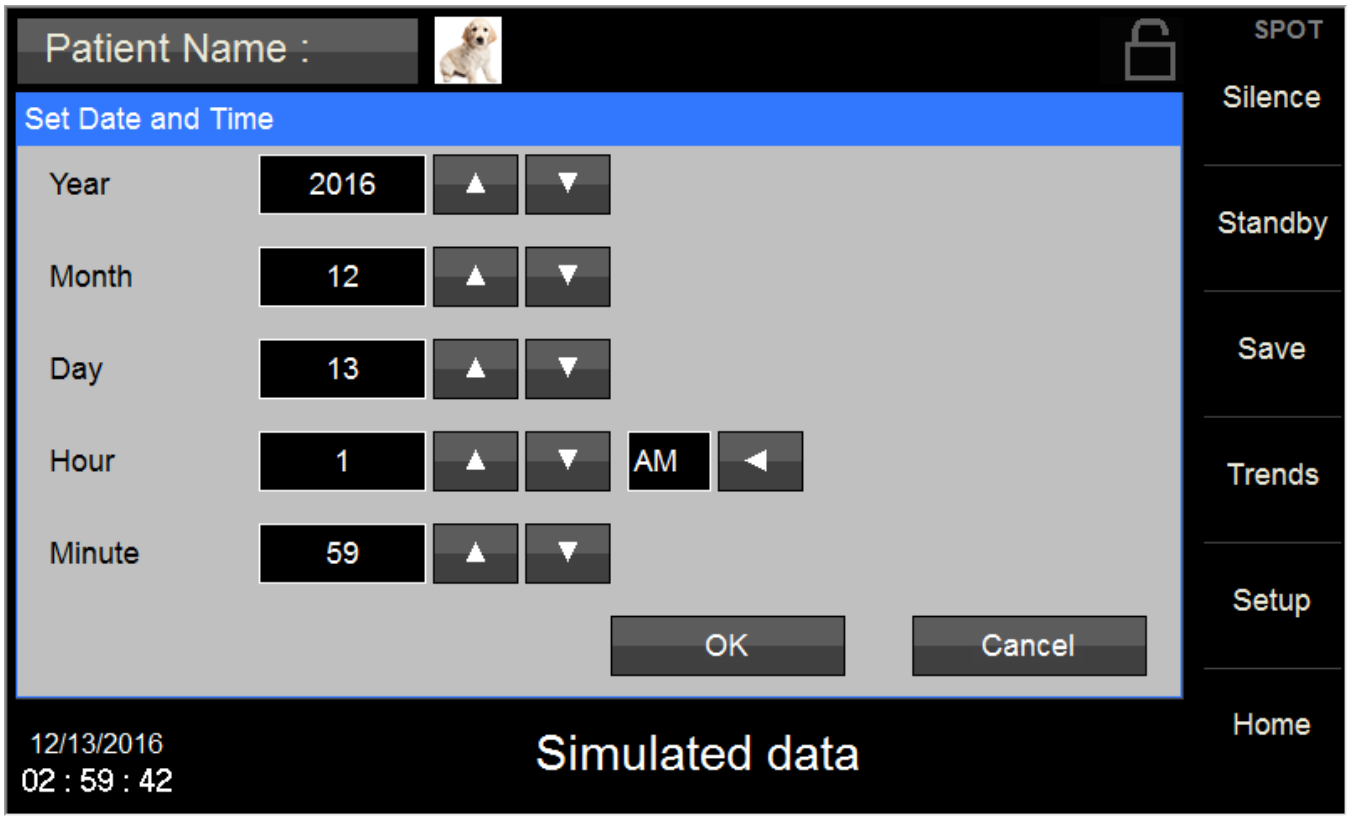


Figure 43: Set Date and Time Screen

8.8.2.5 Set Units of Measure / Weight Units

The patient weight can be displayed in either pounds or kilograms.

To configure the patient weight units, complete the following steps:

1) Select Setup followed by the Administrator and System menu.
2) Enter the required password 986.
3) From the Weight Units drop down menu select the desired weight units. The selected units will appear in the dialog box.
4) Select OK to confirm the selection and close the window.

> ***Note***
> *Altering the Weight units will not adjust the Weight value previously entered for the patient. The user should verify the patient's entered Weight*

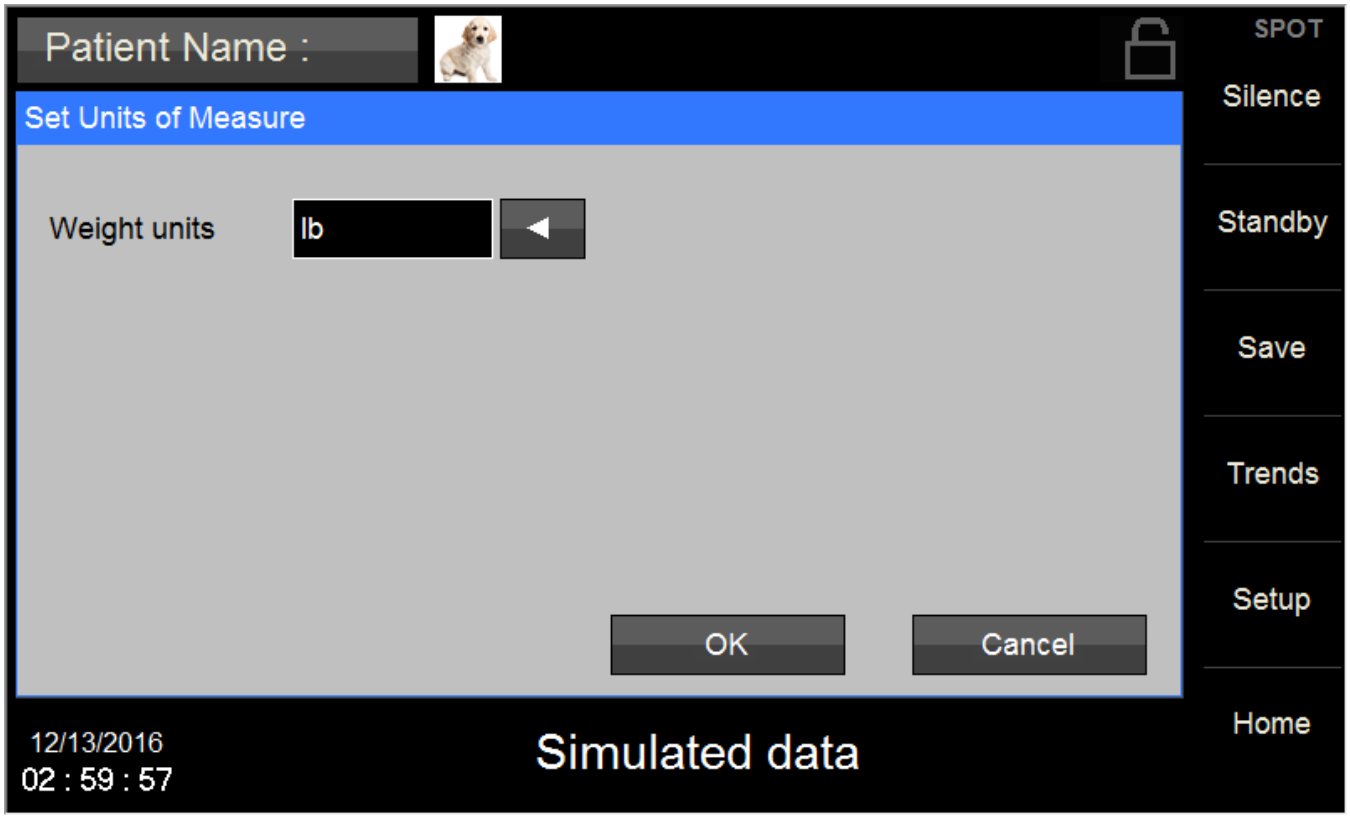


Figure 44: Set Units of Measure screen

8.8.2.6 Save User Defaults

User set alarm limits, settings and monitor features may be saved as User Defaults.

To save user alarm limits, settings and monitor features complete the following steps:

1) Make desired changes to Alarm Limits, Settings and Monitor features.
2) Select Setup followed by Administrator/System.
3) Enter the required password 986.
4) Select Save User Defaults to open the Save User Default window. Select OK.
5) Selecting OK generates an audio beep and a “Setup saved” confirmation message in the monitor message window. The screen automatically returns to the Setup System window.

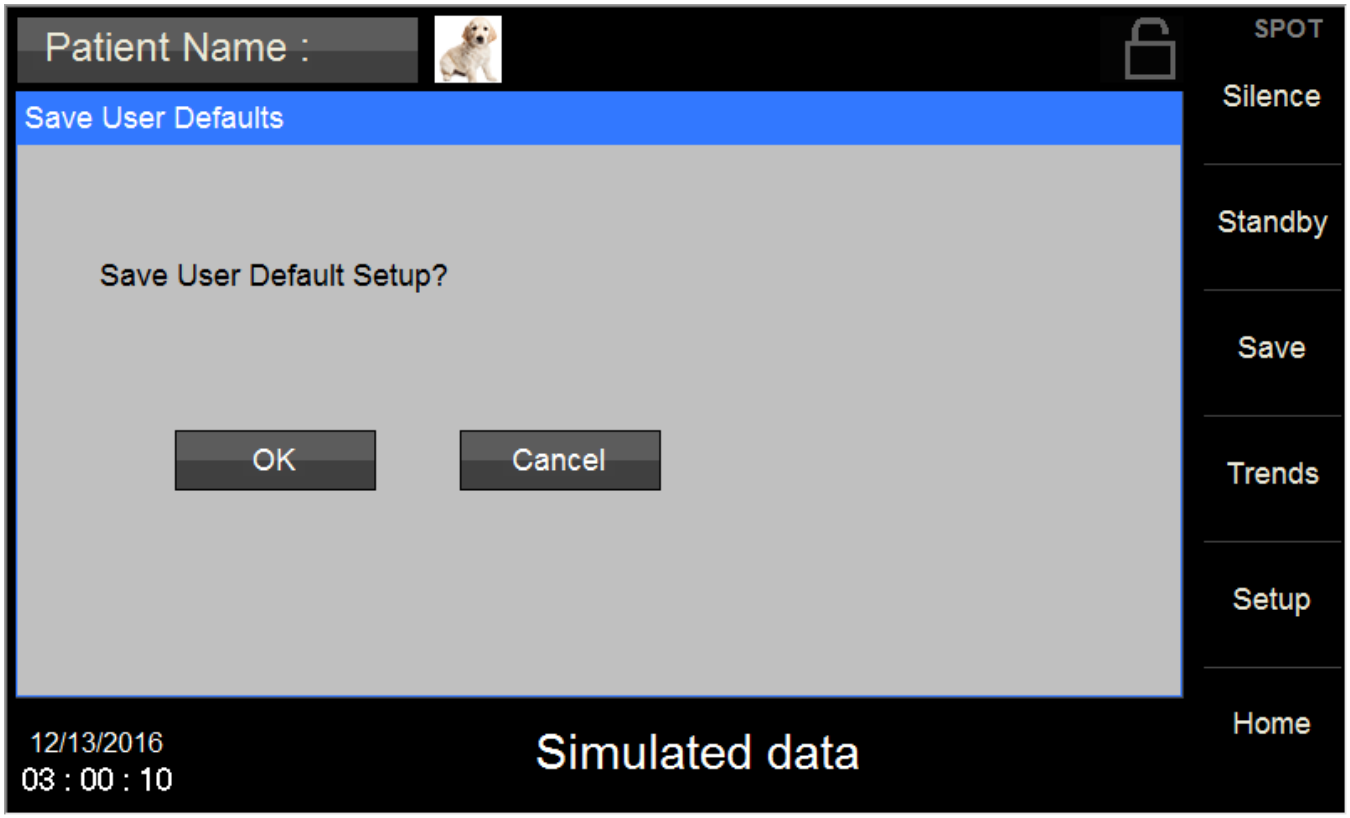


Figure 45: Save User Defaults Screen

8.8.2.7 Show Event Log

The Event Log is intended to be used by Midmark technical support (refer to Figure 46).

The log provides NIBP and SpO_2 (if installed) information, etc.

The user may access the Event Log by performing the following steps:

1) Select Setup followed by Administrator/System.
2) Enter the required password 986.
3) Select Show Event Log.
4) Navigation buttons are provided to view the log from top/bottom and right/left.
5) Select Close to exit the Event Log.

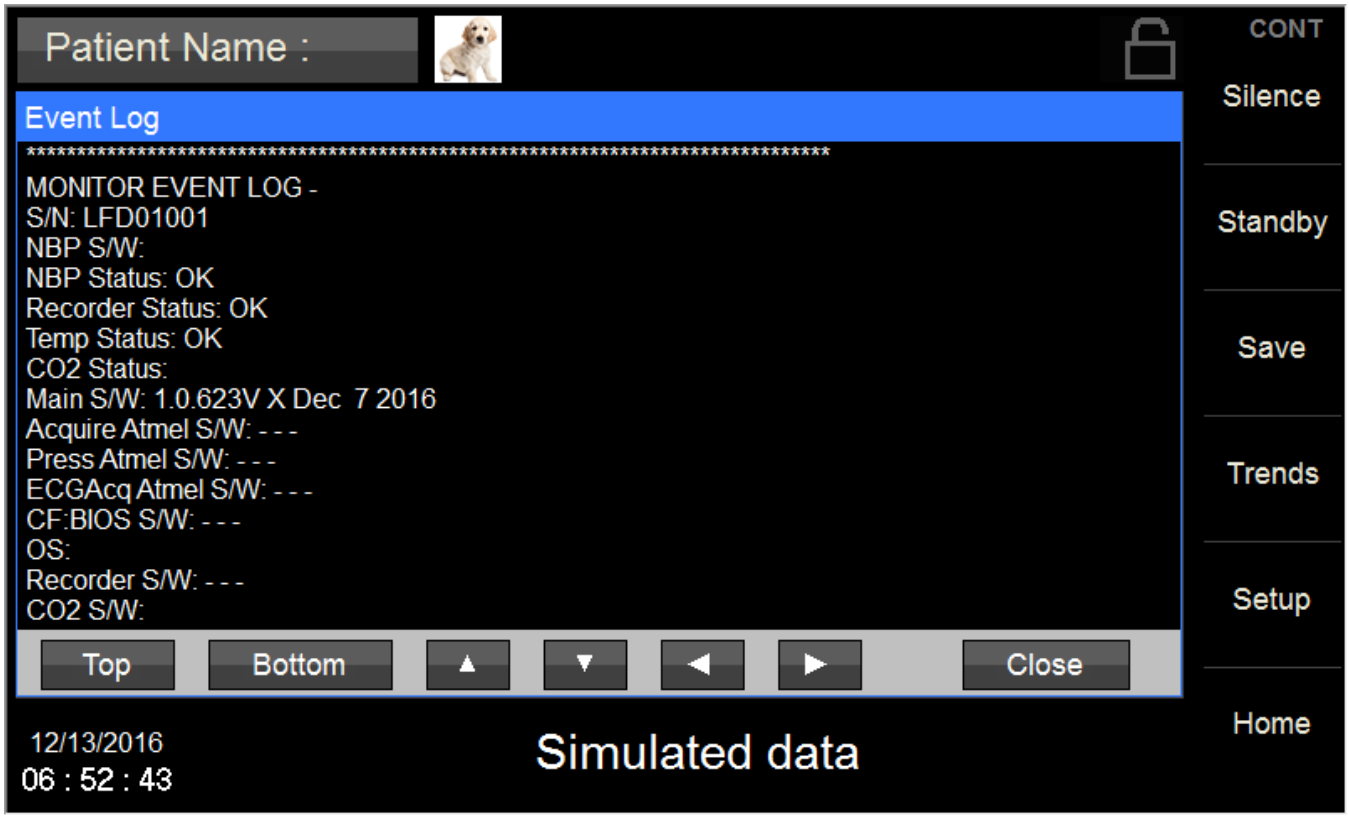


Figure 46: Show Event Log Screen

8.8.3 Service

Service Screen is password protected and is typically accessed by Midmark technical support.

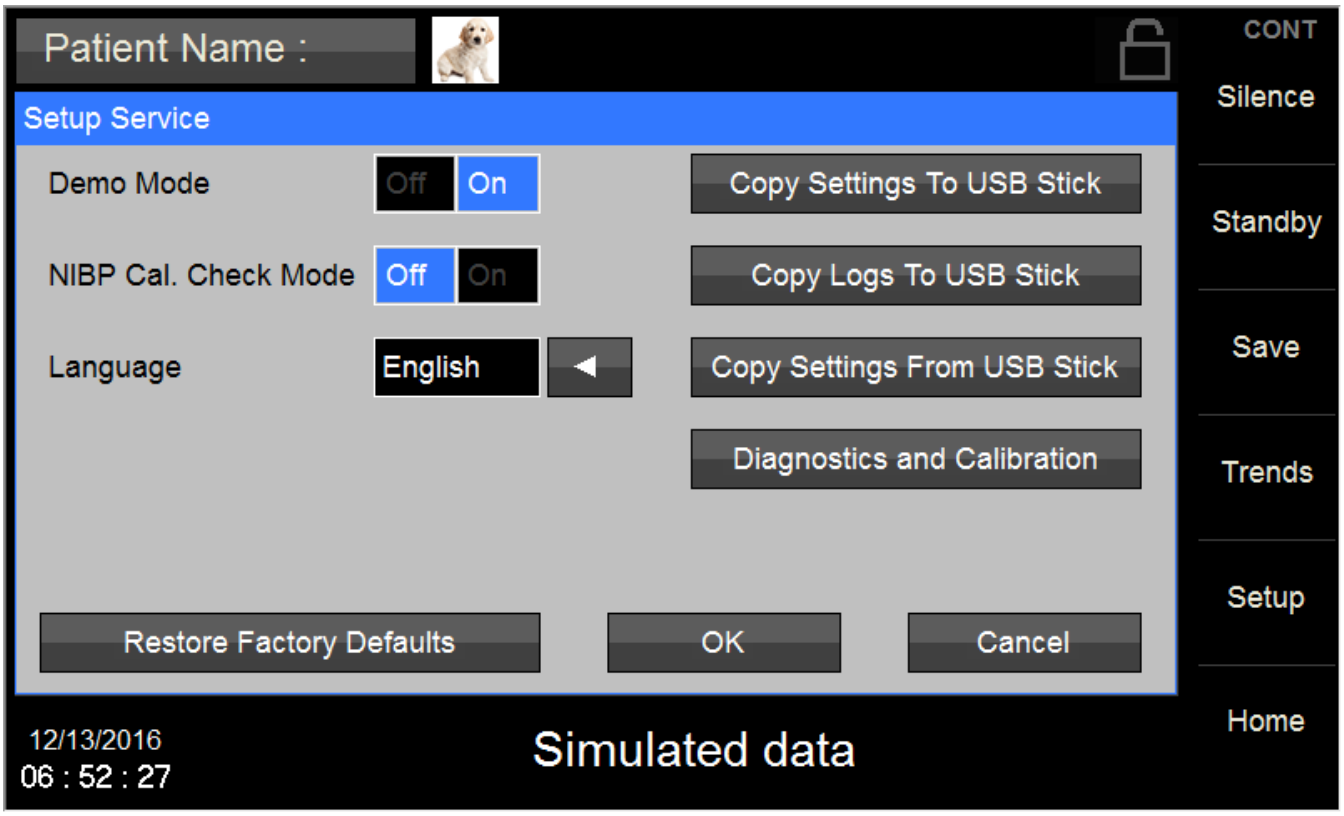


Figure 47: Setup Service Screen

8.8.4 Configuration

The Configuration menu lists monitor details including Model Type, monitor serial number, and current monitor software version of its operating system and that of the internal modules as applicable (NIBP and SpO_2 parameters) if installed.

8.8.5 Factory

Factory is reserved and not accessible; it does not contain user related or bio-med related functions.

8.8.6 Display

The Setup Display Menu is used to configure the following features

- **Patient Button Label** – Use the drop-down menu to select how patient information will be displayed on the main screen. User configurable selections are: Patient No., Patient Name, Client Name, Leave Blank.
- **Monitor Button Label** – Provides a method to uniquely identify the Cardell Insight monitor for institutional tracking purposes and enable the entry of a Monitor ID as applicable. Use the on-screen keyboard to enter the Monitor ID Tag (Example: MEDSURG 12) or Clinician IDN (Example: NURSE SMITH).
- **Auto Dim Timeout (minutes)** – Allows the user to manage touch screen brightness automatically (night mode). Display screen will automatically dim after the set time has lapsed. The display screen automatically returns to full brightness if an alarm condition occurs or when the screen is touched by the user.
    - Settings are: Off, 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 minutes
    - Use the Up/Down arrows to change setting

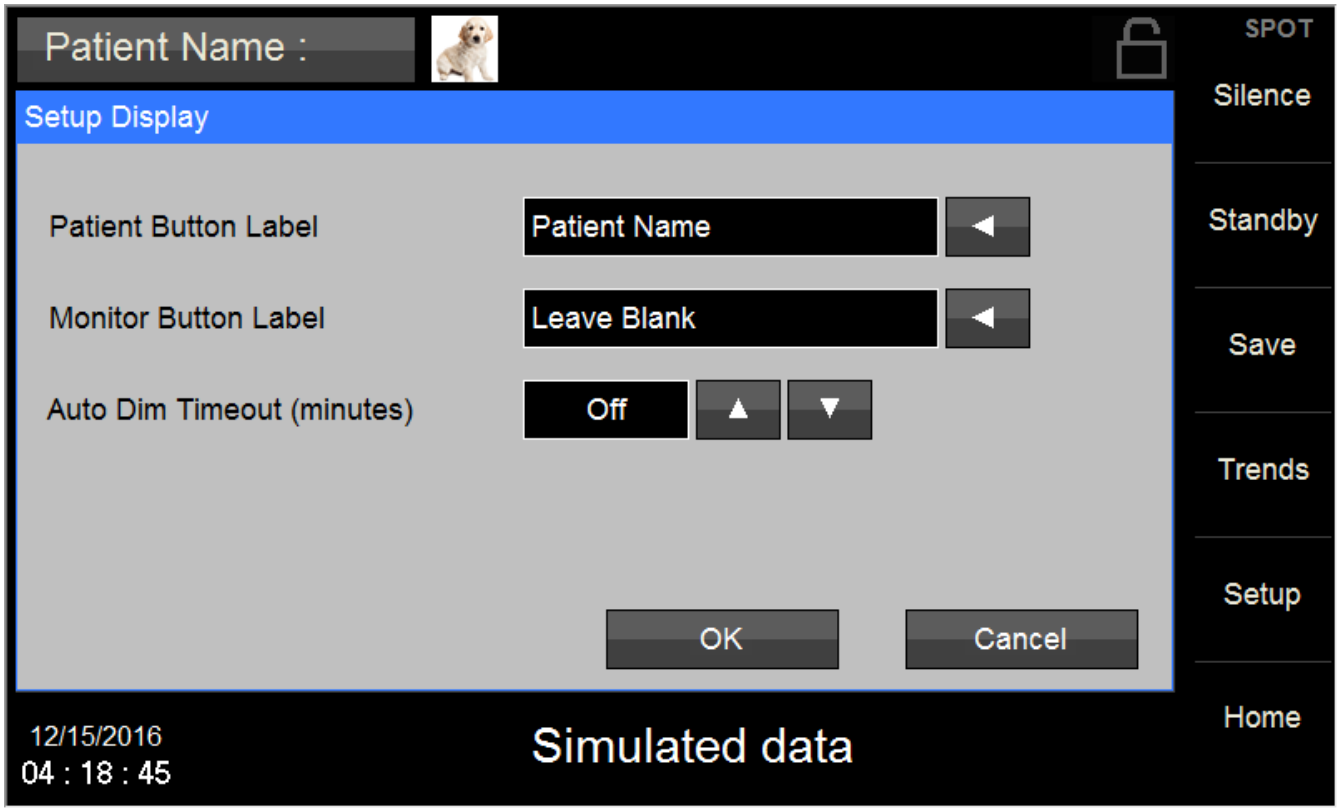


Figure 48: Setup Display Screen

9. Blood Pressure Monitoring

Important - Be sure to read and understand all the Warnings and Cautions found in Section 5: Monitor Safety Measures, before starting Blood Pressure Monitoring.

9.1 General Information

The Cardell® Insight uses oscillometric principles to calculate the systolic (SYS), diastolic (DIA), and mean arterial pressure (MAP) values. The MAP is calculated as the lowest cuff pressure that provides the maximum cuff oscillations. Therefore, MAP is the largest signal received and is the most accurate reading using oscillometric methods. Systolic pressure is calculated as the cuff pressure at which an increase in cuff oscillations is perceived. The diastolic pressure is the cuff pressure when oscillations are no longer decreasing as pressure is released from the cuff. Special veterinary specific algorithms have been designed to ensure reliable and accurate measurements from kittens to horses. The veterinary monitor first inflates the cuff to a pressure of around 30 mmHg higher than the systolic pressure, then, slowly deflates the cuff. When the cuff pressure is higher than systolic pressure, the artery is blocked and there are small amplitude oscillometric waveforms. When the cuff pressure is equal to the systolic pressure, the oscillometric amplitude will increase. With the decrease of the cuff pressure, the oscillometric amplitude increases. When the cuff pressure reaches a certain value, the oscillometric amplitude reaches a maximum value, and then the cuff pressure is mean arterial pressure. It uses the changes of the oscillometric amplitude under different cuff pressures to identify mean pressure and calculate the systolic and diastolic pressure.

9.2 Safety Measures

The monitor has been designed to promote patient safety:

- The maximum amount of time allowed to complete a blood pressure measurement is 120 seconds. If the measurement has not been completed within that time, the cuff is deflated automatically, and a message is displayed indicating the problem.
- To prevent exposure of the extremity to an inordinately high pressure, the cuff is deflated automatically when the pressure in the system is greater than 290 mmHg.
- The cuffs used by the monitor are designed without transducers for patient safety. The transducers used for NIBP measurement are located inside the monitor on the NIBP board and are isolated from the patient.
- In the event of a microprocessor failure, the cuff will be deflated automatically within ten (10) seconds.
- All equipment parts are protected against the effects of the discharge of a defibrillator. No separate actions are required when using this equipment with a defibrillator.
- If the power is interrupted coming into the monitor, the monitor automatically runs off battery power.

WARNING

- ⇨ *Blood pressure and pulse can fluctuate between measurements; the monitor cannot alert the user to changes in blood pressure occurring between measurement cycles.*
- ⇨ *The cuff should not be applied on a limb being used for intravascular access or therapy, or a shunt.*
- ⇨ *Do not place the cuff on any extremity being used for SpO2 monitoring. If the cuff is applied on a limb being used for oxygen saturation monitoring %SpO2 results will be altered during each blood pressure measurement due to the occlusion of blood flow.*
- ⇨ *When monitoring over an extended period of time, or at frequent intervals, periodically observe the patient's limb to make sure that the circulation is not impaired for a prolonged period of time.*
- ⇨ *Do not allow the inflation tube to be kinked that may allow continuous cuff pressure and blood flow interference resulting in injury.*
- ⇨ *Too frequent measurements can cause injury due to blood flow interference.*
- ⇨ *Do not apply a cuff over a wound, as this can cause further injury.*
- ⇨ *There may be a marked difference between readings taken from the left and right limbs.*
- ⇨ *Regardless of these safety features, always be sure to check that there are no signs of prolonged impairment of patient circulation and that the monitor is functioning properly.*
- ⇨ *As with any non-invasive oscillometric blood pressure monitor, the accuracy of the measurements obtained may be adversely affected by the presence of agents that alter the patient's cardiovascular system.*

Caution

- ⇨ *Consult a veterinarian for interpretation of blood pressure measurements.*
- ⇨ *Do not operate the monitor unless it has been properly calibrated. Inaccurate blood pressure readings may result. A calibration check is recommended yearly. A pneumatic check is recommended once a year. Refer to Section 13.3: NIBP Calibration Check.*
- ⇨ *Do not alter the monitor's internal or external air hose. Proper monitoring cannot be ensured if the tubing is altered. Modification of the air hose will void the warranty. Avoid compression or restriction of pressure tubes.*
- ⇨ *In shock conditions, the low amplitude of the blood pressure signal may make it difficult for the monitor to accurately determine the blood pressure.*

9.3 Tips

Rationale to optimize performance and data accuracy of an automated NIBP system:

Tip	Rationale
Clear the prior patient's data and reset the initial inflation pressure to the default value for patient comfort (Refer to * NOTE below)	For patient comfort and avoids clinician loss of NIBP data
Cuff should be correctly sized, secured, positioned, and placed on the same limb as done previously.	For data accuracy and consistency
Do not place the cuff on a limb unsuitable for NIBP measurement (Refer to ** NOTE below).	If only one limb can be used
Measurement environment should be quiet, not brightly lit and neither too cold nor hot.	For data accuracy
Use the correct monitor position (activation switch within reach of caregiver, tubing without kinks or touching itself, display readily visualized by caregiver).	For data accuracy and clinician visualization
Clinician should remain calm to avoid "white-coat" hypertension (discuss and avoid caregiver appearance).	For data accuracy
Patient should be correctly positioned and rested before beginning: Readings can be affected by the measurement site, position of the patient, activity level, or the patient's physiological condition.	For data accuracy
Patient should not be moving immediately prior to or during a measurement. Patient should be in a relaxed state. (Refer to *** NOTE below).	For data accuracy
Maintain a correct measurement sequence (discard the first measurement and wait at least 5 minutes before initiating the next measurement inflation). If unexpected readings are obtained wait 5 minutes and repeat the measurement.	For patient comfort and data accuracy

*** NOTE**: The default initial inflation pressure is 160mmHg. This may be adjusted if the patient's blood pressure range is known.

**** NOTE:** Do not place the Cuff on limbs unsuitable for NIBP measurement (e.g., limbs that have any trauma/incisions). Cuff should not be applied over a peripherally inserted central catheter (PICC) or midline catheter site but may be placed distally to the insertion site. NIBP measurements should not be taken in extremities with peripheral IV while an infusion is running.

***** NOTE:** Environmental or operational factors can affect the performance of the measurement (e.g., arrhythmias, patient motion, trembling, shivering).

9.4 Cuff Selection and Application

The use of professionally designed and sized cuffs is essential for the accurate measurement of blood pressure. Small and medium sized animals (e.g. cats, dogs) use cuff sizes SV1 to SV5. Large animals (e.g. horses, cows) use cuff sizes SV8 to SV10. A cuff that is too small for the limb will not supply sufficient pressure to the artery. This can cause an erroneously high blood pressure reading. Substitution of a cuff different from that supplied might result in a measurement error. When taking a NIBP measurement, ensure the proper cuff size range (small or large) is selected on the monitor (refer to Figure 49). This parameter can be changed in the Setup NIBP menu. Measurements made above the level of the heart will give reduced blood pressure readings while measurements made below the heart level will give increased readings.

> ***Caution***
> *Use only the inflation hose supplied with the monitor or authorized accessory kit.*

> ***Note***
> *Overlapping the cuff will not affect the measurement results.*

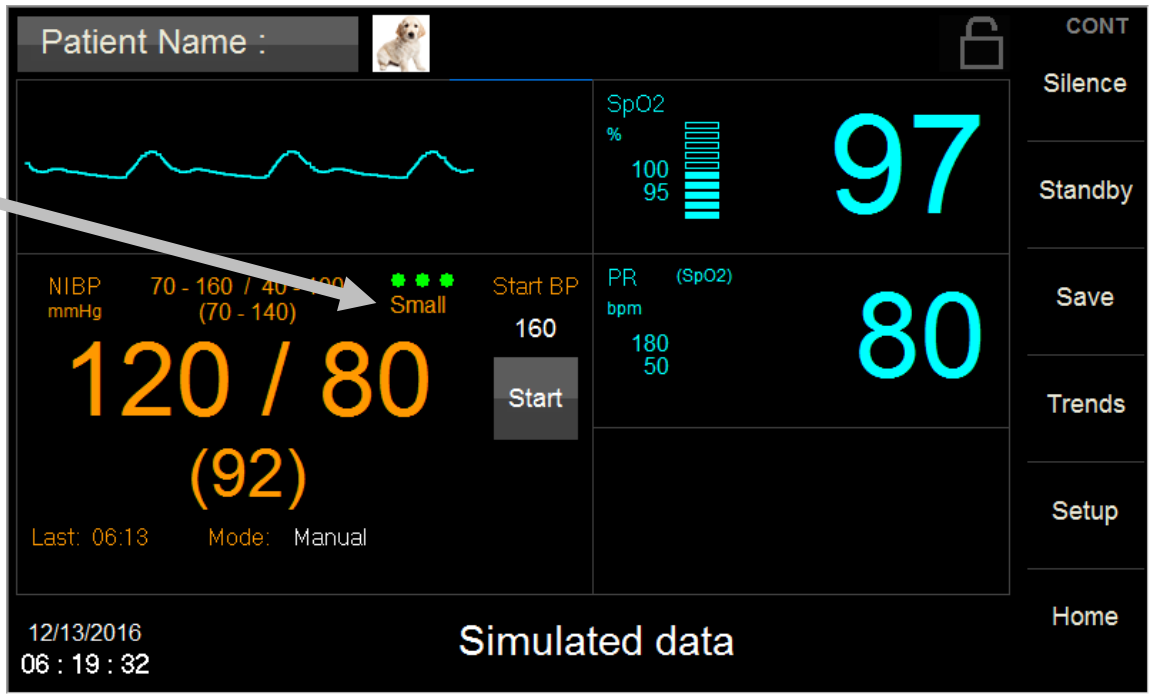


Figure 49 Cuff Size Indication

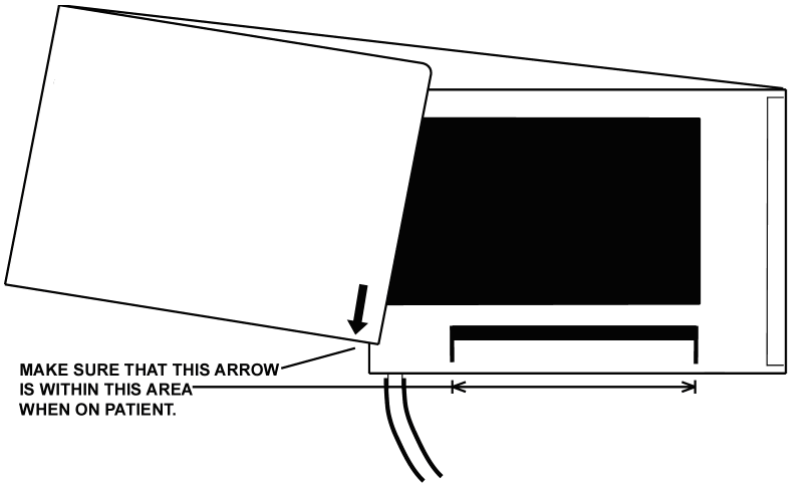


Figure 50: Cuff Application

Proper cuff application is essential. The end of the cuff is marked with an arrow. To ensure that the proper cuff size has been selected, wrap the cuff around the patient's extremity, the marker should fall between the range identifier on the cuff (refer to Figure 50).

9.4.1 Cuff Placement for Cats

A cat may be left in its owner's lap to keep it calm. Measurements are best done in an area of the hospital away from noise and bright lights. The animal may be held so that the front limbs are free for cuff placement. In conscious patients, the tail may be the most appropriate location for placement of the cuff. Cats may be most comfortable in sternal recumbency making the tail a preferable site. For the median artery on the foreleg, place the cuff around the forelimb, between the elbow and carpus. It is not necessary to center the cuff over the artery which is on the medial side of the leg because of the fully encircling bladder design. Hair need not be clipped except when heavily matted. For cats weighing less than five (5) pounds, when measurements are difficult to obtain, place the cuff around the leg above the elbow to obtain measurements from the brachial artery. Measurements from the coccygeal artery may be used by placing the cuff around the base of the tail.

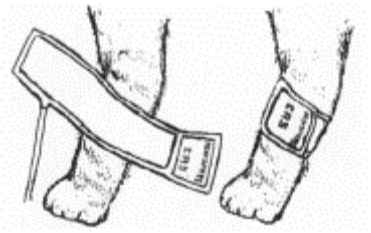


Figure 51: Cuff Placement on Cat

9.4.2 Cuff Placement for Dogs

For measurements in dogs, it is preferable to use the right lateral, sternal or dorsal recumbent positions. That is not a problem in anesthetized patients, but it may be difficult to get large dogs to cooperate for proper positioning when conscious. If the dog is in a sitting position, place the front paw on the operator's knee and take measurements from the metacarpus. Sites for cuff placement are the metacarpus, metatarsus, and anterior tibia. In anesthetized patients, most surgeries are done on the posterior part of the body, so the metacarpal area of the forelimb is most convenient. In situations where this is not possible, the cuff should be wrapped around the metatarsus just proximal to the tarsal pad or around the hind leg just distal to the hock. It is not necessary to center the cuff over the artery because of the fully encircling bladder design. If the hair over the artery site is too thick or matted for good contact, it should be clipped.

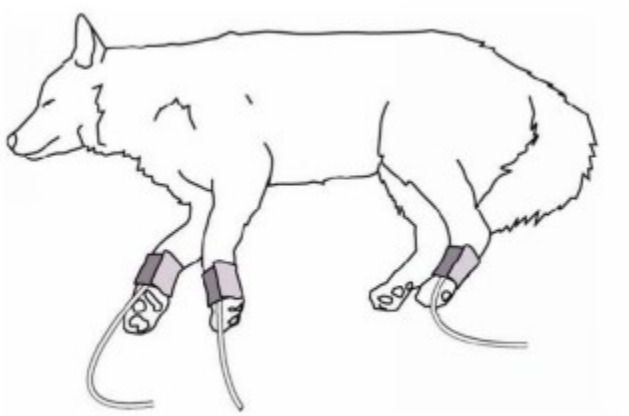


Figure 52: Cuff Positioning on Dog

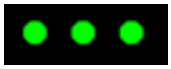
9.4.3 Cuff Placement for Large Animals

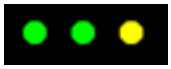
A large animal such as a horse should be in a stall, standing still, or lying down. For horses and cows, the cuff can be wrapped around the base of the tail using the coccygeal artery on the ventral surface.

9.5 NIBP Measurement

> ***WARNING***
> *Excessive patient motion can contribute to inaccurate measurements. It is important that the patient be kept still during a measurement. Make every attempt to alleviate fear, anxiety, and pain.*

1) Select the appropriately sized cuff for the patient and apply it to the proper extremity.
2) Connect the cuff to the end of the monitor tubing. Connect the monitor tubing to the NIBP connector, located on the left side of the monitor.
3) Select the appropriate cuff size range in the Setup NIBP menu: Small (cuffs SV1-SV5) or Large (cuffs SV8-SV10)
    a. Initial Inflation Pressure (mmHg) can be specified via the Setup NIBP menu. Initial Pressures range from 60 mmHg to 240 mmHg in increments of 20mmHg. Quick Initial Inflation Pressure options can be shown or hidden on the Home Screen using the Start BP Options toggle.
4) Press the Start Button (found in the NIBP Numeric field) to begin a measurement. For the first measurement, the monitor will inflate to the default setting or the Initial Inflation Pressure selected per the Start BP Option setting.
    a. The monitor's NIBP display will display an increasing numeric value while the measurement is in progress and the NIBP displays the Inflation Pressure in the format "XXX", where "XXX" is the pressure value. For subsequent measurements (Start BP Options = No), the monitor will inflate 30 mmHg higher than the previously determined Systolic pressure.
    b. The measurement typically takes less than 30 seconds to complete. The cuff will not remain pressurized for more than 120 seconds.
    c. When the measurement is completed, the cuff will automatically deflate and the monitor will display the Systolic, Diastolic, MAP and Pulse Rate values on the front panel. The NIBP Numeric field displays a time stamp of the NIBP measurement in the format "HH:MM". Where "HH" is the hour and "MM" is the minute of the measurement taken.
5) When the blood pressure measurement is completed, a Signal Quality Status Indicator will be displayed. The indicator provides user information related to the NIBP signal quality and degree of artifact present during the measurement. The state is represented by 1 of 3 icons:


Excellent signal quality, low artifact present


Good signal quality, moderate artifact present


Poor signal quality, excessive artifact present

Press the Stop Button at any time to stop a measurement and deflate the cuff during the measurement process. The NIBP Systolic, Diastolic, MAP and Pulse Rate values will change to blank (no numeric will be displayed in the numeric field).

The Start/Stop BP button can be pressed twice very quickly to clear the current NIBP measurement.

> ***Note***
> *NIBP parameter values are automatically removed from the display after 24 hours.*

9.5.1 NIBP Alarm Limits

> ***WARNING***
> *Setting the NIBP Parameters Upper or Lower Alarm Limit to "Off" will not generate any visual or audible indication of an alarm condition.*

> ***Caution***
> *Switching modes from Horse, Dog or Cat to any other patient mode, shall recall the last stored values for the patient alarm limits.*

> ***Note***
> *Alarms for Systolic, Diastolic and MAP values are produced at the time the measurement is taken.*

Table 5: Default NIBP Alarm Limits

Limit	**SYS**	**MAP**	**DIA**
Upper	160	140	100
Lower	70	70	40

To set the NIBP Alarm limits:

1) Touch the NIBP Numeric field.
2) Adjust the desired NIBP Parameter (Sys, Map or Dia) Upper or Lower Alarm Limit value.
    a. The Upper and Lower Alarm Limits can be adjusted independently.
    b. Each NIBP Parameter Alarm Limit can be set to Off.
3) Touch OK to accept or Cancel to ignore the selection.
4) Touch the Home touch area to return to the Main screen.

9.5.2 Manual Mode

Manual Mode allows the user to initiate blood pressure measurements by pressing the Start button in the NIBP Numeric field (on the Home screen). The user can configure the monitor to use a predetermined inflation pressure or show a selection of inflation pressure options using the Start BP Options function (refer to Section 7.7.6: NIBP Numeric Field)

9.5.3 Automatic (AUTO) Mode

Automatic blood pressure measurements can be taken at pre-selected time intervals. To choose a NIBP Interval, touch the NIBP Numeric field. Select the desired NIBP Interval value and then touch OK to accept or Cancel to ignore the selection. Touch the Home touch area to return to the Main screen.

Once a NIBP Interval has been selected, pressing the Start Button will begin the first measurement. The next NIBP measurement will automatically start after the desired Interval time has passed (e.g., the 5-minute NIBP Interval setting prompts automatic NIBP measurement every 5 minutes).

The measurement results are displayed in the NIBP numeric field until the end of the next measurement cycle.

> ***Note***
> *If a measurement is desired between measurement cycles, press Start Button. After this measurement, the monitor will re-enter the Automatic Cycle mode and countdown to the next measurement based on the Cycle time selected.*

Pressing the Stop button while taking a measurement will cause the monitor to stop the current measurement but remain in Auto Cycle mode.

Pressing the Stop button during idle time between measurements will cause the monitor to stop the measurement cycle but remain in Auto Cycle mode.

The NIBP numerals will indicate the reading of the previous measurement taken and the time stamp of that reading.

9.5.4 STAT Mode

> ***WARNING***
> *In some cases, rapid, prolonged cycling of an oscillometric, noninvasive blood pressure monitor cuff has been associated with any or all of the following: ischemia, purpura, or neuropathy. Apply the blood pressure cuff appropriately, per instructions, and check the cuff site and cuffed extremity regularly when blood pressure is measured at frequent intervals or over extended periods of time.*

An automatic series of blood pressure measurements can be taken for a five (5) minute interval with a brief (approx. 5 second) pause between determinations to allow venous blood return.

To choose STAT mode, touch the NIBP Numeric field. Select the STAT Mode and then touch OK to accept or Cancel to ignore the selection. Touch the Home touch area to return to the Main screen.

After five (5) minutes of determinations the monitor will stop taking measurements and exit the STAT mode. The monitor remains in STAT mode once the measurement series in the last STAT mode is done.

Pressing the Stop button during a STAT measurement stops the current measurement and remains in STAT mode.

Clicking on "End STAT Mode" in-between STAT mode measurement is only avoiding any other measurement to take place until the user selects "Start".

To exit STAT mode, enter the NIBP SETUP Menu. From the Mode drop down menu select the appropriate NIBP mode then select OK.

WARNING

When monitoring over an extended period of time or at frequent intervals, periodically observe the patient's limb to make sure that the circulation is not impaired for a prolonged period of time.

10. Pulse Oximetry Monitoring

For Monitors equipped with SpO_2:

Important - Be sure to read and understand all the Warnings and Cautions in Section 5: Monitor Safety Measures, before starting Pulse Oximetry Monitoring.

The SpO_2 technology may be used on large, medium and small patients (refer to Section 15: Specifications for additional information on horse, dog and cat settings).

10.1 Safety Measures

WARNING

- ⇨ *A pulse oximeter should be considered an early warning device. As a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory oximeter to completely understand the patient's condition.*
- ⇨ *Accurate oxygen saturation measurements cannot be obtained when the oximeter is not measuring the pulse properly. If the Plethysmograph waveform is erratic or the Pulse Rate display is erratic or inaccurate, first examine the patient for any sign of distress and only then re-examine sensor placement.*
- ⇨ *Explosion hazard - Do not use the monitor in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.*
- ⇨ *Electric shock hazard - Do not open the monitor cover except to replace the batteries. Only qualified personnel may perform maintenance procedures specifically described in this Manual. Contact Midmark for assistance.*
- ⇨ *A monitor should be considered an early warning device. As a trend towards patient hypoxemia is indicated, blood samples should be analyzed by laboratory instruments to completely understand the patient's condition.*
- ⇨ *The monitor is to be operated by qualified personnel only. This Manual, accessory direction for use, all precautionary information, and specifications should be read before use.*
- ⇨ *As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.*
- ⇨ *Do not place the monitor or accessories in any position that might cause it to fall on the patient. Do not lift the monitor by the patient cable.*

WARNING

- ⇨ *Interfering Substances: Carboxyhemoglobin may erroneously increase SpO_2 readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.*

- ⇨ *SpO_2 is empirically calibrated to functional arterial oxygen saturation in healthy volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb). A pulse oximeter cannot measure elevated levels of COHb or MetHb. Increases in either COHb or MetHb will affect the accuracy of the SpO_2 measurement.*
    - o *For increased COHb: COHb levels above normal tend to increase the level of SpO_2. The level of increase is approximately equal to the amount of COHb that is present.*
    - o *Note: High levels of COHb may occur with a seemingly normal SpO_2. When elevated levels of COHb are suspected, laboratory analysis (Oximetry) of a blood sample should be performed.*
    - o *For increased MetHb: the SpO_2 may be decreased by levels of MetHb of up to 10% to 15%. At higher levels of MetHb, the SpO_2 may tend to read in the low to mid 80s. When elevated levels of MetHb are suspected, laboratory analysis (Oximetry) of a blood sample should be performed.*

- ⇨ *Severe anemia may cause erroneous SpO_2 readings.*

- ⇨ *Do not use the monitor or oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The monitor may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.*

- ⇨ *If using pulse oximetry during full body irradiation, keep the sensor out of the irradiation field. If the sensor is exposed to the irradiation, the reading might be inaccurate, or the unit might read zero for the duration of the active irradiation period.*

- ⇨ *Always remove the sensor from the patient and completely disconnect the patient from the monitor before bathing the patient.*

- ⇨ *Do not place the monitor on electrical equipment that may affect the monitor, preventing it from working properly.*

- ⇨ *Do not expose the monitor to excessive moisture such as direct exposure to rain. Excessive moisture can cause the monitor to perform inaccurately or fail.*

- ⇨ *Do not place containers containing liquids on or near the monitor. Liquids spilled on the monitor may cause it to perform inaccurately or fail.*

- ⇨ *Patient Safety - If a sensor is damaged in any way, discontinue use immediately.*

WARNING

- ⇨ *The monitor may be used during defibrillation, but the readings may be inaccurate for up to 20 seconds.*

- ⇨ *This equipment has been evaluated and found to comply with the limits for medical devices to the EN 60601-1-2, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur during or after an installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:*
  - o *Reorient or relocate the receiving device*
  - o *Increase the separation between the equipment*
  - o *Consult the manufacturer for help*

- ⇨ *A study of SpO_2 accuracy versus blood gas readings from a co-oximeter, as defined in ISO 80601-2-61, has only been performed on humans. SpO_2 readings on animals may vary based on the type of animal and the measurement site.*

- ⇨ *Reusable sensors may be used on the same site for a maximum of four (4) hours, provided the site is inspected routinely to ensure skin integrity and correct positioning. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients. If skin integrity changes, move the sensor to another site.*

- ⇨ *If the sensor is applied too tightly or supplemental tape is used, venous congestion/pulsations may occur, causing erroneous readings.*

- ⇨ *Exercise caution when applying a SpO_2 sensor to a site with compromised skin integrity. Applying pressure to such a site may reduce circulation and/or cause further skin deterioration.*

- ⇨ *With very low perfusion at the monitored site, the readings may read lower than core arterial oxygen saturation.*

- ⇨ *Sensors applied too tightly may cause erroneously low readings.*

- ⇨ *Misapplied sensors or sensors that become partially dislodged may cause either over or under reading of actual arterial oxygen saturation.*

- ⇨ *To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not attempt to sterilize.*

WARNING

- ⇨ *Intravascular dyes may lead to inaccurate SpO_2 measurements.*
- ⇨ *Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO_2 measurements.*
- ⇨ *Elevated levels of Methemoglobin (MetHb) will lead to inaccurate SpO_2 measurements.*
- ⇨ *Elevated levels of Total Bilirubin may lead to inaccurate SpO_2.*
- ⇨ *Motion artifact may lead to inaccurate SpO_2 measurements.*
- ⇨ *To protect against injury from electric shock, follow the directions below:*
  - o *Avoid placing the monitor on surfaces with visible liquid spills.*
  - o *Do not soak or immerse the in liquids monitor.*
  - o *Always turn off and disconnect the power cords from the power supply before cleaning the monitor.*
  - o *Use cleaning solutions sparingly.*
- ⇨ *To ensure patient electrical isolation, connect only to other equipment with electrically isolated circuits.*
- ⇨ *Do not use damaged sensors or patient cables. Do not use a sensor or patient cable with exposed optical or electrical components.*
- ⇨ *Do not immerse the sensor or patient cable in water or, solvents, or cleaning solutions (The sensors and connectors are not waterproof).*
- ⇨ *Unless otherwise specified, do not sterilize sensors or patient cables by irradiation, steam, autoclave, or ethylene oxide.*
- ⇨ *Do not attempt to reprocess, recondition, or recycle any SpO_2 sensors or patient cables as these processes may damage the electrical components, potentially leading to harm.*
- ⇨ *To avoid cross contamination only use SpO_2 single use sensors on the same patient.*
- ⇨ *Loss of pulse signal can occur when:*
  - o *The sensor is too tight*
  - o *The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia*
  - o *There is arterial occlusion proximal to the sensor*
  - o *The patient is in cardiac arrest or is in shock*
- ⇨ *High intensity extreme lights (including pulsating strobe lights) directed on the sensor may not allow the monitor to obtain readings.*

WARNING

- ⇨ *Failure to apply the sensor properly may cause incorrect measurements.*
- ⇨ *Avoid placing the sensor on any extremity with an arterial catheter or blood pressure cuff.*
- ⇨ *The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify patient's pulse rate against the ECG heart rate.*
- ⇨ *Do not modify or alter the sensor in any way. Alterations or modification may affect performance and/or accuracy.*
- ⇨ *Venous congestion may cause under reading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from monitored site. Sensor should not be below heart level (e.g., sensor on limb dangling to the floor).*
- ⇨ *Venous pulsations may cause erroneous low readings (e.g., tricuspid value regurgitation).*
- ⇨ *Circulation distal to the sensor site should be checked routinely.*

Note

A functional tester cannot be utilized to assess the accuracy of the monitor or any sensors.

10.2 Alarm Limit Values

There are three sets of alarm limit parameters, one set each for Horses, Dogs and Cats. Alarm Limits will operate on the parameters for the current monitor patient mode. Table 6 lists the SpO_2 Default Alarm Limits.

Table 6: Default SpO_2 & SpO_2 Pulse Alarm Limits

	SpO_2		SpO_2 Pulse Rate	
	Upper	**Lower**	**Upper**	**Lower**
Horse	100	95	50	24
Dog	100	95	180	50
Cat	100	95	180	90

To set the SpO_2 Alarm limits:

1) Touch the SpO_2 Numeric field.
2) Adjust the desired SpO_2 High or Low Limit value.
    a. The SpO_2 Upper and Lower Alarm Limits can be adjusted independently.
    b. The SpO_2 Upper and Lower Alarm Limit can be set to “Off”.
3) Touch OK to accept or Cancel to ignore the selection.
4) Touch the Home touch area to return to the Main screen.

WARNING
Setting the SpO_2 Upper or Lower Alarm Limit to “Off” will not generate any visual or audible indication of an alarm condition.

A SpO_2 Alarm limit condition may be programmed to have a 0 or 10 sec delay. The audio and visual Alarm signal generation delay within the system is less than 1 second.

To set the SpO_2 Pulse Rate Alarm limits:

1) Touch the SpO_2 Pulse Rate Numeric field.
2) Adjust the desired SpO_2 Pulse Rate Upper or Lower Alarm Limit value.
    a. The SpO_2 Pulse Rate Upper and Lower Alarm Limits can be adjusted independently.
    b. The SpO_2 Pulse Rate Upper and Lower Alarm Limit can be set to “Off”.
3) Touch OK to accept or Cancel to ignore the selection.
4) Touch the Home touch area to return to the Main screen.

A SpO_2 Pulse Rate Alarm limit condition may be programmed to have a 0 or 3 sec delay. The audio and visual Alarm signal generation delay within the system is less than 1 second.

WARNING
Setting the SpO_2 Pulse Rate Upper or Lower Alarm Limit to “Off” will not generate any visual or audible indication of an alarm condition.

10.3 SpO_2 Measurement

WARNING
Prior to patient monitoring, ensure the monitor is configured to the appropriate patient mode – Horse, Dog or Cat. The current patient mode is displayed on the main screen.

Equipment Alert
Monitors equipped with Nellcor oximetry will have the Nellcor OxiMax SpO_2 connector.

The monitor is shipped with Nellcor V-SAT sensors. No other manufacturer's sensors should be used.

The preferred sensor application site for canine, feline and equine animals is on the tongue, with the sensor's optical components positioned on the center of the tongue. Alternatively, the sensor and clip may be applied to the animal's lip, toe, ear, prepuce, or vulva.

If the sensor does not track the pulse reliably, it may be incorrectly positioned, or the sensor site may be too thick, thin, or deeply pigmented to permit appropriate light transmission. If any of these situations occur, reposition the sensor or try another sensor site. If the sensor site is covered with fur, try shaving the site and reapplying the sensor.

Be sure to position the sensor cable along the side of the animal's face and body to avoid entanglement with the animal.

10.3.1 Attachment Procedure

1) Select and apply a sensor that is the appropriate size for the patient according to the instructions provided by Nellcor.
2) Connect the sensor assembly to the Interface Cable:
    a. Place the plastic hinged cover in the unlocked position (perpendicular to the connector).
    b. Connect the sensor assembly to the Interface Cable.
3) Lock the plastic hinged cover to prevent accidental cable disconnection.
4) Plug the Interface Cable into the SpO_2 connector located on the left-hand side (patient input panel) of the monitor. Both the Nellcor SpO_2 connector and side panel input connector are keyed to ensure proper orientation for this connection. Push the connector in until you hear an audible "click".
5) Press the On/Off switch to turn "ON" the monitor.
6) Check the Alarm Limits and configure them appropriately for the patient.
7) When SpO_2 monitoring is complete, remove the sensor from the patient.

WARNING

Reusable sensors may be used on the same site for a maximum of four (4) hours, provided the site is inspected routinely to ensure skin integrity and correct positioning. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients. If skin integrity changes, move the sensor to another site.

When the SpO_2 sensor is removed from the patient, the message "SpO_2 check sensor placement" appears in the monitor message area and an audible alarm sounds, indicating a connection has been lost.

Pressing the Silence button mutes the audible alarm tone, but the visual message remains. The audible alarm will return once the Audio silence time has lapsed.

To clear this alarm, enter the Setup SpO_2 screen and select the SpO2 Alarm Acknowledge button to remove the alarm condition. Once selected an audio tone will be generated and the confirmation message: **SpO2 alarm acknowledged** will appear briefly in the message area.

Note

If the Alarm Silence is enabled, no audio will be heard but a visual message will appear in the SpO_2 Numeric field.

10.3.2 Removing the Interface Cable

Equipment Alert

To avoid damage to the Interface Cable, hold it by the connector rather than the cable when connecting or disconnecting either end.

When SpO_2 monitoring is not required, disconnect the Interface Cable by squeezing the grey tabs with your thumb and index finger while pulling the connector away from the monitor.

When the SpO_2 sensor is disconnected from the monitor, the message "SpO_2 unplugged" appears in the SpO_2 Numeric field and an audible alarm sounds indicating a connection has been broken. Press the Silence Button to silence the visual and audible alarm.

Refer to Section 14: Accessories for Nellcor SpO_2 sensor types and part number information. Consult instructions enclosed with each sensor for proper application.

10.4 Plethysmograph

The monitor has the capability to display the Plethysmograph waveform from the SpO_2 sensor.

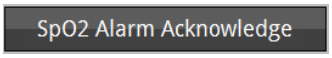
To enable the SpO_2 waveform:

1) Press Setup
2) Select Home Screen.
3) Select SpO_2 Waveform On.
4) Touch OK to accept or Cancel to ignore the selection.
5) Touch the Home touch area to return to the Main screen.

> ***Note***
> *The SpO_2 sensor must be kept as motionless as possible to make a proper determination. Use the Plethysmograph waveform to determine if a strong rhythmic pulse signal is present.*

When initially placing a sensor on the patient, the message area will display the message "SpO_2 searching" until the signal is acquired or a SpO_2 alarm is generated.

Upon removing the SpO_2 sensor from the patient the user may address the "SpO_2 check sensor placement" alert by performing either of the following:

- From the Main Menu, Select (Audio) Silence to temporarily silence the alert for the pre-determined interval
- Enter the SpO_2 Setup screen and select the 

button to permanently silence the SpO_2 equipment alarms until the sensor is reapplied to the patient.

When selected, the **SpO_2 alarm acknowledged** message appears to confirm the selection.

10.5 SpO_2 Messages

WARNING

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by an alternate method.

Caution

- ⇨ *The loss of a pulse signal can occur in any of the following situations:*
  - *a blood pressure cuff is inflated on the same extremity as the one with the SpO_2 sensor attached*
  - *excessive ambient light such as from a surgical lamp or sunlight*
  - *the patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia*
  - *the patient is in cardiac arrest or is in shock*
  - *the sensor is too tight*
  - *there is arterial occlusion proximal to the sensor*

- ⇨ *Inaccurate measurements may be caused by:*
  - *anemia or low hemoglobin concentrations*
  - *electrosurgical interference*
  - *excessive ambient light*
  - *excessive patient movement*
  - *incorrect sensor application or use*
  - *intravascular dyes such as indocyanine green or methylene blue*
  - *moisture in the sensor*
  - *placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line*
  - *venous pulsations*

When no SpO_2 sensor is attached to the monitor, the SpO_2 and SpO_2 Pulse numerals will be blank.

- When the SpO_2 sensor is connected to the monitor, but is not attached to the patient, the SpO_2 and SpO_2 Pulse Rate numeric may be displayed as dashes or blank.
  - The SpO_2 numeric field displays the message "SpO_2 check sensor placement".
- Press Silence Button. The monitor silences the audible alarm tone, but the message remains.
- If the message "SpO_2 check sensor" should appear in the SpO_2 numeric field, verify that the correct SpO_2 sensor is being used or that the SpO_2 sensor is not defective.
  - Press Silence Button. The monitor silences the audio alarm tone, but the message remains.
  - Remove the defective SpO_2 sensor and replace it with a working SpO_2 sensor.

If the internal SpO_2 Module should fail, the message "SpO_2 problem detected" will appear in the monitor numeric field. Press the Silence button and the monitor will silence the audio alarm tone, and the message remains. Should any of the above problems persist, contact Midmark.

11. Trends

Trends allow the user to recall all trended physiologic patient measurement records and Saved Snapshots. Each trend value and Snapshot is date and time stamped and color coded to match the main display screen displayed values. Up/Down arrows allow the user to view trend information by latest or oldest date and time.

Pressing Trends reveals a record that can contain up to 72 hours of data, displayable at user selectable intervals of 1, 5, 15, minutes, 1 or 4 hours (refer to Figure 53). Regardless of the user selected interval, all available measured values are saved every minute consisting of:

- A one (1) minute average of the %SpO_2 values (if installed)
- Data and Time Stamp of measurement
- NIBP measured value (Sys/Dia/MAP)
- SpO_2 values (if installed)
- PR values (if installed)
- Patient ID (if data is entered in Setup/Patient Setup/Patient No.)

General Information:

- NIBP values are saved at the time they were captured
- Turning the power “Off” does not clear the History memory
- Automatically deletes the oldest record first (FIFO)

Press **Close** to return to “Main Display” screen menu or after thirty (30) seconds of inactivity the monitor will automatically return to Main Display.

Trends can be saved to a .csv file on a USB / Flash Drive. See System Menu.

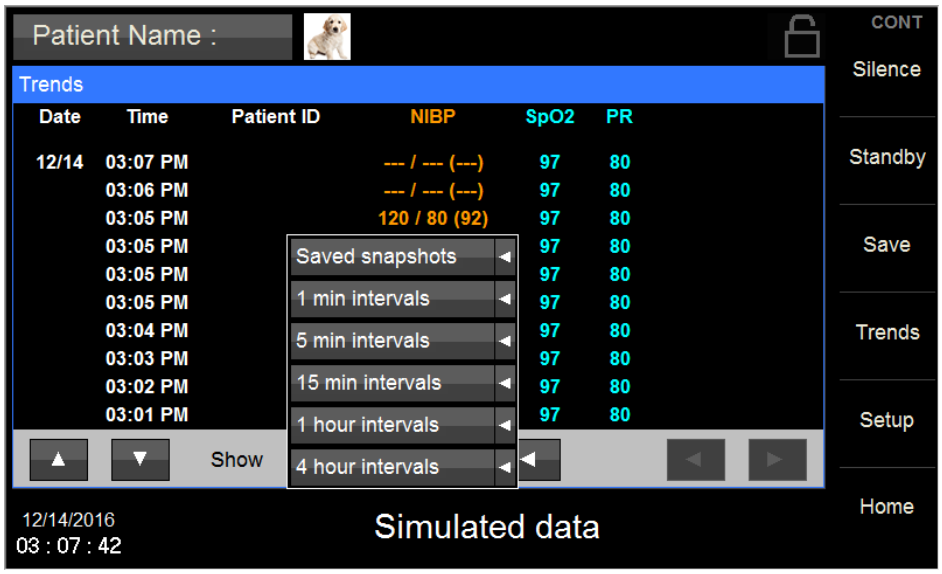


Figure 53: Trends - Time Frame Selection

12. Cleaning

12.1 Overview

WARNING
Do not, under any circumstances, perform any testing or maintenance on the monitor while the monitor is being used to monitor a patient. The monitor must be turned "Off". Unplug the monitor from the AC power source and remove the internal battery.

Caution
Do not open the monitor to clean or repair it. Contact Midmark for service needs.

Caution
Disconnect all accessories from the monitor before cleaning. Do not immerse any part of the electrical connector of the cable or accessories in the cleaning or disinfection solution at any time. Do not use an abrasive cloth or cleaner on the accessories.

12.2 Display

Caution
Use care when cleaning the display. Scratches may occur.

Occasionally, as needed, clean the display using a soft, lint-free cloth sprayed with an alcohol-free glass cleaner. Do not use either isopropyl alcohol or solvent to clean the display. Use of these cleaners can cause damage to the display. The use of paper towels is not recommended as it may scratch the display surface.

12.3 Monitor

Examine the monitor's case daily for any damage and check the AC cord, power supply and DC power cord for bent or broken prongs, cracks, or fraying. Neither the monitor, the power supply nor power cords should be used if damaged. If any damage is noted, contact Midmark.

Caution
Do not spray any water or cleaning solution directly onto the monitor.

As needed, clean the monitor using a soft cloth dampened with a mild dishwashing detergent solution and gently rub the soiled area until clean. Be sure to avoid the touchscreen display. Use a clean soft cloth to dry the monitor. Do not use abrasive cleaners on the monitor. Do not use either isopropyl alcohol or solvent to clean the monitor. Use of these cleaners can cause damage to the monitors' surface and touch screen display. Do not immerse the monitor, power supply or power cords in the cleaning solution.

When necessary, the monitor surfaces may be disinfected using a soft cloth saturated with a 10% (1:10) solution of chlorine bleach in tap water. Be sure to avoid the touchscreen display. After disinfecting, wipe down the monitor using a soft cloth dampened with fresh water to remove any trace amounts of residue and/or fumes.

Equipment Alert
Thoroughly wipe off any excess cleaning solutions. Care should be taken to prevent water or cleaning solution to run into connector openings or crevices.

12.4 Blood Pressure Cuffs

Prior to each patient use, inspect the blood pressure cuff and its hose for damage.

WARNING
If the cuff should become contaminated with blood or other bodily fluids, it should be discarded.

Equipment Alert
Refer to the product packaging for additional Cleaning and Disinfecting Instructions where applicable.

Equipment Alert
Midmark does not recommend submersion of the cuff. Liquid should not be permitted to enter the cuff bladder because instrument damage may occur. The cuff should be allowed to thoroughly dry before use.

12.5 Pneumatic Tubing

WARNING
If the hose should become grossly contaminated with blood or other bodily fluids, it should be discarded.

Equipment Alert
Midmark does not recommend submersion of the hose. Liquid should not be permitted to enter the hose because instrument damage may occur. The hose should be allowed to thoroughly dry before use.

Prior to each patient use, inspect the NIBP Inflation Hose for proper connection, cracks, and kinks. As necessary, clean the pneumatic tubing using a soft cloth dampened with a germicidal solution (e.g. CIDEX).

12.6 SpO_2 Interconnect Cable

Prior to each patient use, inspect the SpO_2 Interconnect cable for damage. As necessary clean the cable using a soft cloth dampened with a germicidal solution (e.g. CIDEX).

12.7 SpO_2 Sensors (Reusable)

As necessary, the sensor may be surface cleaned by wiping it with a 70% isopropyl alcohol pad. Allow the sensor to dry prior to placement on a patient.

Caution
Do not soak or immerse the sensor or its cable in any liquid solution. Do not attempt to sterilize.

For more information, refer to the Directions for Use pamphlet enclosed with each sensor.

13. Maintenance

13.1 Maintenance Intervals

13.1.1 Preventative Maintenance

Periodically inspect the following areas:

- Power cord(s) should be free of cuts or other visible damage.
- All fasteners should be in place and tightened securely.
- All mechanical functions should operate properly.

If the monitor requires repair, it must be referred to the appropriate service personnel. Service performed by unauthorized personnel could be detrimental to the monitor and may void the warranty. For service, contact Midmark.

13.1.2 Painted Metal / Plastic Surfaces

Clean the painted metal and plastic surfaces weekly using a clean soft cloth, and mild cleaner. Periodic applications of common furniture wax will ease cleaning and maintain the finished luster of the surfaces.

13.2 Oximetry Calibration Check

The oximetry modules are factory calibrated. No user calibration is required.

The device should be checked for accuracy using a calibrated SpO_2 simulator, such as a *Fluke Biomedical Index 2 Pulse Oximeter Tester*, every six (6) months. If a simulator is unavailable, a basic calibration check can be performed by taking an SpO_2 measurement on yourself. The SpO_2 saturation reading should be 95-100% for non-smokers.

Facilities that require a Preventative Maintenance Calibration Certificate may contact Midmark about this service.

13.3 NIBP Calibration Check

Preventive maintenance of the monitor is an important function that should be performed routinely by the user to ensure safe and efficient monitor operation. Midmark recommends that you do the following:

- Perform yearly NIBP pneumatic check (leak test)
- Perform a NIBP transducer check once per year or when there is doubt about the validity of the blood pressure readings

These checks can be performed by connecting the device to a calibrated Blood Pressure simulator, such as a *Fluke Biomedical BP Pump 2 NIBP Blood Pressure Simulator*. Place the device in Calibration Check Mode shown in Figure 54. The device then closes its internal valves and displays the cuff pressure from its internal transducer. Use the simulator's test function to inflate the system to 150 mmHg. Next, confirm that the simulator's internal cuff pressure is within +/- 2 mmHg of the pressure reported by the device under test. Finally, confirm the leak rate is less than 5 mmHg/min.

If a simulator is unavailable, these same tests could be performed using a manual blood pressure gauge and inflation bulb.

If such tools are unavailable, a basic calibration check can be performed by taking a blood pressure measurement on yourself. The blood pressure reading should be within +/- 5 mmHg of the reading that is normal for you. In addition, the cuff pressure should deflate smoothly, without excessive pumping sounds that would suggest a leak in the system.

Facilities that require a Preventative Maintenance Calibration Certificate may contact Midmark about this service.

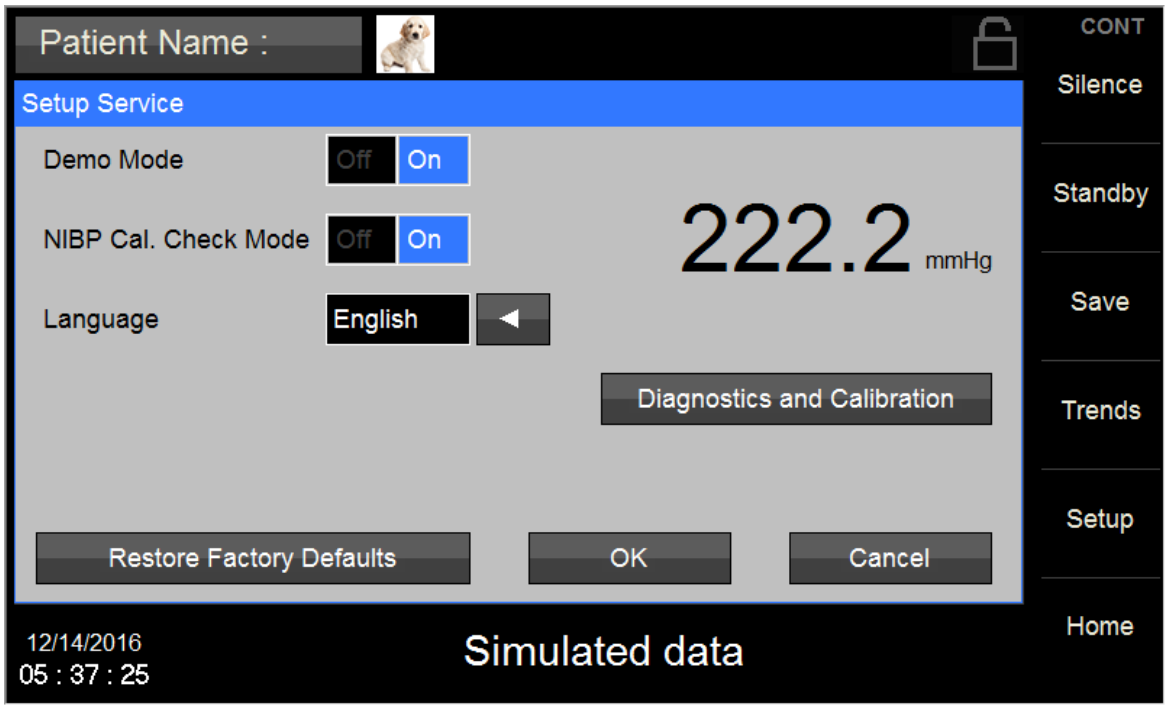


Figure 54: Displayed pressure for NIBP Calibration Check

13.4 Monitor Battery

When the battery fails to hold a charge, it will need to be replaced. Midmark recommends replacing the monitor's battery every (3) three years. When the Cardell Insight monitor is going to be stored for six (6) months or more, remove the battery prior to storage. Contact Midmark for guidance.

> ***Equipment Alert***
> *Batteries not charged and left in storage for more than six (6) months could degrade and not recharge to full capacity.*

If the Cardell Insight has been stored for more than thirty (30) days, charge the battery. A fully discharged battery requires five (5) hours to receive a full charge. The battery is being charged whenever the Monitor is connected to a power source (AC Line Power or +12 VDC).

- The battery is charging whenever the Monitor is plugged into a power source.
- A green Battery Charging Visual Indicator (located to the right of the On / Off button) on the front panel is lit when the battery is charging.
- Batteries will self-discharge when they are not used.
- It is recommended that the battery be maintained at full charge by leaving the Monitor connected to a power source whenever possible.
- The standard 10.8 Volt 7800 mAh battery pack, when new, fully charged, is capable of approximately 10 hours of operation when the monitor is set in the 5-minute Automatic Mode (Continuous SpO_2 measurements).
- The battery icon  appears when the monitor is disconnected from mains power. The icon provides an indication of relative battery charge level.
- When the message "Low Battery" 

appears on the screen, approximately (30) minutes of battery operation remain. Three (3) audio "beeps" are heard every twenty-five (25) seconds.

13.4.1 Replacing the Monitor Battery

> ***WARNING***
> *Use only the battery listed in Section 14: Accessories*

> ***Caution***
> *This product contains a rechargeable battery that is recyclable. Under various state and local laws, it may be illegal to dispose of this battery into the municipal waste stream. Check with your local authorities for instructions on recycling options in your area.*

> ***Caution***
> *Risk of fire, explosion, or burns. Do not short circuit, crush, expose to high temperature, incinerate, or disassemble the battery.*

13.4.1.1 Removing the Battery

Perform the following steps to remove the battery:

1) Place the monitor on its back to expose the battery cover retaining screws.
2) Remove the 4 screws holding the battery cover to the monitor (refer to Figure 55).
3) Gently remove the battery cover.
4) Remove the battery from the battery cover by lifting the battery up (non-connector side).
5) Gently slide the battery out of the battery cover. DO NOT REMOVE THE BATTERY CONNECTOR FROM THE COVER
6) Properly dispose of the old battery per the local requirements.

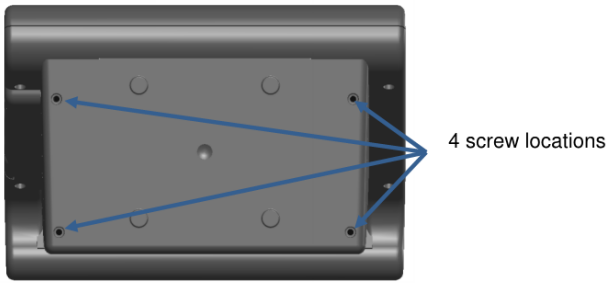


Figure 55 Battery Cover Retaining Screws

13.4.1.2 Installing the Battery

> ***Caution***
> *Failure to install the battery properly within the Monitor may lead to a risk of fire, explosion, or burns.*

> ***Note***
> *Charge battery fully before initial use.*

Perform the following steps to install a battery:

1) Remove battery cover as described above.
2) If the battery connector was removed from the cover, make sure the battery connector is aligned as illustrated in Figure 56.

3) Align the battery with the battery pack contacts or each connector. Note the polarity and orientation of the connectors.
4) Gently slide the battery into the battery cover.
5) Push the battery sideways for a firm connection to the battery connector and lower the battery into the battery cover. Refer to Figure 56.
6) Align the battery cover to the bottom of the monitor.
7) Install the 4 screws that hold the battery cover in the monitor – Do not over-tighten the screws.

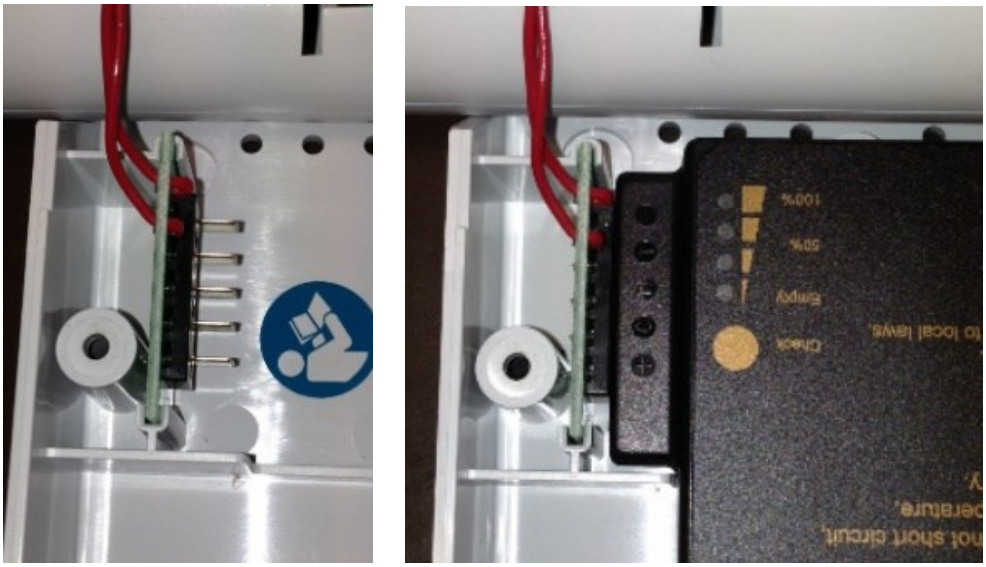


Figure 56: Battery Connector Orientation

14. Accessories

Contact Midmark's Customer Service Department or go to www.midmarkanimalhealth.com/store for the latest product information and ordering.

Reorder #	Description	Qty.
SV-1	Small animal BP cuff for 3-6cm limb circumference	1
SV-2	Small animal BP cuff for 4-8cm limb circumference	2
SV-3	3.5cm BP cuff for 6-11cm limb circumference	3
SV-4	4.0cm BP cuff for 7-13cm limb circumference	3
SV-5	5.0cm BP cuff for 8-15cm limb circumference	2
SV-8	Large animal BP cuff for 13-20cm limb circumference	1
SV-10	Large animal BP cuff for 18-26cm limb circumference	1
V-SAT	Nellcor VetSat SpO2 sensor w/ lingual clips (8015 only)	1
VSC-S	Small animal SPO2 sensor clip (8015 only)	1
VSC-L	Large animal SPO2 sensor clip (8015 only)	1
01-02-0183	Nellcor SpO2 extension cable (8015 only)	1
016-10028-00	NIBP Inflation tube	1
015-10094-00	Power cord, domestic, hospital grade	1
015-3604-00	Transformer, power supply; Vendor PN: 01-02-0806	1
3-009-0014	Rechargeable Battery	1
061-1016-00	Blood pressure cuff selector	1

The following are optional accessories for use with the Cardell® Insight series:

Reorder #	Description
SV600	Package of 5 Midmark small animal cuffs (1 of each size)
MaxFast-1	Nellcor MaxFast Reflectance sensor & Posey wrap (8015 only)
015-10098-00	Power cord, UK
015-10099-00	Power cord, Australia
01-02-0386	Power cord, Europe
8008-005	Mobile Stand with Monitor mount
8008-006	Monitor mount, Canis Major lift table
9A465-009	Monitor mount, VMS Plus
9A465-010	Monitor pole mount
9A465-011	Monitor stud mount
9A465-012	Monitor wall mount

15. Specifications

15.1 Monitor Configuration Examples

Catalog No.	Model Number	Model Description
8014	Insight-X0000	Cardell Insight NIBP only
8015	Insight-XN000	Cardell Insight NIBP and Nellcor Pulse Oximetry

15.2 NIBP Measurement

Characteristic	Specification
Technique:	Oscillometric, Microprocessor software eliminates most ambient noise and motion artifact
Parameter	Range
Systolic:	35 – 260 mmHg
Diastolic:	15 – 215 mmHg
MAP:	20 – 235 mmHg
Pulse Rate Range:	30 – 240 BPM
Accuracy:	±5 mmHg with a standard deviation no greater than 8 mmHg
Pulse Rate Accuracy:	±2% or ±2 BPM, whichever is greater
Self-Test:	System self-test is performed each time power is turned on.
Auto Zero:	Zero pressure reference is automatically established after every reading.
Inflation Pressure (mmHg):	Initial: 160
	User Selectable: 60, 80, 100, 120, 140, 160, 180, 200, 220, or 240
Adaptive Pressure:	Subsequent inflation to approximately 30 mmHg greater than previous Systolic pressure
Operating Modes:	Manual, STAT or Automatic (at preset intervals)
Automatic Cuff Deflation:	If cuff pressure exceeds 290 mmHg
	If measurement time exceeds 120 seconds
	If safety timer detects microprocessor failure
	Power loss – Cuff will deflate automatically

15.3 Oximetry

A SpO2 simulator may be used to verify the operation of the pulse oximetry.

Characteristic	Specification
Nellcor OxiMax	Use only with Nellcor Pulse Oximeter
Type:	Functional Oxygen Saturation
Sensors:	V-SAT
Application Site:	Tongue, Ear, Lip, Toe, Prepuce, or Vulva
Display SpO_2 % Range:	1 - 100%
SpO_2% Accuracy	70 – 100, ± 2.5 digits (1 SD)
Averaging time:	Normal mode: 4.5 - 6.5 sec
Measurement Wavelengths:	Red 660 Nanometers
	Infrared 890 Nanometers
Power:	Not exceeding 15 mW
Display Pulse Rate Range:	20 - 240 BPM
Pulse Rate Accuracy:	± 3 digits
Numerals:	Updated every (1) one second
Operating Mode:	Continuous Monitoring

15.4 Patient Alarms

Parameter	Units	Horse		Dog		Cat	
		Default	Range	Default	Range	Default	Range
NIBPs upper	mmHg	160	41 - 240 Off	160	41 - 240 Off	160	41 - 240 Off
NIBPs lower	mmHg	70	40 - 239 Off	70	40 - 239 Off	70	40 - 239 Off
NIBPm upper	mmHg	140	21 - 230 Off	140	21 - 230 Off	140	21 - 230 Off
NIBPm lower	mmHg	70	20 - 229 Off	70	20 - 229 Off	70	20 - 229 Off
NIBPd upper	mmHg	100	11 - 210 Off	100	11 - 210 Off	100	11 - 210 Off
NIBPd lower	mmHg	40	10 – 209 Off	40	10 – 209 Off	40	10 – 209 Off
PR upper	bpm	50	21-240 Off	180	21-240 Off	180	21-240 Off
PR lower	bpm	24	20 - 239 Off	50	20 - 239 Off	90	20 - 239 Off
SpO_2 upper	%	100	1 - 100 Off	100	1 - 100 Off	100	1 - 100 Off
SpO_2 lower	%	95	0 - 99 Off	95	0 - 99 Off	95	0 - 99 Off

Note
Each alarm limit may also be selected "Off" individually or as a whole.

Note
Lower Alarm Limit cannot be set above the associated Upper Alarm Limit.

Note
Upper Alarm Limit cannot be set lower than the associated Lower Alarm Limit.

15.5 Control Panel

Characteristic	Specification
Display:	7” Color LCD display of measurement results, instructions & troubleshooting messages
Parameters Displayed:	NIBP Systolic Pressure, Diastolic Pressure and Mean Arterial Pressure (MAP)
	NIBP Pulse Rate
	%SpO_2 and Pulse Rate
Patient Types:	Horse, Dog or Cat modes
Trends:	Review of previous measurements

15.6 Power

Characteristic	Specification
Source:	External line or internal battery
AC Power:	100-240 VAC, 1.2A Max (1.2A to 0.5A) 50-60 Hz Class II device
Battery:	10.8 VDC, 7800 mAh, Lithium Ion (Li-ion) battery pack Charge Time: 5 hours (fully depleted battery) Operation on battery: Capable of approximately 10 hours of operation set in 5-minute Automatic Mode
Leakage Current:	100 microamp (maximum)
Ingress Protection	IPX1

15.7 Storage/Transport Environment

Characteristic	Specification
Storage / Transport Temp:	-20°C to 60°C (-4°F to 140°F)
Humidity:	15 to 95% RH, non-condensing
Altitude:	0 to 40,000 ft (101 to 19 kPa)

15.8 Physical Dimensions & Weight

Characteristic	Specification
Height x Depth x Width:	7.63 x 5.75 x 11.00 (inches)
Weight	4.3 lbs. (1.95 kg)

15.9 Settings and Defaults

15.9.1 Initial Inflation Pressure

Start BP Options = No (Adaptive BP Enabled)

Default	Range (mmHg)
160	60-240
	(Increments of 20)

Start BP Options = Yes (Adaptive BP Disabled)

Default	Range (mmHg)	
200 160 120 100	High: Medium High: Medium: Low:	120-240 100-220 80-200 60-180
	(Increments of 20)	

15.9.2 Main Screen

	Setting	Default	Range
NIBP	NIBP mode	Manual	Manual, Auto Interval, STAT
	NIBP Interval	3	1, 2, 3, 4, 5, 10, 15, 30, 60, 90 minutes
	Start BP Options	No	Yes, No
	Cuff Size	Small	Small, Large
Nellcor SpO_2	SatSeconds	Off	Off, 10, 25, 50, 100
	Response Mode	Normal	Normal, Fast
Pulse Rate	Beat Volume	4	1, 2, 3, 4, 5, 6, 7, 8, 9, 10
	Beat Sound	Off	On, Off
	Pulse Icon	On	On, Off
Trends	Interval	Snapshot	Saved: 1 min, 5 min, 15 min, 1 h, 4 h
Screen	Lock	Unlocked	Un-locked, Locked
			Password: Current date in monitor (mmddyy)

15.9.3 Setup Screen

	Setting	Default	Range
Home Screen	Pulse Icon	On	On, Off
	SpO2 Waveform	On	On, Off
Patient Setup	Client Name	Blank	Up to 20 alphanumeric characters
	Patient Name	Blank	Up to 20 alphanumeric characters
	Patient No./ ID	Blank	Up to 12 alphanumeric characters
	Doctor	Blank	Up to 16 alphanumeric characters
	Species	Dog	Cat, Dog, Horse
	Sex	Male	Male, Female
	Weight	Blank	0 - 1100 lbs.
			0 - 500 kg
Audio	Alarm Volume	6	1 – 10
	Beat Volume	4	1 – 10
	Beat Sound	Off	On, Off
	Touch Click	Off	On, Off

Equipment Alert
Settings associated with SpO_2 parameters will not be available for monitors without that option installed.

15.9.4 Administrator Screen

(Password Protected)

	Setting	Default	Range
Setup Alarms	Alarm Silence Time	1.5 minutes	1, 1.5, 2 minutes
	Alarm Pause Time	2 minutes	1, 1.5, 2 minutes
	Second Speaker Time	2 minutes	0, 1, 2, 3 minutes
	Limit Alarm Validation	On	On, Off
Setup System	Monitor ID	(Blank)	Alphanumeric entry via keyboard
	On Power Up	Ask if new patient	Ask if new patient, Assume new patient, Assume same patient
	Workflow	Continuous	Continuous, Spot Check
	Set Date and Time	MM:DD: YY	Month: 1-12, Day: 1-31, Year: 00-99
		HH:MM: SS	Hour: 1-12, Minute: 0-59
		AM	AM, PM
	Set Unit of Measure	lbs.	lbs., kg
	Save User Default	(Blank)	OK, Cancel
Setup Service	Demo Mode	Off	On, Off
	NIBP Cal. Check Mode	Off	On, Off
	Language	English	English
	Copy Settings to USB Stick	Bio-Med Selectable Functions	
	Copy Logs to USB Stick		
	Copy Settings from USB Stick		
	Diagnostics and calibration (Update Software, diagnostic messages)		
	Restore Factory Defaults		
Setup Display	Patient Button Label	Patient Name	Patient No., Patient Name, Client Name, Leave Blank
	Monitor Button Label	Leave Blank	Monitor ID, Doctor, Leave Blank
	Auto Dim Timeout (minutes)	Off	Off, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 minutes

15.10 Standards

Unit complies with the following requirements:

- IEC 60601-1
- ANSI/AAMI ES60601-1
- ANSI/AAMI/ISO 81060-2
- CSA C22.2 No. 60601-1
- ISO 9919
- IEC 60601-1-2
- IEC 60601-1-6
- IEC 60601-1-8
- IEC 80601-2-30
- IEC 80601-2-49
- ISO 80601-2-61
- IEC 60068-2-27
- IEC 60068-2-31
- IEC 60068-2-64
- IEC 60529

Possession or purchase of this device does not convey any express or implied license to use the device with replacement parts which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

The Cardell Insight monitor is CE marked.

The IEC 60601-1 and IEC 60601-1-2 standards require that the Essential Performance of a device be maintained during basic safety and electro-magnetic compatibility (EMC) testing, respectively. The primary performance characteristics that are needed to maintain the residual risk at post-mitigation levels are as follows:

Any disturbance that is induced during testing shall not generate false physiological parameter results by the monitor's algorithms.

Alarm annunciation shall remain functional during testing and the device shall not generate false alarms.

Any waveform distortion shall be small enough to be distinguishable from physiologically produced signals.

In tests where momentary interference to the monitor is allowed, such interference shall be self-recoverable within 10 seconds and shall not change the device's operating mode or stored settings.

The device shall retain its clinical utility during testing (e.g., operating mode, menu navigation).

16. Electromagnetic Compatibility

Manufacturers Declaration of Conformity

Electronic Emissions and Immunity

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the monitor

The Cardell Insight is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Cardell Insight can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Cardell Insight as recommended below, per the maximum output power of the communications equipment.

Rated maximum output power of transmitter (Watts)	Separation distance according to frequency of transmitter (Meters)		
	150 kHz to 80 MHz $d = 3.5 / 3 \sqrt{P}$	80 MHz to 800 MHz $d = 3.5 / 20 \sqrt{P}$	800 MHz to 2.5 GHz $d = 7.0 / 20 \sqrt{P}$
0.01	0.12	0.02	0.04
0.1	0.38	0.06	0.11
1	1.17	0.18	0.35
10	3.69	0.55	1.11
100	11.67	1.75	3.50

For transmitters operating at a maximum output power not listed above, the recommended separation distance *d* in meters can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Cardell Insight is intended for use in the electromagnetic environment specified below. The customer or the user of the Cardell Insight should assure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	The Cardell Insight uses RF energy only for its internal function. Therefore, its RF emissions are exceptionally low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Cardell Insights is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Cardell Insight is intended for use in the electromagnetic environment specified below. The customer or the user of the Cardell Insight should assure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If user of the monitor requires continued operation during power mains interruptions, it is recommended that the monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the A.C. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Cardell Insight is intended for use in the electromagnetic environment specified below. The customer or the user of the Cardell Insight should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Cardell Insight, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 3.5 / 3 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	20 V/m	$d = 3.5 / 20 \sqrt{P}$ 80 MHz to 800 MHz $d = 7.0 / 20 \sqrt{P}$ 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strength from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Cardell Insight is used exceeds the applicable RF compliance level above, the Cardell Insight should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Cardell Insight.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

17. Warranty Information

Product Registration

Register your monitor at midmark.com/vet-register to:

- Log your product warranty with Midmark
- Keep you informed on important warranty information and product updates
- Provide you with faster, more convenient service in the event you experience a problem
- Enhance customer service benefits tailored to your product and account

Scope of Warranty

Midmark Corporation (“Midmark”) warrants to the original retail purchaser that it will repair or replace components of the animal health products manufactured by Midmark (except for products and components not warranted under “Exclusions”) that are defective in material or workmanship under normal use and service. The sole remedy under this limited warranty is the repair or replacement, at Midmark’s option, of the applicable products or components. This limited warranty shall only apply to defects that: (i) are reported to Midmark within the applicable warranty period; and (ii) are determined to exist upon examination by Midmark. This limited warranty extends only to the original retail purchaser of a product and is not transferable or assignable.

Applicable Warranty Period

The applicable warranty period for each Midmark product commences on the date of delivery to the original retail purchaser of the product and shall continue for the period specified. The Cardell® Insight Monitor is warranted against defect in material and workmanship for a period of two years from the time of delivery.

Monitor Accessories are warranted against defect in material and workmanship for a period indicated below from the time of delivery:

- Battery 1 year
- Nellcor V-SAT SpO2 Sensors 9 months
- Nellcor SpO_2 Extension Cable 6 months
- Blood pressure cuffs and hose* 6 months

*The warranty as to blood pressure cuffs only applies if they are defective in material or workmanship at the time of delivery to the original retail purchaser and such defects are reported to Midmark within three (3) days from the date of delivery.

Exclusions

This limited warranty does not cover and Midmark shall not be liable for the following:

- defects, damage, or other conditions caused, in whole or in part, by misuse, abuse, negligence, alteration, accident (including
- animal acts of any kind), freight damage, tampering, or failure to seek and obtain repair or replacement in a timely manner.
- matching of color, grain, or texture except to commercially acceptable standards.
- changes in color caused by natural or artificial light.
- products which are not installed, used, and thoroughly cleaned and maintained as required in the Users Manuals and Quick Reference Guide for the applicable product.
- products considered to be of a consumable nature.
- accessories or parts not manufactured by Midmark.
- specially manufactured products.
- charges by anyone (including Midmark's authorized dealers) for adjustments, repairs, replacement parts, installation, or other work performed upon or in connection with such products which are not expressly authorized in writing in advance by Midmark.
- costs and expenses of routine maintenance and cleaning.
- all sinks, faucets, and plumbing accessories.
- representations and warranties made by any person or entity other than Midmark; and
- with respect to software that is a product or a component thereof, that the software will be error free, can be used without problems or interruptions, or will be free from vulnerability to intrusion or attack by viruses or other methods.

Exclusive Remedy; Consequential Damages Disclaimer

Midmark's only obligation under this LIMITED warranty is the repair or replacement of defective parts. Midmark shall not be liable for and hereby disclaims any direct, special, indirect, incidental, exemplary or consequential damages or delays including, but not limited to, damages for loss of profits or income, loss of use, downtime, cover, and employee or independent contractor wages, payments, and benefits. This disclaimer shall survive any failure or asserted failure of the essential purpose of this limited warranty or its remedies specified herein.

No Authorization

No person or firm is authorized to create or approve for Midmark any other obligation or liability in connection with Midmark products.

Warranty Disclaimer

THIS WARRANTY IS MIDMARK'S ONLY WARRANTY AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. MIDMARK MAKES NO IMPLIED WARRANTIES OF ANY KIND INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

Statute of Limitations

No action may be brought against Midmark for breach of this limited warranty, an implied warranty, if any, or for any other claim arising out of or relating to the products, more than ninety (90) days following expiration of the warranty period. In the event multiple warranty periods exist with respect to a product, the ninety (90) day period provided for herein shall begin to run from expiration of the warranty period for the component to which the claim relates.

Warranty Service Returns Policy:

Warranty service must be obtained through either Midmark or an authorized dealer in the Midmark product line for which warranty service is requested. Midmark may be contacted for warranty service inquiries or issues via email at www.midmark.com, by mail to Midmark Corporation, 60 Vista Drive, Versailles, Ohio 45380, or by phone at: 1-800-MIDMARK. It is the retail purchaser's obligation to arrange for delivery of a product to Midmark or one of its authorized dealers for warranty service, which delivery shall be at retail purchaser's expense. It is also the retail purchaser's obligation to comply with the warranty service instructions provided either by Midmark or its authorized dealer. The retail purchaser must provide Midmark with completed warranty registration information within thirty (30) days after purchase to obtain the benefits of this limited warranty.

Non-Warranty (Billable) Service Returns Policy:

It is the customer's responsibility to return the product to Midmark; Midmark is responsible for the return of the monitor. Customer must contact Midmark for an RMA number to initiate a return. The customer will be required to provide a P.O. for the repair at a flat rate price. If an estimate is required, a P.O. will be required to initiate the process and a flat rate charge will be applied for the estimate. The customer is responsible for shipping charges to send the monitor to Midmark and for the return shipping back to the customer.

If an estimate is required and the estimate of repairs is declined after the monitor has been evaluated at Midmark, the customer is responsible for the evaluation fee ** plus the shipping back to the customer.

** Contact Midmark Customer Support for current flat rate and estimate fees.

18. After-sale Service and Support

To obtain service or product support, please contact Midmark at 1-800-643-6275 or visit the website at midmark.com. Have the following information available:

- Model and serial number of the equipment
- Date of purchase and distributor name

Equipment Alert
Model/Serial number information is required when calling for service. This information can be found on the rear of the monitor.

Notes:

Midmark Corporation
60 Vista Drive
Versailles, OH 45380 USA
1-800-643-6275
1-937-526-3662
www.midmark.com

MIDMARK
Because we care.