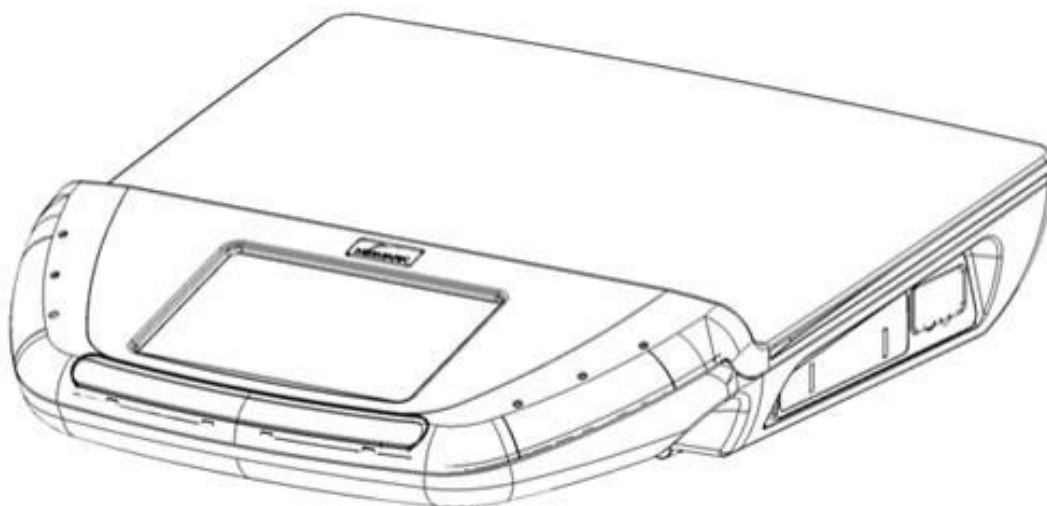




IQvitals[®] Zone[™]

For Models:

1-200-0310
1-200-0320
1-200-0330
1-200-0340
1-200-0350
1-200-0360



User Guide

Notice

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Fairbanks is a trademark of Fairbanks Scales, Inc. Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device.

For Masimo patent information visit www.masimo.com/patents.htm.

This Operation Manual P/N 22-78-0002 Rev EB1 applies to IQvitals with Serenity BP and Zone connectivity model numbers: 1-200-0310, 1-200-0320, 1-200-0330, 1-200-0340, 1-200-0350 and 1-200-0360.

The information in this manual is subject to change without notice.



Caution

Federal Law restricts this device to sale by or on order of a physician or properly licensed practitioner.

Product Information

Warranty Registration

Product registration and warranty information can be found at <http://www.midmark.com/warranty-registration>.

Technical Service Information

Technical Support is available Monday through Friday (except holidays), 6:00 am to 4:00 pm Pacific Standard Time. Midmark Corporation

60 Vista Drive, Versailles, OH 45380

Email: techsupport@midmark.com

T: 844.856.1230, option 2

Fax: 310.516.6517

midmark.com

[Diagnostic Product Support](#)

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Important Information

Safety Symbols



WARNING

Indicates a potentially hazardous situation or practices that could result in serious injury.



Caution

Indicates a potentially hazardous situation or unsafe practices that may result in minor or moderate injury, equipment damage, or inaccurate measurements.



Equipment Alert

Indicates a potentially hazardous situation that could result in equipment damage.



NOTICE

Indicates practices not related to physical injury.

Product Symbols

The following symbols are associated with the IQvitals® Zone™ connectivity and approved accessories.

Symbol	Description
	Follow instructions for use
	Do not dispose of this product as unsorted municipal waste. For more disposal information see " Disposal ".
	Manufacture date
IPX1	Ingress protection against dripping water
	Patient connections are type BF and protected against defibrillation
	Blood Pressure Cuff Connector
	Temperature module connector
	Lithium-ion Power Input: Use only Midmark Power Supply (P/N 5-200-0052)
PC 	PC Custom Link USB
Firmware 	Firmware Update USB
	Scale connector
	Wireless Communication
	"On" (only for part of Equipment)
	WARNING
	Manufacturer
	Caution
	Consult instructions for use
	Power button
	Direct current
	Not made with natural rubber latex

	Non-sterile
RxOnly	Federal law (U.S.A.) restricts this device to sale by or on the order of a physician
	Body weight
	Do not discard
	Lot code
	Catalogue (model) number
IPX0	Ordinary Equipment
 5001979	MEDICAL EQUIPMENT WITH RESPECT TO ELECTRICAL SHOCK FIRE AND MECHANICAL HAZARDS ONLY CONFORMS TO AAMI STD E6061-1, ISO STD 80601-2-56, IEC STDS 60601-1, 60601-1-6 & 62366
	Serial number
>	Greater than
<	Less than
	Recycle lithium-ion battery
	Storage temperature range
	Storage humidity range
	Keep dry
	Shipping direction
	Fragile
	Single use only

	Use by date
	Contains phthalates. DEHP: Di (2-ethylhexyl phthalate)
	Do not use if package is damaged
	Single patient – multiple use
	Blood Pressure Cuff

Introduction

This operation manual is a comprehensive guide, designed to educate the user on the operation and functions of the IQvitals® Zone™ device. The information in this manual includes use of all features that are available with IQvitals® Zone™, such as SpO₂ and use of a medical grade, approved, digital scale.

The manual may contain information about functions that are not included with all devices.

Product Overview and General Information

IQvitals® Zone™, depending on the model selected, automatically and noninvasively measures systolic and diastolic blood pressure, pulse rate, temperature (temporal), and oxygen saturation (SpO₂) for adult and pediatric patients. All functions of the device are performed via the touch screen display, except the on/off function, which is a separate button on the back of the device.

The Masimo rainbow® SET Pulse CO-Oximeter® and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂), pulse rate (PR) for adult and pediatric patients over 30 kg.

The Nellcor Adult SpO₂ Sensor and accessories are indicated for use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for patients weighing greater than 40 kg. The Nellcor Adult SpO₂ sensor is contraindicated for use on active patients or for prolonged use. It is not designed for long-term monitoring. It must be moved every 4 hours (or more often, if indicated by circulatory status and/or skin integrity and reapplied to a different site.

Temperature is measured at Temporal Artery and the Temperature Probe is connected serially to the IQvitals Zone. Compatible digital weight scales can be used for weight, and BMI input.

The IQvitals® Zone™ can transmit data to data management software (e.g., Electronic Medical Records, Midmark stand-alone software) through USB or wirelessly through Bluetooth Low Energy (BLE).

IQvitals® Zone™ connectivity wirelessly connects to mobile computers and has the ability to measure a patient's vital signs and provide alarms when a measurement falls outside of the preset values.

IQvitals® Zone™ has a rechargeable lithium ion battery and two mounting options: a mobile cart and a wall mount.

All vitals parameters can be simultaneously measured and are easily viewed on the touch screen display or connected computer.

The top surface of the IQvitals® Zone™ device can be used as a work surface for a mobile computer or paper documentation at the point of care.

Note	IQvitals® Zone™ is not intended for use on neonatal patients.
Note	Accuracy of blood pressure readings is dependent on the correct cuff size regardless if the patient is pediatric or adult. For pediatric blood pressure measurements, the smallest cuff approved for use on small children is the Child cuff (#3-200-0030* for reusable or 3-200-0040* for single use). It is important that the child's arm fits within the range markings on the cuff being used. *Step deflation algorithm only.
Note	The blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ISO 81060-2:2013) in relation to mean error and standard deviation.
Note	IQvitals® Zone™ is not intended for use during patient transport or for acute care.
Note	Review the user instructions for all accessories used before operating IQvitals® Zone™.
Note	Accessories, including cables, are designed for specific use with the IQvitals® Zone™. The operator/user is responsible for checking and only use approved accessories for the IQvitals® Zone™. Incompatible components can result in degraded performance.

Indications for Use

The IQvitals Zone is intended to be used by clinicians and medically qualified personnel for measuring:

- Noninvasive blood pressure for adult and pediatric patients (3 years and above)
- Pulse rate for adult and pediatric patients
- Noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO₂) for adult and pediatric patients
- Body temperature measured at Temporal Artery for adult and pediatric patients

Models 1-200-0320 and 1-200-0330 provide Pulse oximetry functions but do not provide alarms, and are not intended for continuous monitoring (i.e. intended for spot check use only).

Models 1-200-0350 and 1-200-0360 provide Pulse oximetry functions and related alarms, and are not intended for continuous monitoring.

The most likely location for IQvitals Zone devices to be used in general medical locations, hospitals and alternative care environments.

Device Models

Model	NIBP	Exergen Temporal Thermometer	Nellcor SpO ₂	Masimo SpO ₂	Alarms & Wireless
1-200-0310	X	X	---	---	---
1-200-0320	X	X	X	---	---
1-200-0330	X	X	---	X	---
1-200-0340	X	X	---	---	X
1-200-0350	X	X	X	---	X
1-200-0360	X	X	---	X	X

Contraindications

The IQvitals Zone is not intended for use:

- on neonatal patients
- on pregnant or pre-eclamptic patients
- for apnea monitoring
- within a magnetic resonance imaging (MRI) environment
- within an electro-static unit (ESU) environment
- for applications requiring arrhythmia detection
- for acute care
- during patient transportation
- near flammable anesthetics
- on patients connected to heart/lung machines
- in a hyperbaric chamber

Consult the manufacturer instructions for use provided with each SpO₂ patient sensor for contraindications of the sensor.

Warnings

Review the following information to avoid an imminently hazardous situation or practices which could result in serious or fatal injury.

	WARNING <i>For pediatric blood pressure measurements, the smallest cuff approved for use on small children is the Child cuff (#3-200-0030 for reusable or 3-200-0040 for single use) and should only be used with the STEP DEFLATION algorithm mode.</i>
	WARNING <i>Do not use this device for any purpose other than its specified intended use.</i>
	WARNING <i>To ensure patient safety and device accuracy, only use supplies and accessories that are supplied with the IQvitals® Zone™ and recommended by Midmark. Using unapproved accessories can affect patient and operator safety and cause inaccurate measurements.</i>
	WARNING <i>Regularly inspect the blood pressure cuff, SpO₂ cable, and other accessories for damage. Replace accessories as needed.</i>
	WARNING <i>If this equipment is modified, appropriate inspection and testing must be conducted by Midmark to ensure safe use of equipment.</i>
	WARNING <i>BLOOD PRESSURE MEASUREMENT: Frequent NIBP measurements can cause injury to the patient due to blood flow interference.</i>
	WARNING <i>Do not apply a NIBP cuff over a wound as this may cause further injury to the patient.</i>
	WARNING <i>INTRAVASCULAR ACCESS OR THERAPY, OR AN ARTERIO-VEINOUS (A-V) SHUNT: Use of a NIBP cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present can cause injury to the patient due to temporary interference to blood flow.</i>
	WARNING <i>MASTECTOMY PATIENTS: No blood pressure measurements should be taken in the affected arm of a mastectomy patient.</i>

	WARNING BATTERY HANDLING: IQvitals® Zone™ contains a lithium ion battery. The following precautions should be taken regarding these batteries: <i>Do not immerse in water. Do not heat or throw in fire.</i> <i>Do not leave in conditions more than 122° F (50° C) or in a heated car.</i> <i>Do not attempt to crush or drop.</i> <i>Only use the battery with the IQvitals® Zone™, Midmark P/N 5-200-0052.</i> <i>Follow the instructions in “Disposal” when the IQvitals® Zone™ is taken out of service.</i>
	WARNING <i>California Proposition 65 warning. This product contains chemical(s) known to the State of California to be carcinogenic.</i>
	WARNING <i>Regularly inspect the IQvitals® Zone™ device for damage. If damage is found contact Midmark Technical Service for service and additional information. Refer to “Maintenance” for additional information.</i>
	WARNING <i>Defibrillator protection requires use of MANUFACTURER specified ACCESSORIES.</i>

Cautions

Review the following information to avoid a potentially hazardous situation or unsafe practice which may result in minor or moderate injury, equipment damage, or inaccurate measurements.

	Caution <i>Thoroughly familiarize yourself with the operational procedures of the device prior to use.</i>
	Caution <i>Substituting components different from those supplied or sold by Midmark could result in measurement error.</i>
	Caution <i>IQvitals® Zone™ is not intended for use during patient transport.</i>
	Caution <i>Only NIBP and SpO₂ applied parts of the monitor are defibrillation-proof. When a defibrillator is applied, keep other accessories away from the patient. Otherwise, it may result in damage to the monitor or harm to the patient.</i>
	Caution <i>No modification of this equipment is allowed. Do not open unit. No user-serviceable parts inside. Opening of device may affect calibration and voids warranty.</i>
	Caution <i>Do not connect more than one patient to the device at the same time.</i>
	Caution <i>Do not route the cables of the device in a way that may present a trip hazard.</i>
	Caution <i>To ensure proper operation, perform routine inspection and maintenance on the device. See “Maintenance, Storage, and Battery Replacement”.</i>
	Caution <i>Do not make any modifications to the device. Any modifications made will void the warranty.</i>
	Caution <i>ARRHYTHMIA PATIENTS: The IQvitals® Zone™ is designed to operate in the presence of cardiac arrhythmias. However, the pulse rate measurement may be adversely affected in some cases.</i>

	Caution BLOOD PRESSURE MEASUREMENT <i>Do not allow the blood pressure cuff or hose to come into contact with fluids. If this occurs. See “Cleaning of IQvitals® and Accessories” for cleaning and drying instructions.</i> <i>Check the hose and cuff frequently for signs of damage or debris. An obstruction in the hose may interfere with inflation and deflation, resulting in inaccurate readings.</i> <i>To obtain accurate blood pressure readings, keep the limb and the cuff motionless.</i> <i>The blood pressure cuff should be at the same level as the patient’s heart.</i> <i>Blood pressure measurements may not be accurate if the patient is convulsive or experiencing tremors.</i> <i>Check for kinks in the blood pressure hose if the device reports a measurement problem.</i>
	Caution PULSE OXIMETRY MEASUREMENT (SpO₂) <i>Read instructions provided with the sensor to understand the best application technique and all relevant safety information.</i> <i>Do not apply the sensor on the same limb as the blood pressure cuff. During blood pressure measurements, the perfusion is temporarily reduced, which can result in inaccurate pulse oximetry readings.</i> <i>Refer to “Accessories and Supplies” for approved SpO₂ sensors. Elevated levels of carboxyhemoglobin or methemoglobin can result in inaccurate pulse oximetry readings.</i> <i>Bright light can create problems with the pulse oximetry measurements, resulting in inaccurate readings. If the sensor is in a place where it may be exposed to bright light, you should cover it with some opaque material.</i> <i>Pulse oximetry readings may be inaccurate in the presence of excessive motion artifact or tremors.</i>

Equipment Alert

Indicates a potentially hazardous situation that could result in equipment damage.

	Equipment Alert Do not operate the IQvitals® near high-frequency emissions (e.g., microwaves). IQvitals® Zone™ is not intended to be used together with high-frequency surgical equipment.
	Equipment Alert The IQvitals® Zone™ is intended for indoor use only.
	Equipment Alert The device and its accessories are not intended to be sterilized by any method. Attempting to do so may permanently damage the equipment.
	Equipment Alert Electronic devices can be damaged by exposure to liquids. Do not use or store the IQvitals® Zone™ near any type of liquid. See “ Cleaning of IQvitals® and Accessories ”.
	Equipment Alert In case of malfunction, call Midmark Technical Service and be prepared to describe the problem and provide the serial and model numbers.
	Equipment Alert Refer servicing to qualified personnel.

System Specifications

General Performance	
Product Name	IQvitals® Zone™
Product Type	Non-invasive, multi-parameter vital signs monitor
Product Weight	3.9 lbs. (1.77 kg)
Product Dimensions	12" L x 11.5" W x 2.75" H (292x304x70 mm)
Power Requirements	100–240 VAC, 50/60 Hz 2 A MAX
Battery Requirements	• Battery type: Rechargeable, 7.2 V lithium ion • Low power indicator • Automatic shutdown on low power • Operating time: Approximately 8 hours • Leakage current: Meets AAMI/IEC/CSA 60601-1 requirements • Battery charge time: up to 8 hours to fully charge
Type of Electrical Protection	Class II
Type of Water Protection	IPX1
Disinfecting Method	Per the instructions in “Cleaning of IQvitals® and Accessories”
Anesthesia Equipment Category	Not suitable for use in the presence of a flammable anesthetic mixture with air
EMC Standard	Per IEC 60601-1-2 and FCC Part 15 (Emissions Class A)
Device Connectivity	USB (Client) or Low Energy Bluetooth® (optional)

Environmental	
Cooling	Natural convection
Operating Temperature	50 to 104° F (10 to 40° C)
Storage Temperature	-4 to 122° F (-20 to 50° C)
Operating Humidity	20 to 90% non-condensing
Storage Humidity	15 to 95% non-condensing
Operating Altitude	0 to 9842 feet (3,000 meters)
Storage Altitude	0 to 40,000 feet (12,192 meters)

Non-Invasive Blood Pressure	
Method	Oscillometric
Cuff	Child, Small Adult, Adult, Adult Long, Large Adult, Large Adult Long, and Thigh
Derived Parameters	Systolic, Diastolic, and Mean Arterial Pressure
Measurement Range	Systolic: 50 to 260 mmHg Mean: 30 to 230 mmHg* Diastolic: 20 to 210 mmHg
Measurement Accuracy	Systolic: ± 5 mmHg Mean: ± 5 mmHg Diastolic: ± 5 mmHg
Pulse Rate Range	40 to 200 BPM
Pulse Rate Accuracy	$\pm 5\%$ or ± 3 BPM, whichever is greater
Initial Cuff Pressure	Automatic or user-selectable
Maximum Cuff Pressure	280 ± 5 mmHg
Overpressure Protection	300 ± 30 mmHg
Measurement Time	Approximately 30 seconds
Applied Part	Reusable and single use BP Cuffs

* Mean Arterial Pressure (MAP) is estimated as the cuff pressure corresponding the peak amplitude of the envelop of oscillometric pulses (see AHA Statement, Recommendations for Blood Pressure Measurement in Humans and Experimental Animals Part 1 Blood Pressure Measurement in Humans, © 2004 American Heart Association, Inc, In Circulation February 8, 2005).

IQvitals Zone was clinically investigated according to the requirements of ISO 81060-2: 2013.

EXERGEN TemporalScanner	
Clinical Accuracy	$\pm 0.2^{\circ}$ F or 0.1° C Per ASTM E1112
Temperature	61 to 110° F (16 to 43° C)***
Arterial Heat Balance Range for Body Temperature*	94 to 110° F (34.5 to 43° C)
Operating Environment	60 to 104° F (16 to 40° C)
Resolution	0.1° F or $^{\circ}$ C
Response Time	~0.04 seconds
Time Displayed On screen	30 seconds
Size	Instrument: 7.9" X 1.8" X 1.6" Cable: 32" retracted
Weight	0.7 lbs
EMI and RFI Protection	Stainless steel enclosure on upper part inside of casing
Storage Conditions	-4 to 122° F (-20 to 50° C)
Display Type and Size	Large bright LED's

The CLINICAL THERMOMETER is an ADJUSTED MODE CLINICAL THERMOMETER. Correction method is proprietary. Laboratory testing protocol for laboratory accuracy available upon request.

* Automatically applied when temperature is within normal body temperature range, otherwise reads surface

temperature.

** Approximate number of readings when scanning for 5 seconds and reading the temperature display for 3 seconds before turning thermometer off.

*** 16° C rounded up from 15.5° C.

EXERGEN TemporalScanner	
Construction Method	• Industrial duty impact resistant casing • Chemically resistant casing and lens • Hermetically sealed sensing system • Stainless steel probe
Warranty	1 year

Masimo Pulse Oximetry (SpO ₂)	
Technology	Masimo rainbow® SET Pulse CO-Oximeter®
Method	Absorption – Spectrophotometric (dual wavelength) (Functional oxygen saturation of arterial hemoglobin)
SpO₂ /Pulse Rate Resolution²	SpO ₂ : 1% PR: 1 bpm (beat per minute)
SpO₂ Measurement Range²	0 to 100%
SpO₂ Measurement Accuracy²	No Motion: 70 to 100% (±2%), Adults/ pediatrics With Motion: 70 to 100% (±3%), Adults/ pediatrics
Pulse Rate Measurement Range	25 to 240 BPM
Pulse Rate Measurement Accuracy	No Motion: 25-240 ±3 bpm, Adults/ pediatrics With Motion: 25-240 ±5 bpm, Adults/ pediatrics
Report Interval	1 second
Patient Size	>10 kg (22 lbs)
Liquid Ingress	IPX1
Biocompatibility	Patient contacting materials are ISO-10993-1 compliant. Patient contacting materials are not made with natural rubber latex.
Cleaning	70% isopropyl alcohol or mild detergent
Skin Surface Temperature	41° C (105.8° F) maximum at 35° C (95° F) ambient temperature
Low Perfusion Accuracy	SpO ₂ : 70-100 ±2%, Adults/pediatrics Pulse rate: 25-240 ± 3 bpm, Adults/ pediatrics
Applied Part	Masimo M-LNCSTM DCI or Masimo RD SET DCI adult SpO ₂ reusable sensor
Measurements	Low Signal IQ; Perfusion Index (PI)
Perfusion Index (PI) Measurement Range	0.02-20%

Note: Pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse Oximeter Equipment measurements can be expected to fall between the above specified accuracy range of SpO₂: over 70 to 100%: ±2% (1 S.D.) and SpO₂: over 70 to 100%: ±3% (1 S.D.).

Nellcor Pulse Oximetry (SpO ₂)	
Technology	Nellcor NELL-1
Method	Absorption – Spectrophotometric (dual wavelength) (Functional oxygen saturation of arterial hemoglobin)
SpO₂ /Pulse Rate Resolution	SpO ₂ : 1% PR: 1 BPM (beat per minute)
SpO₂ Measurement Range	0 to 100%

SpO₂ Measurement Accuracy	No Motion: 70 - 100% ($\pm 2\%$), Adults/pediatrics With Motion: 70 - 100% ($\pm 3\%$), Adults/pediatrics
Pulse Rate Measurement Range	25 to 240 BPM
Pulse Rate Measurement Accuracy	No motion: ± 3 BPM With motion: ± 5 BPM
Report Interval	1 second
Patient Size	>10 kg (22 lbs)
IP Classification	IP22
Biocompatibility	ISO 10993-1 compliant
Applied Part	Nellcor™ DS100A adult SpO ₂ reusable sensor

Note: All accuracies are expressed as ± 1 SD. Because pulse oximeter equipment measurements are statistically distributed, about two-thirds of the measurements can be expected to fall in this accuracy (ARMS) range.

Minimum Computer Requirements

The versatility of the IQvitals® Zone™ connectivity device allows for it to be used with or without connection to a computer. If using this IQvitals® Zone™ device with a computer, refer to the Minimum Computer Requirements document [through this link](#) or contact [Midmark Technical Service](#).

Device Unpacking and Setup

Before unpacking the IQvitals® Zone™, inspect the external package for obvious signs of damage. If there are any signs of damage, file a claim immediately with the shipping company.

Contact [Midmark Technical Service](#) immediately to report any product damage and to arrange for repair or replacement of damaged goods.

IQvitals® Zone™ Contents Checklist

The IQvitals® Zone™ shipping carton contains the items listed below. Upon receipt, check the contents to confirm all items are present. Inspect them for any signs of damage. If an item is missing or damaged, contact [Midmark Technical Service](#) for a replacement. Depending on the device configuration purchased, not all items listed below will be in the box.

Quantity Each	Description
1	IQvitals® Zone™ device
1	AC power cord
1	AC power supply
1	Reusable Adult blood pressure cuff (26-35 cm)
1	Reusable Large adult blood pressure cuff (32–42 cm)
1	6.5' blood pressure hose
1	Reusable, adult SpO ₂ finger sensor*2
1	4' SpO ₂ patient cable*2
1	Laptop accessory tray (15 in.)
1	Main storage bin
1	IQVITALS ZONE IFU QR CODE SHEET
1	Quick Reference Guide
1	Warranty card
1	Custom USB Cable

* Brand of accessory will depend on the SpO₂ technology option purchased. May not be applicable to all devices.

Device Setup

The display screen and work surface are on the front of the device (see Figure 1). The display screen will display all IQvitals® Zone™ results, whether or not the device is connected to a computer. See “[Computer Connectivity](#)” for information on connecting IQvitals® Zone™ to a computer through Bluetooth Low Energy or a USB cable.

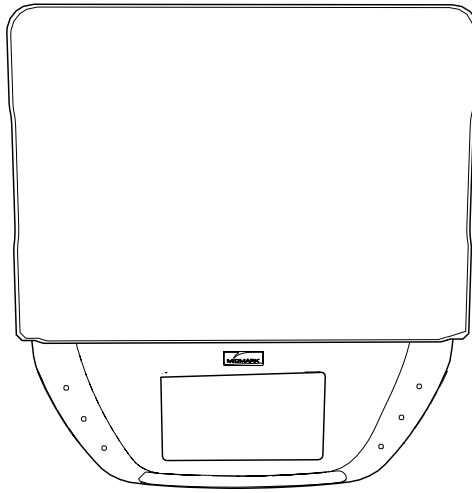
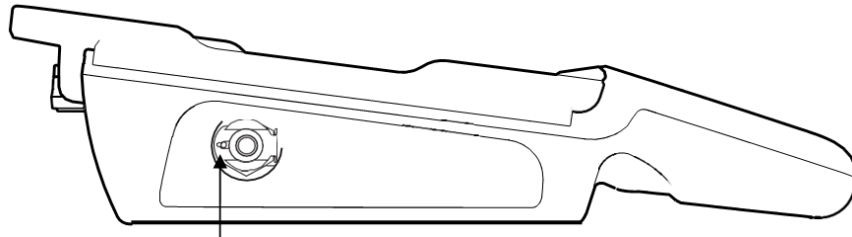


Figure 1

Attach all accessories to the device before attaching the power cord and turning the power on.



Blood pressure hose connector

Figure 2

Blood pressure hose

- A) Attach the blood pressure hose to the connector located on the left side of the device (see Figure 2).
- B) Attach the appropriate size blood pressure cuff to the fitting at the end of the blood pressure hose.

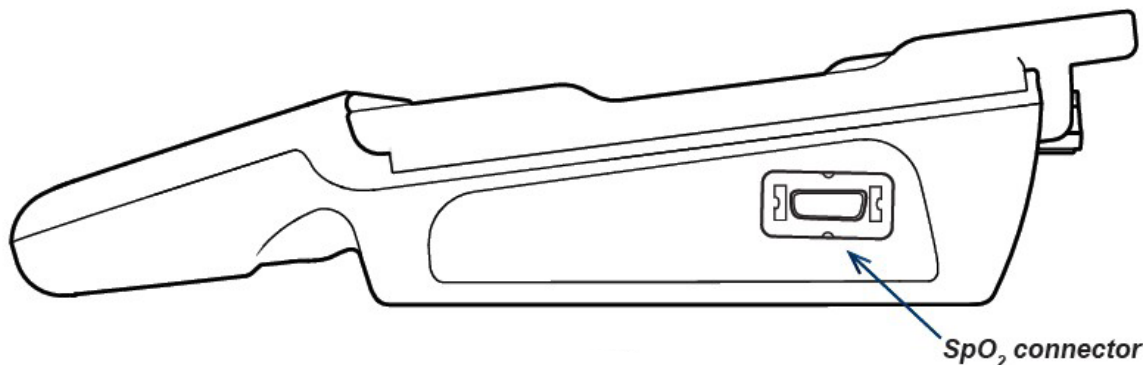


Figure 3

SpO₂ Sensor

- A) Attach the SpO₂ patient/extension cable to the SpO₂ connector on the right side of the device (see Figure 3).
- B) Attach the SpO₂ sensor to the SpO₂ extension cable.
- C) See the installation manual that corresponds with the selected mounting option (mobile cart or wall mount) for instructions on placing the sensor at the sensor holder at the right of the front bin and using the front bin and using the front bin right cable management to wrap around the SpO₂ patient/extension cable and sensor cable.

Note: Applicable only to devices with the SpO₂ feature (refer to [Device Model](#)).

Temperature probe

- A) Connect the temperature probe cable to its connector located on the back of the device (see Figure 4).
- B) See the installation manual that corresponds with the selected mounting option for instructions on threading the temperature probe cord through the temperature cord guide, inserting the temperature probe into its well, and placing the box of probe covers (included in the kit) in the probe cover holder of the device.

Power cord

The power input is located on the back of the device (see Figure 4). Attach the DC Power Input Cord to the back of the device and plug the other end into the power supply. The AC Power Cord can now be plugged into an AC wall outlet.

Note: Fully charge the battery for at least six hours before using the device. A lightning bolt will display in the Battery icon to indicate the battery is charging.

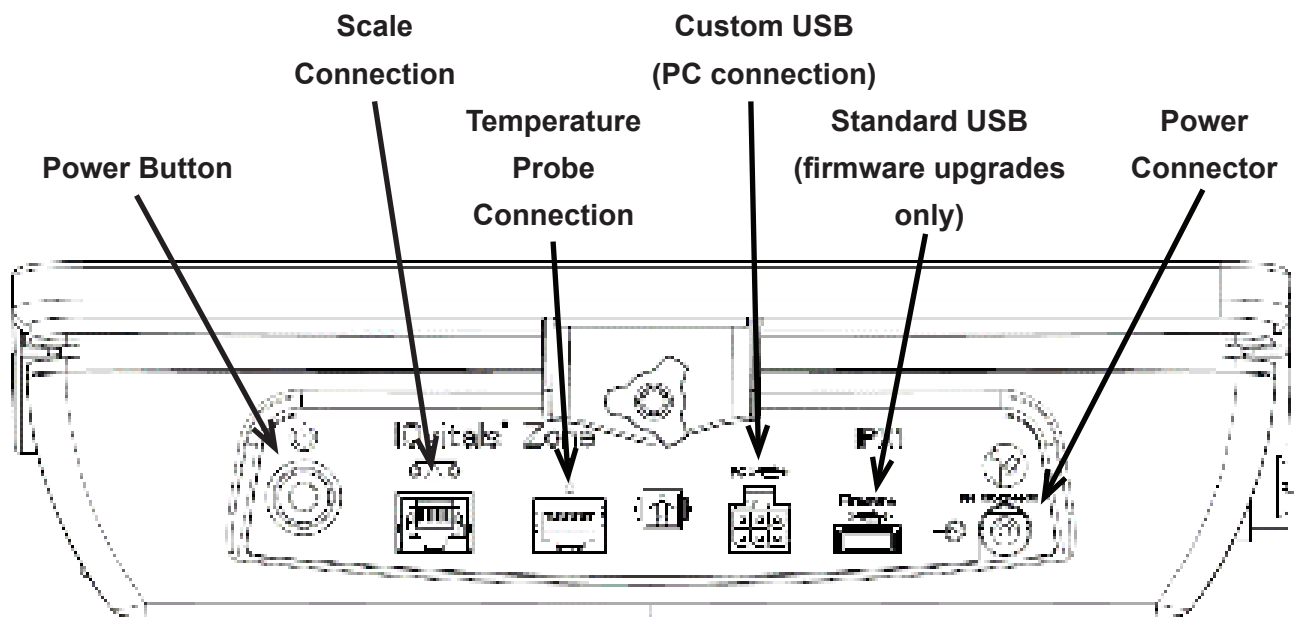


Figure 4

Computer Connectivity

Wireless Connectivity

If using the IQvitals® Zone™ device with a mobile computer, the computer and device can be automatically connected using Bluetooth Low Energy (BLE) by simply placing the mobile computer onto the work surface of the vital signs device. Disconnection of the computer and device is accomplished by removing the computer from the vital signs device work surface by a distance of at least 6 feet (depending, among other factors, on the environment and the receiver BLE sensitivity). Automatic connection is achieved only when IQmanager® is open and running on the mobile computer. A wireless connection allows data to pass between the vital signs device, along with its connected devices, and the computer. If the computer is connected to the EMR database of the facility, then the data can pass into the EMR database upon approval of the user.

IQvitals® Zone™ Wireless Connection Range Adjustment

This section provides instructions for adjusting the wireless connection range between a mobile computer and an IQvitals® Zone™ device.

Follow these steps to:

Reduce the range in which a mobile computer detects an IQvitals® Zone™ device.

Note: This will reduce the range of connection between the mobile computer and the targeted IQvitals® Zone™ device when multiple IQvitals® Zone™ devices are available.

Or

Increase the range in which a mobile device detects an IQvitals® Zone™ unit.



USB cable (P/N 2-200-0004)



Mobile computer



Step 1: Locate the USB port on the IQvitals® Zone™

- Connect the mobile computer to the IQvitals® Zone™ with the USB cable (P/N 2-200-0004) included in the device kit.
 - Launch IQvitals® software from IQmanager® or EMR software.
 - Open up settings (see User Guide, Settings).
 - Select the "More..." tab.
 - Enter password: 1590.
 - Select "Radio Power" button on the right side of the screen*.
- (*only available on units with wireless option)



Step 2: Adjust BLE Radio Power

- Radio Power window is displayed on screen.
- Shift slider left to reduce range; right to increase range.

- C) After adjusting to the desired level, press "Apply".*
- D) Close IQvitals® software and disconnect USB cable.*
- E) Restart IQvitals® software to reconnect wirelessly.*
- F) If necessary, repeat these steps to obtain desired connection range.*

Note: To avoid electromagnetic interference (EMI) noise in the device to computer connection, use the USB connection or disconnect the computer and view the vital signs data on the device display screen.

Wired Connectivity

The IQvitals® Zone™ devices may be used with PC computers running Microsoft Windows 7 or higher. The IQvitals® Zone™ companion software must be installed on the connected computer (check with Midmark for availability). The USB Custom port uses a proprietary USB cable (P/N 2-200-0004) available from Midmark and included in each device kit. The custom USB port is electrically isolated with a special USB digital isolator. It can be connected to any computer's USB port that meets the USB standard.

Basic Functions

AC Power

The IQvitals® Zone™ device can be run with AC or battery power once the battery has been charged.

Battery

- Check the battery level when the device is turned on.
- The device can be operated when the battery is not fully charged.
- It takes up to eight hours to fully charge the battery.
- For optimal battery life, charge the battery before it reaches 20 percent remaining battery power.
- A lightning bolt will display in the **Battery** icon to indicate the battery is charging.
- When the battery reaches 40% and 20% remaining power, the device will activate a low-level alarm.
 - Connect the device to a wall outlet to recharge the battery.
- When the battery reaches 10% remaining power, the device will issue a high-level alarm and the battery icon outline will turn red. At this point the device may have approximately 30 minutes of battery power remaining, depending on usage.
 - Connect the device to a wall outlet to recharge the battery.

Power Button

To activate power to the device, press the Power button on the back of the device (see Figure 4). When the unit is on, a green light will appear in the lower left front of the device top surface.

To power off the device, press the Power button on the back of the device (see Figure 4). When the unit is off, the green light in the lower left front of the device will be off and the device screen will be blank.

Note: Midmark recommends stopping any vital sign measurement in process before powering off the device.

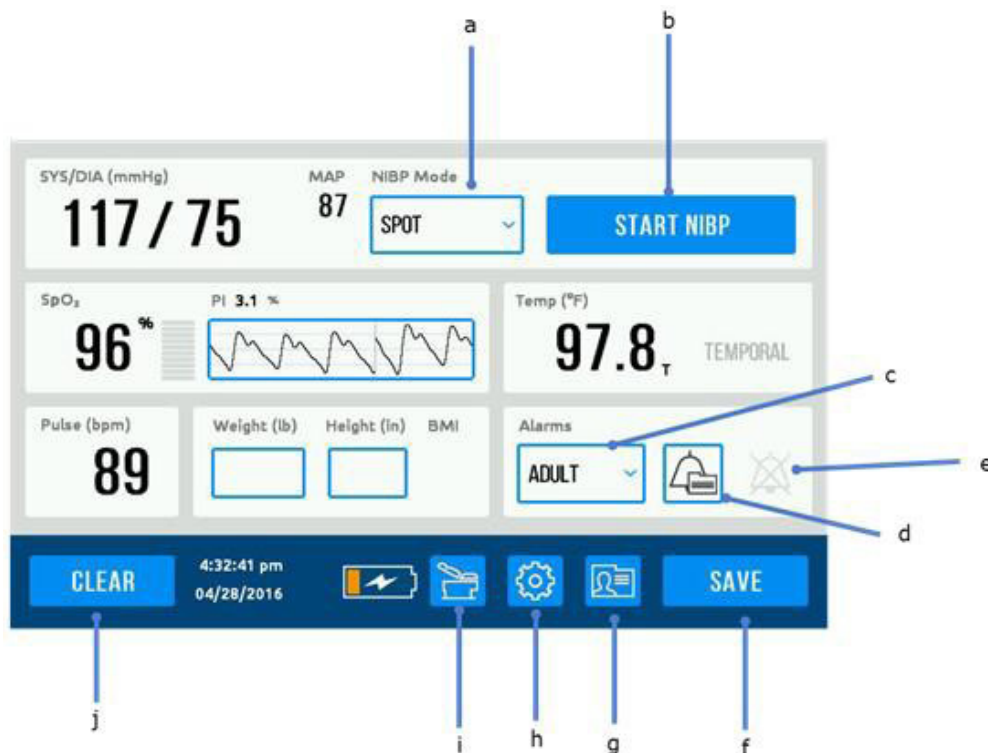
Start-Up Screens

The IQvitals® Zone™ device will display two screens before the Main Screen appears. The Midmark IQvitals screen will appear and then the Midmark logo screen.

Main Screen

Buttons and Dropdown Menus

- a. NIBP Mode dropdown menu
- b. Start NIBP button
- c. Alarms Mode dropdown menu
- d. Alarm List button
- e. Alarm Reset button
- f. Save button
- g. Patient Records button
- h. Settings button
- i. Midmark chair button
- j. Clear button



Start NIBP

The **Start NIBP** button displays when the NIBP method is set to **Linear Deflation** (see “[Settings](#)” for more information about changing the NIBP method). The **Start NIBP** button initiates a blood pressure reading. See “[Blood Pressure](#)” for more information taking a blood pressure reading.

Patient Records Button

The **Patient Records** button displays the **Patient Records** screen. See “[Patient Records](#)” for more information on viewing patient records.

Settings Button

The **Settings** button displays the **Settings** screen. See “[Settings](#)” for more information on changing settings.

Save Button

The **Save** button displays an Alpha-numeric keypad for saving current data under a patient ID.

Clear Button

The **Clear** button will clear weight and height data entered and any other data displayed on the **Main Screen**. It will also clear any data when in SPRINT or Custom NIBP modes. The **Clear** button will not clear any saved patient records or saved parameter or alarm settings.

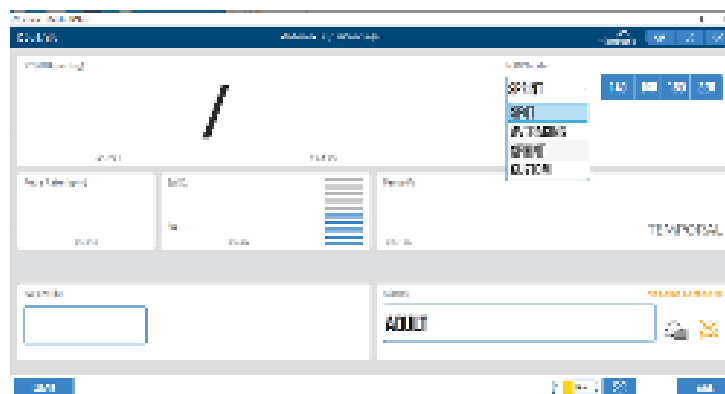
Dropdown Menus

Dropdown menus are indicated with a blue outline and an arrow icon on the right side. When any dropdown menu is active, all other buttons outside the pulldown menu are disabled.

Click anywhere outside the dropdown menu or back on the original choice to close the dropdown menu and activate the entire main screen.

NIBP Mode

The **NIBP Mode** dropdown menu allows users to select from **Spot**, **Averaging**, **SPRINT** and **Custom** modes. See “[Blood Pressure](#)” for more information taking a blood pressure reading.



Alarms

For a full explanation of the alarm states and priority levels please see [Appendix A](#).

The Alarms box on the **Main Screen** contains the **Alarms Mode** dropdown menu, the **Alarm List** button, and the **Alarm Reset** button.

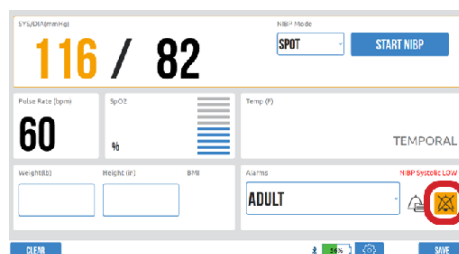
- Press the Settings button and select the Alarms tab at any point except during cuff inflation/deflation to edit the alarm thresholds. See “[Alarm Settings](#)” for more information.
- The Alarm Reset button is only available when an audible alarm is sounding.

Use the Alarms Mode dropdown to change the alarm thresholds between adult settings and pediatric settings.



If a reading falls above or below the pre-determined alarm threshold:

- The number(s) violating the threshold will be displayed in amber.
- The corresponding vital sign will be outlined in amber.
- The **Alarm Reset** button will become active if there is an audible alarm for the alarm state.
- A message will be displayed in the **Alarm** field detailing the reason for the alarm.



Press the **Alarm Reset** button to reset or pause an audible alarm. The **Alarm Reset** button will be outlined in amber.

- If a new alarm state occurs with a corresponding audible alarm, the **Alarm Reset** button becomes active again.
- All other visual alarm indicators persist until the alarm state is no longer in effect.
- If multiple alarm states exist simultaneously, the highest priority alarm will display. Once the high priority alarm is corrected the device will then display the next alarm to be addressed. See "[Alarm Priority](#)" for additional details.

Patient Records

To access all patient data that is stored in IQvitals® Zone™, press the **Patient Records** icon on the **Main Screen**.

Patient Records List

IQvitals® Zone™ is capable of holding 99 patient records in device memory. When the memory is full and another patient test is saved, the first saved test will be deleted in order to save the current test.

To view other saved records, use the **Up** and **Down** arrows.

No.	Date/Time	PATIENT ID	SYS/DIA	MAP	PR	SpO ₂
0	04/26/2016 10:47:45am	8675309	109/74	84	56	96
1	04/26/2016 10:49:29am	012345689012	109/75	85	59	97
2	04/26/2016 10:52:21am	456123789	107/77	86	56	96
3	04/26/2016 10:54:30am	007007007007	109/82	90	55	97
4	04/26/2016 10:56:09am	YGH952753	114/74	86	63	97

DELETE CANCEL SELECT

To return to the **Main Testing** screen, press the **Cancel** button.

Touch the screen to select a record. Once the record is highlighted, the **Delete** and **Select** buttons will become active.

No.	Date/Time	PATIENT ID	SYS/DIA	MAP	PR	SpO ₂
0	04/28/2016 04:25:12pm	6543380098	118/76	87	65	96
1	04/28/2016 04:26:46pm	832109864763	120/80	91	69	96
2	04/28/2016 04:27:46pm	764300924466	110/82	89	67	96
3	04/28/2016 04:28:41pm	6598ED429800	117/75	87	67	95

DELETE CANCEL SELECT

Patient Record Detail

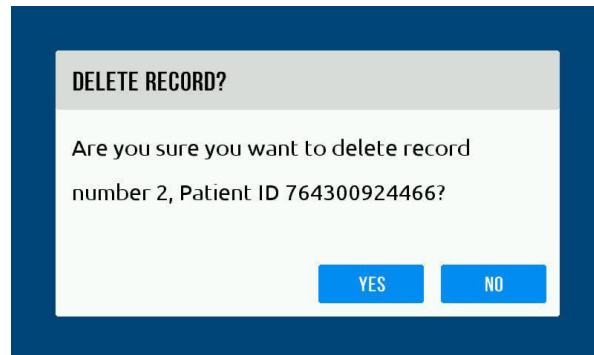
To view a patient record, highlight a record and press **Select**. The detailed patient record is displayed. Press the arrow buttons in the bottom-middle to navigate through records one at a time.

NIBP SYS/DIA (mmHg)		MAP	04/26/2016 11:08:35am	
119/69		85	PATIENT ID: ED7340932145	
Pulse (bpm)	SpO ₂	Temp (°F)	TEMPORAL	
64	96	94.8		
Weight (lb)	Height (in)	BMI		
0.0	0.00	0.0		
DELETE	< 6 >	CLOSE		

- The **Close** button returns to the **Patient Records List**.

Delete Patient Record

1. To delete data for a single record, touch the patient record in the **Patient Record** list to highlight it. The highlighted entry will be deleted once the **Delete** button is pressed. Or **Select** to view a record then in the record detail screen press Delete.
2. After pressing **Delete**, a confirmation screen will appear.
3. Press **Yes** or **No**.

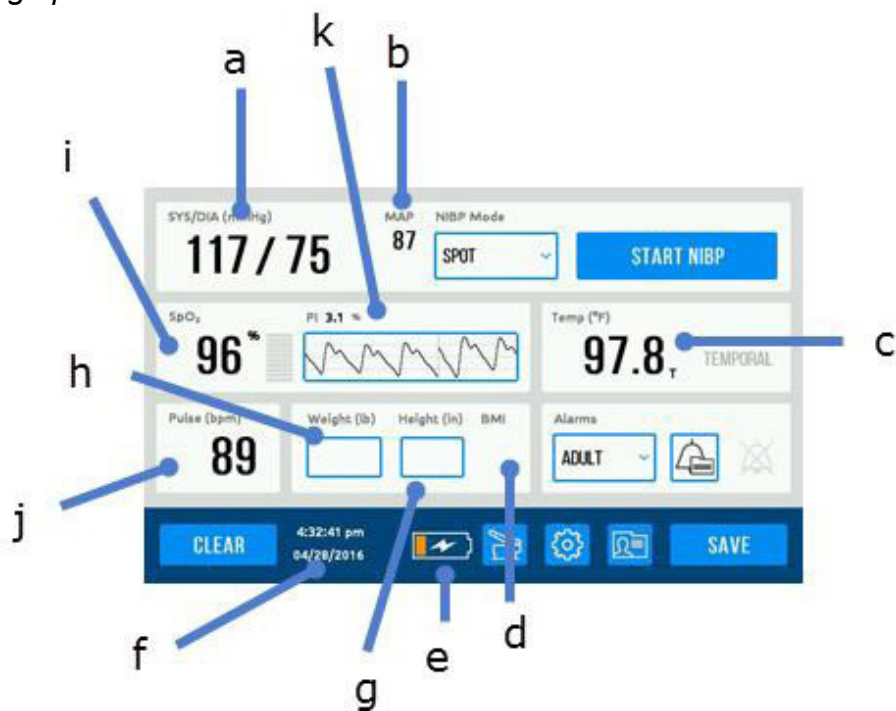


Note: All patient records should be cleared from the device memory prior to removal of the device from service or prior to device repair. The user may use the **Select** and **Delete** records one at a time or may use the **Clear Memory** option in the **More** settings screen to delete all records

Display of Data

The **Main Screen** will display the following patient data:

- a. Blood pressure
- b. Mean Arterial Pressure (MAP)
- c. Temperature
- d. Body Mass Index (BMI)
- e. Battery Power icon
- f. Time and date
- g. Patient Height
- h. Patient Weight
- i. SpO₂
- j. Pulse rate
- k. Perfusion index graph



Manual Entry of Data

Buttons that have a blue outline and no arrow are data entry buttons and allow for data to be entered manually. Weight and height can be entered manually by pressing each corresponding button on the **Main Screen**.



Touch inside the **Weight** or **Height** data entry box and a screen with a numeric keyboard will appear where the data can be manually entered.



Once the data is entered, press **OK** to save the data and return to the **Main Screen**, or press **Cancel** to return to the previous screen without saving the data.

Both the **Weight** and **Height** fields have an allowable range. The following table shows the allowable range for each measurement.

Information	Allowable Range
Height	10.00 – 100 inches (25.4 – 254 cm)
Weight	1.0 – 1000 lbs (0.45 – 455kg)

BMI Calculation

BMI is automatically calculated once the height and weight are entered. Both data points must be present in order for the BMI to be displayed.

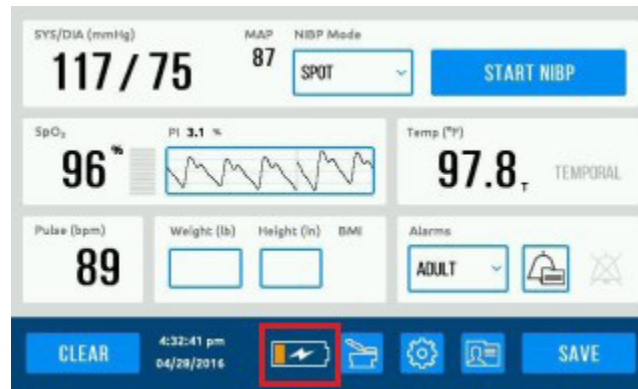
Date and Time

On the **Main Screen**, the date and a digital clock is displayed in the bottom panel to the right of the **Battery** icon. This clock is updated every second.

Battery Charging

When the battery is charging, a lightning bolt icon appears over the **Battery** icon.

- A light will display in the **Battery** icon to indicate the battery is charging.



Battery Power

If the unit is running on battery power, the battery charge level will be indicated by the **Battery** icon color.

- When the battery reaches 40% and 20% remaining power, the device will activate a low-level alarm. At 10% it will activate a high-level alarm.
 - Connect the device to a wall outlet to recharge the battery.
- When the battery reaches 10% remaining power, the device will issue a high-level alarm and the **Battery** icon outline will turn red.
 - At this point the device may have approximately 30 minutes of battery power remaining, depending on usage.
 - Connect the device to a wall outlet to recharge the battery.
- When battery reaches around 3% remaining power, the device will automatically turn off.



Device Operation

Blood Pressure

	WARNING BLOOD PRESSURE MEASUREMENT: Frequent NIBP measurements can cause injury to the patient due to blood flow interference.
	WARNING Do not apply a NIBP cuff over a wound as this may cause further injury to the patient.
	WARNING INTRAVASCULAR ACCESS OR THERAPY, OR AN ARTERIO-VEINUS (A-V) SHUNT: Use of a NIBP cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present can cause injury to the patient due to temporary interference to blood flow.
	WARNING MASTECTOMY PATIENTS: No blood pressure measurements should be taken in the affected arm of a mastectomy patient.
	WARNING BLOOD PRESSURE MEASUREMENT: Be sure that the blood pressure hose does not become kinked or compressed during a measurement. If left unattended, this could result in sustained pressure in the blood pressure cuff and may cause patient injury, device errors, or inaccurate measurements.
	WARNING Regularly inspect the blood pressure cuff, SpO ₂ cable, and other accessories for damage. Replace accessories as needed.
	WARNING For pediatric blood pressure measurements, the smallest cuff approved for use on small children is the Child cuff (#3-200-0030 for reusable or 3-200-0040 for single use) and should only be used with the STEP DEFLATION algorithm mode.



Caution

Inaccurate NIBP measurements could result from various factors, including; improperly fitted NIBP cuffs, incorrect measurement site used, the positioning of the patient during the measurement, patient movement or exercise during or prior to the measurement, or the patient's physiologic condition. Follow your facility protocol for actions to take in case unexpected readings are obtained.

Before Initiating a Blood Pressure Measurement

- Allow the patient to sit quietly for at least 5 minutes before taking the first measurement.
- Be sure the patient is seated comfortably in a chair that supports their back and arms, with their legs uncrossed and feet flat on the floor.
- Support the patient's arm during the measurement, keeping the cuff at heart level.
- To keep the patient relaxed during a blood pressure measurement, instruct the patient to refrain from

talking or moving. The clinician should refrain from engaging the patient in any conversation during measurements.

During normal use, the clinician should remain close to the patient during any vital sign measurements.

Blood Pressure Cuff Selection

Using the proper size blood pressure cuff is important for accurate blood pressure readings. Midmark recommends using only Midmark reusable or disposable cuffs with the IQvitals® Zone™ device.



Caution

For accuracy and safety in pediatric blood pressure measurements, the smallest cuff approved for use on small children is the Child cuff (#3-200-0030 for reusable or 3-200-0040 for single use) and can only be obtained using the STEP DEFLATION algorithm mode.

- Cuffs that are too small may result in erroneously high blood pressure readings, and cuffs that are too large may result in erroneously low blood pressure readings.
- To verify the proper cuff size for a patient, wrap the cuff around the patient's extremity. The index line (white arrow) should fall within the white range markings on the cuff. If a patient falls between two cuff sizes, always use the larger cuff.



Refer to the following table to identify the size ranges of reusable blood pressure cuffs offered by Midmark. This table lists the cuff part number, name, and size range (based on the circumference of the patient's arm) in centimeters (cm) and inches (in).

Midmark Part #	Name	Size Range (cm)	Size Range (in)
3-200-0030 (reusable)	Child*	13–20	5.1–7.9
3-200-0031 (reusable)	Small Adult	18–26	7.1–10.2
3-200-0032 (reusable)	Adult	26–35	10.2–13.8
3-200-0033 (reusable)	Adult Long	29–38	12.6–16.5
3-200-0034 (reusable)	Large Adult	32–42	11.4–15
3-200-0035 (reusable)	Large Adult Long	35–44	13.8–17.3
3-200-0036 (reusable)	Thigh	42–50	16.5–19.7
3-200-0040 (single use)	Child*	13–20	5.1–7.9
3-200-0041 (single use)	Small Adult	18–26	7.1–10.2
3-200-0042 (single use)	Adult	26–35	10.2–13.8

3-200-0043 (single use)	Large Adult	32–42	12.6–16.5
3-200-0044 (single use)	Adult Long	29–38	11.4–15
3-200-0045 (single use)	Large Adult Long	35–44	13.8–17.3
3-200-0046 (single use)	Thigh	42–50	16.5–19.7

*Use step deflation algorithm only.

Proper Application and Positioning of Blood Pressure Cuff

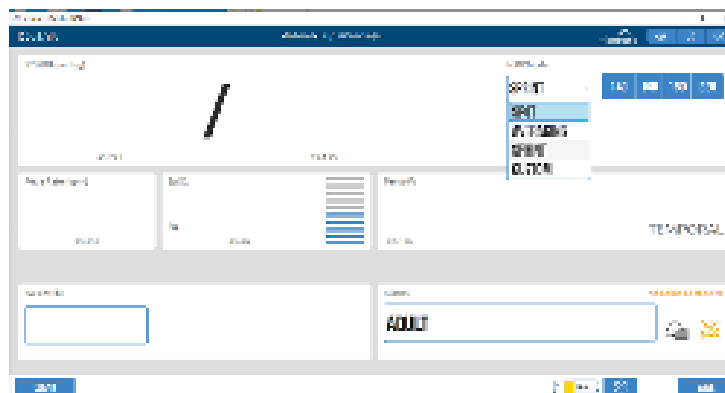
The measurement site for adults and children is the upper arm. Do not wrap a cuff over a patient's clothing; inaccuracies can occur. There may also be a marked difference between readings taken from the left arm and right arm.

The middle of the cuff should be positioned level with the patient's right atrium of the heart. Measurements made with a cuff placed above this level will produce lower blood pressure readings, and measurements made with a cuff placed below this level will produce higher blood pressure readings.

Place the cuff brachial artery marker over or close to the brachial artery. For best results, wrap the cuff snugly so that there is room for no more than two fingers under the cuff.

Blood Pressure Modes

The **NIBP Mode** dropdown provides the user with up to four choices for blood pressure mode: Spot, Averaging, SPRINT and Custom. The user may elect to disable the Averaging, SPRINT or Custom modes in the NIBP tab within the Settings menu, but the Spot mode will always be available. See "[NIBP Settings](#)" for more information.



- **Spot** mode takes a single NIBP reading.
- **Averaging** mode takes a series of five readings, disregards the first reading, and averages the next four readings to report an average BP reading.
- **SPRINT** shows initial BP Protocol in Progress screen for five minutes and then takes a series of three readings and reports averages of all correct readings. The inflation buttons which are displayed on the screen depend on the highest reading of all the BP trials and they are the first of the four starting inflation values from settings that is greater than the highest reading taken during the session, but never higher than the second highest button.
- **Custom** shows initial BP Protocol in Progress screen for a custom set delay start time and then it takes custom number of readings with custom interval time between all measurements. There is an option to discard first reading. All custom setting can be defined by user in the device setting page. After all measurements it reports average of them. The inflation buttons which are displayed on the screen depend on the highest reading of all the BP trials and they are the first of the four starting inflation values from settings that is greater than the highest reading taken during the session, but never higher than the

second highest button.

Blood Pressure Algorithms

The user may choose between linear and step deflation algorithms for blood pressure in the **NIBP** tab within the **Settings** menu. See “NIBP Settings” for more information. This setting must be changed before initiating an NIBP reading.

It is important to be aware of the patient age and size when determining which NIBP algorithm to use. Please reference the table to the right prior to proceeding.

Cuff Sizes for	Linear Mode	Step Mode
Child	NO	YES
Small adult	YES	YES
Adult	YES	YES
Large Adult	YES	YES
Adult long	YES	YES
Large Adult Long	YES	YES
Thigh	YES	YES

Linear Deflation

In **Linear Deflation** the device will rapidly inflate the blood pressure cuff and take an estimated systolic reading while still inflating. The estimated systolic reading is then quickly translated to a maximum inflation pressure by adding 30 mmHg to the estimated systolic reading, telling the pump when to stop inflating and potentially saving the patient from the uncomfortable feeling of extra pressure in the cuff. Once the maximum inflation is reached, the cuff begins to linearly deflate at a rapid pace and determines the systolic and diastolic pressures during that deflation period.

During linear deflation, the cuff will detect the correct initial inflation pressure; therefore, the user does not need to select an initial inflation value and only a **Start NIBP** button will display in the upper right-hand corner of the **Main Screen**.

To start a blood pressure measurement using linear deflation, press the **Start NIBP** button on the upper right corner of the **Main Screen**.



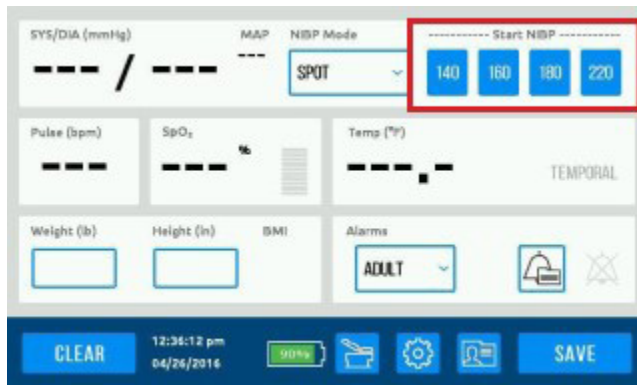
Note: Linear deflation method is only applicable for Spot NIBP mode. The rest of the NIBP modes run only in “Step Deflation” method.

Step Deflation

When a blood pressure measurement is initiated using **step deflation**, the device will rapidly inflate the blood pressure cuff to the user selected maximum inflation pressure. Once the maximum inflation pressure is reached, the cuff begins to deflate incrementally at preset pressure steps while listening for the appropriate sounds which indicate systolic and diastolic pressure. Since the deflation is done in a slow, stepwise fashion, this may take longer to finish the blood pressure reading.

When taking a measurement using step deflation, the user must select an initial inflation value, which will then begin the reading. Depending on the **NIBP Mode** selected, either two or four initial inflation pressure buttons will display in the upper right-hand corner of the Main Screen. These initial inflation values may be adjusted to the user's choice in the Settings menu, **NIBP** tab. See "[NIBP Settings](#)" for more information.

- To start a blood pressure measurement using step deflation, press the appropriate inflation pressure button on the **Main Screen**.



Note: Step deflation method is applicable for Spot, Averaging, SPRINT and Custom BP modes.

Note: Ideally, the initial inflation pressure should be about 30 mmHg above the patient's systolic pressure. Using a higher inflation pressure may cause the patient unnecessary discomfort. Choosing an inflation pressure that is too low may cause the device to re-inflate the cuff in order to obtain a systolic pressure.

Note: There are four pre-set inflation pressure buttons for Adult patients: 140, 160, 180 and 220. These values can be changed in the **NIBP** tab of the **Settings** menu.

Note: There are four pre-set inflation pressure buttons for Pediatrics patients: 110, 120, 130 and 140. These values can be changed in the **NIBP** tab of the **Settings** menu.

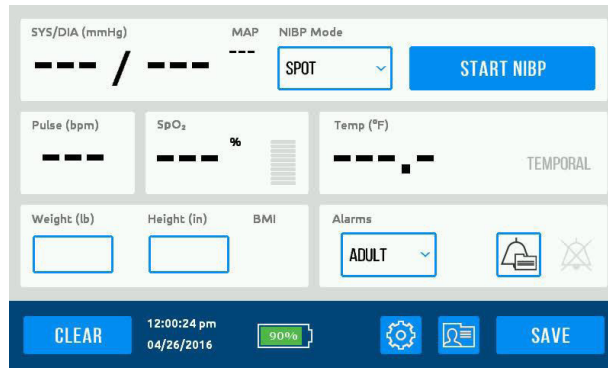
Initiating a Blood Pressure (BP) Measurement: Spot Mode

Before proceeding, ensure the IQvitals® Zone™ device is powered on and the correct size of blood pressure cuff is properly positioned on the patient.

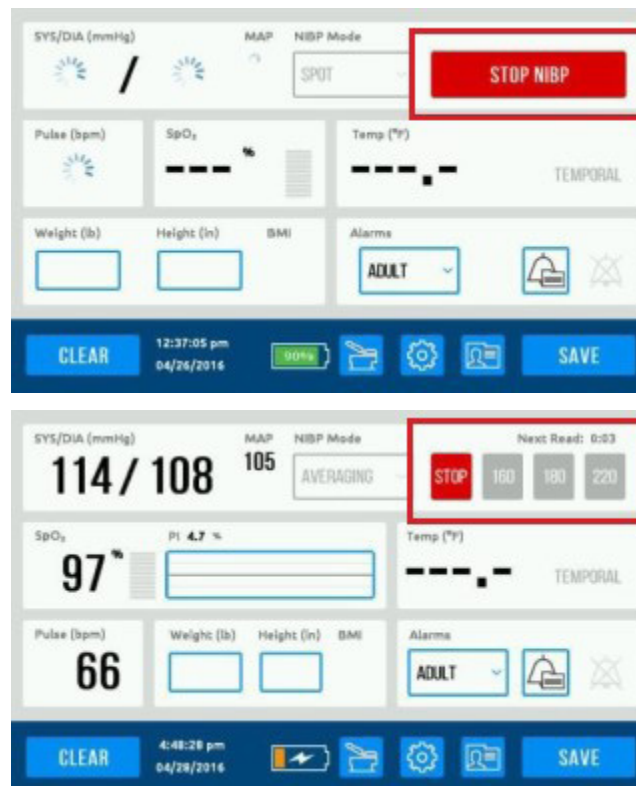
Note: Keep the patient's arm relaxed and motion-free during the measurement. The patient should not talk or move during the BP measurement.

From the **Main Screen**:

1. Select **Spot** from the **NIBP Mode** dropdown menu.
2. Press **Start NIBP** to start the reading.



- During an NIBP reading, the **NIBP Mode** dropdown becomes inactive. When a BP measurement is started, the **Start NIBP** button (or the initial inflation pressure buttons if you are using Step Deflation method) changes to a red **Stop** button.



- To stop a BP measurement at any time, press **Stop**. When the measurement is stopped, the cuff will deflate, and all buttons will be enabled.
- While the BP measurement is running, the **progress wheel icon** will appear under the **SYS/DIA** field.
- The **Clear** button is disabled during a BP or any other measurement.
- The **Clear** button will be enabled when the measurement is complete.
- The systolic and diastolic values appear on the screen when the BP measurement is complete.

- The pulse rate will appear below Pulse Rate (BPM) when a BP measurement is complete. Press the **Save** button to store the data into the patient record.

Initiating a Blood Pressure (BP) Measurement: Averaging Mode

Before proceeding assure the IQvitals® device is powered on and the correct size of blood pressure cuff properly positioned on the patient.

Note: Keep the patient's arm relaxed and motion-free during the measurement. The patient should not talk or move during the BP measurement.

From the **Main Screen**:

- Select **Averaging** from the **NIBP Mode** drop down menu on the **Main Screen**.

The screenshot shows the Main Screen of the IQvitals device. At the top, the 'SYS/DIA(mmHg)' field displays a large slash '/'. To the right, the 'NIBP Mode' dropdown menu is set to 'AVERAGING'. Next to it are four buttons labeled '120', '160', '180', and '220', with the '120' button highlighted. Below these are fields for 'Pulse Rate (bpm)', 'SpO2 %', and 'Temp (F)'. The 'TEMPORAL' label is visible on the right. At the bottom, there are fields for 'Weight (lb)', 'Height (in)', and 'BMI'. The 'Alarms' dropdown menu is set to 'ADULT'. A 'CLEAR' button is on the bottom left, and a 'SAVE' button is on the bottom right. A row of icons (USB, Wi-Fi, Bluetooth, Settings, and a printer) is located between the bottom buttons.

- Press **any inflation button** to commence the reading.

- The **NIBP Mode** dropdown becomes inactive and
- The selected **inflation** button changes to a red **Stop** button.
- The **Next Read** timer is displayed in the upper right corner above the **Stop** button. This is the time remaining until the next measurement.
- All the buttons (Clear, Settings, Table Icon, Patient Info, Save), Alarms dropdown and NIBP mode dropdown) are disabled until the Averaging session is completed or canceled.
- The system takes five BP measurement and displays each measurement in sequence.
- At the end of the session the system ignores the first measurement and displays the average of the last four measurements.
- A reading count appears in the upper-right above the **Stop** button.

The screenshot shows the Main Screen during a BP measurement. The 'NIBP Mode' dropdown is still 'AVERAGING'. The '120' button is now a red 'STOP' button. Above the 'STOP' button, the text '0 Readings' is displayed. The 'SYS/DIA(mmHg)' field now shows two circular progress indicators on either side of the slash '/'. The 'Pulse Rate (bpm)' field also shows a circular progress indicator. The 'SpO2 %' and 'Temp (F)' fields are still empty. The 'TEMPORAL' label is still visible. The 'Weight (lb)', 'Height (in)', and 'BMI' fields are still empty. The 'Alarms' dropdown is still 'ADULT'. The 'CLEAR' and 'SAVE' buttons are now disabled (grayed out). The row of icons at the bottom is also disabled.

- To stop a BP measurement at any time, press **Stop**. When the measurement is stopped, the cuff will deflate, and all buttons will be enabled.
- When each BP measurement is complete, the systolic and diastolic values are displayed on the screen.

5. A pulse rate will be displayed when each BP measurement is complete. The pulse rate will appear below **Pulse Rate (bpm)** on the screen.
6. When the Averaging session is complete, the average of the last four BP measurements and other data are displayed on the **Main Screen**. The total number of BP readings is displayed in the upper right corner.

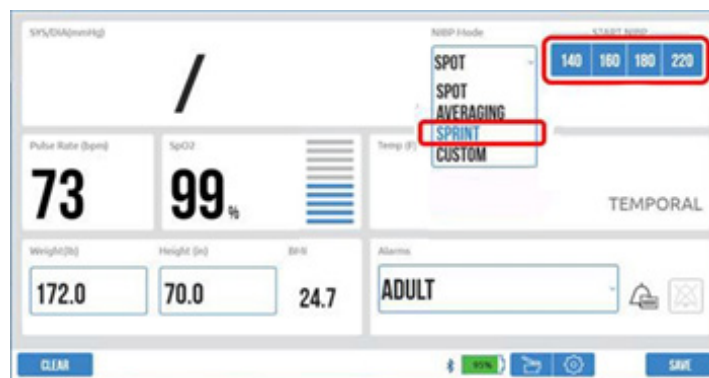
Initiating a Blood Pressure (BP) Measurement: **SPRINT Mode**

Before proceeding assure the IQvitals® Zone™ device is powered on and the correct size of blood pressure cuff properly positioned on the patient.

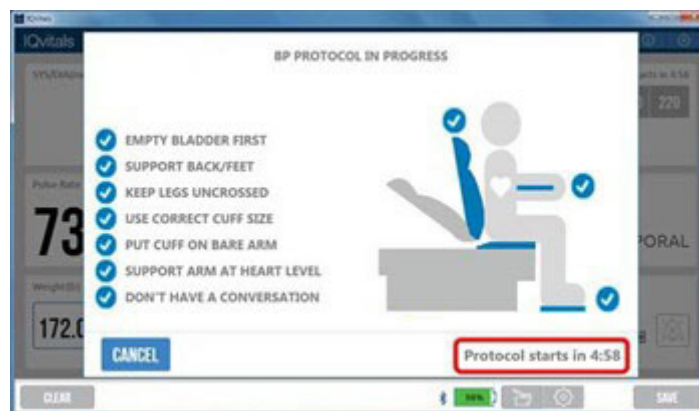
Note: Keep the patient's arm relaxed and motion-free during the measurement. The patient should not talk or move during the BP measurement.

From the **Main Screen**:

1. Select **SPRINT** from the **NIBP Mode** dropdown menu on the Main Screen. The screen displays the SPRINT option with **Start** button.



2. Press **Start** to commence the SPRINT protocol.
 - The BP Protocol In Progress screen appears with a five-minute countdown timer on lower right corner.
 - The screen includes a checklist for patient positioning recommended by American Medical Association (AMA) to ensure an accurate blood pressure reading.
 - To cancel the SPRINT protocol at this time, press the **Cancel** button.



The system will take three BP measurements after a five-minute delay, with a one-minute interval between measurements. At the end of the protocol, the system displays the average of the three BP measurements. A reading count appears in the upper-right above the **Review** button.

The Main Screen appears after the five-minute delay:

- The **NIBP Mode** dropdown becomes inactive and the **Start** button changes to a red **Stop** button.

- While BP measurement is running, a reading count appears in the upper-right corner of the display.
 - All the buttons (Clear, Settings, Table Icon, Patient Info, Save), Alarms dropdown and NIBP mode dropdown are disabled until the protocol is completed or canceled.
3. To stop a BP measurement at any time after the initial delay, press **Stop**. When the measurement is stopped, the cuff will deflate and all buttons will be enabled
 4. When each BP measurement is complete, the systolic and diastolic values are displayed on the screen. A **Next Read** timer is displayed in the upper right corner. This is the time remaining until the next measurement. The pulse rate will appear below **Pulse Rate (bpm)** on the screen.
 5. When the SPRINT protocol is complete, the average of three BP measurements and other data are displayed on the **Main Screen**. The total number of BP readings is displayed in the upper right corner.



6. You may press **Review** button to view the list of all acquired BP measurements from the current session.



- All data on the Review screen will be discarded when any of the following selection is made on the Main Screen: **Save**, **Clear**, any other NIBP modes, or device power off.
 - Press **Cancel** to return to the **Main Screen**.
7. Press **Save** on the **Main Screen** to save the averaged BP measurement into the patient record.

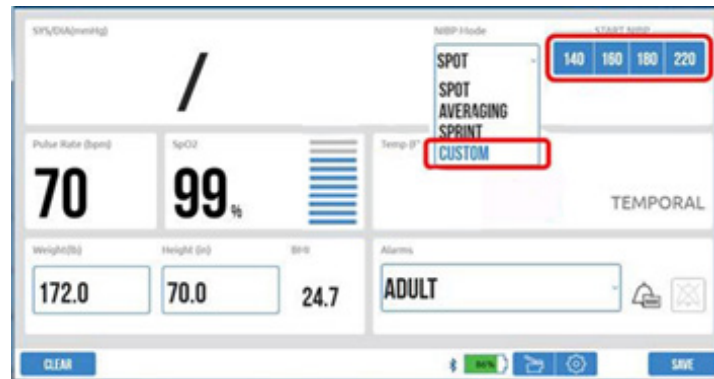
Initiating a Blood Pressure (BP) Measurement: Custom Mode

Before proceeding assure the IQvitals® Zone™ device is powered on and the correct size of blood pressure cuff properly positioned on the patient.

Note: Keep the patient's arm relaxed and motion-free during the measurement. The patient should not talk or move during the BP measurement.

From the **Main Screen**:

1. Select **Custom** from the **NIBP Mode** dropdown menu on the Main Screen. The screen displays the Custom option with **Start** button.

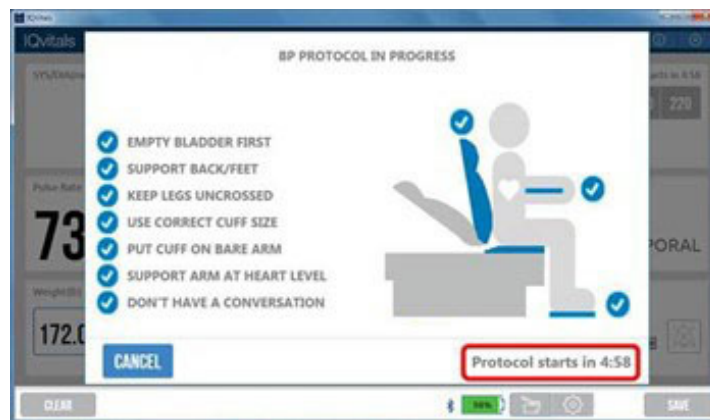


2. Press **Start** to commence the Custom protocol.

- The BP Protocol In Progress screen appears with a five-minute countdown timer on lower right corner.

The screen includes a checklist for patient positioning recommended by American Medical Association (AMA) to ensure an accurate blood pressure reading.

- To cancel the Custom protocol at this time, press the **Cancel** button.



The system will take a preset number of BP measurements after a preset delay, with preset interval between measurements as defined in the Custom Settings. You may preselect to discard first reading in the Custom Settings. See [NIBP Settings](#) for more information. At the end of the session, the system displays the average of pre-defined number of BP measurements. A reading count appears in the upper-right above the **Review** button.

The **Main Screen** appears after the preset delay:

- The **NIBP Mode** dropdown becomes inactive and the **Start** button changes to a red **Stop** button.
- While BP measurement is running, a reading count appears in the upper-right corner of the display.
- All the buttons (Clear, Settings, Table Icon, Patient Info, Save), Alarms dropdown and NIBP mode

dropdown are disabled until the protocol is completed or canceled.

3. To stop a BP measurement at any time after the initial delay, press **Stop**. When the measurement is stopped, the cuff will deflate, and all buttons will be enabled
4. When each BP measurement is complete, the systolic and diastolic values are displayed on the screen. A **Next Read** timer is displayed in the upper right corner. This is the time remaining until the next measurement. The pulse rate will appear below **Pulse Rate (bpm)** on the screen.
5. When the Custom protocol is complete, the averaged BP measurements and other data are displayed on the **Main Screen**. The total number of BP readings is displayed in the upper right corner.



6. You may press **Review** button to view the list of all acquired BP measurements from the current session.



- All data on the Review screen will be discarded when any of the following selection is made on the Main Screen: **Save**, **Clear**, any other NIBP modes, or device power off.
 - Press **Cancel** to return to the **Main Screen**.
7. Press **Save** on the **Main Screen** to save the averaged BP measurement into the patient record.

EXERGEN TemporalScanner

The TemporalScanner is an infrared thermometer designed for accurate, completely non-invasive temperature assessment by scanning the temporal artery (TA).

Temperature is measured by gently stroking the TemporalScanner across the forehead, and includes a momentary touch of the probe to the neck area behind the ear lobe, to account for any cooling of the forehead as a result of diaphoresis. The patented arterial heat balance technology (AHB™) automatically measures the temperature of the skin surface over the artery and the ambient temperature. It samples these readings some 1000 times a second, ultimately recording the highest temperature measured (peak) during the course of the measurement. The TemporalScanner emits nothing - it only senses the natural thermal radiation emitted from the skin.

It has been clinically proven in premier university hospitals to be more accurate than ear thermometry, and better tolerated than rectal thermometry, and is supported by more than 50 peer-reviewed published studies covering all ages from premature infants to geriatrics in all clinical care areas. It is a superior method for patient and clinician alike.

A 40-page compendium on Temporal Artery Temperature Assessment is available at www.exergen.com/medical/PDFs/tempassess.pdf, and a complete list of peer-reviewed published clinical studies are available at www.exergen.com/c. Complete multi-language information on clinical use, instruction manuals, and training is available at www.exergen.com/s, which includes links to a specialized clinical site <http://www.exergen.com/tathermometry/index.htm>.

The link to www.exergen.com/s appears on the front label of the instrument as a scannable “QR” symbol for easy linking to the site.



[exergen.com/s](http://www.exergen.com/s)

Important Safety Instructions

READ ALL INSTRUCTIONS BEFORE USING

If you have any additional questions regarding use or care of the thermometer, please see www.exergen.com or call customer service at 617-923-9900.

When using the product basic safety precautions should always be followed, including the following:

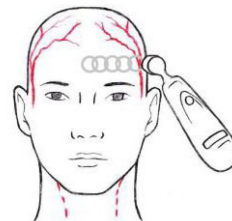
	Caution <i>Use this product only for its intended use as described in this manual.</i>
	Caution <i>Do not take temperature over scar tissue, open sores or abrasions.</i>
	Caution <i>The operating environmental temperature range for this product is 60 to 104° F (15.5 to 40° C).</i>
	Caution <i>Always store this thermometer in a clean, dry place where it will not become excessively cold (-4° F/-20° C), or hot (122° F/50° C) or humid (max RH 93% non- condensing, at 50 to 106 kPa).</i>
	Caution <i>The thermometer is not shockproof. Do not drop it or expose it to electrical shocks.</i>

	Caution <i>Do not Autoclave. Please note: cleaning and sterilizing procedures in this manual.</i>
	Caution <i>Do not use this thermometer if it is not working properly, if it has been exposed to temperature extremes, damaged, been subject to electrical shocks or immersed in water.</i>
	Caution <i>There are no parts that you can service yourself except for the battery, which you should replace when low by following the instructions in this manual. For service, repair, or adjustments return your thermometer to Exergen. Warning: no modification of this equipment is allowed.</i>
	Caution <i>Never drop or insert any object into any opening, unless stated in this manual.</i>
	Caution <i>If your thermometer is not used regularly, remove the battery to prevent possible damage due to chemical leakage.</i>
	Caution <i>Follow the battery manufacturer's recommendations or your hospital policy for the disposal of used batteries.</i>
	Caution <i>Not suitable for use in the presence of flammable anesthetic mixtures.</i>

Introduction to Temporal Artery Thermometry

Temporal artery thermometry (TAT) is a completely new method of temperature assessment, using infrared technology to detect the heat naturally emitting from the skin surface. In addition, and of key importance, this method incorporates a patented arterial heat balance system to automatically account for the effects of ambient temperature on the skin.

This method of temperature assessment has been shown to improve results and reduce costs by non-invasively measuring body temperature with a degree of clinical accuracy unachievable with any other thermometry method.



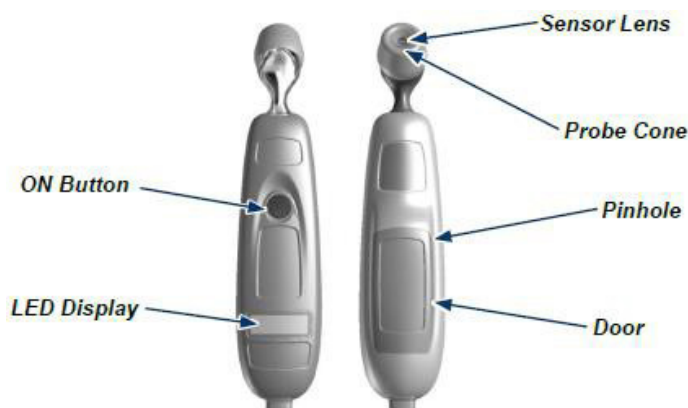
Before Using, Familiarize Yourself with the Instrument

1. To Scan: Depress the red button. The instrument will continually scan for the highest temperature (peak) as long as the button is depressed.
2. Clicking: Each fast click indicates a rise to a higher temperature, similar to a radar detector. Slow clicking indicates that the instrument is still scanning, but not finding any higher temperature.
3. To Retain or Lock Reading: The reading will remain on the display for 30 seconds after button is released. If measuring room temperature, the temperature will remain on the display for only 5 seconds.
4. To Restart: Depress the button to restart. It is not necessary to wait until the display is clear, the thermometer will immediately begin a new scan each time the button is depressed.

Alternate sites when temporal artery or behind ear are unavailable:

- Femoral artery: slowly slide the probe across groin.
- Lateral thoracic artery: slowly scan side-to-side in the area ~midway between the axilla and the nipple.

Note: Let the instrument acclimatize for at least 10 minutes in the area in which it will be used.



2-Step Infant Temperature Measurement

	1. Place probe flush on center of forehead and depress button. Keeping button depressed, slowly slide probe mid-line across forehead to the hair line button is depressed.
	2. Release button remove from head and read.

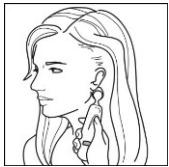
How to improve the accuracy of your measurement on infants

The preferred site is the temporal artery area. Unless visibly diaphoretic, one measurement here is typically all that is required.		If the temporal artery is covered, then the area behind the ear, if exposed, can be an alternate site.	
Measure straight across the forehead and not downside of face. At mid-line, the temporal artery is about 2 mm below the surface but can go deeply below the surface on the side of the face.		Brush the hair aside if covering the area to be measured. Measurement site must be exposed.	

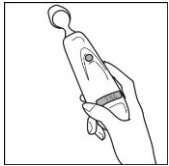
3-Step Adult Temperature Measurement



1. Slide across forehead. Place probe flush on center of forehead and depress button. Keeping button depressed slowly slide probe mid-line across forehead to the hair line.



2. Keeping button depressed, lift probe from forehead, touch behind ear halfway down the mastoid process and slide down to the soft depression behind the earlobe.



3. Release button, remove from head, and read.

How to improve the accuracy of your measurement on adults



Measure only the up-side on a patient in a lateral position.

The down-side will be insulated preventing the heat from dissipating, resulting in falsely high readings.



Think of a sweatband.

Measure straight across the forehead and not down the side of the face. At mid-line, the temporal artery is about 2mm below the surface, but can go deeply below the surface on the side of the face.



Measure exposed skin.

Brush the hair and bangs aside if covering the area to be measured.

Minimum measuring time: 2 seconds.

Minimum time between successive measurements: 30 seconds.

Resposable/Disposable Covers:

Resposable/Disposable covers, meaning they can be used once and discarded, or reused on the same patient, are available for all levels of cross-contamination protection should they be preferred for certain patient populations, and are still very cost effective. These options include resposable caps and full instrument sheaths, the sheaths being mainly used for isolation patients.



Using the Resposable/Disposable Caps:

1. Apply cap by pushing onto the probehead with fingers.
2. Remove cap by pushing edge forward with thumb.
3. Caps may be reused on the same patient.

FAQ's

How does the temperature from a temporal scanner relate to core temperature?

Temporal artery temperature is considered a core temperature because it has been demonstrated as accurate as the temperature measured by a pulmonary artery and esophageal catheter, and as accurate as a rectal temperature on a stable patient. Rule of thumb: Rectal temperature is about 1° F (0.5° C) higher than an oral temperature and 2° F (1° C) higher than an axillary temperature. It will be easy to remember if you think of core temperature as a rectal temperature and apply the same protocol you would use for a rectal temperature.

If your thermometer is marked Arterial/Oral and has a serial number beginning with "O" (standard model starts with "A"), it is programmed to compute the normal average cooling effect at the mouth, and automatically reduces the higher arterial temperature by that amount. This calibration allows the hospital to maintain existing protocols for fever workups based on oral temperature, and results in a reading consistent with the 98.6°F (37°C) mean normal oral temperature, in the range of 96.6 - 99.5° F (35.9 - 37.5° C) you now see.

What should I do if I get an abnormally high or low reading, how do I confirm my reading?

- Repeat the reading with the same Temporal Scanner; a correct reading will be reproducible.
- Repeat the reading with another Temporal Scanner. Two Temporal Scanners with the same reading will confirm the reading.
- Sequential readings on the same patient in rapid succession will cool the skin; it is best to wait about 30seconds for the skin to recover from the cold probe.

Possible causes of abnormal readings:

Type of abnormal Temperature	Possible Cause	Helpful Hint
Abnormally Low Temperature	Dirty Lens	Clean lens of scanner every two weeks.
	Releasing the button before finished measuring	Release the button after finished measuring.
	Measuring when an ice pack or wet compress is on the forehead	Remove ice pack or wet compress, wait 2 minutes, and re-take temperature
	Measuring a completely diaphoretic patient	Complete diaphoresis includes diaphoresis of area behind the ear and suggests that the temperature is rapidly dropping. Use an alternative method of temperature measurement in these cases until the patient is dry and the temporal artery measurement can be repeated.
	Improperly scanning down the side of the face	Scan straight across forehead. The temporal artery is closest to skin in that area.
Abnormally High Temperature	Anything covering the area to be measured would insulate and prevent heat from dissipating, resulting in false high readings.	Confirm measurement site has not recently been in contact with heat insulators such as hats, blankets, and hair. Scan the area not covered or wait about 30 seconds for the previously covered area to equilibrate to the environment.

DISPLAY DIAGNOSTICS CHART

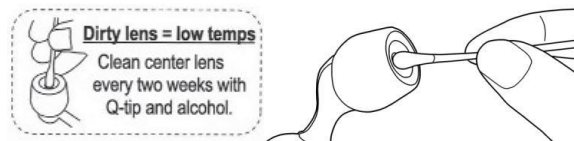
The following chart summarizes the conditions that may occur while the TemporalScanner is in use, and the associated indications:

Condition	Display	Range
High Target	HI	> 110°F (43°C)
Low Target	LO	< 61°F (16°C)
High Ambient	HI A	> 104°F (40°C)
Low Ambient	LO A	< 60°F (16°C)
Low Battery	bAtt	
No or Very Low Battery	Blank display	
Processing Error	Err	Restart. Return to Exergen for repair if error message persists.

Scanning (Normal Operation)		
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Care and Maintenance

- **Handling:** The TemporalScanner is designed and built to industrial durability standards in order to provide long and trouble-free service. However, it is also a high precision optical instrument, and should be accorded the same degree of care in handling as you would provide other precision optical instruments, such as cameras or otoscopes.
- **Cleaning the case:** The TemporalScanner case can be wiped down with a lint-free cloth, moistened with warm water (40 C/104 F maximum) and soap, a diluted non-caustic detergent, or alcohol-based cleaning agent, followed by drying with a clean lint-free cloth. Do not use strong solvents such as acetone. Avoid pouring any liquid on the thermometer while cleaning.
- **Cleaning the sensor lens:** With normal use, the only maintenance required is to keep the lens on the end of the probe clean. It is made of special mirror-like, silicon infrared-transmitting material. However, dirt, greasy films or moisture on the lens will interfere with the passage of infrared heat and affect the accuracy of the instrument. Regularly clean the lens with a cotton swab dipped in alcohol in accordance with the instruction label on the instrument (see below). Use only light force for cleaning, to avoid damaging the lens. Water can be used to remove any residual film left by the alcohol. Do not use bleach or other cleaning solutions on the sensor lens.



Disinfection: Clean the TemporalScanner before disinfecting. Recommended disinfecting agents are rubbing alcohol, Virex®, and dilute bleach solutions (1:10 to 1:100).

Sterilization: Sterilization is not recommended for cabled versions of the TemporalScanner.

DO NOT SUBMERSE THE THERMOMETER IN ANY CLEANING SOLUTION.

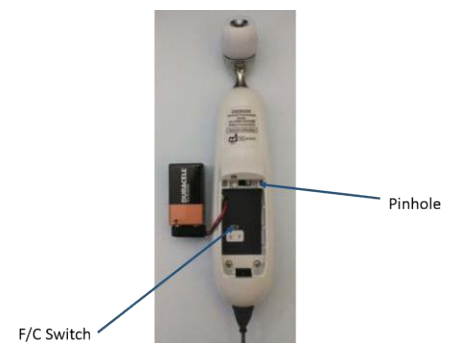
- **Calibration:** Factory calibration data is installed via a computer which communicates with the TemporalScanners microprocessor. The instrument automatically self-calibrates each time it is turned on using this data, and will never require recalibration. If readings are not correct, the instrument should be returned for repair.
- **Battery:** A standard alkaline 9V battery provides approximately 15,000 readings. ** To replace, insert the end of a bent paper clip into the pinhole on the side of the unit to release the battery compartment door. Disconnect the old battery and replace with a new one in the same location. Replace the cover. Use only high quality alkaline batteries.

Instructions for Fahrenheit or Celsius Conversion

The TemporalScanner can be used in either °F or °C. To convert from one scale to the other, the only tools necessary are a paper clip and the tip of a small screwdriver.

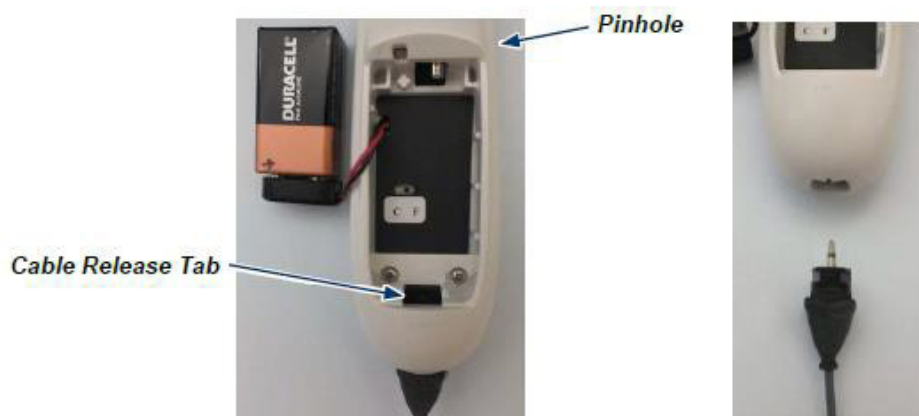
For °F/°C Conversion:

1. Insert the end of a bent paper clip into the pinhole on the side to release and remove the cover. Remove the battery from the compartment.
2. Locate the switch, and with the tip of a screwdriver, slide left or right to the opposite position.
3. Remove the screwdriver.
4. Replace cover.



Cable Replacement (TAT-5000S-RS232-QR only)

1. Disconnect the scanner cable from the monitor's communication port.
2. Insert the end of a bent paper clip into the pinhole on the side to release and remove the cover. Remove the battery from the compartment.
3. Locate the cable release tab, and with the tip of a screwdriver in the small round depression in the tab, push the tab down.
4. Pull the cable out.
5. Replace with new cable - push the cable in until it clicks.
6. Put the battery back into the compartment and replace the cover.
7. Reconnect the scanner cable to the monitor's communication port.



Repair

If repair is required, contact Exergen at (617) 923-9900 or rma@exergen.com for a Return Materials Authorization (RMA) Number.

- Mark the RMA number on the outside of your package and packing slips.
- Include a description of the fault if possible.
- Send the instrument freight/postage prepaid to:

Exergen Corporation
400 Pleasant Street
Watertown, MA 02472

- Include the address the instrument should be returned to. The instrument will be returned freight/postage prepaid.

Part Numbers

Exergen p/n	Midmark p/n	Description
1224264-AF-MD	3-200-0047	TAT-5000S-RS232-QR, Arterial, Deg F
134203	2-200-0115	Exergen Disposable Caps Covers

Pulse Oximetry Operation (SpO₂)

The SpO₂ capable IQvitals® devices offer two options of SpO₂ technology: The Masimo Pulse CO-Oximeter and the Nellcor OxiMax. Each SpO₂ capable device will ship with one (1) reusable, adult or pediatric finger clip sensor of the matching manufacturer's brand of technology. Carefully read the manufacturer's directions for use that accompanies the sensor.

The label on the right side of the device, surrounding the SpO₂ probe connection point, will display either Masimo or Nellcor (see Figure 3).

Note: Refer to "[Accessories and Supplies](#)" for approved SpO₂ sensors.

Masimo SpO₂ Sensor

The Masimo Pulse CO-Oximeters deliver accurate pulse oximetry during motion and low perfusion. The pulse co-oximeter is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use. For accuracy information, see [Footnotes: Masimo Accuracy Rate Determination](#).

	WARNING <i>As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.</i>
	WARNING <i>Do not place the pulse co-oximeter or accessories in any position that might cause it to fall on the patient.</i>
	WARNING <i>Do not start or operate the pulse co-oximeter unless the setup was verified to be correct. (See Device Setup for setup instructions.</i>
	WARNING <i>Do not use the pulse co-oximeter during magnetic resonance imaging (MRI) or in an MRI environment.</i>
	WARNING <i>Do not use the pulse co-oximeter if it appears or is suspected to be damaged.</i>
	WARNING <i>EXPLOSION HAZARD: Do not use the pulse co-oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.</i>
	WARNING <i>To ensure safety, avoid stacking multiple devices or placing anything on the instrument during operation.</i>
	WARNING <i>To protect from electric shock, always remove the sensor and completely disconnect the pulse co-oximeter before bathing the patient.</i>

	WARNING <i>If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse co-oximeter for proper functioning.</i>
	WARNING <i>To protect against injury, follow the directions below:</i> • Avoid placing the device on surfaces with visible liquid spills. • Do not soak or immerse the device in liquids. • Do not attempt to sterilize the device. • Use cleaning solutions only as instructed in this operator's manual. • Do not attempt to clean the device while monitoring a patient.
	WARNING <i>Inaccurate SpO₂ readings may be caused by:</i> • Improper sensor application. • Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO₂. • When elevated levels of COHb or MetHb are suspected, laboratory analysis (co- • Oximetry) of a blood sample should be performed. • Intravascular dyes, such as indocyanine green or methylene blue. • Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc. • Elevated levels of bilirubin. • Severe anemia. • Low arterial perfusion. • Motion artifact.
	WARNING <i>Interfering substances: dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.</i>
	WARNING <i>The pulse co-oximeter is intended only as an adjunct device in patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions, it must be used in conjunction with clinical signs and symptoms.</i>
	WARNING <i>The pulse co-oximeter is not an apnea monitor.</i>
	WARNING <i>The pulse co-oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.</i>

	WARNING <i>To protect from electric shock, always remove the sensor and completely disconnect the pulse co-oximeter before bathing the patient.</i>
	WARNING <i>The pulse co-oximeter should not be used for arrhythmia analysis.</i>
	WARNING <i>SpO₂ is empirically calibrated in health adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).</i>
	WARNING <i>Do not adjust, repair, open, disassemble, or modify the pulse co-oximeter or accessories. Injury to personnel or equipment damage could occur. Return the pulse co-oximeter for servicing if necessary.</i>

	Caution <i>Do not place the pulse co-oximeter where the controls can be changed by the patient.</i>
	Caution <i>Electrical shock and flammability hazard: before cleaning, always turn off the instrument and disconnect from any power source.</i>
	Caution <i>When patients are undergoing photodynamic therapy, they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.</i>
	Caution <i>Do not place the pulse co-oximeter on electrical equipment that may affect the instrument, preventing it from working properly.</i>
	Caution <i>If SpO₂ values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.</i>
	Caution <i>If the Low Perfusion message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.</i>
	Caution <i>If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate, or the instrument might read zero for the duration of the active irradiation period.</i>
	Caution <i>The instrument must be configured to match your local power line frequency to allow for the cancelation of noise introduced by fluorescent lights and other sources.</i>
	Caution <i>To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the pulse co-oximeter is used.</i>
	Caution <i>Variation in hemoglobin measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.</i>
	Caution <i>Do not submerge the pulse co-oximeter in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse co-oximeter.</i>

	Caution <i>Electrical shock hazard: carry out periodic tests to verify that leakage currents of patient- applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1.</i> <i>The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquid occurs, retest before further use. Injury to personnel could occur.</i>
	Caution <i>Disposal of product - Comply with local laws in the disposal of the instrument and/or its accessories.</i>
	Caution <i>To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the pulse co- oximeter.</i>

Note: A functional tester cannot be used to assess the accuracy of the pulse co-oximeter.
Note: High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the pulse co-oximeter to obtain vital sign readings.
Note: Changes or modifications not expressly approved by Masimo shall void the warranty of this equipment.
Note: When using the Maximum Sensitivity setting, performance of the “Sensor Off” detection may be compromised. If the instrument is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental, “noise” such as light, vibration, and excessive air movement.

	WARNING <i>Inspect the sensor site as directed in the sensor's Directions for Use to ensure skin integrity and correct positioning and adhesion of the sensor.</i> • Tissue damage can be caused by incorrect application or use of a sensor, for example by wrapping the sensor too tightly. • Avoid placing the sensor on any extremity with an arterial catheter or blood pressure cuff. • Misapplied sensors or sensors that become partially dislodged may cause either over or under reading of actual arterial oxygen saturation. • If the sensor is wrapped too tightly or supplemental tape is used, venous congestion/ pulsations may occur, causing erroneous readings. • Do not use tape to secure the sensor to the site; this can restrict blood flow and cause inaccurate readings. Use of additional tape can cause skin damage or damage the sensor.
	WARNING <i>With very low perfusion at the monitored site, the readings may read lower than core arterial oxygen saturation.</i>
	WARNING <i>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 hand of a patient in a bed with arm dangling to the floor).</i>
	WARNING <i>Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.</i>
	WARNING <i>Do not use damaged sensors or patient cables. Do not use a sensor or patient cable with exposed optical or electrical components.</i>
	Caution <i>Do not use the Pulse CO-Oximeter or oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The Pulse CO-Oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.</i>
	Caution <i>Exercise caution when applying a sensor to a site with compromised skin integrity. Applying tape or pressure to such a site may reduce circulation and/or cause further skin deterioration.</i>
	Caution <i>Circulation distal to the sensor site should be checked routinely.</i>

	Caution <i>A functional tester cannot be utilized to assess the accuracy of the Pulse CO- Oximeter or any sensors.</i>
	Caution <i>Do not modify or alter the sensor in any way. Alterations or modification may affect performance and/or accuracy.</i>
	Caution <i>Do not place the Pulse CO-Oximeter on electrical equipment that may affect the Pulse CO- Oximeter, preventing it from working properly.</i>
	Caution <i>Do not lift the CO-Oximeter by the patient cable.</i>
	Caution <i>Do not expose the Pulse CO-Oximeter to excessive moisture such as direct exposure to rain. Excessive moisture can cause the Pulse CO-Oximeter to perform inaccurately or fail.</i>
	Caution <i>Do not immerse the sensor or patient cable in water or, solvents, or cleaning solutions. (The sensors and connectors are not waterproof.)</i>
	Caution <i>Unless otherwise specified, do not sterilize sensors or patient cables by irradiation, steam, autoclave or ethylene oxide. See the cleaning instructions in the directions for use for the Masimo re-useable sensors.</i>
	Caution <i>High intensity extreme lights (including pulsating strobe lights) directed on the sensor may not allow the Pulse CO-Oximeter to obtain readings.</i>

Note: The Pulse CO-Oximeter can be used during defibrillation, but the readings may be inaccurate for up to 20 seconds.

Note: 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.

Note: Masimo SET technology with LNOP, LNCS, M-LNCS and RD SET sensors have been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing studies in the range of 70-100% SpO₂ against a laboratory co- oximeter and ECG monitor. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.

Note: Masimo SET technology with LNOP, LNCS, M- LNCS and RD SET sensors have been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in ranges of 70-100% SpO₂ against a laboratory co-oximeter and ECG monitor. 1% has been added to the saturation accuracy for neonatal sensors to account of the effects of fetal hemoglobin. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.

Note: Ambient light (including photodynamic therapy); physical movement (patient and imposed motion); diagnostic testing; electromagnetic interference; HF Surgical Equipment; dysfunctional hemoglobin; presence of certain dyes; inappropriate positioning of the Pulse Oximeter Probe.

Footnotes: Masimo Accuracy Rate Determination

1. SpO₂ accuracy was determined by testing on healthy adult volunteers in the range of 60 -100% SpO₂, 0-40% SpCO, and 1-15% SpMet against a laboratory CO-Oximeter. SpO₂ accuracy was determined on 16 neonatal NICU patients ranging in age from 7 -135 days old and weighing between 0.5-4.25 kg. Seventy-nine (79) data samples were collected over a range of 70 -100% SaO₂ and 0.5-2.5% MetHb with a resultant accuracy of 2.9% SpO₂.
2. The Masimo sensors have been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70 -100% SpO₂ against a laboratory CO- Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.
3. The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70 -100% SpO₂ against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
4. The Masimo SET Technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
5. The Masimo sensors have been validated for pulse rate accuracy for the range of 25 -240 bpm in bench top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.
6. The following substances may interfere with pulse CO-Oximetry measurements:
 - Elevated levels of Methemoglobin (MetHb) may lead to inaccurate SpO₂ measurements.
 - Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO₂ measurements.
 - Severe anemia may cause erroneous SpO₂ readings.
 - Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
 - Elevated levels of total bilirubin may lead to inaccurate SpO₂ readings.

Instructions for Using the Masimo M-LNCS OR RD SET DCI Reusable Adult SpO₂ Sensor

Site Selection

1. Choose a site that is well perfused and least restricts a conscious patient's movements. The ring finger of the non- dominant hand is preferred. Alternatively, the other digits on the non-dominant hand may be used.
2. Always choose a site that will completely cover the sensor's detector window. The great toe or long toe (next to the great toe) may be used on restrained patients or patients whose hands are unavailable. Site should be cleaned of debris prior to sensor placement.



WARNING

Use only Masimo brand sensors and accessories. Incompatible components can result in degraded performance and/or device malfunction.



Caution

Before using the sensor, ensure that the sensor is physically intact, with no broken or frayed wires or damaged parts.

Attaching the Sensor to the Patient

Note: Refer to figures in section [Disconnecting the Sensor from the Patient Cable](#).

1. Open the sensor by pressing on hinge tabs. Place the selected digit over the sensor window of the M- LNCS sensor. The fleshiest part of the digit should be covering the detector window in the lower half of the sensor. The top half of the sensor is identified by the cable. On a finger site, the tip of the finger should touch the raised digit stop inside the sensor. If the fingernail is long, it may extend over and pass the finger stop (Fig. 1 of 5).
2. The hinged tabs of the sensor should open to evenly distribute the grip of the sensor along the length of the finger. Check position of sensor to verify correct positioning. Complete coverage of the detector window is needed to ensure accurate data (Fig. 2 of 5).
3. Orient the sensor so that the cable will be running towards the top of the patient's hand (as shown in (Fig. 3 of 5). Connect the sensor connector to a patient cable.

Note: With smaller digits, in order to completely cover the detector window, it may be necessary to use a lower weight range sensor. The sensor is not intended for use on the thumb or across a child's hand or foot.

Attaching the Sensor to the Patient Cable

1. Properly orient the sensor connector {1} and insert the sensor connector completely into the patient cable connector
2. {2} (Fig. 4 of 5).
3. Completely close the protective cover {3} (Fig. 5 of 5).

Disconnecting the Sensor from the Patient Cable

1. Lift the protective cover {1} to gain access to the sensor connector {2} (Fig. 5 of 5).
2. Pull firmly on the sensor connector {2} to remove from the patient cable {3}. To avoid damage, pull on the sensor connector, not the cable.

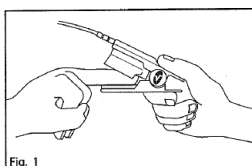


Fig. 1

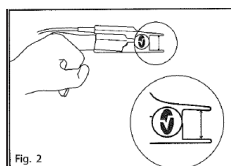


Fig. 2

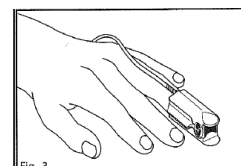


Fig. 3

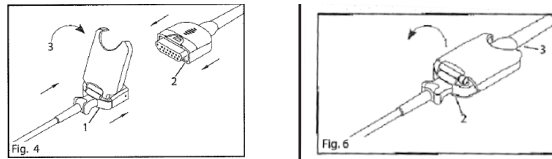


Figure 8

Cleaning

1. Remove the sensor from the patient and disconnect it from the patient cable.
2. Clean the sensor by wiping with a 70% isopropyl alcohol pad.
3. Allow the sensor to dry thoroughly prior to placement on a patient.

or

1. If low-level disinfection is required, use a 1:10 bleach / water solution.
2. Saturate a cloth or gauze pad with the cleaning solution and wipe all surfaces of the sensor and cable.
3. Saturate another cloth or gauze pad with sterile or distilled water and wipe all surfaces of the sensor and cable.
4. Dry the sensor and cable with a clean cloth or dry gauze pad.



Cleaning Cautions

Do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the sensor may occur.

Do not immerse the sensor or connector in any liquid solution.

Do not sterilize by irradiation, steam autoclave or ethylene oxide.

Nellcor™ OxiMax™

See Nellcor™ OxiMax™ Technology Pulse Oximetry Sensor DFU (Directions for Use) [R-G6].

The Nellcor™ OxiMax™ technology deliver continuous monitoring with precise SpO₂ readings, even for patients with weak pulse signals or fragile skin.

	WARNING <i>Use only Nellcor™ OxiMax™ sensors and accessories from Covidien. Incompatible components can result in degraded performance and/or device malfunction.</i>
	WARNING <i>Intravascular dyes (such as indocyanine green, methylene blue, etc.) and darkly pigmented skin can adversely affect SpO₂ readings.</i>
	WARNING <i>Significant amounts of dysfunctional hemoglobins (such as carboxyhemoglobin, methemoglobin, etc.) may adversely affect oximetry performance.</i>
	WARNING <i>Oximetry performance may be impaired when patient perfusion is low or signal attenuation is high.</i>
	WARNING <i>This product contains DEHP. The intended use limits exposure to intact skin, minimizing the risk of DEHP absorption. In order to avoid undue risk of DEHP exposure in children and nursing or pregnant women, product should only be used as directed.</i>
	WARNING <i>If the sensor is misapplied with excessive pressure for prolonged periods, a pressure injury can occur.</i>
	WARNING <i>Long cables (such as the sensor or extension cable) may cause patient strangulation if routed incorrectly.</i>
	WARNING <i>The user must not be in simultaneous contact with device connectors and patient.</i>
	WARNING <i>Do not immerse the sensor.</i>
	WARNING <i>Do not use the oximeter in close proximity to an MRI, ESU, or defibrillator.</i>
	WARNING <i>Do not use NIBP or other constricting instruments on same appendage as the sensor.</i>

	WARNING <i>Review all safety labeling based on the intended use of the equipment.</i>
	Caution <i>Periodically inspect extension cables and sensors for damage and discontinue the use of these if damage is found.</i>
	Caution <i>Consult the sensor DFU for proper sensor application.</i>
	Caution <i>Failure to apply the DS-100A properly may cause incorrect measurements.</i>
	Caution <i>Using the DS-100A in the presence of bright lights may result in inaccurate measurements. In such cases, cover the sensor site with an opaque material.</i>
	Caution <i>Intravascular dyes or externally applied coloring such as nail polish, dye, or pigmented cream, may lead to inaccurate measurements.</i>
	Caution <i>Reusable sensors must be moved to a new site at least every four hours. 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.</i>
	Caution <i>The performance of the DS-100A is compromised by motion.</i>
	Caution <i>Do not apply tape to secure the sensor in place or to tape it shut; venous pulsations may lead to inaccurate saturation measurements.</i>
	Caution <i>As with all medical equipment, carefully route cables to reduce the possibility of patient entanglement or strangulation.</i>
	Caution <i>Do not use the DS-100A or other oximetry sensors during MRI scanning. Conducted current may cause burns. Also, the DS-100A may affect the MRI image, and the MRI unit may affect the accuracy of oximetry measurements.</i>
	Caution <i>Do not alter or modify the DS-100A. Alterations or modifications may affect performance or accuracy.</i>

Note: Use only differentially wired extension cables of 10 feet or less in length. Reference the Covidien DOC-4 extension cable.

Note: Ambient light (including photodynamic therapy); physical movement (patient and imposed motion); diagnostic testing; low perfusion; electromagnetic interference; HF Surgical Equipment; dysfunctional hemoglobin; presence of certain dyes; inappropriate positioning of the Pulse Oximeter Probe.

Instructions for using the Nellcor Reusable Adult SpO₂ Sensor DS100A

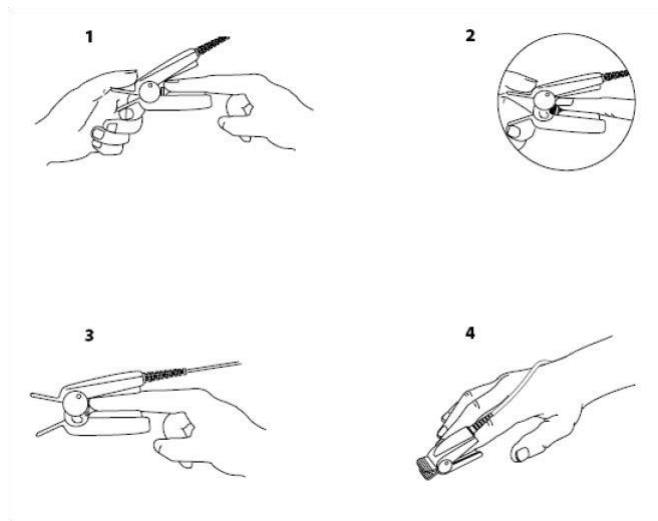


Figure 9

Use this sensor only with Nellcor instruments and instruments containing Nellcor oximetry, or with instruments licensed to use Nellcor sensors (Nellcor-compatible instruments). This sensor integrates Nellcor OxiMax technology into its design. When connected to an OxiMax-enabled instrument, this sensor uses OxiMax technology to provide additional advanced sensor performance features. Consult individual manufacturers for features and compatibility of particular instruments and sensor models.

Reusable sensors may be used on the same site for a maximum of 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.

To apply the DS-100A sensor

1. Place an index finger over the sensor window of the DS-100A with the fingertip against the Stop. (1)
2. If the fingernail is long, the nail tip will extend over the finger stop. (2)
3. Spread open the rear tabs of the sensor to provide even force over the length of the pads. Check the position of the sensor. If an index finger cannot be positioned correctly, or it is not available, a smaller finger can be used, or use an OxiMax or an Oxisensor II oxygen sensor. Do not use the DS-100A on a thumb or toe or across a child's hand or foot. (3)

Note: When selecting a sensor site, priority should be given to an extremity free of an arterial catheter, blood pressure cuff, or intravascular infusion line.

4. The sensor should be oriented in such a way that the cable is positioned along the top of the hand. (4)
5. Push the DS-100A into the oximeter and verify proper operation as described in the oximeter operator's manual.

Note: If the sensor does not track the pulse reliably, it may be incorrectly positioned or the sensor site may be too thick, this, or deeply pigmented, or otherwise deeply colored (for example, as a result of externally applied coloring such as nail polish, dye, or pigmented cream) to permit appropriate light transmission. If any of these situations occurs, reposition the sensor or choose an alternate Nellcor sensor for use on a different site.

Cleaning the Nellcor DS-100A sensor

The DS-100A may be surface-cleaned by wiping it with a solution such as 70% isopropyl alcohol. If low -level disinfection is required, use a 1:10 bleach / water solution. Do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the sensor could occur.



Caution

Do not expose connector pins to cleaning solution as this may damage the sensor.

To Clean or Disinfect the Sensor:

1. Saturate a clean, dry gauze pad with the cleaning solution. Wipe all surfaces of the sensor and cable with this gauze pad.
2. Saturate another clean, dry gauze pad with sterile or distilled water. Wipe all surfaces of the sensor and cable with this gauze pad.
3. Dry the sensor and cable by wiping all surfaces with a clean, dry gauze pad.



Caution

Do not sterilize by irradiation, steam, or ethylene oxide. Such sterilization could damage the sensor.

Taking an SpO₂ Measurement

	WARNING <i>All vital signs measurements must be verified by medically trained personnel.</i> <i>Should the accuracy of a measurement be questioned, use another clinically accepted method to verify the measurement or data.</i>
	WARNING <i>Various environmental factors may result in inaccurate SpO₂ measurement data including: ambient light (including photodynamic therapy); physical movement (patient and imposed motion); diagnostic testing; low perfusion; electromagnetic interference; electrosurgical units; dysfunctional hemoglobin; presence of certain dyes; inappropriate positioning of the pulse oximeter probe.</i>

1. To perform an SpO₂ measurement, insert the patient's finger (preferably the index finger) completely into the sensor. Place the sensor with the LED light positioned on the fingernail.

Note: If patient is moving or the finger size is inappropriate, select a different sensor that is appropriate for the patient.

Note: The thumb should not be used with the finger clip sensor.

Note: If the blood pressure measurement is occurring simultaneously, place the finger clip sensor on the limb opposite the one with the blood pressure cuff.

Note: Avoid dark nail polish or direct sunlight on the probe, as these conditions may result in inaccurate readings.

2. When the SpO₂ sensor is attached to a patient's finger, an audible tone will sound. The default settings display the SpO₂ percentage and the ten PI Bar segments.

3. When the SpO₂ measurement is complete, the SpO₂ value will appear. The SpO₂ value continues to update as long as the sensor is on the patient's finger.



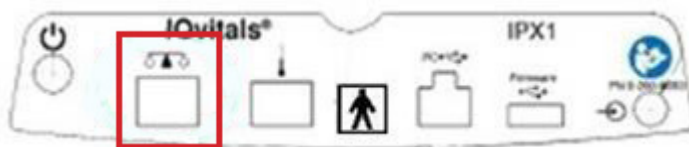
The signal strength indicator will show if the SpO₂ signal is strong enough. If the signal is not strong enough, the display values are potentially incorrect.

Note: If the sensor remains on the patient, the Perfusion Index (PI) Graph on the screen will become active. The SpO₂ value continues to update as long as the sensor is on the patient's finger. After the sensor is removed from the patient, the Perfusion Index Graph will disappear, and the patient's last SpO₂ measurement will be displayed on the screen.

Digital Scales

The IQvitals® Zone™ device is compatible with serial-connection, medical grade approved digital scales. When a compatible scale is connected to the device through the RS232 port on the back of the device the IQvitals® will automatically detect that the scale has been connected and is ready for use. The scale will automatically transfer the weight measurement to the IQvitals® Zone™ device.

Scale connection
on the back of the
device

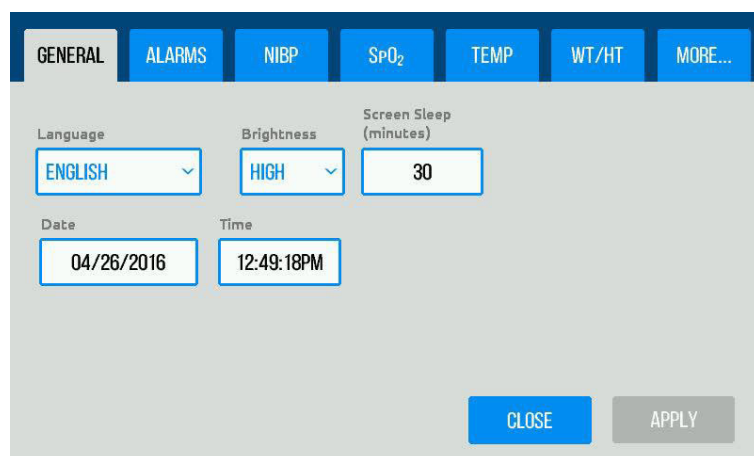


Settings

Press the **Settings** button from the **Main Screen** to access the **Settings** menu.



The **Settings** menu displays the following tabs:

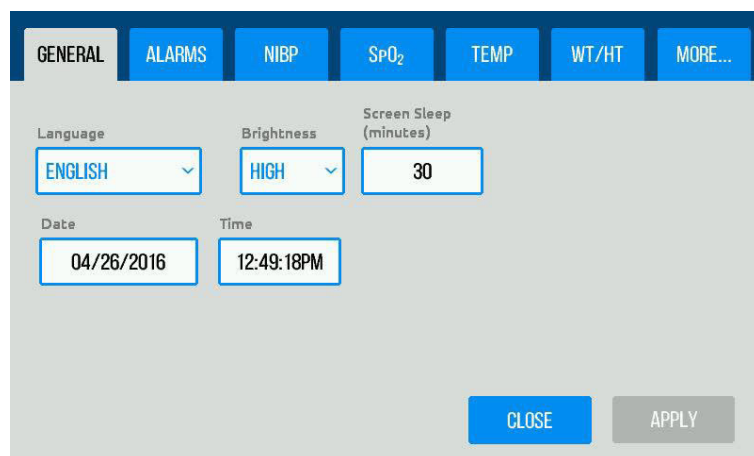


Settings Tabs

- General
- Alarms
- NIBP
- SPO₂
- Temp
- WT/HT
- More

General Settings

The **General** tab within **Settings** allows the user to change the following basic system features:



General Tabs

- Language—English, and French
- Brightness
- Screen sleep time
- Date
- Time

The **Apply** button is inactive until a change is made to the settings.

- Press the **Apply** button to save any changes made.
- If the **Apply** button is not pressed, and the user selects another tab or the **Close** button, a window appears to prompt the user to apply the change or cancel the change.

Alarms Settings

The **Alarms** tab in the **Settings** menu allows users to set the upper and lower thresholds that will activate an alarm state. There are two alarm threshold modes that can be saved in IQvitals® Zone™: Adult and Pediatric.



WARNING

Alarm limits are user adjustable. All alarm limit settings should take into account the patient's condition and acute care needs. Alarm limits should be set accordingly to the individual needs of each patient.

Default	Alarm Mode	NIBP Systolic (mmHg)	NIBP Diastolic (mmHg)	MAP
☒	ADULT	65	245	65

SpO ₂ Alarm Delay	Pulse Rate (bpm)	SpO ₂ (%)	Temp (°F)
10	25	235	70

Disable/Enable
DISPLAY ALARM THRESHOLDS ☐

Alarms Enable ☒

CLOSE APPLY

- Check the **Default** checkbox to specify the default alarm mode.
- Select Adult or Pediatric alarm threshold from the dropdown menu in the upper-left side, and then enter the threshold values.
- Use the **Display Alarm Thresholds** slide to enable or disable the display of alarm threshold values on the **Main Testing** screen.
- When Masimo Board is installed **SIQ Alerts** slider and **PI** threshold values will be displayed.
- When **SIQ Alerts is enabled** it enables alert messages indicating the poor signal quality from the SpO₂ device.
- Press **Apply** to save all threshold changes.
- Modify the SpO₂ alarm display by entering a value of 0, 5, 10, or 15 seconds in the **SpO₂ Time Alarm** box.
 - This will delay the SpO₂ alarm by the amount of time entered.

Note: Even if the Display Alarm Thresholds option is disabled, the alarm settings are still active and will cause the device to alarm if a value is outside the permitted threshold range. The setting only disables the display of the alarm threshold values on the Main Testing screen.

If the **Display Alarm Thresholds** slider is enabled, each alarm threshold value is displayed on the **Main Screen**. This setting reduces the font size of the data. The factory default is to disable the **Display Alarm Thresholds**.

SYS/DIA (mmHg) 106 / 73
65-245 65-155

MAP 81
50-200

NIBP Mode SPOT START NIBP

Pulse (bpm) 64
25-235

SpO₂ 96%
70-99

Temp (°F) 86-104 TEMPORAL

Weight (lb) 210.0 Height (in) 72.80 BMI 27.9

Alarms ADULT Sensor Off Patient

CLEAR 12:50:53 pm 04/26/2016 80% SAVE

Note: Different alarm threshold values can be saved in the Alarm Settings for both Adult and Pediatric patients.

To edit the alarm thresholds, select the alarm thresholds for either **Adult** or **Pediatric** from the dropdown menu. Press one of the following alarms to edit:

- NIBP
 - Systolic (mmHg)
 - Diastolic (mmHg)
 - MAP
- Pulse Rate (bpm)
- SpO₂ (%)
- Temp (°F)

The numeric keypad is displayed. Manually enter the lower and upper thresholds. The cursor automatically moves from the lower threshold box then to the upper threshold box when a value has been entered.

The screenshot shows the 'TEMP PEDIATRIC' screen. At the top, there are two input boxes for temperature thresholds: 'Lower (°F)' with the value '86' and 'Upper (°F)' with the value '107'. Below these is a numeric keypad with digits 1-9, a decimal point, and a zero. To the right of the keypad is a 'LEGEND' box containing the following text: '0=Alarm Off', 'Temperature', '86=MIN', and '109=MAX'. At the bottom left is a blue 'CANCEL' button, and at the bottom right is a grey 'OK' button.

Press **OK** to save the entry.

If an alarm threshold value is entered that is outside the permitted range, an explanation message will display.

The screenshot shows the 'NIBP PEDIATRIC' screen. At the top, there are three input boxes for blood pressure thresholds: 'Systolic (mmHg)' with the value '35', 'Diastolic (mmHg)' with the value '220', and 'MAP' with the value '25'. The 'Diastolic' box is highlighted with a red border. Below these is a numeric keypad with digits 1-9, a decimal point, and a zero. To the right of the keypad is a 'LEGEND' box containing the following text: '0=Alarm Off', 'Systolic', 'Low: 35=MIN, 125=MAX', 'High: 35=MIN, 130=MAX', 'Diastolic', 'Low: 20=MIN, 100=MAX', 'High: 20=MIN, 105=MAX', 'MAP', 'Low: 25=MIN, 115=MAX', and 'High: 25=MIN, 120=MAX'. Below the keypad, a red error message reads: 'Systolic upper threshold is above maximum permitted (130).'. At the bottom left is a blue 'CANCEL' button, and at the bottom right is a grey 'OK' button.

NIBP Settings

The **NIBP** tab in the **Settings** menu allows users to select the NIBP reading method, disable/enable NIBP modes and displayed on the Main Screen, and set the default interval time between Interval NIBP readings.

Note: Linear Deflation method is only applicable for SPOT NIBP mode. The rest of the NIBP modes shall run using Step Deflation method only.

The screenshot shows the NIBP Settings screen with the following configuration:

- Reading Method:** LINEAR DEFLATION
- DISABLE/ENABLE:**
 - AVERAGING: ON
 - SPRINT: ON
 - CUSTOM: ON
- CUSTOM Settings:**
 - Delay Start Time: 5 MIN
 - Interval Time: 60 SEC
 - Number of Readings: 4
 - Discard 1st Reading: ☐
- Map Enable:** ☐
- Buttons:** CLOSE, APPLY

Use the **Reading Method** dropdown menu to select between linear and step deflation.

Note: See “[Blood Pressure Algorithms](#)” for full descriptions of linear and step deflation.

If the **Step Deflation** method is selected, the initial inflation values for **Adult** and **Pediatric** mode may be edited.

The screenshot shows the NIBP Settings screen with the following configuration:

- Reading Method:** STEP DEFLATION
- Initial Inflation Values:**
 - Adult: 140, 160, 180, 220
 - Pediatric: 110, 120, 130, 140
- DISABLE/ENABLE:**
 - AVERAGING: ON
 - SPRINT: ON
 - CUSTOM: ON
- CUSTOM Settings:**
 - Delay Start Time: 5 MIN
 - Interval Time: 60 SEC
 - Number of Readings: 4
 - Discard 1st Reading: ☐
- Map Enable:** ☐
- Buttons:** CLOSE, APPLY

The **NIBP** tab in the **Settings** menu also allows the user to enable or disable **Averaging**, **SPRINT** and **Custom** modes using the slider.

- **Averaging** mode takes a series of five readings, disregards the first reading, and averages the next four readings to report an average BP reading.
- **SPRINT** mode is based on the BP protocol used in the Systolic Blood Pressure SPRINT Intervention Trial (SPRINT) study. The protocol starts with a five-minute quiet rest before reading, then three BP read-

ing are taken with one-minute interval in between. The final and reported BP result is an average of the three readings.

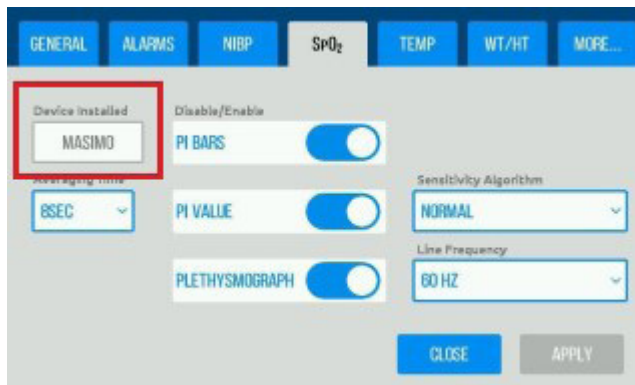
- **Custom** mode allows the user to pre-define a delay start time, interval time between readings, number of readings and option to discard first reading. The following are the options. Default settings are in bold.
 - **Delay Start Time: 1 min**, 2 min, 3 min, 4 min, 5 min.
 - **Interval Time: 30 sec**, 45 sec, 60 sec
 - **Number of Readings: 3**, 4, 5
 - **Discard 1st Reading:** Check / **Uncheck**

Note: When turning on the Custom mode in Settings, press Apply to see the options.

When done, press **Apply** on the **NIBP** tab to save all changes.

SpO₂ Settings

The **SpO₂** tab in the **Settings** menu allows the user to disable or enable the features associated with each pulse oximeter. IQvitals® will automatically detect if a Masimo or Nellcor sensor is attached to the IQvitals® Zone™ device.



- The **Device Installed** box displays the pulse oximeter attached to the IQvitals® Zone™ device.
- Use the slider bars to enable or disable the following SpO₂ features.
 - **PI Bars** to display the 10-segment pulse amplitude indicator on the **Main Screen**.
 - **PI Value** to display the perfusion index percentage on the **Main Screen**.
- **Plethysmograph** to display the graph on the **Main Screen**. When this feature is enabled, the **Pulse Rate** moves to the third row of the vital signs main screen to allocate space for the additional features.

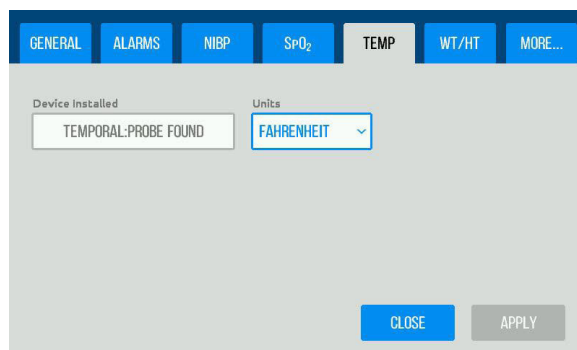
Press **Apply** on the **SpO₂** tab to save all changes.

Below is the Main screen when all MASIMO options enabled:



Temperature Settings

The **Temp** tab in the **Settings** menu displays the connection Status of the EXERGEN Temporal probe (P/N 3-200-0047). Also, while in the Temperature Settings screen the User may change the temperature units.



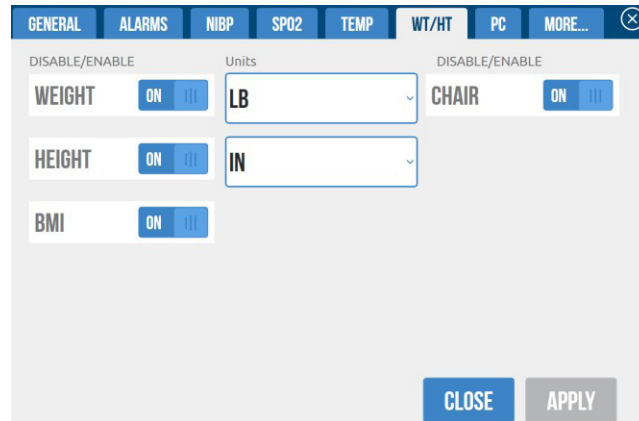
The screenshot shows the 'TEMP' tab selected in the settings menu. The 'Device installed' status is 'TEMPORAL:PROBE FOUND'. The 'Units' dropdown is set to 'FAHRENHEIT'. The 'APPLY' button is visible at the bottom right.

- Use the **Units** dropdown menu to select the unit of measurement (Fahrenheit or Celsius).
- Press **Apply** on the **Temp** tab to save all changes.

Weight and Height Settings

The **WT/HT** tab in the **Settings** menu allows users to enable or disable the following features:

- Weight
- Height
- BMI
- Exam Chair



The screenshot shows the 'WT/HT' tab in the settings menu. At the top, there is a navigation bar with tabs: GENERAL, ALARMS, NIBP, SP02, TEMP, WT/HT (selected), PC, and MORE... with a close icon. Below the navigation bar, the interface is divided into sections. On the left, under 'DISABLE/ENABLE', there are three rows: 'WEIGHT' with an 'ON' toggle, 'HEIGHT' with an 'ON' toggle, and 'BMI' with an 'ON' toggle. In the center, under 'Units', there are two dropdown menus: 'LB' for weight and 'IN' for height. On the right, under 'DISABLE/ENABLE', there is one row: 'CHAIR' with an 'ON' toggle. At the bottom right, there are two buttons: 'CLOSE' and 'APPLY'.

If either the weight or height is disabled, the BMI will automatically become disabled.

The user can change the units of measurement for weight and height using the **Units** dropdown menus.

More...

The **More** tab in the **Settings** menu allows users to access the following:

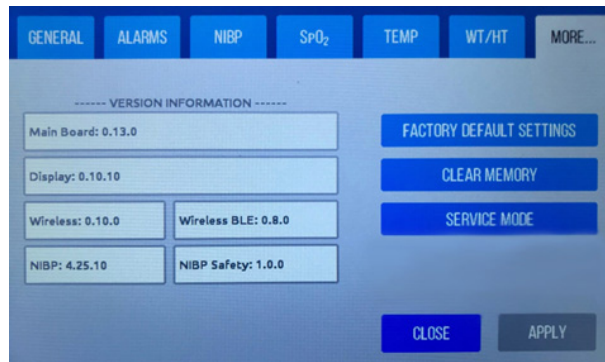
- UPDATE VERSIONS Information
- FACTORY DEFAULT SETTINGS
- CLEAR MEMORY
- SERVICE MODE

1. On the main screen, confirm that the NIBP mode is set to **Spot**.
2. Select **Settings** Mode
3. Press the **More** tab



Use the numeric keypad to enter the Service Mode password 1590, then press **OK**.

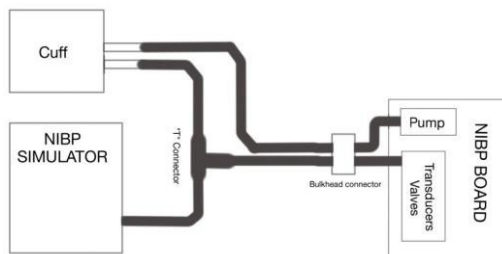
The **More** screen is displayed.



Performing Check Calibration

Note: The **Start** button in the Service mode will be disabled during Blood pressure measurement or while the system is in Monitoring mode. This function should only be performed by qualified service personnel. For additional information contact [Midmark Technical Service](#).

1. Select **Service** mode. Connect a calibrated NIBP simulator, aneroid, mercury column or pressure transducer (with known accuracy) to the NIBP cuff with a “T” connector. The NIBP cuff shall be wrapped around a suitable mandrill. Connect the hose coming from the pump on the bulkhead connector to the remaining cuff connection. Connect the remaining “T” connection to the return on the NIBP bulkhead connection as shown in the following illustration.



2. Select at least one low, one midrange and one high value then Press **Start**. Enter a value between 50 and 260 mmHg.



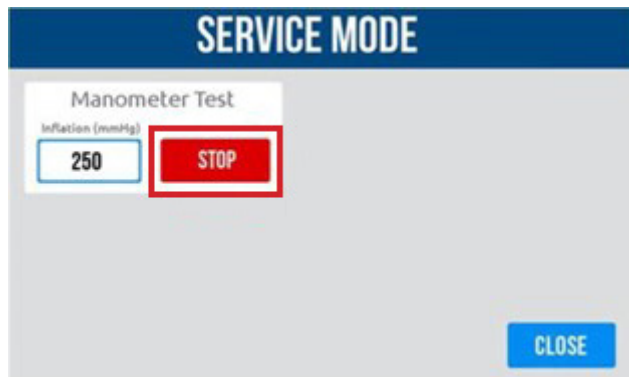
3. Device will inflate to and maintain the value entered in the manometer test window. The **Start** button will change to a **Stop** button. Compare this value to the reading given on your measurement device. Record the three measured values.
4. Add the Vital signs monitor accuracy tolerance (+/- 3mmHg or 2% whichever is greater) to the measurement transducer's accuracy tolerance to determine if the Vital signs monitor is within calibration.

Example:	Vital signs accuracy tolerance	+/- 3 mmHg or 2%
	Measurement device tolerance	+/- 1 mmHg
	Total tolerance	+/- 4 mmHg or 2% + 1mmHg

Pressure #1 = 250 mmHg +/- 3mmHg plus +/-1 mmHg = 244 to 256 mmHg PASS if between these values

Pressure #2 = 100 mmHg +/- 3 mmHg plus +/- 1mmHg = 96 to 104 mmHg PASS if between these values

Pressure #3 = 50 mmHg +/- 3 mmHg plus +/- 1mmHg = 47 to 53 mmHg PASS if between these values

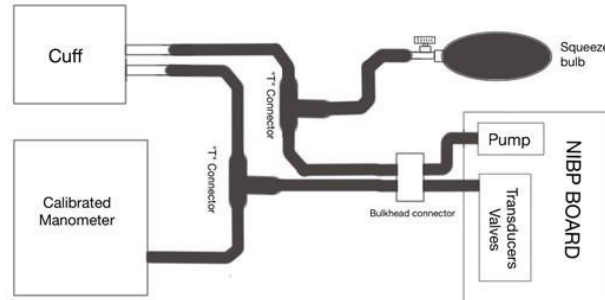


5. Press the **Close** button to return to the **More** tab.

Performing Over Pressure Check

1. Connect a calibrated NIBP simulator, aneroid, mercury column or pressure transducer (with known accuracy) to the NIBP cuff with a “T” connector. The NIBP cuff shall be wrapped around a suitable mandrill. Assure that the “T” connection is attached to the measurement side of the bulkhead connector.

Note: If necessary, the measurement side can be determined by running the NIBP pump. The side producing a pressure is the pressure side. The no pressure side is the measurement side. Connect a squeeze bulb to the remaining cuff connection and the pressure side of the bulkhead connector on the bulkhead connector using a “T” connection. See figure below.



2. Touch the inflation (mmHg) entry window and enter 250 mmHg. Press the **START** button. Allow the device to attain 250 mmHg. Monitor the manometer device and squeeze the squeeze bulb slowly until the cuff pressure releases. Record the pressure on the manometer at the moment pressure releases. PASS if between 285 to 315 mmHG.



Note: If more than one repetition of the overpressure test is performed, the Power Button to the device must be turned off then back on between tests to reset the over pressure feature.

3. Press the **Close** button to return to the **More** tab.

Cleaning of IQvitals® and Accessories

The following table provides instructions for cleaning the IQvitals® and its accessories. The IQvitals® should be cleaned monthly or as warranted. Before cleaning, refer to the cautions listed below.

Part	Recommended Cleaning Method								
IQvitals® Zone™ Power Supply Power Cord	Materials Soft cloths and/or soft-bristled brushes Protective gloves and eyewear Distilled water Cleaning Agents Only the following cleaning agents are approved for use on the IQvitals Zone device: <table> <tr> <td>Water</td><td>Ammonia Aq. 10%</td></tr> <tr> <td>Sulfuric Acid (3% or 30%)</td><td>Sodium Carbonate 2%</td></tr> <tr> <td>Sodium Hydroxide (10 or 40%)</td><td>Sodium Carbonate Aq. 10% Hydroperoxide 3%</td></tr> <tr> <td>Potassium Hydroxide 40%</td><td></td></tr> </table> Procedure 1. Disconnect the unit from the wall outlet. 2. Put on gloves and protective eyewear. 3. Prepare the enzymatic detergent or disinfectant solution according to the manufacturer's instructions and in separate containers. 4. Apply detergent to product using a soft cloth. If material is dried on, allow to sit for one minute. 5. Wipe smooth surfaces with the cloth. 6. Use a soft-bristle brush on visibly soiled areas and irregular surfaces. 7. Remove detergent from product using cloth dampened in distilled water. 8. Repeat as necessary. 9. Apply disinfectant solution on affected area using a soft cloth. Allow product to sit for five minutes 10. Wipe away excess solution, and clean product again with cloth dampened in distilled water. 11. Allow two hours for drying.	Water	Ammonia Aq. 10%	Sulfuric Acid (3% or 30%)	Sodium Carbonate 2%	Sodium Hydroxide (10 or 40%)	Sodium Carbonate Aq. 10% Hydroperoxide 3%	Potassium Hydroxide 40%	
Water	Ammonia Aq. 10%								
Sulfuric Acid (3% or 30%)	Sodium Carbonate 2%								
Sodium Hydroxide (10 or 40%)	Sodium Carbonate Aq. 10% Hydroperoxide 3%								
Potassium Hydroxide 40%									

SpO ₂ Sensor	Materials 70% isopropyl alcohol pad Procedure Remove sensor from patient and disconnect sensor cable from the device. Wipe off with alcohol pad. Allow sensor to dry before placing it on a patient.
Reusable BP Cuffs and Hose	For normal cleaning: mild detergents or a diluted bleach solution (1-2%), wipe cuff with the solution, rinse with water, and dry. For disinfecting: use a disinfecting solution such as Enzol, Cidezyme, Cidex, Sporidicin, Isopropyl Alcohol 70%, or Ethanol (70%), wipe or spray the cuff and allow to stand for approximately one minute. Rinse well with water and dry. Note: If the cuff is submerged in the disinfecting solution, the fittings should be capped to prevent liquid from getting inside the cuff.

	Caution <i>Always disconnect the IQvitals® from AC power before cleaning.</i>
	Caution <i>Electronic devices can be damaged by exposure to liquids. Do not use or store the IQvitals® near any type of liquids.</i>
	Caution <i>Do not use harsh chemicals for cleaning, especially disinfectants that contain phenol, as they can cause plastics to crack, soften, and spot. Do not steam- autoclave, gas-sterilize, or irradiate the unit; subject the unit to intense vacuum; or immerse the unit in water or cleaning solution. Keep cleaning liquids out of the unit and connectors. If any liquid gets inside the unit, allow it to dry in warm air for two hours, and then check to make sure all monitoring functions are working properly.</i>
	Caution <i>Take particular care when cleaning the blood pressure cuff, blood pressure hose, and blood pressure connector on the IQvitals® to prevent fluid from entering the connectors. Fluid in the blood pressure airway may affect blood pressure determination accuracy and damage the monitor.</i>
	Caution <i>Accessories that fall on the floor should be inspected for contamination and proper functionality. In case of contamination, follow the cleaning procedure detailed above.</i>
	Caution <i>The user accepts responsibility for any deviations from the recommended method of cleaning and disinfection.</i>

Maintenance, Storage, and Battery Replacement

Maintenance

The following table shows the recommended maintenance procedures for the IQvitals® device and its accessories. IQvitals® requires periodic calibration checks. It is a good idea to check that the device is in good working order, as described in the table. Calibration checks should be done every 12 months and can be performed by qualified service personnel.

IQvitals® Function	Procedure
Mechanical Integrity	Check for cracks, abrasive edges, and other signs of damage.
Touch Screen	Verify that screen is responsive to touch.
On/Off LED	Verify that the green On/Off LED is illuminated on the front of the IQvitals® when the unit is on.
Speaker	Power-cycle the IQvitals® and verify that the power-up speaker test tones are generated.
SpO2	Apply the pulse oximeter probe to your finger. Verify that the reported pulse rate matches your pulse rate as measured on your wrist and that the SpO ₂ value seems reasonable (above 95% for a healthy non-smoker).
NIBP	Apply an appropriately sized blood pressure cuff to your arm. Measure your blood pressure and verify that the reported blood pressure is reasonably close to your typical blood pressure.
Temperature	None (self-checking).
Alarms	Testing of the alarm system is part of the IQvitals Zone device start process. To test the alarm system, restart the device (see Power Button). If the alarms do not trigger at start up please contact Midmark Technical Service for service information.

If one of the checks results in a functional failure, please contact If an IQvitals® needs to be returned for repair or calibration, a return authorization number must first be obtained from [Midmark Technical Service](#).

Storage

Storage Temperature	-4 to 122° F (-20 to 50° C)
Storage Humidity	15% to 95% non-condensing
Storage Altitude	0 to 40,000 feet



Caution

The IQvitals® may not conform to all of its performance specifications if stored outside these environmental specifications or used outside of the environmental specifications in "[System Specifications](#)".

Battery Replacement



Caution

This device uses a lithium ion battery designed specifically for this device and is not field replaceable. Contact [Midmark Technical Service](#) to arrange battery replacement service.



Battery Cautions

Risk of fire and burns

Do not open, crush, puncture, incinerate, or short circuit external contacts

Do not disassemble or alter battery pack

Do not expose to heat in excess of 122° F (50° C)

Note: The battery is a lithium ion battery and must be recycled or disposed of properly according to national or local regulations.

Appendix A – Alarm States and Priority Levels

The following list provides the alarm capabilities of each IQvitals device model.

Device Model Number	Technical Alarms	Physiological Alarms
1-200-0310	X	
1-200-0320	X	
1-200-0330	X	
1-200-0340	X	X
1-200-0350	X	X
1-200-0360	X	X

A technical alarm will occur if a device function needs to be addressed. Devices providing technical alarms are shipped with these alarms ENABLED.

A physiological alarm will occur when a vital sign measurement being taken falls outside a preset threshold. The devices that provide physiological alarms are shipped with these alarms ENABLED. Each vital sign parameter will have factory determined thresholds. The user may change the parameter threshold settings in the Settings menu for each parameter. Physiological alarms are considered global meaning that the alarm feature will apply to all vital sign parameters the device is capable of measuring. The user cannot select which individual vital sign parameter will have an alarm and which will not.

Factory set default thresholds can be restored through the "[Alarm Settings](#)". The IQvitals® Zone™ device does not keep a perpetual log of alarm occurrences.

Visual and Audible Alarm Notification

The IQvitals® Zone™ provides three priorities: High, Medium and Low. Each alarm provides both visual and audible notifications.

Note: It is important to remain in close proximity to the device to maintain clear visual contact with the monitor and to be able to hear the audible alarms should they occur.

Alarm State	LED Light		Audible Alarm Tone	Audible Alarm Repeat
	Color	Steady or Flash		
High	Red	Steady	3 beeps followed by 2 beeps, (runs 2 consecutive times)	Every 2.5 seconds
Medium	Amber	Steady	3 beeps	Every 7.5 seconds
Low	Amber	Steady	2 beeps	Every 20 seconds

Text will be provided on the device screen informing the user which alarm requires attention.

The screenshot displays the NIBP device's main testing screen. At the top, it shows 'SYS/DIA(mmHg)' with large orange numbers '116 / 82'. To the right, there's a 'NIBP Mode' dropdown set to 'SPOT' and a 'START NIBP' button. Below this, the 'Pulse Rate (bpm)' is '60', 'SpO2' is shown with a bar graph, and 'Temp (°F)' is 'TEMPORAL'. The bottom section includes input fields for 'Weight(lb)', 'Height(in)', and 'BMI', with 'ADULT' selected in the 'Alarms' dropdown. A red alarm message 'NIBP Systolic LOW' is visible next to the 'ADULT' dropdown. At the bottom, there are 'CLEAR' and 'SAVE' buttons, along with some status icons.

Both physiological and technical alarms will display in the Alarms box (lower right) on the Main Testing screen.

All alarm states will continue to display or sound until the applicable issue is corrected. The **Alarm Reset** button in the Alarms box allows the user to reset or pause the audible portion of the alarm and disable the LED light bar, however, the alarm message will continue to display on the **Main Screen** until the issue is corrected.

Alarm Priority

Should more than one parameter require attention and activate an alarm, the highest urgency alarm will display first. For example: should a Medium alarm activate then a High alarm activate, the HIGH priority parameter that triggered the alarm will be highlighted on the screen and the light on the front of the device will display red for the HIGH priority alarm. Once the High priority alarm is corrected the device will then display the next alarm to be addressed.

Should two or more MEDIUM alarms occur at the same time, the device will display which alarm occurred first. Once the first Medium alarm is corrected the device will then display the next Medium alarm to be addressed. Same applies should two or more LOW alarms occur at the same time.

Alarm buttons for the IQvitals® and a brief description of each.

Button	Description
	Alarm. This button will appear this way to indicate there are no active alarms.
	Alarm Reset. The Alarm button (above) will be highlighted in amber in the event of an active alarm or multiple active alarms.
	The Alarm button will return to this state if the Alarm Reset button (above) is pressed indicating an alarm has been reset or paused but not yet corrected. The alarm description will remain on the Main Screen just above this button until the issue is corrected.

Note: The IQvitals® Zone does not store activated alarms by patient.

Alarm Reset

An audible alarm can be reset or paused by the user by pressing the **Alarm Reset** button on the **Main Screen**. If an audible alarm is paused, the light bar will be extinguished and the audible tones will stop, however, the text notification on the **Main Screen** within the Alarms box will continue to display the be addressed or corrected.



Should multiple alarms require attention, the device will provide audible and visual indicators for the highest priority alarm. If the **Alarm Reset** button is pressed, the first (or highest priority) alarm will silence. The device will then provide audible and visual indicators for the next alarm. If the **Alarm Reset** button is pressed for all remaining active alarms, the device light bar will then indicate the color associated with the first (or highest priority) alarm that needs attention.

Note: Although the audible tone and the light bar is extinguished, the trained clinician must address and correct the indicated issues.

The only way an alarm can truly be stopped is for the associated issue to be corrected. Once corrected, all audible and visual indicators will cease.

Physiological and Technical Alarms

The following list explains the physiological and technical alarm messages and their priority level.

Physiological Alarms Messages

Alarm messages	Displayed Message	Priority
Alarm limit exceeded. NIBP systolic HIGH.	NIBP Systolic HIGH	High
Alarm limit exceeded. NIBP systolic LOW.	NIBP Systolic LOW	High
Alarm limit exceeded. NIBP diastolic HIGH.	NIBP Diastolic HIGH	High
Alarm limit exceeded. NIBP diastolic LOW.	NIBP Diastolic LOW	High
Alarm limit exceeded. NIBP MAP HIGH.	NIBP MAP HIGH	High
Alarm limit exceeded. NIBP MAP LOW.	NIBP MAP LOW	High
Alarm limit exceeded. SpO2 HIGH.	SpO2 HIGH	High
Alarm limit exceeded. SpO2 LOW.	SpO2 LOW	High
Alarm limit exceeded. Pulse rate HIGH.	Pulse Rate HIGH	Medium
Alarm limit exceeded. Pulse rate LOW.	Pulse Rate LOW	Medium
Alarm limit exceeded. PI HIGH.	PI HIGH	Medium *
Alarm limit exceeded. PI LOW.	PI LOW	Medium *
Alarm limit exceeded. Temperature HIGH.	Temperature HIGH	Low
Alarm limit exceeded. Temperature LOW.	Temperature LOW	Low

* Only MASIMO

Technical Alarms Messages

Alarm messages	Displayed Message	Priority
SPO₂ (Masimo)		
No cable Connected	No cable Connected	Low
Cable Life Expired	Cable Life Expired	Low
Incompatible Cable	Incompatible Cable	Low
Unrecognized Cable	Unrecognized Cable	Low
Defective Cable	Defective Cable	Low
Cable Life Near Expiration	Cable Life Near Expiration	Low
No Sensor Connected	No Sensor Connected	Low
Sensor Life Expired	Sensor Life Expired	Low
Incompatible Sensor	Incompatible Sensor	Low
Unrecognized Sensor	Unrecognized Sensor	Low
Defective Sensor	Defective Sensor	Low
Check Cable and Sensor Fault	Check Cable and Sensor Fault	Low
Sensor Life Near Expiration	Sensor Life Near Expiration	Low
No Adhesive Sensor	No Adhesive Sensor	Low

Adhesive Sensor Life Expired	Adhesive Sensor Life Expired	Low
Incompatible Adhesive Sensor	Incompatible Adhesive Sensor	Low
Unrecognized Adhesive Sensor	Unrecognized Adhesive Sensor	Low
Defective Adhesive Sensor	Defective Adhesive Sensor	Low
Adhesive Life Near Expiration	Adhesive Life Near Expiration	Low
Sensor Initializing	Sensor Initializing	Low
Sensor Off patient	Sensor Off patient	Low
Pulse Search	Spinning Wheel	Low
Interference Detected	Interference Detected	Low
Low Perfusion Index	See Physiological alarms	Low
Check Sensor Connection	Check Sensor Connection	Low
SPO2 (NELLCOR)		
Sensor Detached from Patient	Sensor Off patient	Low
Sensor Disconnect	No Sensor Connected	Low
Interference Detected	Interference Detected	Low
NIBP		
NIBP air leak; check cuff and tubing connections	NIBP Air Leak	Low
Unable to determine NIBP; check connections and tubing for kinks	Unable to determine NIBP	Low
Inflation too quick; checking NIBP cuff and tubing connections	Inflation too quick	Low
Pressure out of the range (Systolic 50 – 260, Diastolic 20 – 210)	Unable to Determine NIBP	High
Battery		
Low battery at 40%	Low Battery	Low
Low battery at 20%	Low Battery	Low
Low battery at 10%	Critical Battery	High
Battery is absent or faulty. Call for service.	Battery is absent or faulty	Low
Weight scale		
Fairbanks Weight scale not functional	Fairbanks scale not functional	Low
625 Table Weight scale not functional	625 Table scale not functional.	Low
System Communication (when each of the items below is part of the system)		

Loss of pairing with wireless devices No Pairing icon is displayed	Loss of wireless pairing	Low
Communication with the Fairbanks scale module Failed	Loss of Fairbanks scale Comm.	Low
Communication with the Exam Chair Scale module Failed	Loss of Chair Comm.	Low
Communication with the wireless Board failed	Loss of wireless Comm.	Low
Communication with SPO ₂ module Failed	Loss of SpO ₂ Comm.	High
Communication with NIBP	Loss of NIBP Comm.	High
Communication with Display Board	Loss of LCD Comm.	High
System		
Set date and time. (warning)	Set date and time	Low
Maximum number of patient records saved. Oldest record will be overwritten.	Max number of patient records	Medium
Unable to access patient information	Cannot access patient info	High
Unable to load configuration; using factory defaults	Unable to load configuration	High

Alarm Threshold Limits

The following list provides the threshold limits for each vital sign parameter and is separated for **Adult** and **Pediatric** patient populations.

Adult - Vital sign parameter threshold limits

Parameter	Adjustment Range	Default	Note
HR high limit	25-235, or off	235	Adjustable in 5 BPM steps.
HR low limit	25-230, or off	25	Adjustable in 5 BPM steps. Must be less than the HR high limit.
Systolic BP high limit	110-245, or off	245	Adjustable in 5 mmHg steps.
Systolic BP low limit	65-240, or off	65	Adjustable in 5 mmHg steps. Must be less than the Systolic BP high limit.
Diastolic BP high limit	65-155, or off	155	Adjustable in 5 mmHg steps. Must be less than the Systolic BP high and low limits.
Diastolic BP low limit	35-150, or off	35	Adjustable in 5 mmHg steps. Must be less than the Diastolic BP high limit.
MAP high limit	70-200, or off	200	Adjustable in 5 mmHg steps.
MAP low limit	50-125, or off	50	Adjustable in 5 mmHg steps. Must be less than the MAP high limit.
SpO ₂ high limit	85-99, or off	99	Adjustable in 1-point steps.
SpO ₂ low limit	85-98, or off	85	Adjustable in 1-point steps. Must be less than SpO ₂ high limit.

Pediatric - Vital sign parameter threshold limits

Parameter	Adjustment Range	Default	Note
HR high limit	25-235, or off	220	Adjustable in 5 BPM steps.
HR low limit	25-230, or off	Off	Adjustable in 5 BPM steps.
Must be less than the HR high limit.			
Systolic BP high limit	35-130, or off	120	Adjustable in 5 mmHg steps.
Systolic BP low limit	35-125, or off	Off	Adjustable in 5 mmHg steps.
Must be less than the Systolic BP high limit.			
Diastolic BP high limit	20-105, or off	80	Adjustable in 5 mmHg steps.
Must be less than the Systolic BP high and low limits.			
Diastolic BP low limit	20-100, or off	Off	Adjustable in 5 mmHg steps.
Must be less than the Diastolic BP high limit.			
MAP high limit	25-120, or off	100	Adjustable in 5 mmHg steps.
MAP low limit	25-115, or off	Off	Adjustable in 5 mmHg steps.
Must be less than the MAP high limit.			
SpO ₂ high limit	85-99, or off	99	Adjustable in 1-point steps.
SpO ₂ low limit	85-98, or off	85	Adjustable in 1-point steps.
Must be less than SpO ₂ high limit.			

Alarm Signal Sound Pressure Range

ALARM CONDITION ⁽¹⁾	Measured sound pressure level (dB)	A-weighted background level ⁽²⁾ (dB)	Remarks
NO ALARMS ACTIVATED	32.7, 32.6, 32.8, 32.7 (mean = 32.7)	32.7	
HIGH PRIORITY ALARM	62.6, 60.9, 62.5, 62.6 (mean = 62.2)	32.7	4.8 second intervals Δ sound press. = 29.5 db
MEDIUM PRIORITY ALARM	61.8, 61.5, 62.6, 61.3 (mean = 61.8)	32.7	7.9 second intervals Δ sound press. = 29.1 db
LOW PRIORITY ALARM	60.9, 60.3, 60.3, 60.2 (mean = 60.4)	32.7	27.8 second intervals Δ sound press. = 27.7 db
Supplementary information: (1) Including HIGH, MEDIUM and LOW PRIORITY ALARM CONDITIONS. (2) Including any INFORMATION SIGNAL or extraneous noise			

Customer Support and Warranty Information

For help diagnosing problems by phone or email, contact [Midmark Technical Service](#). Self-help knowledge base and live chat can be accessed at <https://www.midmark.com/service-support/technical-support/medical/diagnostic-support> (Diagnostic Product Support).

Warranty

Midmark warrants IQvitals® to be free from manufacturing and material defects for two (2) years from the original date of purchase. Warranty periods for accessories shipped at the time of original purchase are: one (1) year for blood pressure cuffs and SpO₂ sensor; 90 days for other accessories. Any misuse or abuse of a Midmark product or accessory voids all applicable warranties.

Please refer to [midmark.com](https://www.midmark.com) for the full and current Warranty Terms and Conditions.

Return Materials Authorization

To return any product for repair, a Return Materials Authorization (RMA) number must be obtained from [Midmark Technical Service](#). This RMA number should be referenced on the package(s) containing the items to be returned and in any correspondence regarding the return.

Shipping

Before shipping any unit to Midmark, be certain that a RMA number has been issued and that all guidelines regarding this authorization are followed. We highly recommend that you follow all guidelines for the shipment of medical products set forth by the shipping company you choose to use. If a question should arise regarding the appropriate method of shipment, please feel free to ask when calling for your RMA number. It is ultimately the responsibility of the customer when shipping a product to ensure that all packages and their contents get to Midmark safely. Midmark will not assume responsibility for damage due to improper packaging, shipment or product use. Such actions will void all applicable warranties.

Disposal

The disposal of Midmark Diagnostic Devices and their accessories should be carried out according to local medical waste disposal policies and procedures. Do not discard these items in unsorted municipal waste. Contact your local waste disposal agency for guidance on proper recycling or disposal.

Certain items contain electronic circuit boards or lithium ion batteries that should not be incinerated, crushed, disassembled or exposed to extreme heat. Do not put the lithium ion battery in a refuse container. Lithium batteries and electronic components should be recycled appropriately.

Accessories and Supplies

The following table shows the accessories approved by Midmark for use with the IQvitals® Zone.



WARNING

Use only approved accessories with the IQvitals® Zone. Substitution of a component different from those suggested could result in measurement error.

Item	Part Number
Fairbanks® TeleWeigh™ Digital Scale	1-100-1603
Blood Pressure Cuff, Dual Tube, Disposable, Child (13-20cm), 5/pk	2-200-0020
Blood Pressure Cuff, Dual Tube, Disposable, Small Adult (18-26cm), 5/pk	2-200-0021
Blood Pressure Cuff, Dual Tube, Disposable, Adult (26-35cm), 5/pk	2-200-0022
Blood Pressure Cuff, Dual Tube, Disposable, Adult Long (29-38cm) , 5/pk	2-200-0023
Blood Pressure Cuff, Dual Tube, Disposable, Large Adult (32-42cm), 5/pk	2-200-0024
Blood Pressure Cuff, Dual Tube, Disposable, Large Adult Long (35-44cm), 5/pk	2-200-0025
Blood Pressure Cuff, Dual Tube, Disposable, Thigh (42-50cm), 5/pk	2-200-0026
SpO ₂ Sensor, Reusable, Masimo®, Pediatric (RD Set DCI-P)	2-200-0041
SpO ₂ Sensor, Reusable, Masimo, Adult (RD SET DCI)	2-200-0040
SpO ₂ Patient Cable, Masimo (RD SET D20-05) - 4'	2-200-0042
SpO ₂ Sensor Kit, Reusable, Nellcor™, Pediatric (D-YS and D-YSPD)	3-200-0007
SpO ₂ Sensor, Reusable, Nellcor, Adult (DS100A)	2-200-0233
SpO ₂ Interface Cable, Nellcor (DOC4) - 4'	2-200-0234
Disposable Caps, Exergen Thermometer, 1000pc/box	2-200-0115
Disposable Caps, Exergen Thermometer, 100pc/box	2-200-0116
Storage Bin Kit, Dual, Cart Mounted	2-200-0074
Storage Bin Kit, Wall Mounted	2-200-0084
Tray, IQvitals Zone - 12"	3-200-0009
TRAY, IQVITALS ZONE, LAPTOP, 15"	3-200-0008
USB Dongle, IQvitals Zone Wireless	3-200-0012
Mobile Cart Scale Holder	9A654001
DC Power Supply Kit (Power Supply & Cord)	3-200-0015
Custom USB Cable 6'	2-200-0004
Quick Disconnect Blood Pressure Hose 6.5'	5-200-0089
Vital Signs Monitor Mobile Cart	6216-001-813
IQvitals Zone Wall Mount Articulating Arm	2-200-0082
Integrated Wall Mount for IQvitals Zone	2-200-0086

Installation Location

Position the IQvitals Zone device in a way that the user can disconnect the device from the power supply if necessary. Do not block the device in a way where it cannot be disconnected from the power supply.

Mounting Options

Articulating Arm Wall Mount

See the [Installation Guide](#) that is packaged with the wall mount for instructions on installing the IQvitals Zone device on the wall mount.

Cart Mount

See the [Installation Guide](#) that is packaged with the cart mount for instructions on installing the IQvitals Zone device on the cart mount.

Electromagnetic Compatibility (EMC) Information

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC). Portable and mobile radio frequency (RF) communications equipment can affect devices like the IQvitals®. As such, the IQvitals® should not be used adjacent to other equipment. If the IQvitals® is used adjacent to such equipment, observe the IQvitals® unit to make sure it is operating properly after installation.

The use of accessories other than those recommended by Midmark may result in increased EMC emissions or decreased EMC immunity of IQvitals®.

Note: This device meets the requirements of IEC 60601-1-2. Please refer to this standard regarding EMC requirements for this device.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions		
The IQvitals® is intended for use in the electromagnetic environment specified below. The user of the IQvitals® should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment/guidance
RF emissions CISPR 11	Group 1	The IQvitals® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class A	
Harmonic emissions IEC 61000-3-2	Class A	The IQvitals® 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.
Voltage fluctuations flicker emission IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The IQvitals® is intended for use in the electromagnetic environment specified below. The user of the IQvitals® should assure that 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	± 2, 4, 6, 8kV contact ± 2, 4, 8, 15kV air	± 2, 4, 6, 8kV contact ± 2, 4, 8, 15kV 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% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the IQvitals® requires continued operation during power mains interruptions, it is recommended that the IQvitals® be powered from an uninterruptible power supply or a fully charged battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The IQvitals® is intended for use in the electromagnetic environment specified below. The user of the IQvitals® should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment/guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 150 kHz and 80 MHz	3 Vrms 6 Vrms in ISM bands	Portable and mobile RF communications equipment should be used no closer to any part of the IQvitals®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance is $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	

a) Field strengths from fixed transmitters, such as base stations for radio cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts, 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 IQvitals® is used exceeds the applicable RF compliance level above, the IQvitals® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the IQvitals®.

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

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the IQvitals®

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) 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 (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

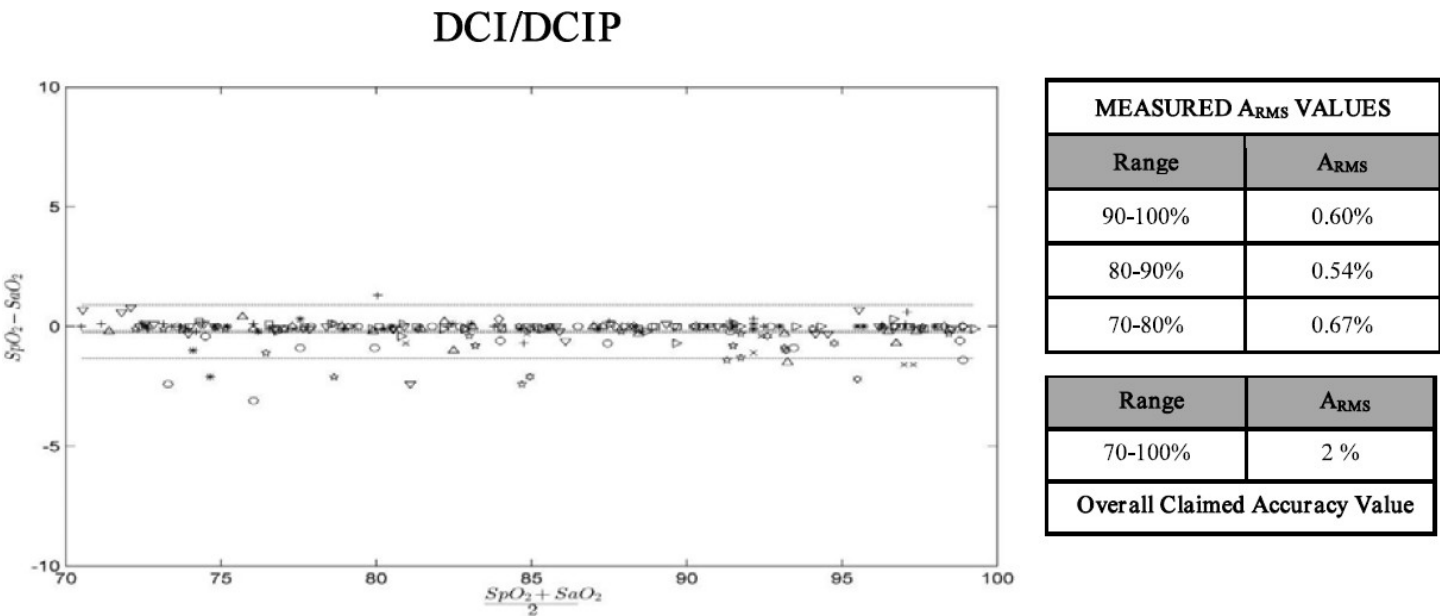
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Appendix B – Pulse Oximeter Measured SpO₂ Accuracy Specification (Graphical Plot and Table)

Masimo

Table information for the Blend-Altman plots show Arms values measured with Masimo SET Oximetry Technology in a clinical study.

SpO₂ Accuracy for Masimo DCI (Adult) / DCIP (Pediatric) Sensor vs. CO-oximeter



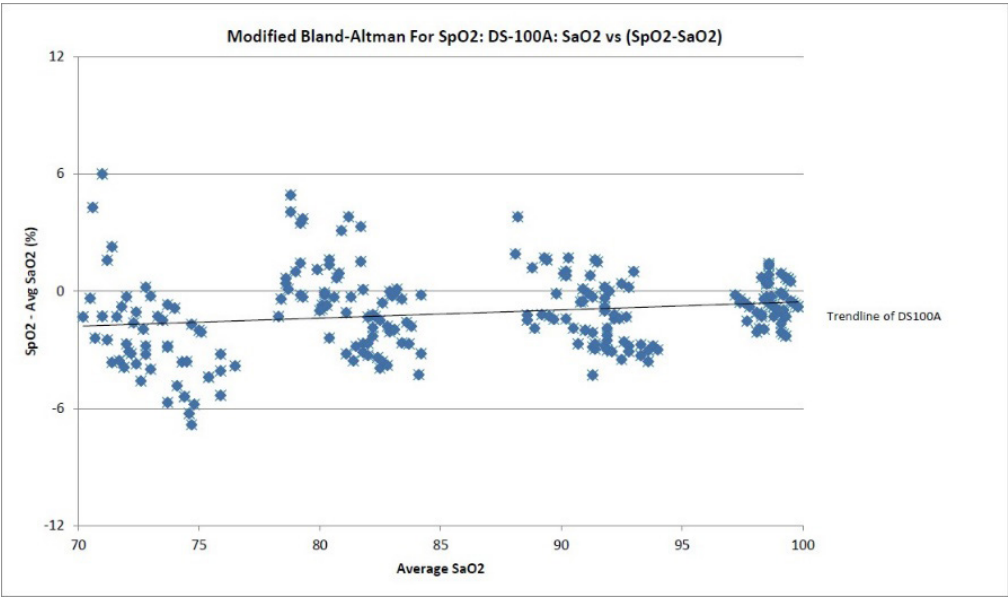
Note: Arms = Accuracy root means square. Arms was calculated from the formula.

$$A_{rms} = \sqrt{\frac{\sum_{i=1}^N (SpO_{2i} - SaO_{2i})^2}{n}}$$

Nellcor

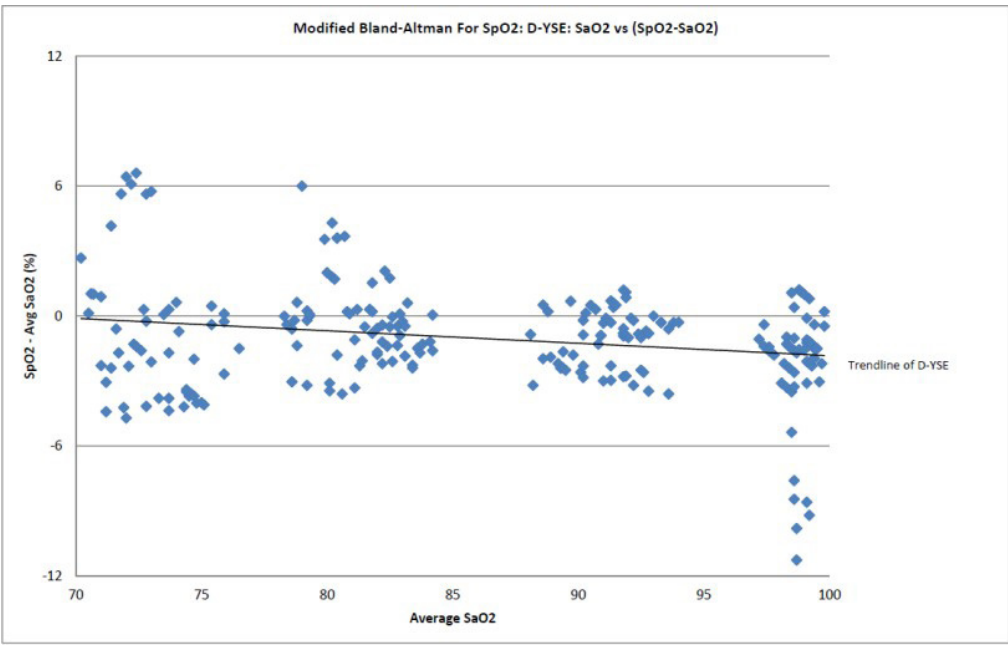
Table information for the Blend-Altman plots show Arms values measured with Nellcor Oximetry Technology in a clinical study.

SpO₂ Accuracy for Nellcor DS100A Sensor (Adult) vs. CO-oximeter



MEASURED Arms VALUES	
Range	Arms
70-80%	3.24%
80-90%	2.13%
90-100%	1.61%

SpO₂ Accuracy for Nellcor NELL1-DY-S Sensor (Pediatric) vs. CO-oximeter



MEASURED Arms VALUES	
Range	Arms
70-80%	3.08%
80-90%	1.90%
90-100%	2.68%
70-100%	2.62%

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