Intra.Ox™ Handheld Tissue Oximeter

Instructions for Use

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ViOptix part number for this IFU: OXY-2-DUR-IFU-1

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1 General Information

1.1 Overview

The ViOptix Intra.Ox™ 2.0 Handheld Tissue Oximeter consists of two components: a reusable main unit that shows a digital readout of %StO2 when the system is in contact with tissue, and a disposable kit that contains a non-sterile single-use battery pack and sterile single-use disposable sheath. The Intra.Ox™ 2.0 is abbreviated as Intra.Ox in this document. This sheath is placed over the reusable main unit with the battery pack attached.

The Intra.Ox™ device non-invasively estimates the percent oxygen saturation (StO_2) in a volume of tissue. The device uses spatially-resolved optical measurements at five wavelengths. The device performs measurements on the patient by direct physical contact to the patient's tissue and displays the StO_2 estimate on the built-in screen. The ViOptix Intra.Ox™ Handheld Tissue Oximeter is constructed from biocompatible materials that can tolerate bodily fluids and other liquids such as disinfectants and marking materials.

This manual has been prepared to assist medical personnel in the operation of the ViOptix Intra.Ox™ Handheld Tissue Oximeter. Prior to operating this device, all personnel must read this manual and gain a thorough understanding of its proper operation. Special attention should be directed to all cautions and warnings regarding the use of the product.

ViOptix cannot, and does not intend within this manual, to give medical advice.

1.2 Indications For Use

The Intra.Ox™ 2.0 Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO_2) in a volume of tissue.

The Intra.Ox™ 2.0 Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.

The Intra.Ox™ 2.0 Handheld Tissue Oximeter is intended to be used by physicians, surgeons, nurses, or other skilled users in a medical environment.

The Intra.Ox™ 2.0 Handheld Tissue Oximeter should only be used on adult patients.

1.3 Intended User

This device is intended to be used by physicians, surgeons, nurses, or other skilled users in a medical environment.

1.4 References

Trademarks

Intra.Ox™ Handheld Tissue Oximeter is a trademark of ViOptix, Inc.

References

References to "ViOptix" in this manual shall imply ViOptix, Inc.

The information in this manual has been carefully checked and is believed to be accurate. In the interest of continued product development, ViOptix reserves the right to make changes and improvements to this manual and the products it describes at any time, without notice or obligation.

Caution: Federal law (US) restricts this device to sale by or on the order of a physician.

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2 Safety

2.1 Contraindications, Warnings, and Cautions

2.1.1 Contraindications

There are no known contraindications for the use of the Intra.Ox™ Handheld Tissue Oximeter.

2.1.2 Warnings

Warnings alert the operator to potential serious outcomes to the patient or operator.

- Never make direct patient contact between the main unit and the patient. All measurements should be taken through the sheath to maintain sterility.
- Once inserted into the sheath, the reusable main unit should not be removed during the course of the procedure.
- Carefully follow all instructions for transfer of the reusable main unit into the sterile field to ensure that sterility is maintained.
- The Intra.Ox™ Handheld Tissue Oximeter comes packaged with a reusable main unit that shows a digital readout of %StO2 and a disposable kit that contains a battery pack and sterile single use disposable sheath, which is placed over the reusable main unit with the battery pack attached.
- Please note that the Intra.Ox™ Handheld Tissue Oximeter is NOT intended to be used in an MR environment.
- Do not look directly at the light-emitting distal tip of the Intra.Ox™.
- Inspect the sensor before each use for visible damage. Do not use the instrument if the sensor has visible damage.
- To prevent damage, do not bend or apply torque to the sensor face.
- Hard knocks, particularly at the distal end of the device, may result in damage to the delicate fiber-optic cables, which could affect instrument performance. Do not use if there is visible damage to the Handheld Tissue Oximeter.
- Avoid extreme changes in temperature and/or humidity.
- To reduce the risk of electrical shock, do not open the equipment's inner housing. Refer servicing to qualified personnel only.
- This device is not to be used in the presence of combustible or flammable gases, anesthetics, or cleaners/disinfectants.
- Dispose of used Intra.Ox™ Handheld Tissue Oximeter, disposable sheath, and battery pack using appropriate biohazard precautions.
- This equipment has been tested and found to comply with the limits of the standard for medical devices, IEC 60601-1-2 for Class A equipment. The limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy, and, if not installed and used in accordance with the manufacturer's instructions, may

cause harmful interference to other devices in the vicinity. Portable and mobile RF communications equipment can affect medical electrical equipment. There is no guarantee that interference will not occur in a particular installation. If this equipment causes interference with other devices, which may be determined by turning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:

- Reorient or relocate the device receiving the interference
- Increase the separation between the equipment
- Consult the manufacturer for help

2.1.3 Precautions

Precautions alert the operator to conditions that could lead to tissue irritation or erroneous results.

- Clean tissue if colored disinfectants are used on or near the measurement location.
- Clean blood or other colored liquids off of tissue before measurements.
- Check the sensor application site frequently to assess positioning, circulation, and tissue sensitivity of the patient. If required, reposition the sensor to a new site or if redness or irritation is noted. If irritation continues, discontinue use.
- Avoid placement directly over bony prominences, scar tissue, dark birthmarks or other visibly non-homogenous tissue, as it could provide improper readings.
- If tissue is uneven, gently flatten tissue or move to a new location.
- When repositioning device, pick up device and replace; do not drag.
- Use extra caution when placing on thin or delicate tissue.

2.1.4 Disposal

2.1.4.1 Sheath

The sheath should be considered biohazardous waste after the procedure. It should be disposed of along with ordinary biohazard waste

2.1.4.2 Re-usable Main Unit

The re-usable main unit contains a variety of electronics. It should be disposed of with electrically hazardous medical waste and in accordance with all local and hospital disposal procedures.

2.1.4.3 Battery Pack

The Intra.Ox™ Handheld Tissue Oximeter battery pack contains lithium batteries and should only be disposed of with electrically hazardous medical waste and in accordance with all local and hospital disposal procedures. Contact the hospital or local environmental control agency for additional instructions. The battery pack must not be incinerated.

2.2 Target Population

The Intra.Ox™ Handheld Tissue Oximeter should only be used on adult patients.

3 Installation and Setup

The Intra.Ox™ Handheld Tissue Oximeter is a prescription-only device. The reusable main unit comes fully assembled and packaged in a protective box along with storage bags and wipes for cleaning the sensor tip between uses. The disposable kit contains one disposable sheath in a sterile double-pouched configuration along with a non-sterile battery pack. The Intra.Ox™ is handheld, battery powered, and requires no external power source.

Before using, inspect the device and packaging for any sign of damage. Do not use if unit has been compromised. No installation is required.

4 Device Configuration and Interface Elements

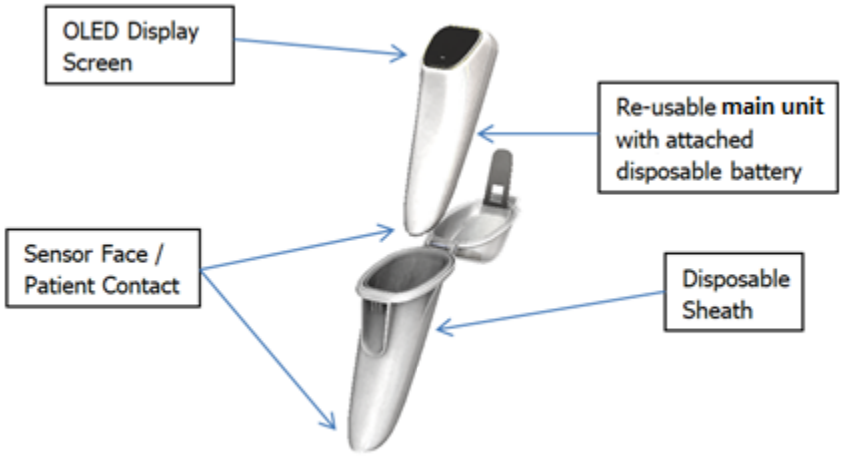


Figure 1: Device Configuration and Interface Elements

4.1 Display

When the battery pack is connected to the reusable main unit, the OLED displays a splash screen, followed by a series of instructions related to sheathing procedure.

When in use during surgery, the OLED display shows the following:

- Current tissue oxygen saturation value, in percent
- Current measurement quality 'Q' on 1-5 scale, represented by a series of ascending bars
- A timer (in format H:MM) displaying the battery life remaining, with color coding to indicate low battery life remaining
- An average StO2, representing the average of the last several StO2 measurements
- A value indicating the number of measurements incorporated into this average

4.2 Sensing Surface (Sensor Face)

The sensor face, which takes measurements through the sterile sheath, includes:

- Light sources
- Light detectors

5 Operating the ViOptix Intra.Ox™

5.1 Device Setup

The procedure for Intra.Ox™ setup requires two operators:

- A 'sterile operator,' inside the sterile field. This operator handles the disposable kit, including the sterile sheath
- A 'non-sterile operator,' outside of the sterile field. This operator handles the non-sterile main unit

The device setup procedure must be followed strictly to ensure sterility of the sterile field.

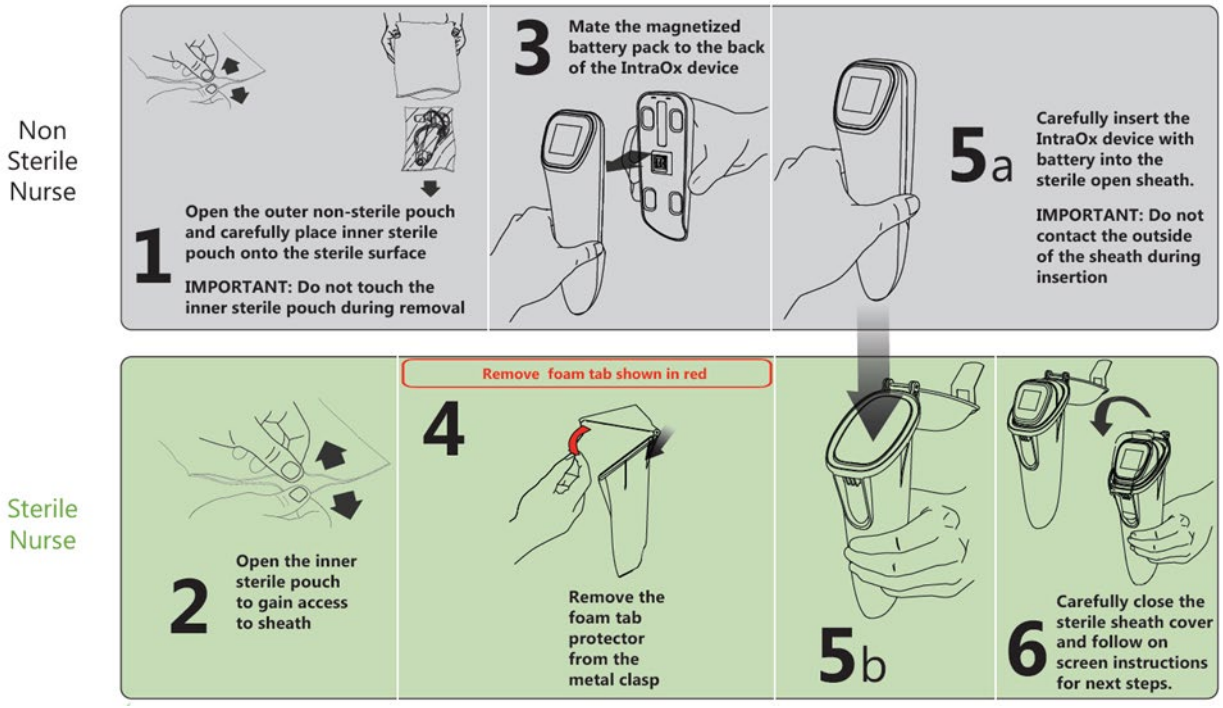


Figure 2: On overview of the device setup process

5.1.1 Step 1: Passing components into the sterile field

IMPORTANT: The outer pouches are non-sterile and should only be handled by the non-sterile operator. The inner pouches are sterile and should only be handled by the sterile operator.

1. The non-sterile operator obtains the double-bagged sheath from disposable kit. The outer pouches are non-sterile, and the inner pouches are sterile.
2. The outer pouches should be opened by the non-sterile operator, and the sterile contents of the inner pouches slid into the sterile field

5.1.2 Step 2: Removal of Sterile Contents

3. The inner, sterile pouches should be opened by the sterile operator in the sterile field. The sheath can be removed from each bag and set aside.

5.1.3 Step 3: Battery Installation

4. The non-sterile operator holds up the reusable main unit and attaches the battery pack to the back of the device. It will attach to the device with magnets.
5. As soon as the battery pack is connected, the OLED screen of the device will turn on. The non-sterile operator will see the Test Pattern, followed by the ViOptix logo.

Figure 3: Left: The test pattern. Right: The ViOptix logo

After a few seconds, the device will authenticate the battery and display the following screens, indicating configuration information and the number of remaining uses for the reusable component. The re-usable main unit can be used for a total of 100 procedures.

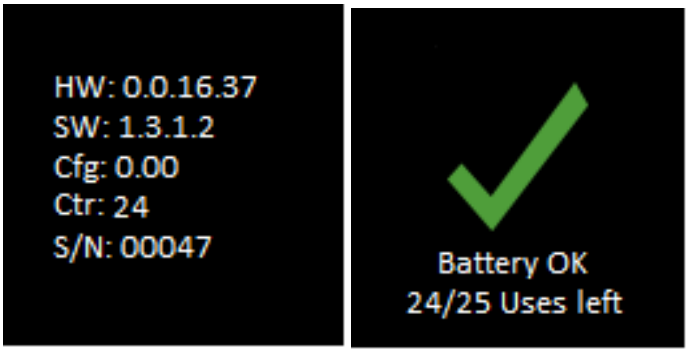


Figure 4: Battery and configuration authentication screens

After battery authentication, the both operators will be prompted to work together install the reusable main unit into the single-use sheath. The device will display an animation of the process.

5.1.4 Step 4: Tab and Foam Removal

6. The sterile operator obtains the sheath, and removes the tab protecting the window by pulling upwards on the exposed plastic component.
7. The sterile operator removes the protective foam tab from the device latch by pulling downwards on the latch

5.1.5 Step 5: Installation into Sheath

8. The non-sterile operator drops the combined reusable main unit and battery pack into the sterile sheath at the edge of the sterile field.

5.1.6 Step 6: Closing the Sheath

9. The sterile operator closes the lid of the sheath until it latches.

At this point, the non-sterile operator has completed their part of the installation process.

Once the sheath is latched closed, it should not be opened again for the duration of the procedure.

After installation, the system will verify the sheath installation process as it goes through the below screens.

The device warm-up may take up to ten minutes. Keep the device away from heat sources (such as bright lights) and from cold circulating air during the warm-up.

If the error 'Missing Calibration' appears on-screen during device warm-up, the device cannot be used. Please use a different reusable main unit for this procedure and contact ViOptix.

5.2 Holding the Device

Hold the tip of the Intra.Ox™ device similarly to a pen, with the wrist in a neutral position. Lightly rest hand on the patient and use fingers to brace the device for maximum stability. The sensing face should be parallel to tissue and in gentle contact. Do not apply pressure to the sample site as blanching may occur, resulting in local ischemia and a misleading measurement.

Avoid non-parallel/angled contact with the tissue, as doing so reduces device measurement accuracy.

5.3 Measuring Percent Oxygen Saturation

Ensure the tissue is clean and the distal tip of the sheath is dry. Place the sensor face on the patient in gentle contact with the tissue of interest. Continue to hold the device against the tissue for a few seconds until an oxygen saturation percentage appears on the display. The display is organized as depicted below:

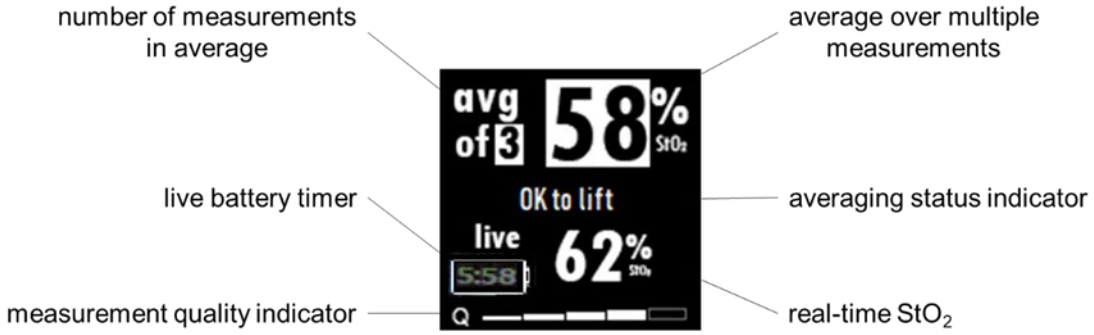


Figure 5: Normal Display Layout

5.3.1 Real-time StO2

The estimated oxygen saturation of the current contact with tissue is indicated in white text on the bottom of the screen, next to the word 'live.'

If no sample is detected by the Intra.Ox™ (ie, the device is being held in air), the digits for Percent Oxygen Saturation and Quality Measure are replaced by dashes. The average StO2 over multiple measurements will persist.

Figure 6: Invalid Measurement Display

Other warning and error messages are addressed in Section 5.6.

If the Intra.Ox™ is positioned on tissue, and no percent oxygen saturation value appears, and no warnings are indicated on the screen, gently wipe the sensor face with a soft cloth moistened with saline solution to remove any contaminants and dry thoroughly before use.

5.3.2 Measurement Quality Indicator

An approximate metric of measurement quality is displayed on the bottom of the screen below the powered-up time. The metric is on a 1-5 scale, 5 being the most desirable. A low number on this scale does not necessarily represent poor contact, as the Quality Measure incorporates both contact quality and tissue homogeneity.

The operator should seek to have both a number displayed for the Quality Measure and to have that number stay constant for several seconds while in gentle contact with the tissue. If at least a '2' cannot be achieved, try taking a measurement on an adjacent measurement site.

5.3.3 Average Over Multiple Measurements

For some applications, it may be useful to average measurements from several different locations.

After approximately five seconds of consistent contact with tissue, the indicator 'OK to lift' will appear in the center of the screen, replacing the default text of 'invert to reset.'

After this point, when the device is removed from the tissue, the value saved into the average will be noted for two seconds.

Once this value is saved, two things will happen:

1) The small field next to the text 'avg of' will increment, indicating that one additional value is saved into the average
2) The average over all saved values will populate the large white area at the top of the device

Each additional contact with the tissue of greater than five seconds will increment the value next to 'avg of' by one. Repeating this process will continue to increment the 'avg of' counter, and the average oxygenation will be the average this many contacts with the tissue.

To reset the counter and return the device to its default state, physically invert the device so that the screen is pointed downwards towards the ground.

5.3.4 Battery Indicator Display

The battery life of the Intra.Ox™ device is 8 hours. The live timer displayed on the screen indicates the remining battery life (in format H:MM). The timer will change to yellow when there is less than 1 hour of battery life remaining, and red when there is less than 30 minutes of battery life remaining.

The battery is not rechargeable.

5.4 Other Device Modes

5.4.1 Standby Mode

If there are no valid measurements and the device has not been moved for 2 minutes, the Intra.Ox™ will automatically go into Standby mode. In this mode, the following screen will appear.

The device will return to normal use mode when it is picked up.

5.4.2 Battery Depleted Mode

When the battery has been used for the 8 hours of life, the Intra.Ox™ device will automatically go into Battery Depleted Mode.

Figure 7: Battery Depleted Display

To continue using the Intra.Ox™ device for the current patient, the device will require installation of a new battery and installation into a new sheath.

5.4.3 Device Dropped Mode

The Intra.Ox™ contains an accelerometer that detects if the system is dropped. If it is dropped on a non-sterile surface, the device cannot continue to be used. However, the Intra.Ox may continue to be used if dropped onto a sterile surface, such as a table within the sterile field in the operating room.

In this mode, the device will display the following guidance:

5.4.4 Sheath Open Mode

If at any time during the procedure the sheath is opened, the device will display the following:

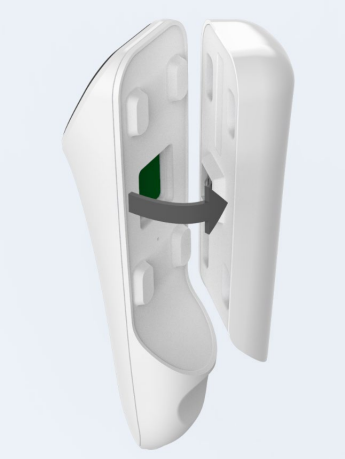
The device should not be used for patient contact while the sheath is open. The device can be returned to measurement mode by re-closing the sheath.

5.5 After the procedure

5.5.1 Disassembly

Once the sterile field is broken, the Intra.Ox™ device may be removed from the sheath by pushing upwards on the metal latch on the front of the device. This will result in the 'Sheath Open Mode' warning appearing on-screen. The re-usable main unit and battery pack can be pulled out of the sheath.

To power off the device, pull apart the battery pack and the re-usable main unit. (see figure below)



The battery pack and sheath should be disposed-of in accordance with Section 2.

5.5.2 Preparing the re-usable main unit component for the next procedure

After the procedure, the re-usable main unit component should be cleaned and disinfected using an approved wipe from the list below. First, use a wipe to clean the device, removing any visible debris from the surfaces of the re-usable main unit component. Then, using additional wipes, disinfect all device surfaces by ensuring all surfaces are wet for the requisite disinfection time of 3 minutes per manufacturer's instructions. After the disinfection time, allow the device to dry for at least 10 minutes prior to use.

Approved wipes:
- CaviWipes™
- Sani-Cloth® AF3 Germicidal Disposable Wipes

5.6 Resolving Warnings and Errors

Warning and error conditions may occur that require the display of an error message on the OLED screen.

5.6.1 Warning Messages

Warning messages appear to alert the user to device conditions. Warnings will display as a yellow on-screen popup like the below.

The following table lists the conditions resulting in a warning message, the message that will be displayed on-screen and the recommended user action that can be taken following the display of one of these warnings.

OLED Message	Recommended User Action
OVERHEATED Place down to cool	Move the device to a cooler area until condition no longer exists
Too much light Reposition Sensor or Reduce Ambient Light	Correct sensor face placement to improve tissue contact or shield the sensor face from bright light
Low Device Temp Hold device to warm	Move the device to a warmer area until condition no longer exists
High Device Temp Allow device to cool	Move the device to a cooler area until condition no longer exists

5.6.2 Critical Error Messages

Error messages represent situations that prevent the continued use of a device during the procedure. Critical errors will display as a red on-screen popup like the below.

The possible critical Errors that may appear are as follows:

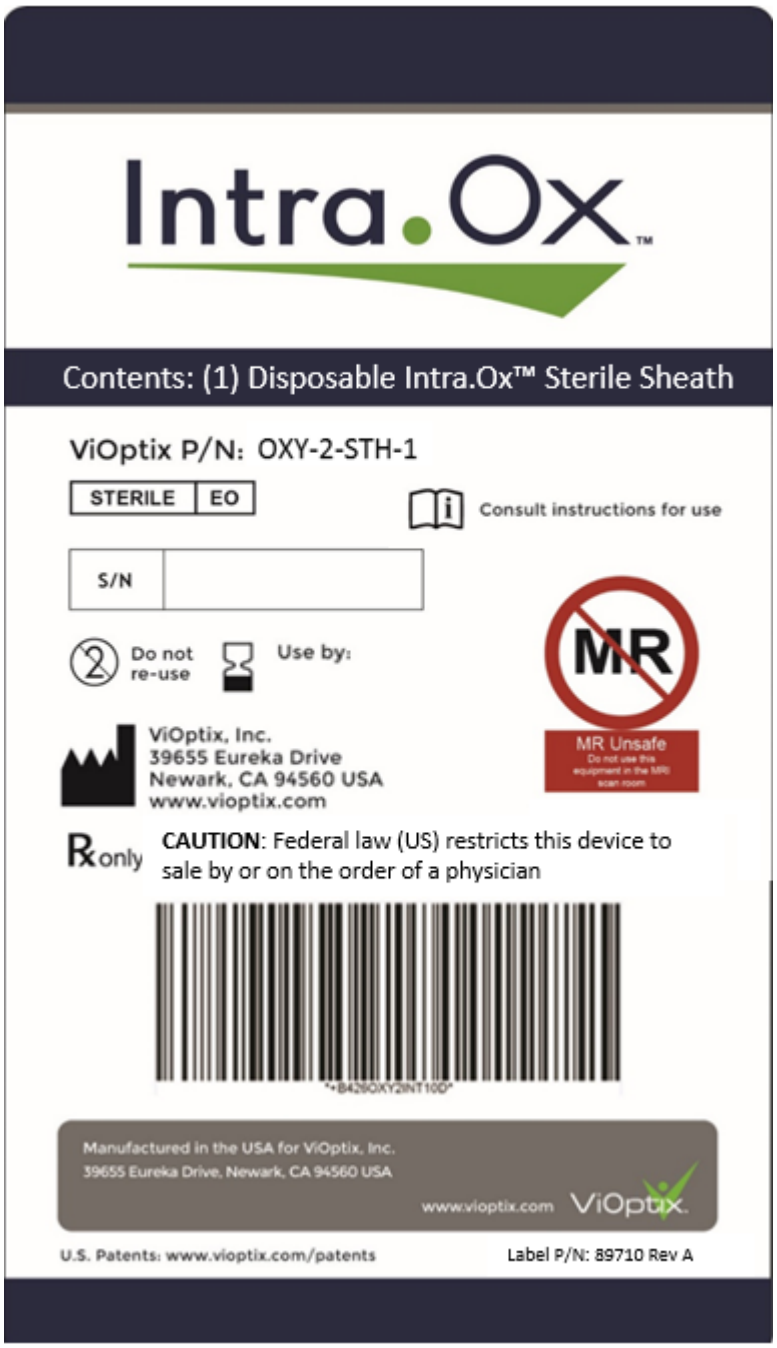
OLED Message	Recommended User Action
Hardware Failure Replace Durable	The device is inoperable.
Battery Depleted Replace Battery	The main unit must be paired with a new battery back and sheath to continue measurements
Sheath Opened	The sheath was opened before the device was in measurement mode inside the sterile field. The sheath and battery pack must be replaced
Sheath Removed	The sheath was removed entirely from the device. The sheath and battery pack must be replaced
No remaining uses	The main unit has reached end of life, and cannot be used for further procedures. Please contact ViOptix to obtain a new main unit

6 Specifications

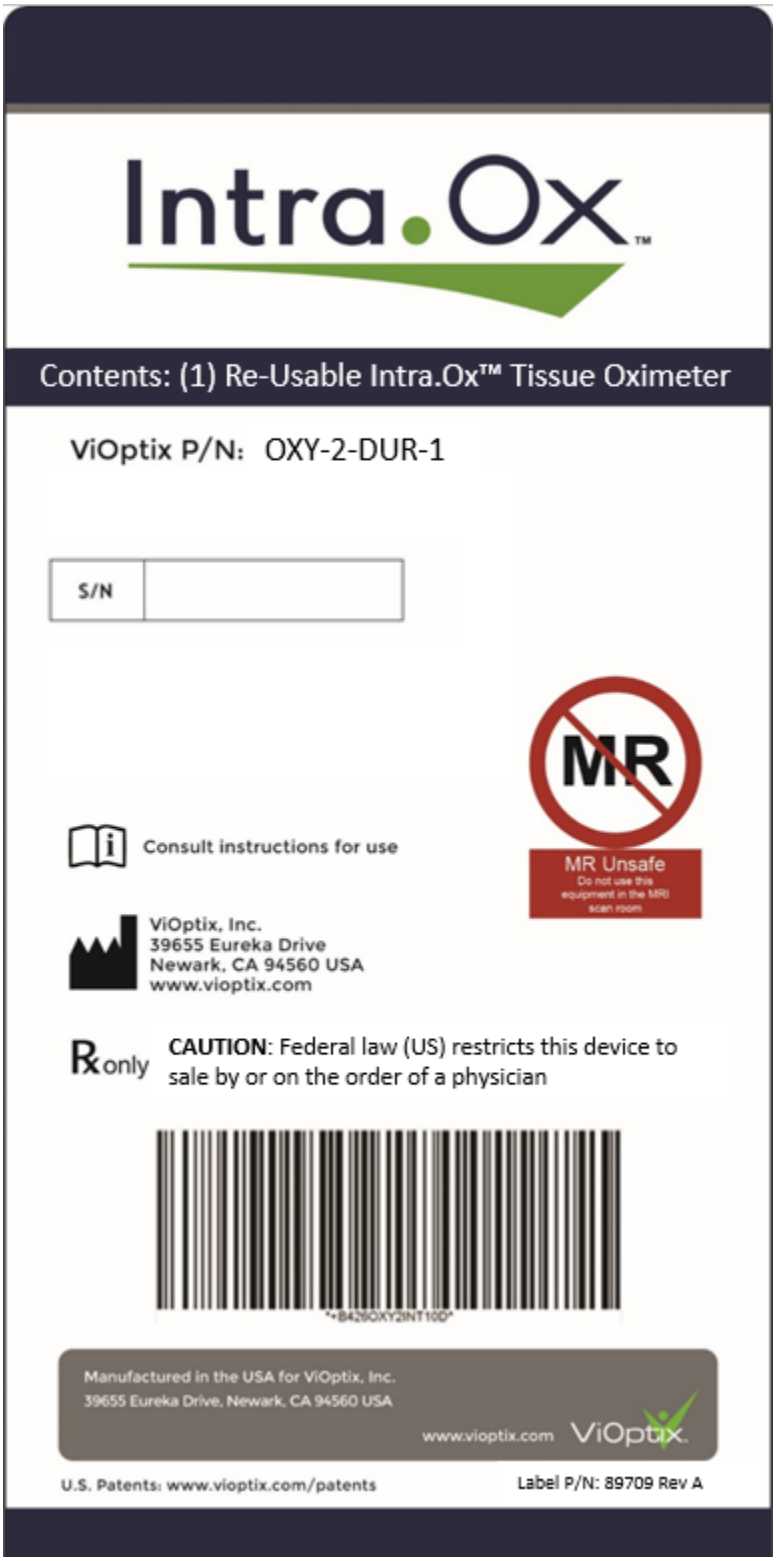
Component	Specification
Tissue Oxygen Saturation Range	1 – 99%
Wavelengths	730, 760, 810, 845, 895 nm LED
System Control	System will perform self-test when power is turned on
Alarms (visual)	Display conditions such as • Low battery • Measurement errors
Battery Life	8 hours of continuous use
Operating Mode	Spot Measurement Mode
Operating Conditions	• Device shall operate normally at ambient temperatures of 18°C to 24°C • Device shall operate normally in a humidity environment of 20% to 80% (non-condensing)
Transport and Storage	• Device (packaged) shall operate normally after storage at -18°C to 60°C Device (packaged) shall operate normally after storage at 10% to 85% (non-condensing).
Dimensions	3″ x 3″ x 7″
Weight	Less than 1 lb.
Sensor Specifications	IEC 60601-1. Any surface of the system that comes into contact with a patient for a time of 1 minute shall not exceed 41ºC. The device complies with ANSI/IESNA RP-27.1-15 (Recommended Practice for Photobiological Safety for Lamps and Lamp Systems – General Requirements) for light output.
IPX Rating	• Main unit Only (No Battery Pack): IPX2 • Sealed Sheath (with Main unit and battery pack installed): IPX2 • Battery Pack: IPX0

7 Labels

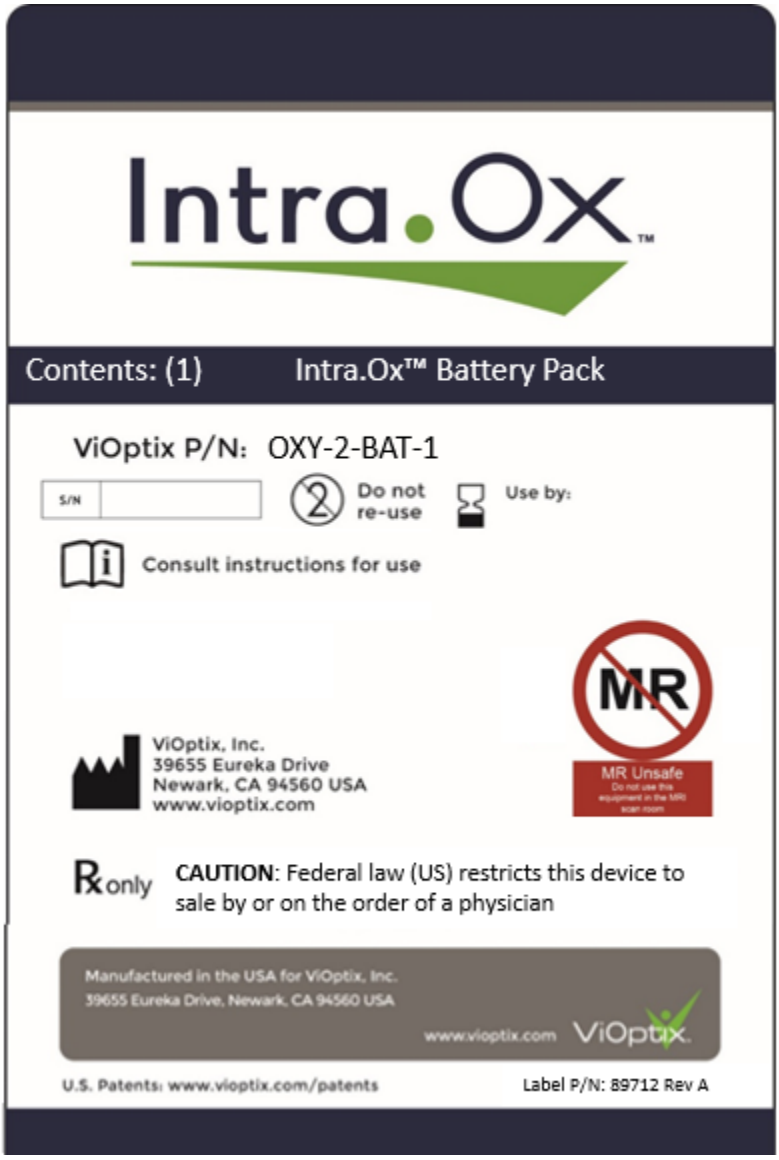
7.1 Box and Pouch label (Sterile Sheath)



7.2 Box label (Re-Usable Main unit)



7.3 Box label (Disposable Battery)



7.4 Device Label(s)

(Placed on the back of the re-usable main unit)

(Place on the front of the re-usable main unit)

(Place on both sides of the re-usable main unit)

7.5 Glossary of Symbols

	The Disposable Sterile Intra.Ox™ Sheath is **intended for single-patient one-time use.** **DO NOT REUSE THE SHEATH, DO NOT RE-STERILIZE**
	**Sterilized by Ethylene Oxide**
	**Use by expiration date stamped**
	**Attention, consult accompanying documents**
ViOptix P/N:	**Model Number (Catalog Number)**
	**Serial Number**
	**Manufactured By**
	**Applied part type BF**
	**Do not use this equipment in the MRI scan room**