



Tissue Oximeter Operator's Manual



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About This Manual

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References

References to “ViOptix” in this manual shall imply ViOptix, Inc.

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Section I. Introduction

A. Overview

The T.Ox™ Tissue Oximeter is an optically based device that non-invasively estimates the percent oxygen saturation (StO₂%) in a volume of tissue underneath the sensor. T.Ox™ Tissue Oximeter measurements are based on its proprietary technology called ODIS. (See “The ODIS Technology” section, below.) The T.Ox™ Tissue Oximeter works by emitting two different wavelengths of near-infrared (NIR) light into tissue at depths of 0–10 mm. The light is transmitted to the tissue by two light sources, and collected by four photo detectors in each sensor.

As the light is collected and measured, the absorption and scattering coefficients of the tissue are calculated. Each tissue component has a unique absorption spectrum or light “signature”. The T.Ox™ Tissue Oximeter uses two wavelengths (690 and 830 nm) of near-infrared light specific to oxyhemoglobin (HbO₂) and deoxyhemoglobin (Hb) for the noninvasive real-time measurements of StO₂.

The ODIS Technology

Optical Diffusion Imaging Spectroscopy (ODIS) is a non-invasive tissue characterization method based on measurement of reflectance or transmittance of near-infrared light shed onto tissue surface.

In biological tissue, near-infrared light is highly scattered and moderately absorbed. This allows photons to travel up to one meter in tissue, in a random walk fashion, before being absorbed. Diffuse optical imaging is achieved by sending various optical signals to various locations of tissue and measuring the corresponding diffuse reflectance or transmittance on tissue surface. ViOptix has developed special source-detector patterns and algorithms, which make the measurements accurate, real-time and insensitive to external factors. The system's self-calibrating approach makes it possible to perform imaging and spectroscopy without a baseline data set. This is particularly important in saving exam time.

B. Device Description

The T.Ox™ Tissue Oximeter is a lightweight and portable, AC power–operated, unit with a 30-minute, lithium-ion battery backup. The console has a color LCD display monitor, a standard one sampling channel (with a two-channel option), and up to two fiber optic sensors. It has adjustable audible and visual alarms for:

- StO₂ low and high alarm limits
- Low battery

The T.Ox™ Tissue Oximeter has visual alarms for:

- Audio muted
- Sensor laser ON
- AC power OFF
- Low Battery

The T.Ox™ Tissue Oximeter consists of three parts:

- Small computer console display module
- AC power cord
- Fiber optic sensor(s)

The standard console configuration is two-channels. If the console has two channels, both channels can be used at the same time. Each channel samples and displays data independently of the other channel. Each channel can accommodate one sensor.

Sensors are available in the following styles:

- Disposable sterile patches for continuous monitoring applications

C. Intended Use

The T.Ox™ Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue. This is performed in medical environments including physician offices, hospitals, ambulatory care and Emergency Medical Services.

The T.Ox™ Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.

The value of these measurements in disease states has not been demonstrated.

Section II. Safety

A. Contraindications, Warnings, and Cautions

1. Contraindications

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

2. Warnings

Warnings are identified by a label or symbol. Refer to the Glossary of Symbols at the end of this document. Warnings alert the operator to potential serious outcomes to the patient or operator.

- Inspect the sensors before each use for visible damage. **Make sure the lasers are off when inspecting, in order to avoid damage to the eyes.** Do not use the sensor if it has visible damage.
- Avoid direct exposure to the laser light beam in the sensor. Looking at it directly could cause permanent damage to the eyes.
- To prevent damage, do not bend or apply torque on the fiber optic cables.
- Use only ViOptix manufactured sensors. These sensors are manufactured to meet the calibration requirements for the T.Ox™ Tissue Oximeter. Use of other manufacturers' sensors may cause improper performance.
- Hard knocks, particularly at the distal end of the sensor, 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 cables. **When inspecting, make sure that the lasers are off, to avoid damage to the eyes.**
- Do not allow any liquid to pass into any electrical connections. **Allow wet surfaces to thoroughly dry before plugging in the system.**
- Do not immerse or soak sensors in liquid solutions.
- Avoid extreme changes in temperature and/or humidity.

- Do not set the alarm volume too low to be heard. Doing so could compromise patient safety.
- Ground reliability can only be achieved when the equipment is connected to “Hospital Only” or “Hospital Grade” receptacle (i.e., approved for use in an operating room environment). Routinely inspect electrical plug and cord. Do not use if inspection reveals damage.
- To reduce the risk of electrical shock, do not open the equipment's inner housing. Refer servicing to qualified personnel only. Removal of panels by unauthorized personnel will void the unit's warranty.
- This device is not to be used in the presence of combustible or flammable gases, anesthetics, or cleaners/disinfectants.
- Disconnect power to the system before conducting any regular maintenance. Read relevant sections of manual before conducting any of the above operations.
- Chemicals from a broken LCD display monitor are toxic when ingested. Use caution when handling a T.Ox™ Tissue Oximeter with a broken display monitor.
- Dispose of a T.Ox™ Tissue Oximeter battery in accordance with local requirements and regulations.
- Do not use the sensor rest assembly or sensor cable wrap assembly as a handle
- Only connect the sensor cable plugs to the console channel connectors
- Device contains metal. **Do not use in a MR environment.**

3. Precautions

- Select alarm settings carefully, using accepted clinical standards.
- The audible alarm of the T.Ox™ Tissue Oximeter is for the convenience of the attendant near the patient. It is not intended to call an attendant from another room or from a distance. The user must determine the audible distance based on the operating environment.
- Check the sensor application site frequently to assess positioning, circulation, and skin sensitivity of the patient. If required, reposition the sensor to a new site at least every 4 hours, or if redness or skin irritation is noted. If irritation continues, discontinue use.
- Limited clinical experience is available for use of the sensor on open wounds.
- Avoid placement directly over bony prominences or dark birthmarks, as it could provide improper reading.

4. Cautions

Cautions alert the operator to conditions that could interfere with the proper functioning of the instrument.

- Carefully read this manual before using the T.Ox™ Tissue Oximeter.

- The T.Ox™ Tissue Oximeter is intended as an adjunct to patient assessment. It must be used in conjunction with clinical assessment of signs and symptoms.
- Do not block air vents of the unit. Adequate cooling is required for proper operation of the unit.
- Inaccurate readings may result if the sensor is not in proper contact with the skin or there is a leakage of light.

Section III. System Setup

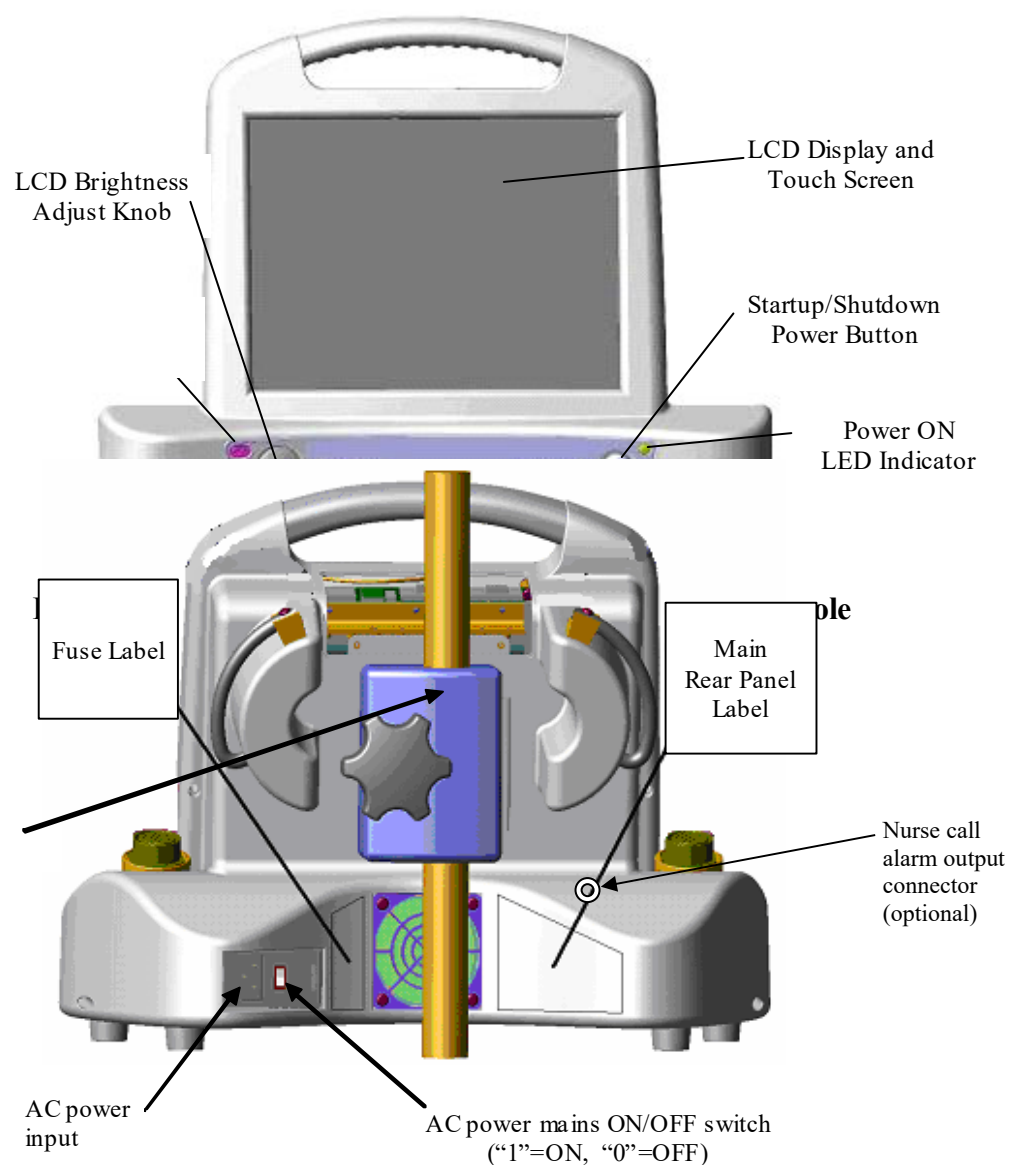


Figure 1: Front Panel of T.Ox™ Tissue O

Figure 2: Rear of ViOptix™ Tissue Oximeter Console

A. System Configuration

1. Connecting the T.Ox™ Tissue Oximeter

- a. Plug the AC (alternating current) power cord into the back of the T.Ox™ Tissue Oximeter computer console module (see Figure 2).
- b. Plug the AC power cord into a power source.
- c. Place the back panel AC Power Switch to the **ON (1)** position
- d. Attach sensor(s) to one or two channels' connector(s).
- e. Attach optional 10 foot nurse call alarm output cable from the nurse call output connector (refer to Figure 2) and an available bedside nurse call system jack. To attach the cable, press the cable's circular connector onto the rear panel connector and rotate until it clicks and locks. To detach cable, pull back on the cable connector's metal sleeve.

2. Turning on the T.Ox™ Tissue Oximeter

Turn on the T.Ox™ Tissue Oximeter by depressing the soft ON/Standby power button on the right front of the console. (Refer to Figure 1) The main screen is displayed after console initialization and self-tests have been performed.

The power ON LED will flash slowly while the system is starting up.

Quick flashing of the power ON LED indicates the battery is being used during startup. Connect AC power to the console; otherwise the battery will eventually be depleted.

3. Battery Operation

The console is not intended to be operated continuously under battery power. The battery will provide up to 30 minutes of normal operation and is rechargeable but continuous use of the battery under low voltage conditions might damage the battery. If AC is removed then use the battery to save logged data and power down the unit.

B. Using the T.Ox™ Tissue Oximeter Controls

1. AC Power Switch

The AC Power switch is on the back of the console. This switch routes AC power to the console's power supply.

2. ON/Standby Button

Depressing the ON/Standby power button on the right front of the console applies power to, or removes power from, the console electronics. (See Figure 1.)

To turn the unit off, hold the ON/Standby button in, then release it after 3 seconds. The console will perform a shutdown sequence and then power off.

Note: If patient data was recorded but not saved before shutdown, the **Oops Save Discard** screen (Figure 3) will be displayed. This screen requires the operator to take action (cancel shutdown, save, or discard the data) before the console powers off.

3. T.Ox™ Tissue Oximeter Monitor Screen Display

The main screen will appear after boot-up, as shown in

Figure 1. This illustration represents one-sensor/single-channel operation. The main T.Ox™ Tissue Oximeter monitor screen includes these functional areas:

- Control bar
- Sensor verification
- Numerical Data display
- Tissue StO₂ trend graphs
- Status & Alarms area (System Status)

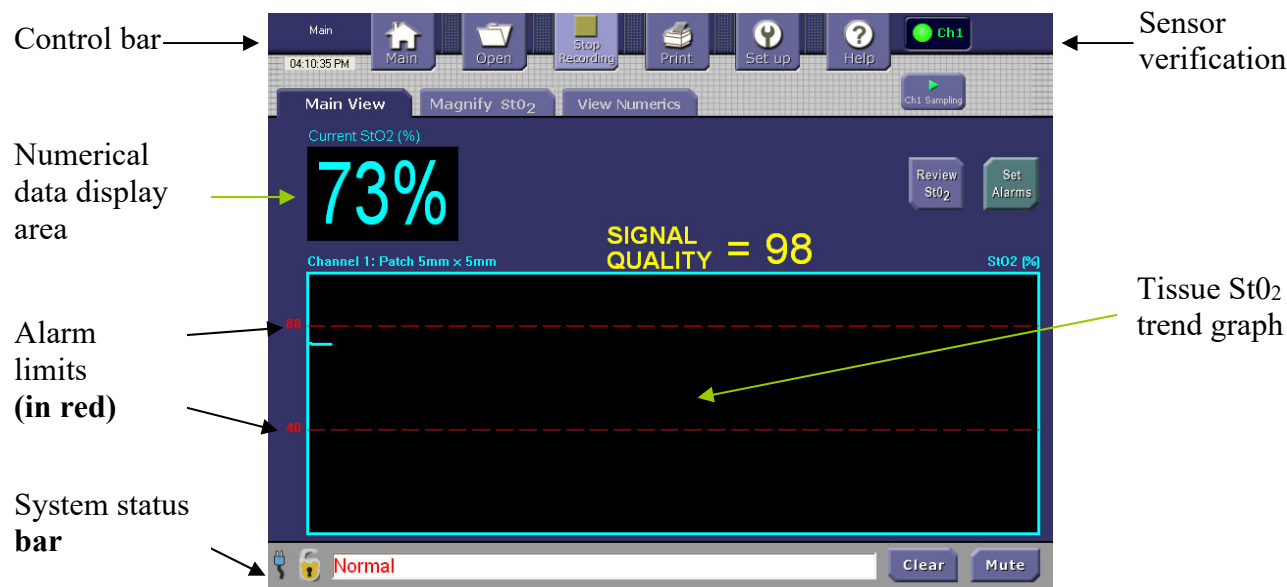


Figure 1. Main Screen Functional Areas (Single Mode)

In two-sensor/dual-channel operation, the main screen provides separate sensor-verification indicators, Numerical Data displays, and Tissue StO₂ trend graphs for each channel, as shown in Figure 2.

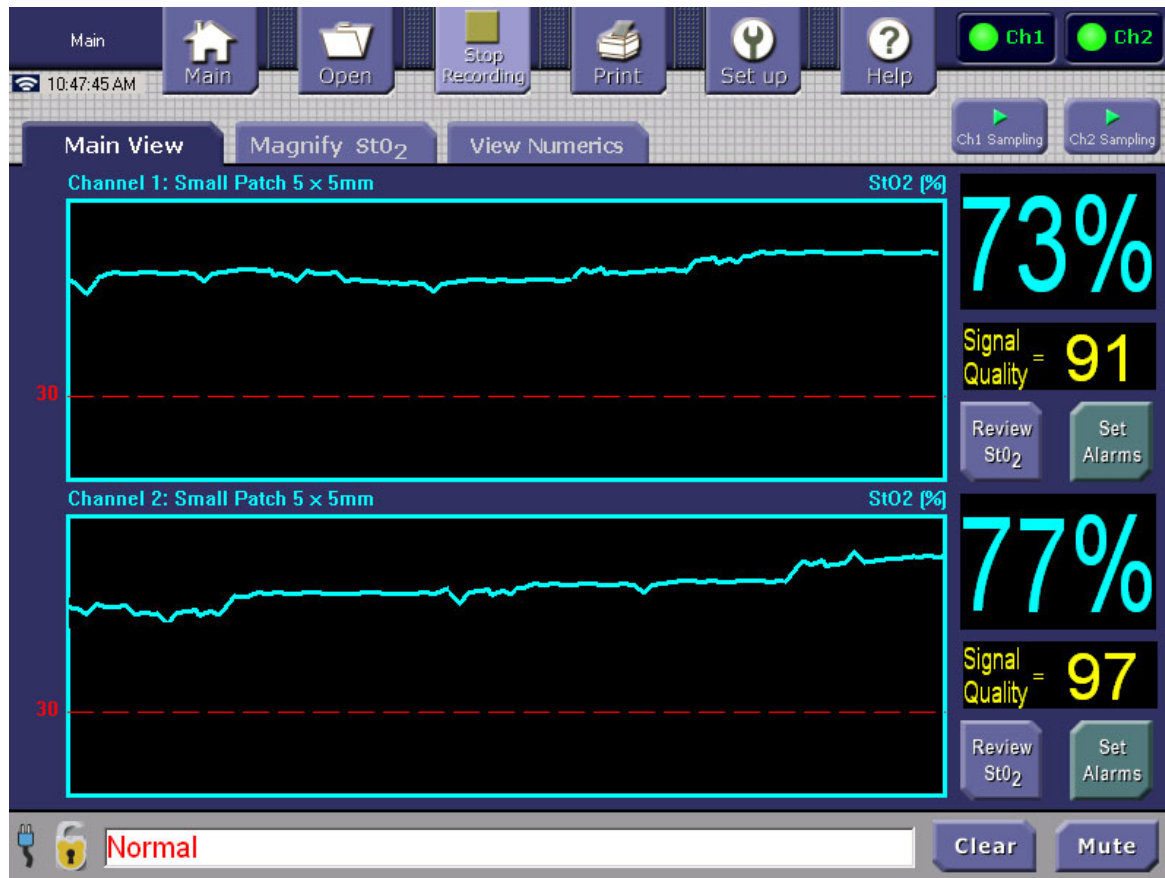
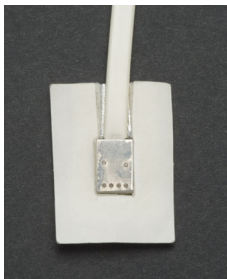


Figure 2. Main Screen Functional Areas (Dual Mode)

4. Patch Sensor Probe Acquisition



Small Patch Sensor

Note: During sampling, laser light will be emitted from two of the apertures in the sensor head. **Avoid direct eye exposure.**

Patch probe acquisition starts when the Main Screen's channel **Paused/Sampling** button is activated to the Sampling position.



6. Recording Patient Data

When the Recording button is lighted (**Stop Recording** text displayed), the function is active and will log and save data while any sampling is being performed. This is the default operating condition.

During channel data acquisition (sampling), the console logs the data in channel-specific temporary files. You can convert these files to permanently-saved data files by tapping the Control Bar's **Stop Recording** button and selecting **Save** in the **Oops Save Discard** screen.

Tapping the **Stop Recording** button will display the **Oops Save Discard** screen if any patient data has been acquired. This screen gives the operator the option (**Oops**) to return to the previous screen, the option to discard the data or the option to save the data. Once the data is saved or discarded the temporary data file is closed. When the operator saves the data in an operator-specified file, that data file will be permanently saved in the console and available for review and off-loading using the Control Bar's Open and Setup/Send files buttons.

If the **Stop Recording** button is tapped and no patient data has been acquired, the console performs no operation and retains the current screen.

You can review the current session's StO₂ data from the Main Screen by tapping the appropriate channel's **Review StO₂** soft button.

Recording is used primarily for long-term monitoring; short-term monitoring may not require the recording of data. There are 200 Megabytes (MB) of disk storage area for logged data. The equivalent of three months of continuously recorded, two-channel data can be stored and reviewed. Reference Recording a New File (Saving) for a description of file/data storage use and limitations.

The Main Screen Review StO₂ buttons become available only after data has been acquired. The console displays only the selected StO₂ data logged at the time the Review StO₂ button is tapped. The console continues to log data while displaying the Review StO₂ screen. To review the latest data the operator must return to the Main Screen and tap the Review StO₂ button again.

7. Oops Save Discard

After pressing the **Stop Recording** button, choose to save, discard, or continue recording. These options are shown in Figure 3.

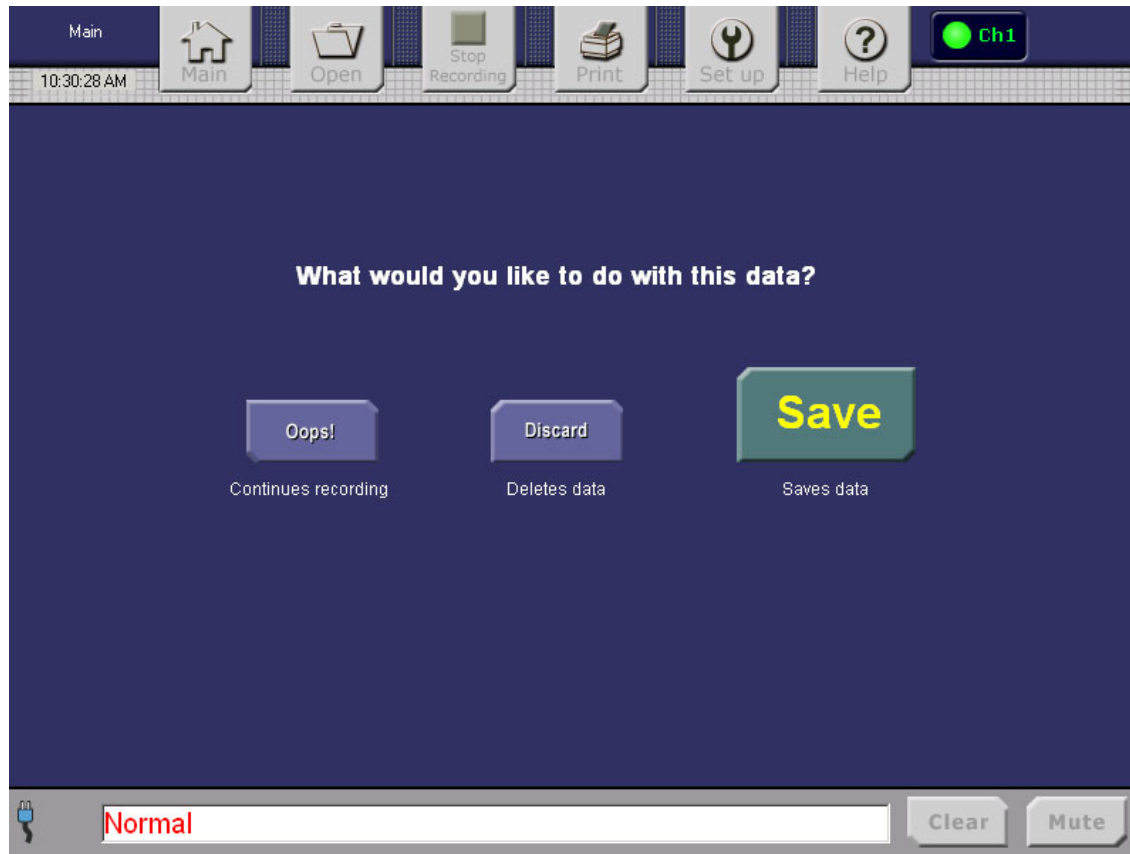


Figure 3. Oops Save Discard Screen

Section IV. System Operation

A. Site Preparation

1. Make sure that the tissue site to be measured is clean and unobstructed to ensure good skin contact. Avoid placement of sensors over large vessels or bony prominences, as readings may be affected.
2. Apply light pressure over the muscle tissue, somewhat greater pressure over adipose tissue.
3. Check for good skin contact and no light leakage around the sensor contact point.
4. Pause data collection when moving the sensor from one tissue site to another. When using a patch sensor, toggle the channel Sampling/Paused button on the display monitor screen to pause data collection.

B. Data Acquisition

1. Understanding the Display Monitor Screen

This section describes the elements on the Display Monitor screens that remain visible on all console screens. Refer to Figure 4.

Control Bar
←

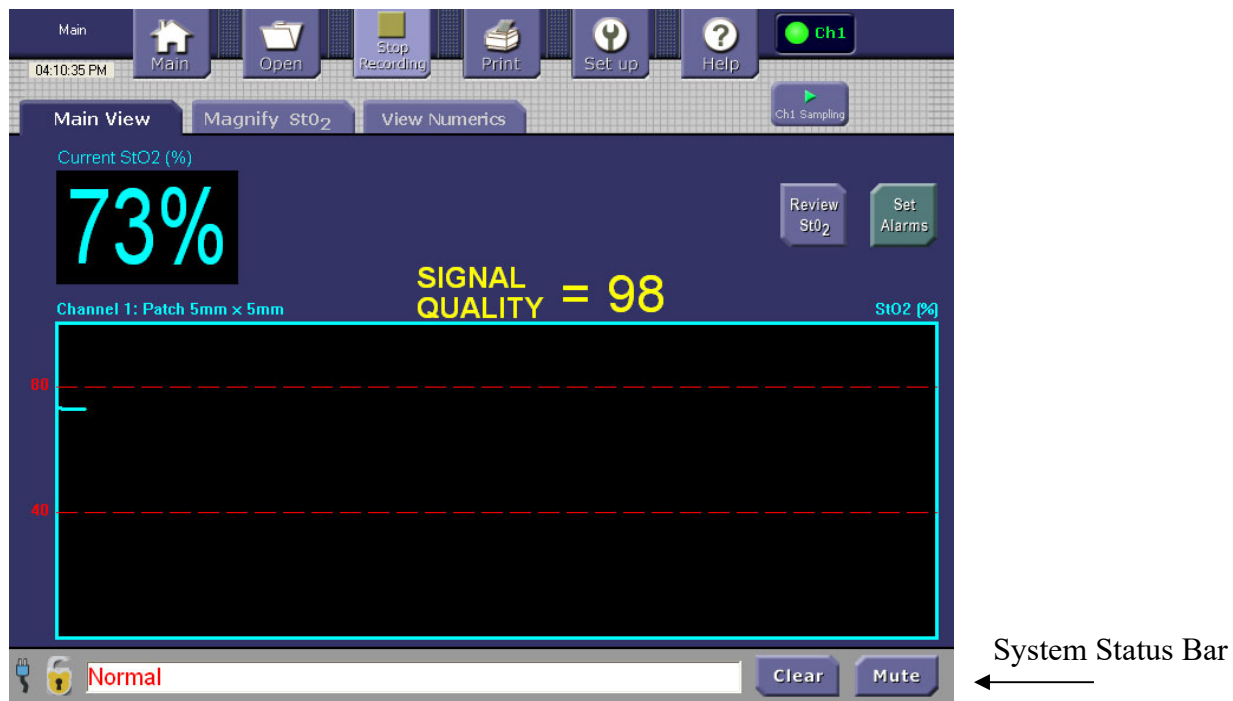


Figure 4. Main Screen, with Control Bar at Top and System Status Bar at Bottom

The Control Bar along the top of the screen displays six buttons that can be used to move from screen to screen as needed. Refer to Table 1. The Screen Name is shown at the top left of the screen. The current time is displayed below the Screen Name. How the time is displayed can be set up in the Time Setup screen.

The display in the upper right corner of the screen indicates the channel(s) that are being used. Figure 4 shows one channel in use. Channel lights will display in green if the corresponding channel is being used to take readings.

Small-Patch Sampling

When using patch sensors, Sampling/Paused soft buttons with lights are displayed to indicate whether readings are actively being taken (Sampling) or if the system is in Paused mode:

When using the patch sensors, press the on-screen **Ch1 Paused** button in the upper right corner to start data sampling.

The **Ch1 Paused** button will change to **Ch1 Sampling**.



When data sampling and collection is in progress, the channel activity indicator changes color from red (**Ch1**) to green (**Ch1**).



Spot-Check Sampling

Depressing the start/stop button on the spot-check sensor begins signal acquisition and data collection. The channel activity indicator changes color from red (**Ch1**) to blinking green while power is being set.



After the StO₂ results become steady, the channel activity indicator changes to a solid green.




The following table describes the Control Bar buttons and what the buttons do:

Table 1. Control Bar Buttons

Control Bar Button	What the Button Does
Main (both single and dual mode)	Returns to the Main screen
Open	Displays the Open File screen; Control Bar functions (Open, Record, etc.) are disabled.
Stop Recording	When tapped displays the Oops Save Discard screen if data has been acquired and saved. Default mode is Recording of all acquired data.
Set up	Displays the Setup screen menu
Help	Displays the Help screen menu

The System Status Bar below the Main Display area shows all information relating to Messages and Alarms, power status, and alarm-sound status. Table 2 below describes each item in the System Status Bar area:

Table 2. System Status Bar

System Status Bar Area or Icon	What the Icon, Button, or Area Indicates
Power Status Icon	<ol style="list-style-type: none"> 1. Displays an icon representing AC power when plugged in.  2. Displays a Battery icon representing battery power when using the battery.  3. Displays a Low Battery icon and alarm when low battery condition exists and the console prepares  to automatically shutdown.
Errors and Alarms area	Displays error and alarm messages in a flashing field of text. Errors and Alarms are displayed in RED. If more than one error and/or alarm occurs messages will scroll to the next message after displaying each alarm or error.
Clear Errors and Alarms button	Allows the operator to clear the error or alarm by pressing the Clear button. This will also clear the screen displayed trend-graph.
Mute Button	Allows the operator to temporarily mute the alarm sound for 2 minutes by clicking

	this button. The flashing text field will continue to indicate the alarm condition.
Screen Lock and Unlock	Allows the operator to lock the screen to prevent inadvertent touching. Locking the screen might be appropriate during long-term monitoring of a patient.

2. Viewing the Main Screen

The T.Ox™ Tissue Oximeter auto-detects the type of sensor(s) connected to the Oximeter.

The Main View screen is the first screen that is displayed when the system is turned on. Its *single mode* automatically displays one channel if only one sensor is connected; refer to Figure 5.



Figure 5. Main Screen (Single Mode)

The Main View screen (dual mode) is displayed when two sensors are attached; refer to Figure 6.



Figure 6. Main Screen (Dual Mode)

The Main screen, whether single or dual mode, provides current numerical readings for StO₂. This data is also displayed in trend-graph format, which indicates where the readings fall with regard to upper and lower alarm settings.

From the Main screen, you can press the buttons listed in Table 3 to view data in enlarged or numerical format. Each of these screens is described in a separate section of this manual.

Table 3. Buttons and Tabs on the Main Screen

Button or Tab Name	What the Button or Tab Does
Main View	Displays the Main screen
Magnify StO ₂ tab	Displays an enlarged view of the StO ₂ graphical data.
View Numerics tab	Displays the data in numeric form rather than graphical form
Review StO ₂ ; this is displayed only after data has been acquired.	Displays data so you can scroll through the data you have collected during sampling.
Set Alarms (to the right of the StO ₂ graph)	Displays the screen to set alarm settings for StO ₂ .

3. Understanding the StO₂ Graph and Data

This area displays a line graph of the real-time data being gathered using the sensor. (Refer to Figure 5.) During long-term monitoring, the graph “advances” to the left so that the current data is always being presented on the right side.

The y-axis of the graph displays the percentage of StO₂ (range 0–100%) in the tissue being measured. The x-axis displays a time scale and the data points as they are gathered in real time.

Alarm settings are displayed as red dotted lines on the graph, showing the upper and lower alarm set levels. There are numbers to the left of the y-axis that indicate the number of the upper and lower alarm set levels. To set the alarm levels, you must press the Set Alarms button.

The current real-time reading of StO₂ is displayed in large numbers in the upper left corner of the screen. If this number violates an alarm setting the number will turn red and the audible alarm will sound. The number will remain red until the calculated reading returns to passing levels or the operator presses the Clear button.

4. Understanding Signal Quality

Use the Oximeter's **Signal Quality** indicator to guide you in positioning the sensor for reliable StO₂ readings. Signal quality measures the consistency of the readings among the sensor's four detectors. The higher the consistency, the more reliable the reading. Specifically:

- Signal quality of 100% is ideal. However, this maximum value is rarely obtained in practice.
- Signal quality of 80%–100% is normally considered “good” or “satisfactory.” This is the Oximeter's operating range.
- Signal quality below 80% is normally considered “low.” Readings in this range may be unreliable. Therefore, when the signal quality falls below this criterion, the Oximeter suppresses StO₂ values in its display and logging.
- Although StO₂ and signal quality are both measured as percentages, keep in mind that they are distinct quantities. The signal quality is a guide to the reliability of the StO₂ reading. The Oximeter's display reinforces this distinction by presenting the two percentages in different sizes and colors.

All other considerations being equal, select a sensor location that gives the highest signal quality. This will typically be a location relatively far from blood vessels, moles, and bones – all of which can interfere with the light wavelength recorded by one or more detectors.

Figure 7 shows a low signal-quality message displayed in the **Setup** screen's **Messages and Alarms** area.

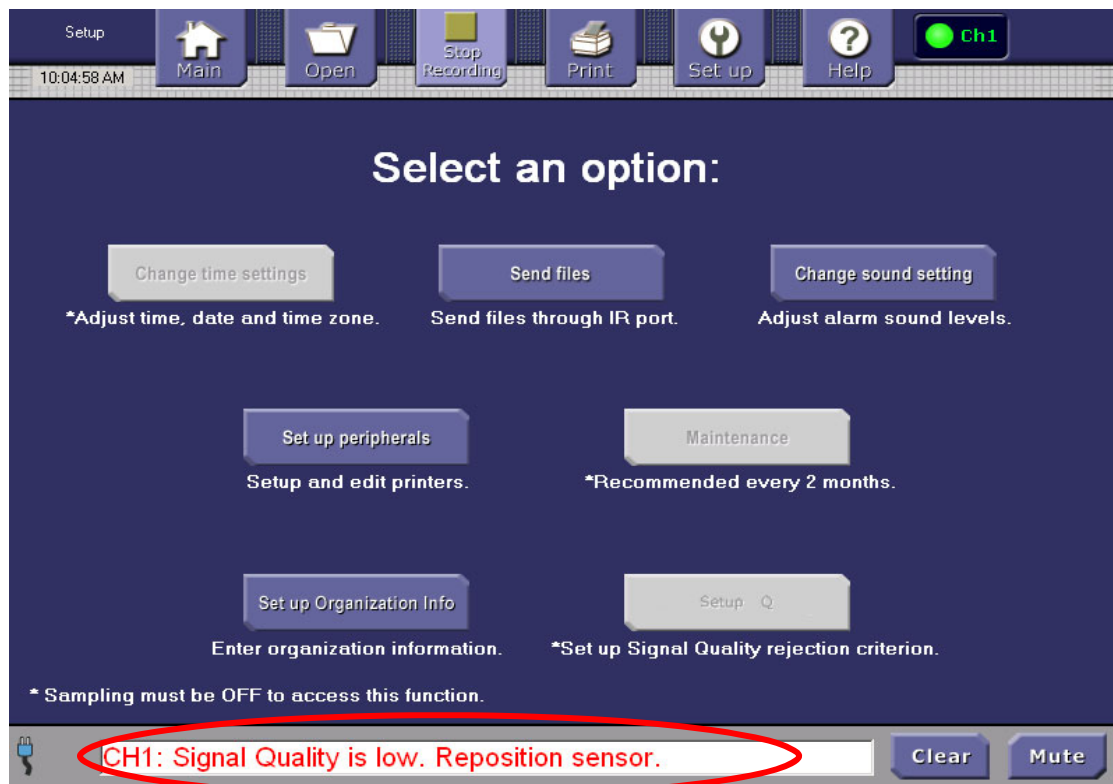


Figure 7. Low Signal-Quality Alarm

Figure 8 shows the StO₂% display under low signal-quality conditions. Because such readings could be unreliable, the Oximeter suppresses their value, and instead displays two dashes.

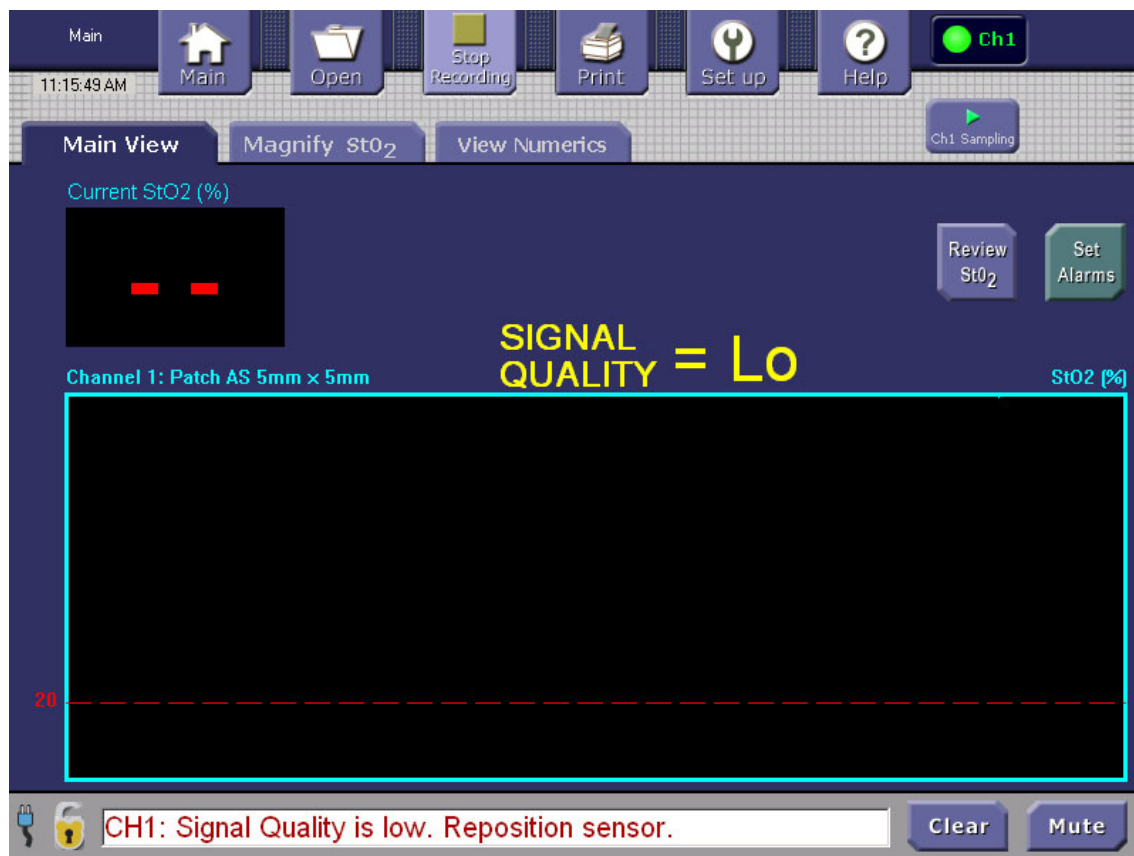


Figure 8. Low Signal Quality Suppresses StO₂% Display

The signal-quality criterion for rejecting StO₂ readings is normally locked at 80%. This criterion helps ensure reliable readings in clinical use.

However, if you are using the Oximeter for research purposes, you can capture a wider range of readings by lowering this 80% criterion, or by defeating it entirely. You access these options by entering a password in the Signal Quality Setup screen, shown in Figure 9.

If you are a researcher who needs to alter the signal quality criterion, contact ViOptix to obtain a valid password for this screen.

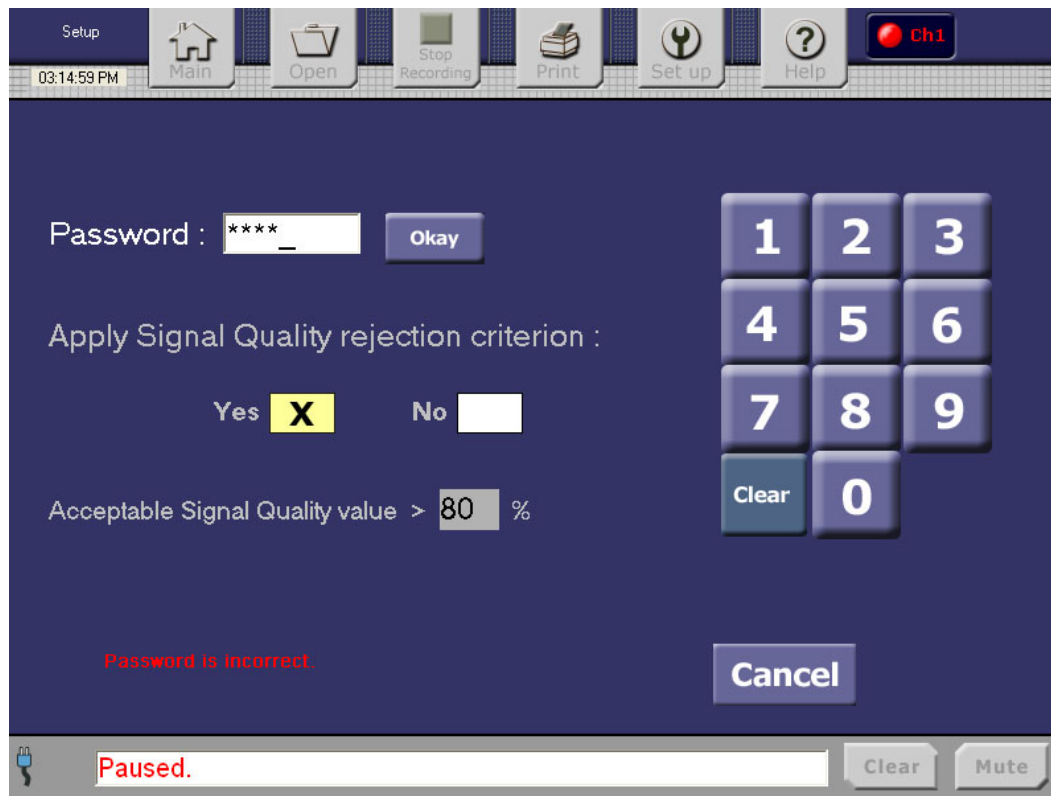


Figure 9. Password-Based Override of Signal-Quality Criterion

5. Setting Alarms

Before starting to sample, set the StO₂ alarm levels. When a reading exceeds a set alarm level, an alarm warning will sound and an alarm message is displayed in the Messages and Alarms area at the bottom of the screen. Also, the current numeric reading is displayed as a large red number.

Channel 1 Alarm 11:48:01 AM Main Open Stop Recording Print Set up Help Ch1 Ch2

1. Sound an alarm when StO₂ Level goes over:
Desired **HIGH** alarm level
[1][2][3][4][5][6][7][8][9][Clear][0]
High Alarm Sound On ☐ Off ☒ X

2. Sound an alarm when StO₂ Level goes under:
Desired **LOW** alarm level
[1][2][3][4][5][6][7][8][9][Clear][0]
The current alarm sound level is: **3** Change Sound Settings

3. Sound an alarm when Drop Rate* goes over:
Desired **HIGH** alarm level
[1][2][3][4][5][6][7][8][9][Clear][0]
Drop Rate Sound On ☒ X Off ☐

* Drop rate is defined as the drop in StO₂% units per hour.

Cancel Done

Normal Clear Mute

Figure 10. StO₂ Alarm Set Screen

6. Setting the StO₂ Alarm

To set the StO₂ alarm:

- On the Main screen, press the **Set Alarms** button to the right of the StO₂ graph.

Note: In dual-mode operation, the Main screen provides a separate **Set Alarms** button for each channel. This allows you to set

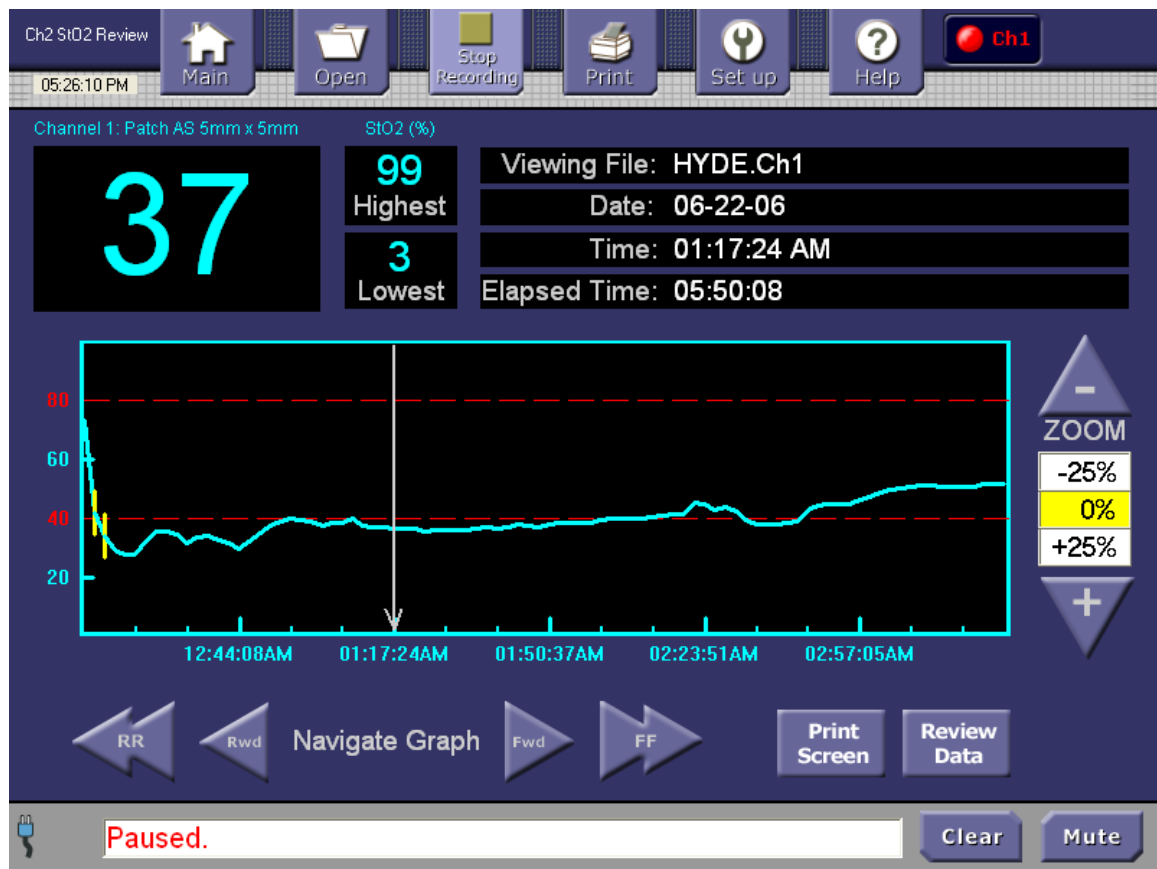
alarm levels separately for each channel.

The StO₂ Alarm Set screen for the selected channel appears. (Refer to Figure 10.)

- b. If no high alarm level is desired, select the **High Alarm Sound: Off box**
- c. To set a high alarm level, tap the **High Alarm Sound: On box** to check it on, then tap the **Clear** button until the entry field is clear of numbers. Select (tap) the desired numeric buttons on the screen to set the high alarm level. The high alarm level can be set from 00.0 to 99.9.
- d. Use the **Clear** button to clear the low alarm level then select (tap) the numeric buttons on the screen to set the low alarm level. The selected alarm levels are displayed in the fields at the top of the numeric keypads.
- e. If the drop rate alarm is desired, select the **Drop Rate Sound: On box**
- f. Use the **Clear** button to clear the drop rate high alarm level then select (tap) the numeric buttons on the screen to set the drop rate alarm level. The drop rate is defined as the drop in tissue oxygen saturation in StO₂ % units per hour. If the drop rate alarm level is exceeded for more than 30 minutes, the alarm will sound.
- g. To change the sound level of the alarm, press **Change Sound Settings** to go to that screen.
- h. When finished, press **Done** to save the selections and return to the previous screen. (Press **Cancel** to discard the selections and return to the previous screen).

7. Reviewing Graphs and Data

The channel-specific StO₂ data can be reviewed in greater detail by opening a logged file or tapping the **Main Screen Review StO₂** soft button. The selected channel's StO₂ data is displayed in a new review screen. This is a display of the logged data at the time the **Review StO₂** button is selected. Using the **Navigate Graph** buttons locate the time period for review.

Figure 11. Review StO₂ Screen

8. Reviewing StO₂ Data

To review data, there must already be a file started by patient sampling. Tap the **Review StO₂** button to the right of the desired channel's StO₂ graph. The **Review StO₂** screen is displayed. Refer to Figure 11.

A graph is displayed for the amount of time elapsed from the moment sampling was started to the moment the **Review StO₂** button was pressed. Move through the graph by using the arrows. Pressing the double arrows moves through the graph page by page (a page is the total number of data points (90) that can be shown on one page of the graphic area). Pressing the single arrows moves through the graph in smaller sections of data; the vertical cursor can also be positioned by tapping the screen.

The y-axis displays the percentage of StO₂ in the tissue being measured. The y-axis does not auto-adjust. The x-axis displays the data points as they are gathered and represents the time scale. The red dotted line(s) across the graph indicates the alarm level(s) and indicates where the data points fall with regard to the alarm level(s). The set alarm level is presented numerically to the left of the graph.

Use the **Zoom +/-** buttons to display the data in different time increments. Press the up or down arrows to select the desired time increment. For example, pressing 50% means that the data on one page represents averaged data points in 5-minute increments; refer to Table 4.

Table 4. Percentage of Zoom

Percentage of Zoom	Meaning of Percentage
-100%	View of 1 minute increments of data around where cursor is focused
-50%	View of 5 minute increments of data around where cursor is focused
-25%	View of 10 minute increments of data around where cursor is focused
0%	View of 30 minute increments of data around where cursor is focused
+25%	View of 1 hour increments of data around where cursor is focused
+50%	View of 2 hour increments of data around where cursor is focused

+100%	View of 4 hour increments of data around where cursor is focused
-------	---

The large number in the upper left corner is the reading for the moment in time represented by where the cursor is on the graph. The highest and lowest numbers displayed indicate the highest and lowest readings for StO₂ during the total elapsed time of the reading.

Also displayed on the Review screen are the following:

- Viewing File: field shows the name of the file
- Date: field shows the date of the data where the cursor is positioned
- Time: field shows the time of the data where the cursor is positioned. Time is displayed in the current 24-hour or AM/PM format selected from the Setup/Change time settings menus.
- Elapsed Time: field shows in hours/minutes/seconds format how much time has elapsed from the start of the recording of the data to the present cursor position..

To print a Summary Report of the data, press the top Control Bar's **Print** button. Refer to the Printing Data section. The Summary Report will print the entire collection of StO₂ data values in numerical table format.

To print a Snapshot Report (Print Screen) of the data, press the **Print Screen** button. The Snapshot Report will only print the segment of data presented on the current Review StO₂ screen.

The **Review Data** button will display the current graphed data in numerical table format. Refer to the "Reviewing StO₂ Data" section on page 38.

If two sensors are being used, the system is in dual mode. Each channel has a **Review StO₂** button to display the StO₂ results for that channel.

9. Reviewing Data

Press the **Review Data** button on the **StO₂ Review** screen to view the data without the graphical representation.

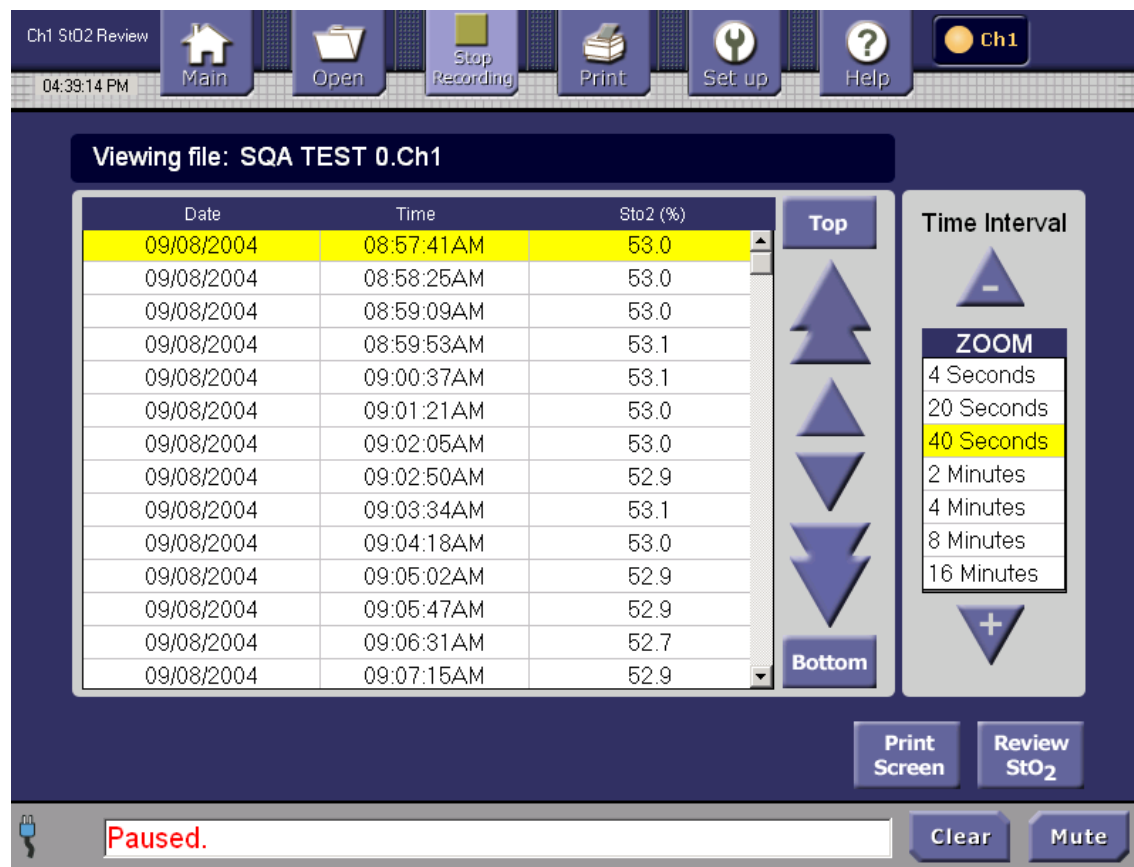


Figure 12. Review Data Screen

The Review Data screen provides the ability to scroll through all the data in a chronological format table. Use the arrows to move up and down through the table. The single arrows move from line to line. The double arrows move through a page of lines at once. Click the **Top** button to go to the most recent data gathered. Click the **Bottom** button to go to the oldest data gathered.

Switch from the Review Data screen to the graphed StO₂ data by pressing the **Review StO₂** button.

Use the Time Interval Zoom +/- buttons to select a time interval to view. As an example, selecting “2 Minutes” will display incremented 2-minute averaged StO₂ data.

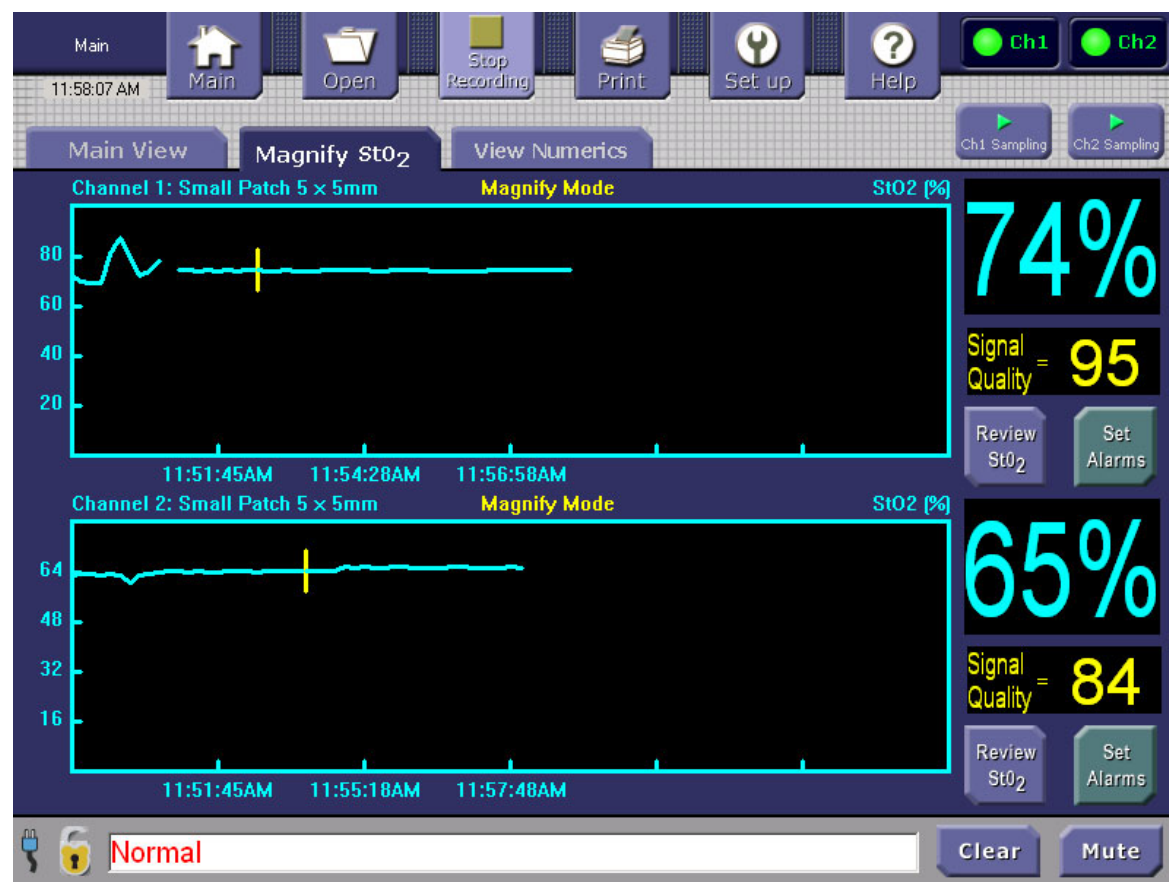
10. Magnifying the StO₂ View

Pressing the **Magnify StO₂** tab, when using one sensor, displays the screen in single mode; refer to Figure 13.



Figure 13. Magnify StO₂ Screen (Single Mode)

Pressing the **Magnify StO₂** tab, when using two sensors, displays the screen in dual mode; refer to Figure 14.

**Figure 14. Magnify StO₂ Screen (Dual Mode)**

Whether in single or dual mode, the **Magnify** screen displays a line graph of the real-time data as it is being gathered. During long-term monitoring, the graph will slide to the left so that the real-time data is always being presented on the right side.

The y-axis displays the percentage of StO₂ in the tissue being measured. The y-axis automatically adjusts to the waveform. The x-axis displays the data points as they are gathered, displays a time scale with time periods displayed in 24-hour or AM/PM format.

Because the Magnify screens are auto-scaled the alarm levels are not displayed. However, if the readings are out-of-bounds an audible alarm will sound and a warning will be displayed in the Status and Alarms area.

From the Magnify StO₂ screen, press the **Review StO₂** button to view a graph of the StO₂ data collected from the time data was acquired to the time the **Review StO₂** button was selected.

11. Viewing Numerics

On the Main screen, press the **View Numerics** tab to see the data in numerical format without a graphical representation.

When in single mode, the following numerics are displayed:

- The current StO₂ reading
- The highest StO₂ reading during the sampling period
- The lowest StO₂ reading during the sampling period

View Numerics will display the single-mode or dual-mode results, depending on the number of sensors attached to channels. The Highest and Lowest are the highest and lowest StO₂ readings from the current sampling period.

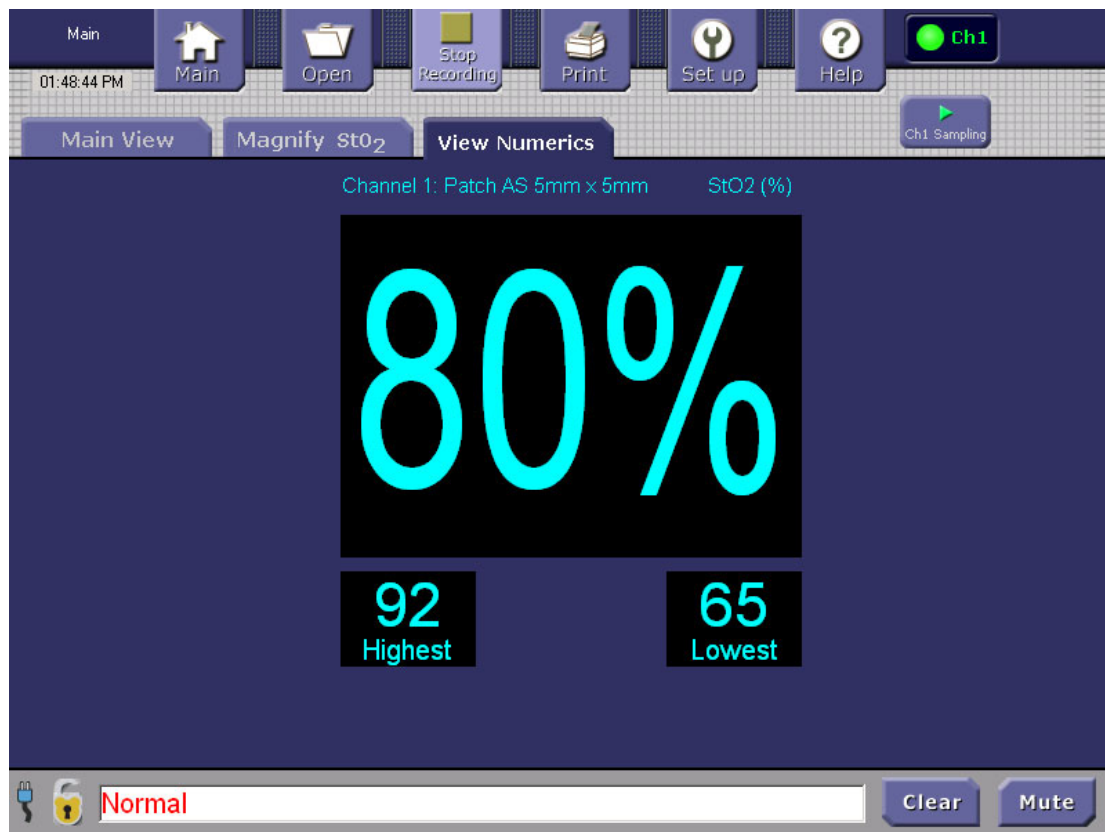


Figure 15. View Numerics Screen (Single Mode)

When in dual mode, the same numerics as described for single mode are displayed for the two sensors that are collecting data; refer to Figure 16.

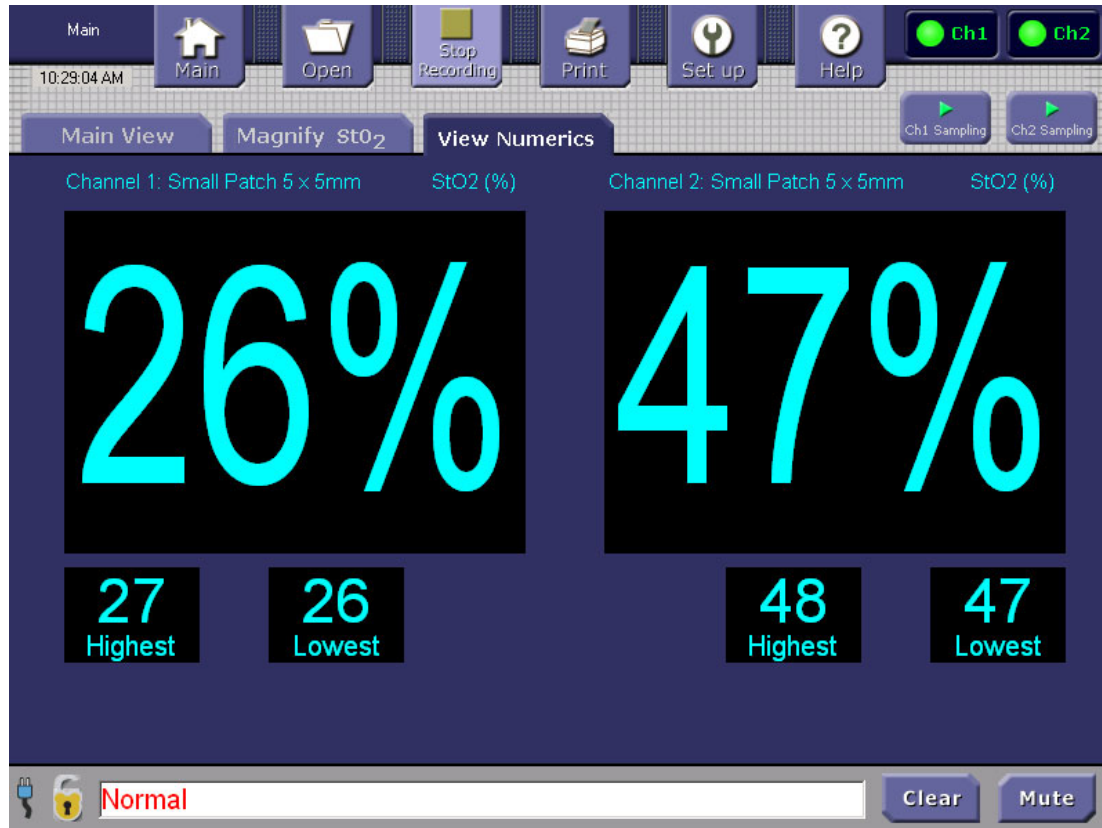


Figure 16. View Numerics Screen (Dual Mode)

12. Setting Parameters in the Setup Screen

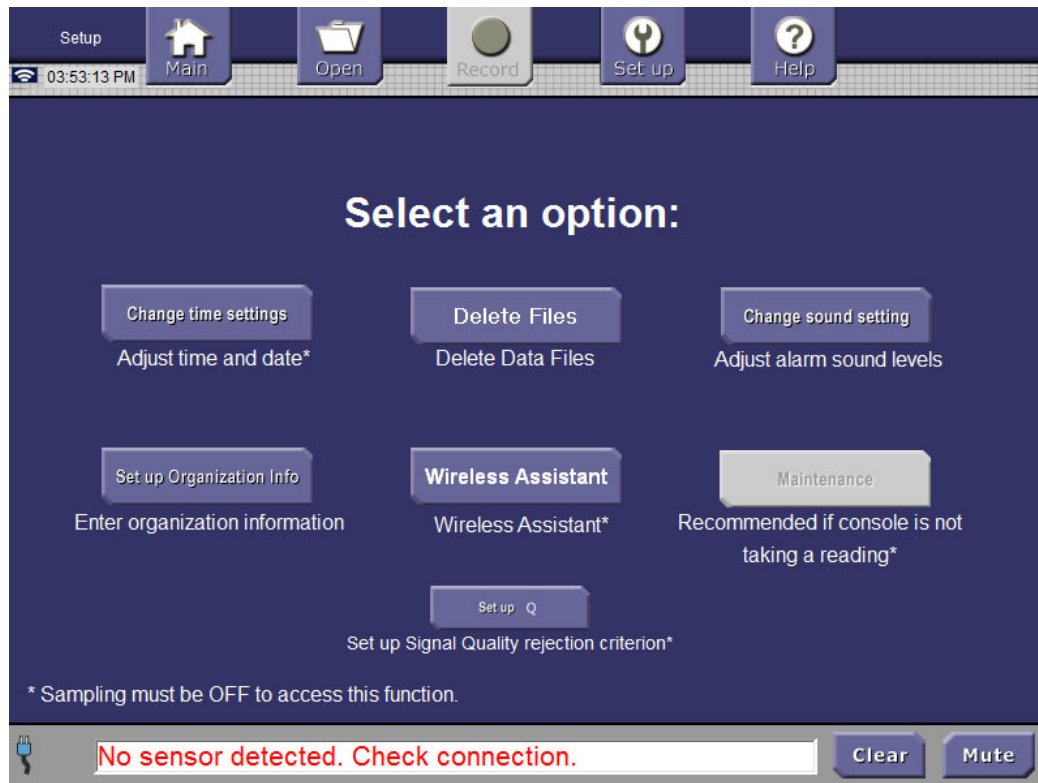


Figure 17. Setup Screen

Go to the **Setup** screen by pressing the **Set up** button in the Control Bar. The **Setup** screen provides soft buttons to define or change the following options:

- Date and time
- Sound level
- Peripherals (printers)
- Maintenance
- Organization Information
- Delete Files

13. Setting the Date and Time or Timezone

The console date and time can be changed from the **Setup menu** that is accessed by tapping the Control Bar's **Set up** button. You cannot change the date and time if Sampling and Recording of channel data is in progress.

1. Press the **Set up** button in the Control Bar to display the **Setup** screen.
2. Press the **Change Time Settings** button.
3. For date and time changes: In the **Set Up Current Date and Current Time** screen, press the **Change date and time...** button located to the right of **Current Time**.
4. Time zone changes: In the **Set Up Current Date and Current Time** screen, press the **Change time zone...** button located below **Current Time**.

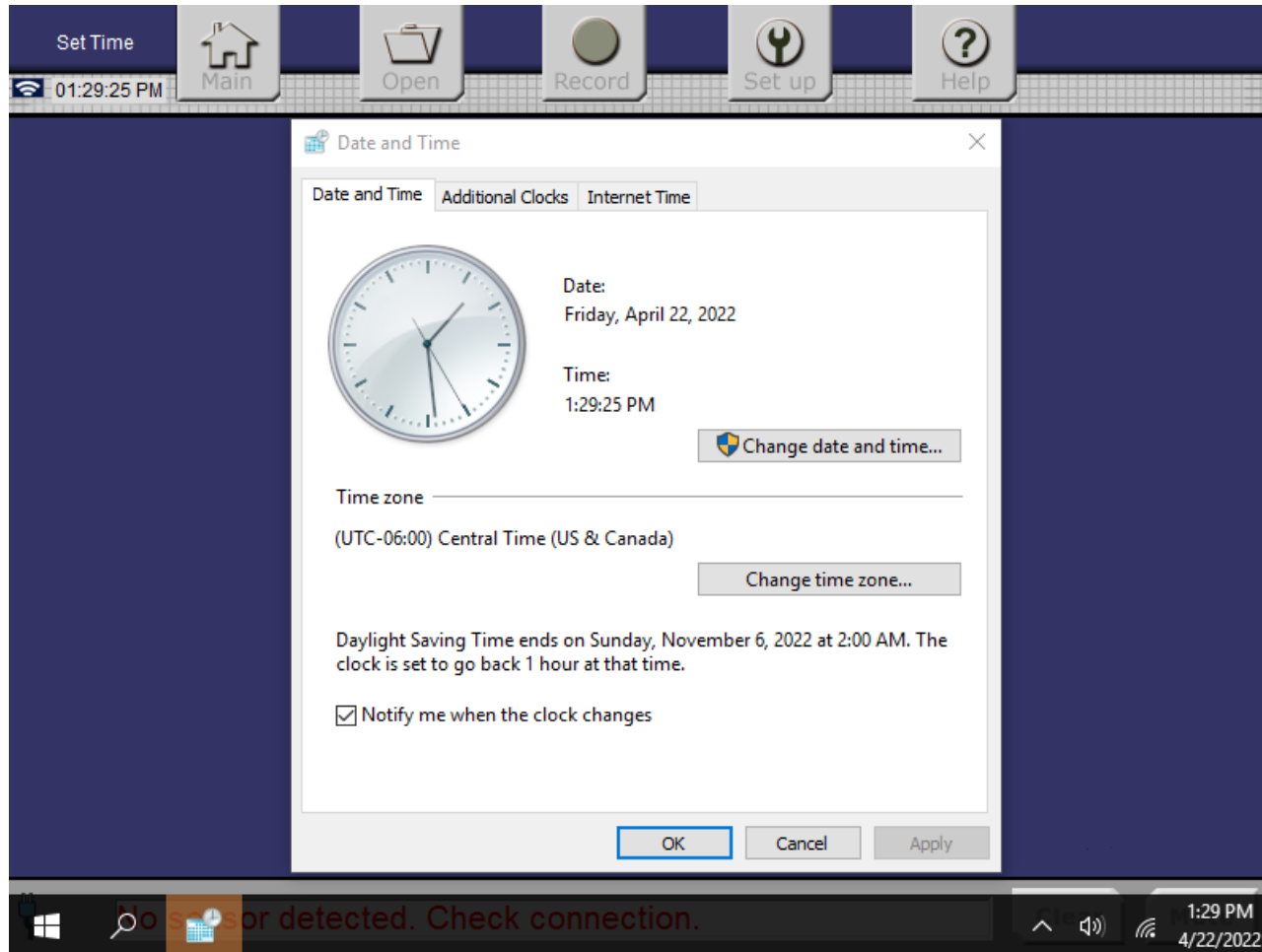


Figure 18. Set Up Current Date and Current Time Screen

5. The **Set Up Current Time** screen appears, as shown in Figure 19. Tap the arrows to scroll to the current time.

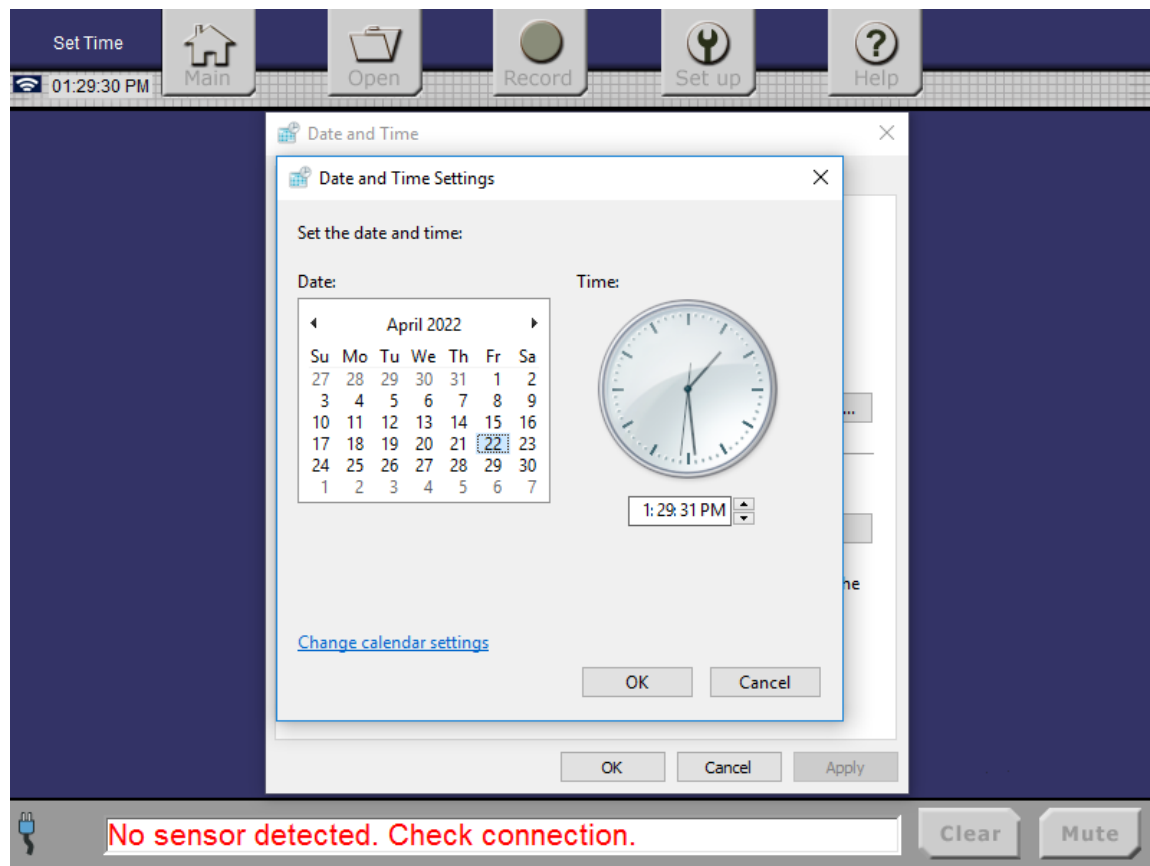


Figure 19. Set Up Current Time Screen

6. Select the desired time with the 12-hour time display (using AM/PM)). .
7. Press **Cancel** to return to the previous **Set Up Current Date and Current Time** screen (Figure 18) without making changes;
Or:
 Press **OK** to update the **Current Time** to the **New Time**, then return to the previous **Set Up Current Date and Current Time** screen (Figure 18).

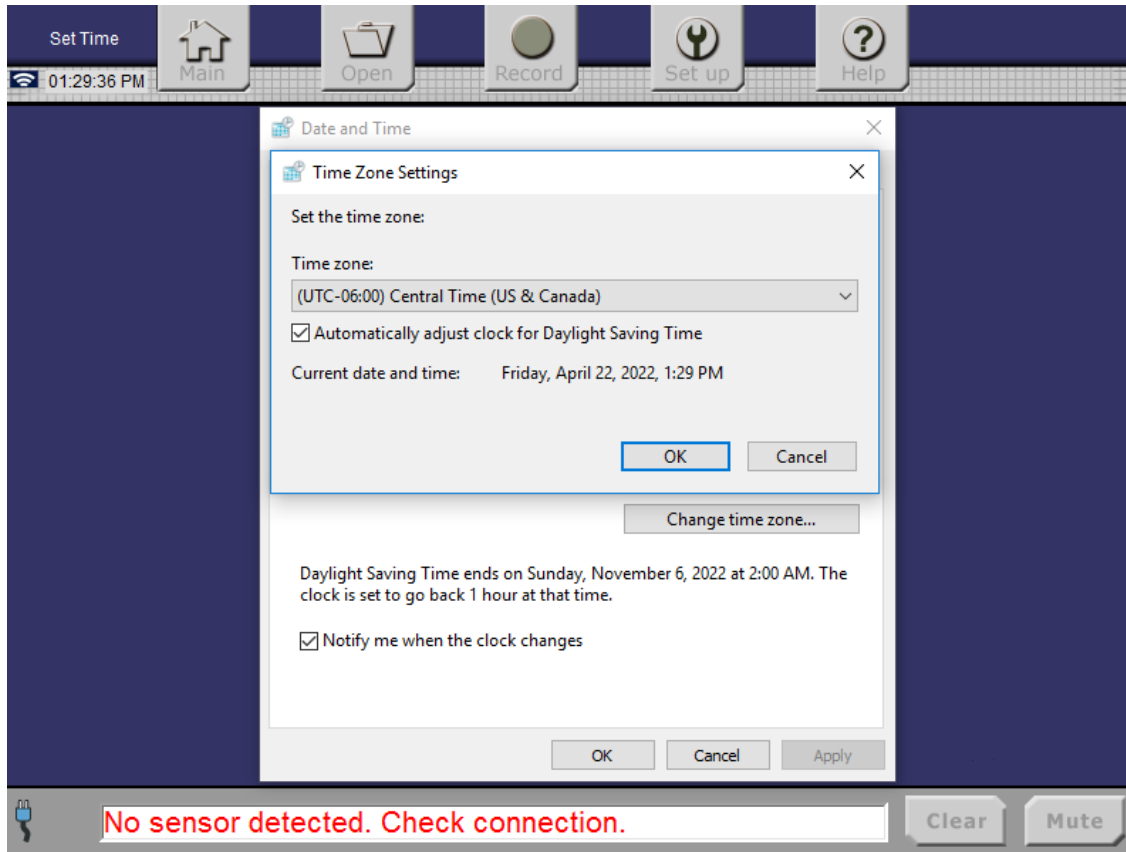


Figure 20. Set Up Time Zone screen

8. Select the desired time zone
9. Press **Cancel** to return to the previous **Set Up Current Date and Current Time** screen (Figure 18) without making changes;
Or:
Press **OK** to update the **Current Time Zone**, then return to the previous **Set Up Current Date and Current Time** screen (Figure 18).

14. Setting the Date

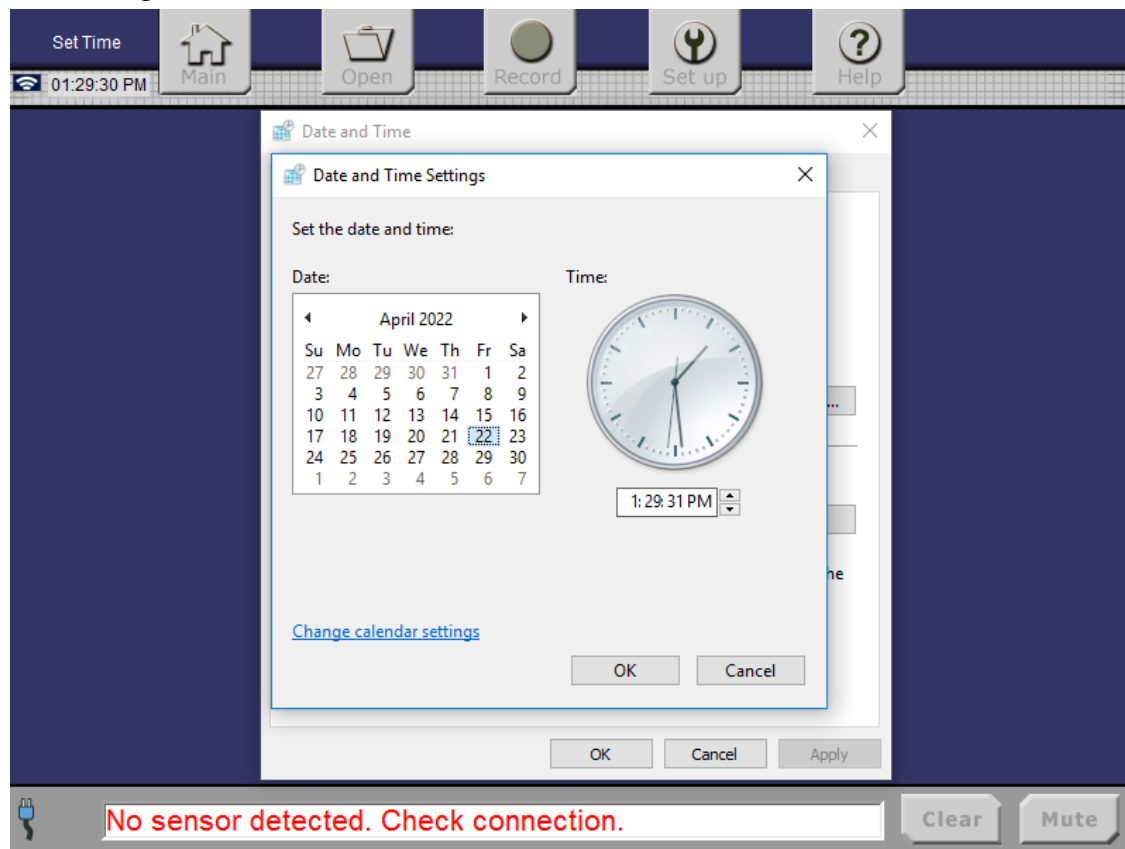


Figure 20. Set Up Date Screen

1. In the **Set Up Current Date and Current Time** screen, press the **Calendar** to set the correct date, as shown in Figure 20.
2. Press **Cancel** to return to the previous **Set Up Current Date and Current Time** (Figure 18) screen without making changes;
Or:
Press **OK** to save the selections.

15. Setting the Sound Level for Alarms

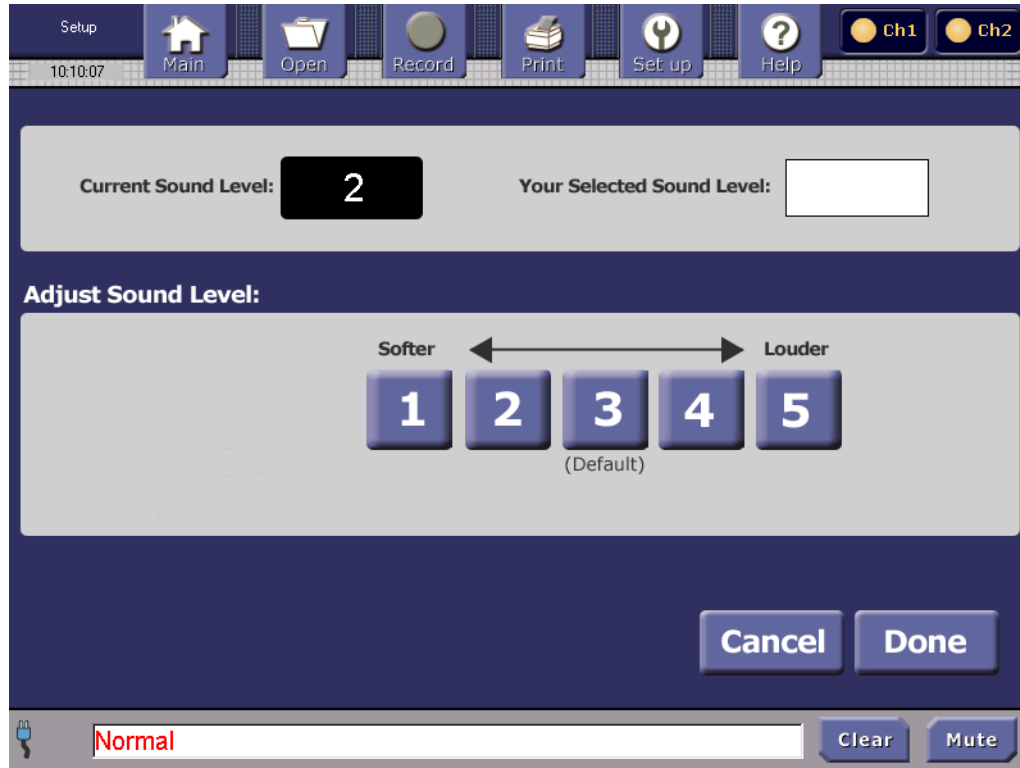


Figure 21. Set Up Sound Level of Alarms

1. In the Setup screen (Figure 17), press the **Change sound setting** button. The **Set Up Sound** screen is displayed, as shown in Figure 21.
2. Press a number from 1 to 5 to select the preferred alarm sound level. The higher the number selected, the louder the volume of the alarm. The new setting is displayed in the box at the top right of the screen.

Note: The audio alarm sound cannot be turned off except using the **Mute** button.

3. Press **Cancel** to not change the sound level and return to the **Setup** screen (Figure 17); **Or:**
Press **Done** to save the setting and return to the **Setup** screen.

16. Performing Maintenance

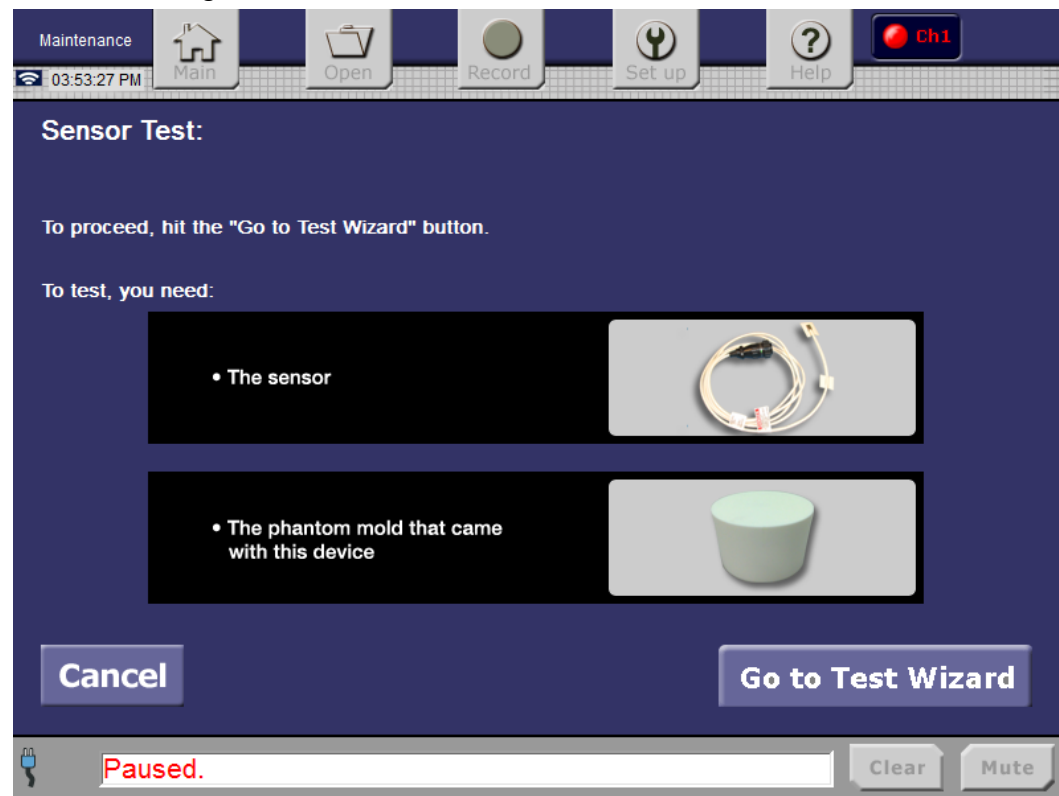


Figure 22. Maintenance Sensor Test Screen

In the Setup screen, press the **Maintenance** button. The **Maintenance Sensor Test** screen will be displayed, as shown in Figure 22. ViOptix recommends that you perform a self-test of the console if a reading cannot be obtained. The test sensors and phantom mold are required to perform a self-test.

Press **Cancel** to return to the **Setup** screen (Figure 17);

Or:

Press the **Go to Test Wizard** button to start the self-test.

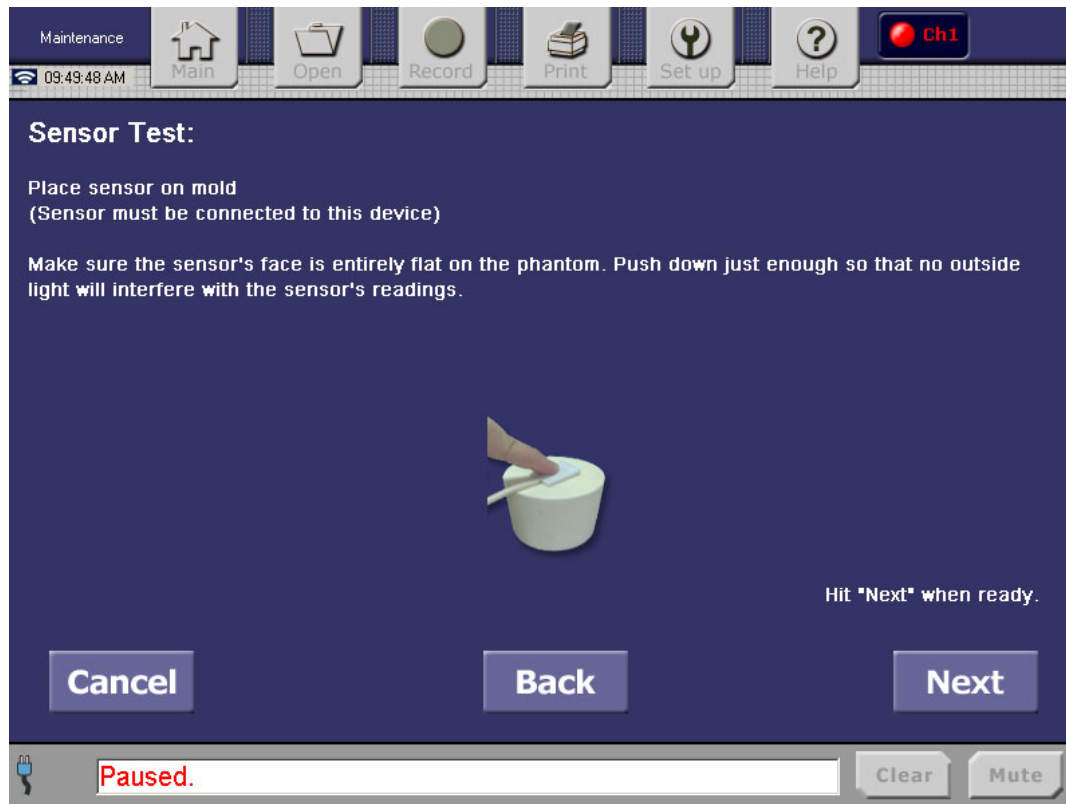


Figure 23. Maintenance Screen, Step 1

The Test Wizard moves through the following steps:

Step 1: Place the sensor on the phantom mold, ensuring that the sensor face is flat on the mold, allowing no light to leak from the sensor.

Note: The start button on a pen or flashlight probe does not need to be activated for the self-test to be completed.

Press **Cancel** to cancel the self-test and return to the **Setup** screen;

Or:

Press **Back** to return to the previous screen;

Or:

Press **Next** to continue the self-test.



Figure 24. Maintenance Screen, Step 2

Step 2: Figure 24 shows that both channels have sensors attached. If only one channel has a sensor, a test will be available only for that channel.

Press **Cancel** to cancel the self-test and return to the **Setup** screen;

Or:

Press **Back** to return to the previous screen;

Or:

Press the selected channel's **Test** button to perform that channel's self-test.

During channel self-test, the console will display the test progress in the **Status and Alarms** area of the screen. After a successful self-test, the instrument will display the screen shown in Figure 25.



Figure 25. Maintenance Screen, Step 3

Step 3: The **Results page** indicates whether the sensor self-test was successful. To perform another sensor self-test, tap the **Back** button. The **Sensor Test** screen, shown in Figure 24, will be displayed.

When you are finished with sensor self-tests, tap the **Done** button to return to the **Setup** screen (shown in Figure 17).

17. Setting Up Organization Information

Setup 12:31:42 Main Open Record Print Set up Help Ch1 Ch2

Hit tab to move from field to field

1. Organization: 3. City,State,Zip:

2. Address1: 4. Phone number:

Address2:

1 2 3 4 5 6 7 8 9 0 Back

TAB Q W E R T Y U I O P

A S D F G H J K L ' #

Z X C V B N M , . -

SPACE

Cancel Done

Paused. Clear Mute

Figure 26. Organization Information

1. In the **Setup** screen, press the **Set Up Organization Info** button. The Organization Information screen, shown in Figure 26, appears.
2. Using the on-screen keyboard, tap the keys to enter the name of the hospital or doctor's office. Tap the **TAB** key to move from field to field. Tap the **Back** key to delete a character. Enter the organization street address, using two lines if needed (27 characters maximum per field).
3. Enter the city, state, and zip code.
4. Enter the phone number. Only numbers are accepted (17 characters maximum).

5. Press **Cancel** to discard and to return to the **Setup** screen;

Or:

Press **Done** to save entries and display the next screen.

Note: The information that is entered in these fields will be displayed in the Summary and Snapshot Report.

6. You will see a confirmation screen (Figure 27), displaying the Organization information that you entered.

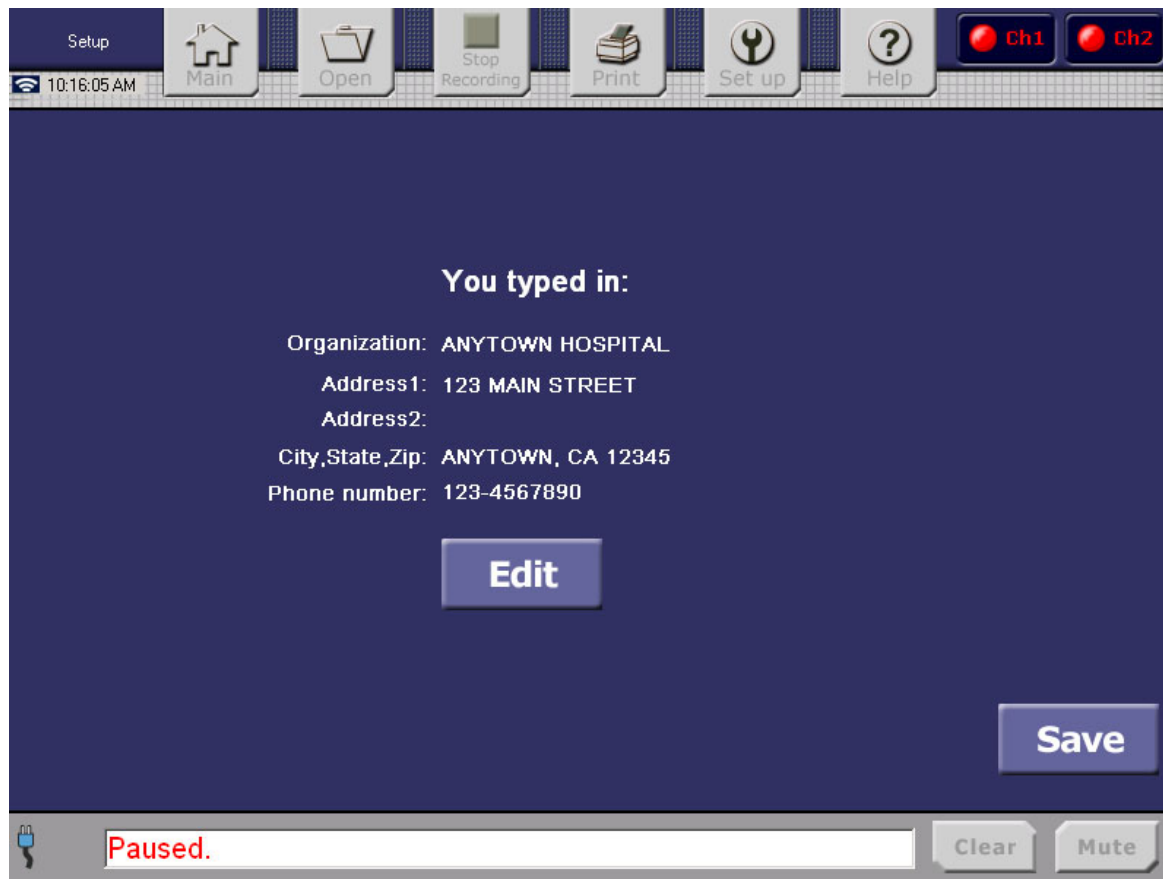


Figure 27. Organization Information Confirmation

Press **Edit** to make any changes to the information;

Or:

Press **Save** to save and exit to the **Setup** screen.

The Organization information will be displayed on the review screens and printed in the print reports.

18. Open an Existing File for Review

To review the data in a file that has already been created, use the Open button on the **Control Bar** at the top of the Main screen.

After the **Open** button is tapped, you will see the **Open File** screen (shown in Figure 28).

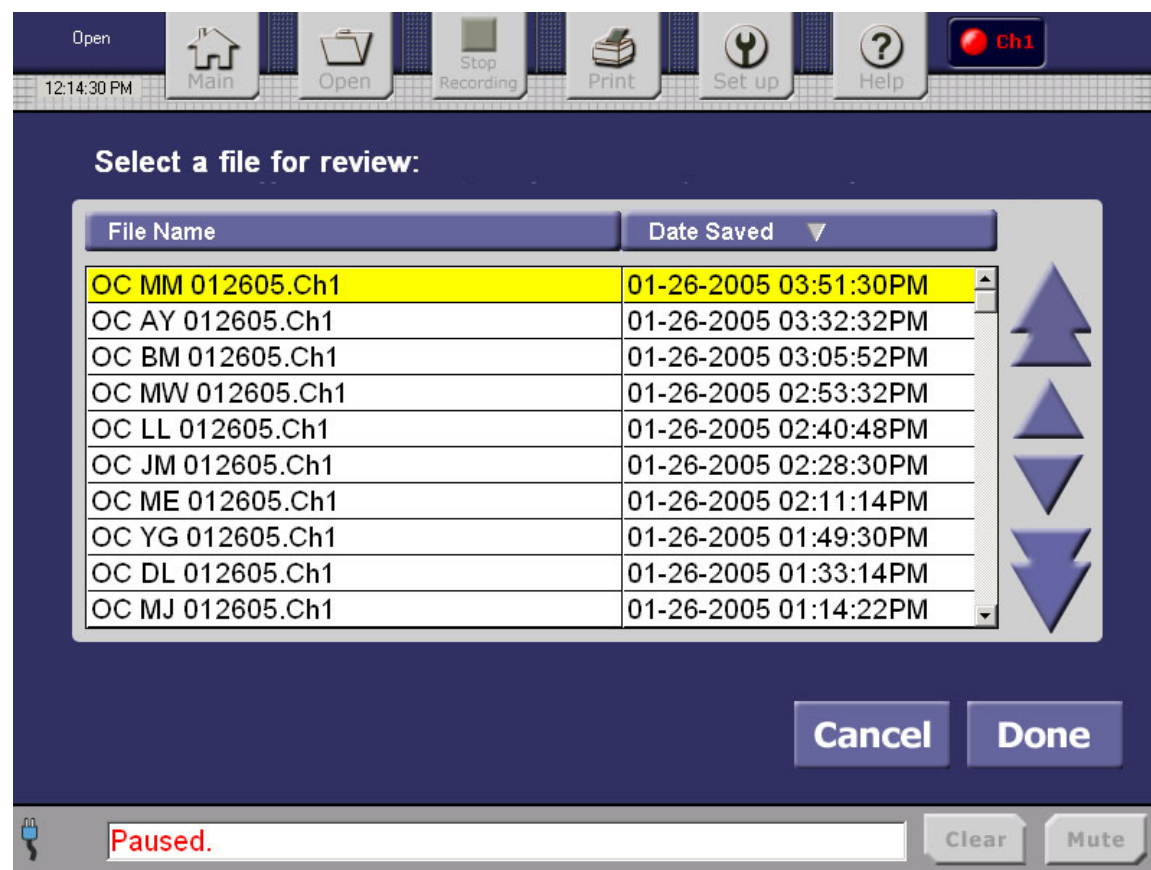


Figure 28. Open File Screen

The most recently saved file is displayed on the top by default. To sort files alphabetically by name, touch the “File Name” button. To sort by date, touch the “**Date Saved**” button.

The only other available options are the **Cancel** and **Done** buttons; the **Control Bar** buttons are unavailable.

Use the arrows to scroll to the desired file.

Press **Cancel** to return to the **Setup** screen;

Or:

Press **Done** to display the file in Review mode.

19. Recording a New File (Saving)

To save the current sampling log of data, use the **Stop Recording** button to create and save a new file record. You will then be prompted to enter the file's name.

If you are recording two channels, each channel's data will automatically be saved in a file with a unique extension. For example, if you entered *filename*, the Oximeter would name the files "*filename. Ch1*" for channel 1 and "*filename. Ch2*" for channel 2.

To stop recording data, tap the Control Bar **Stop Recording** button. The **Oops Save Discard** screen is displayed, as shown in Figure 29.

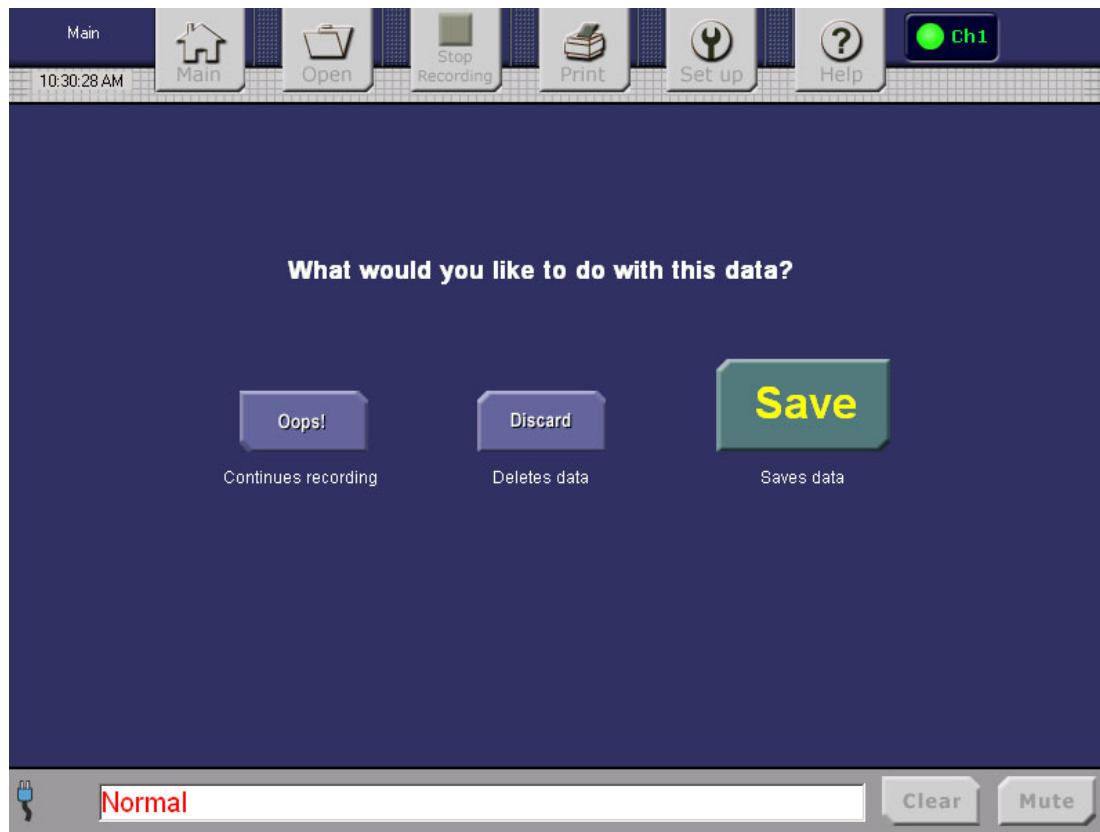


Figure 29. Oops Save Discard Screen, Step 1

Saving Data to a File

Step 1: From the **Oops Save Discard** screen, tap **Discard** to proceed to the **Discard Confirmation** screen (Figure 33) for a confirmation to delete the data.

Select **Oops!** to cancel and return to the **Main** screen (Figure 4) to continue data sampling;

Or:

Select **Save** to save the data in a file. You will see the on-screen keyboard, as shown in Figure 30.

**Figure 30. Save File Screen**

Saving Data to a File

Step 2: Using the keyboard, enter the name of the file in the **Save file as:** block.

The file name's maximum length is 18 characters. (The console will automatically add file extensions, as described below.)

Then tap **Cancel** to return to the **Save or Discard** screen without saving data;

Or:

Tap **Done** to save the data in the named file and return to the **Main** screen.

Note: If both channels are being sampled, the console will create a separate file for each channel. It will give both channels the same file name that you entered, but will automatically give each channel's file a unique filename extension: ".Ch1" versus ".Ch2".

Duplicate Filename Entered

If you enter a duplicate filename, the console will display the following **Duplicate Filename** screen.

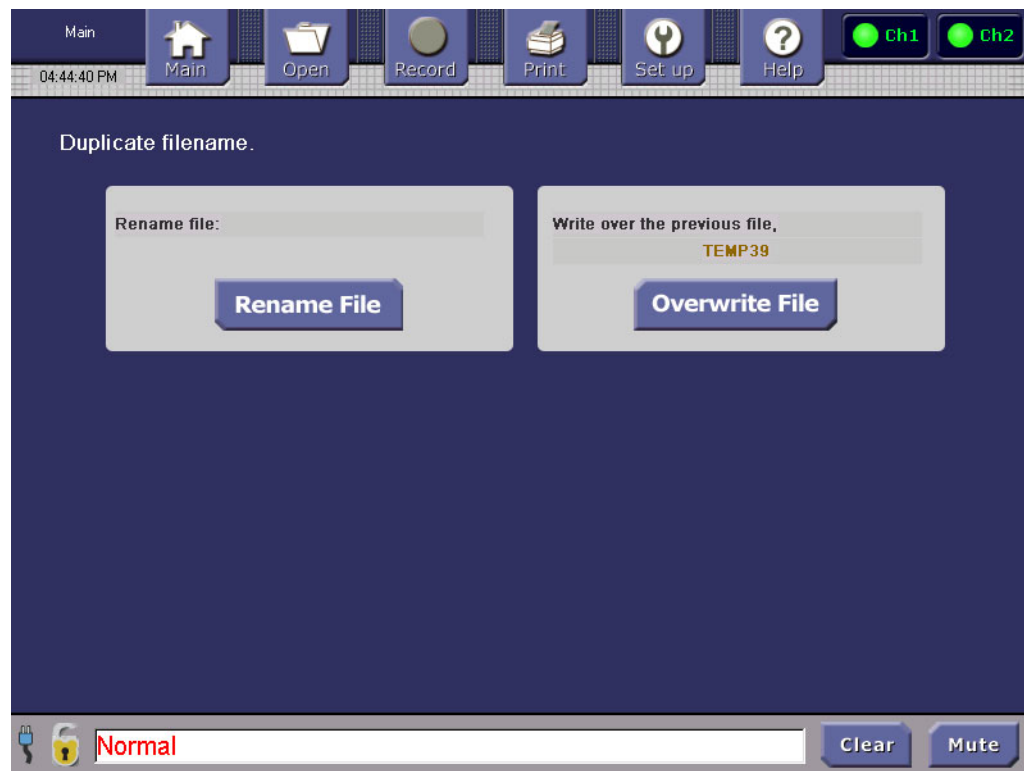


Figure 31. Duplicate Filename Screen

Tap the **Rename File** button to rename the new log file, or tap the **Overwrite File** button to overwrite the existing file with the same filename.

Warning: Selecting Overwrite File will delete the old saved file.

Saving Data When Disk Space Is Limited

There are 200 Megabytes (MB) of disk storage for data log files. This is equivalent to three months of continuous recording of data for two channels. If the operator tries to save a logged file that would exceed the 200 MB limit, the console will display the **Free Disk Space for File Save** screen (shown in Figure 32).

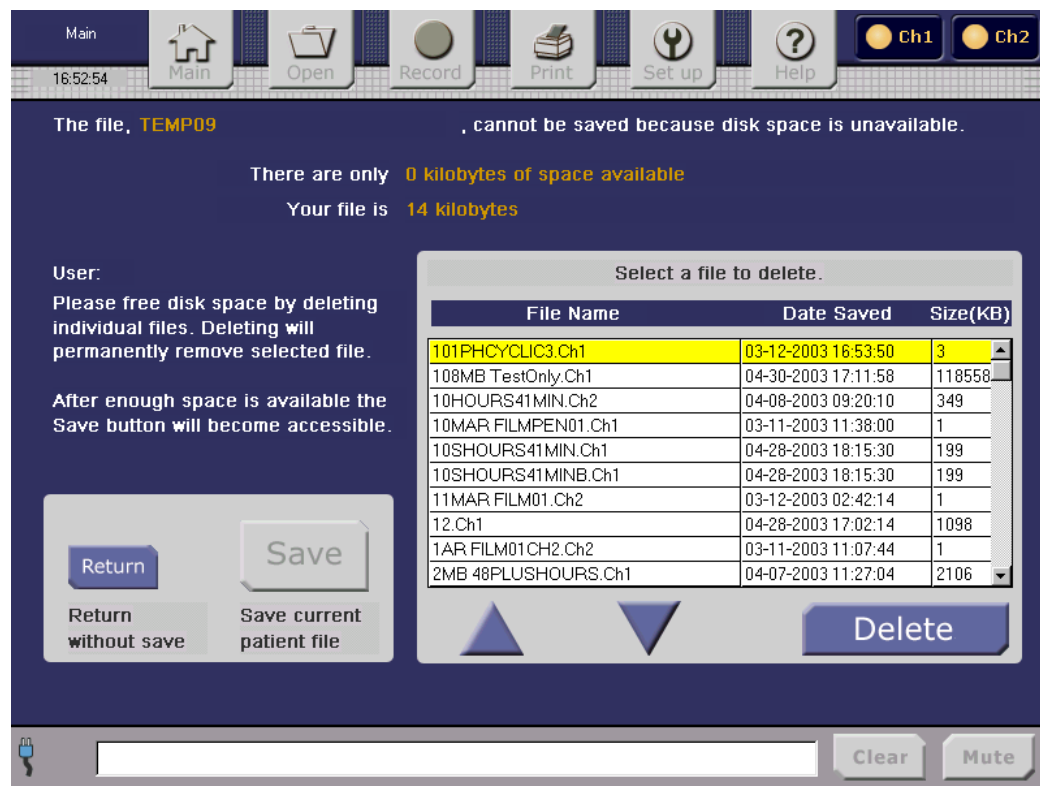


Figure 32. Free Disk Space for File Save Screen

In this case, to save the current data log, you must first delete some file(s) from the disk. Note the size of the file that you wish to save, and delete enough files to free at least that much disk space. You must delete each file individually, by using the arrow buttons to select the file and then tapping the **Delete** button. Once enough space is available, the **Save** button will become accessible.

Tapping the **Return** button will return to the **Oops Save Discard** screen (Figure 29).

Confirming the Discard of Logged Data

If you select **Discard** from the **Oops Save Discard** screen (Figure 29), you will be prompted to confirm the deletion of the temporary log files. Figure 33 shows the **Discard Confirmation** screen.

Selecting the **Yes** button here will delete the temporary log files and return to the **Main** screen (Figure 4), where recording will be stopped.

Selecting **No** will return to the **Oops Save Discard** screen. , without deleting files.

Selecting **Oops!** will return to the **Main** screen, without deleting files, and continue recording of data.

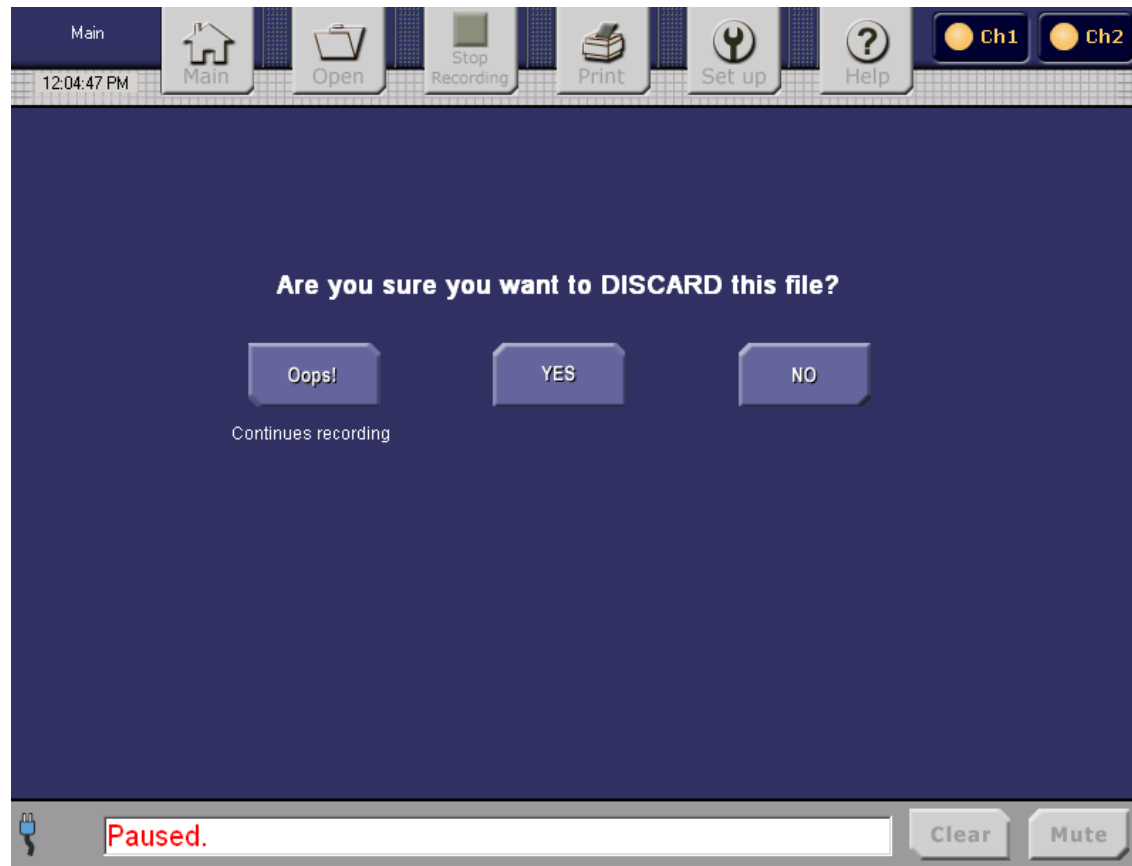


Figure 33. Discard Confirmation Screen

20. Using the Help System

To get information about how to use the screens, press the **Help** button at the top of the screen. The Help Index displays buttons offering more information about each screen. A Glossary of terminology is also included.

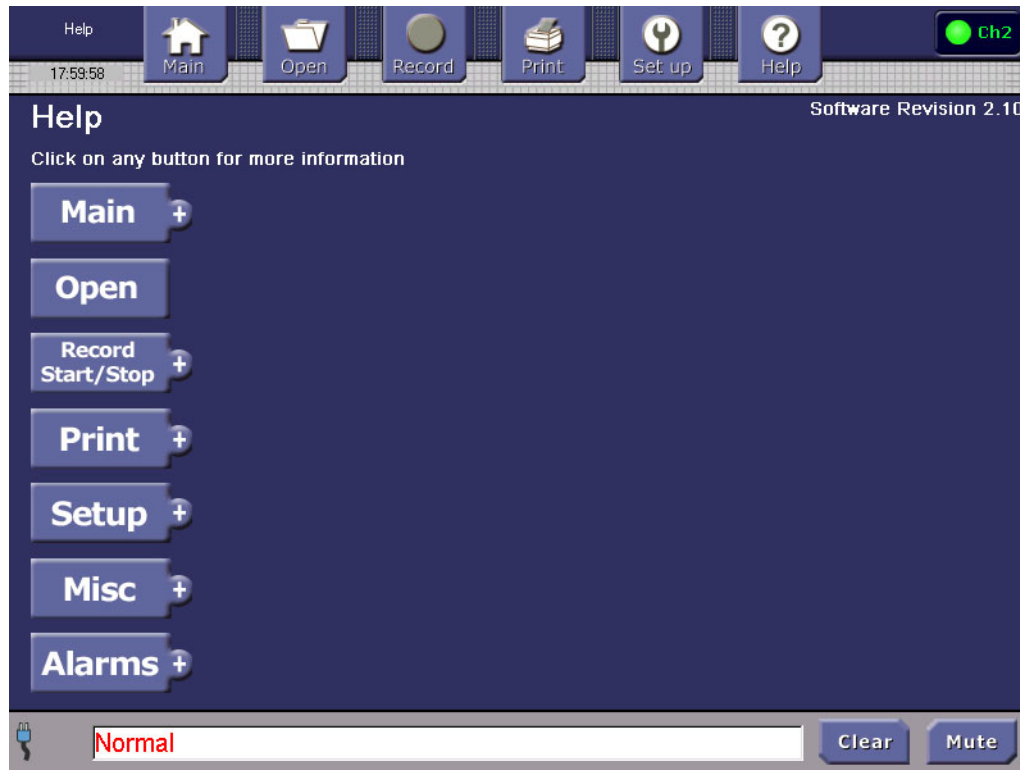


Figure 34. Help Index

1. Press the **Help** button. The Help Index and current software version is displayed, as shown in Figure 34.
2. Use the arrows to scroll up and down through the Help text. Double arrows scroll through the text page by page. Single arrows scroll through the text line by line. Holding an arrow down scrolls through several pages or lines at once.
3. Press the mini-screen in the upper left corner to display a full view of the screen.
4. Press the **Help Index** button to return to the menu of all Help screens.

C. Device Failure and Recovery

The device incorporates a watchdog timer that restarts the operating system and device application in the event of a device failure. Each time a device failure occurs the device will reboot, sound a continuous audible alarm (a continuously repeating sequence of 3 beeps, 1.5-second delay, 3 beeps...), and display a message screen (Figure 35) notifying the user of the failure and requiring user action to continue.

The previous state device parameter settings are retained in the event of a device failure and reboot. Following a device failure and reboot, when the user selects the “Okay” button on the message screen (Figure 35) the device will attempt to restore the state the instrument was in before the failure occurred. The following device parameters/settings are stored and retained:

- Channel 1 “Sampling” or “Paused”
- Channel 2 “Sampling” or “Paused”
- Recording Mode “On” or “Off”

If the device was sampling and recording when the failure occurred, the screen shown in Figure 36 will be displayed after the **Okay** button (shown in Figure 35) is tapped. The screen shown in Figure 36 will give the user the following options for dealing with the sensor data that was collected prior to the failure:

- Continue logging sensor data, after the saved settings and the state of the device are restored
- Discard the current channel sensor data located in the temporary files
- Save the current channel sensor data from the temporary files into user-specified files

Once one of these buttons is chosen, the instrument restores its saved parameter settings and attempts to restore its pre-failure state.

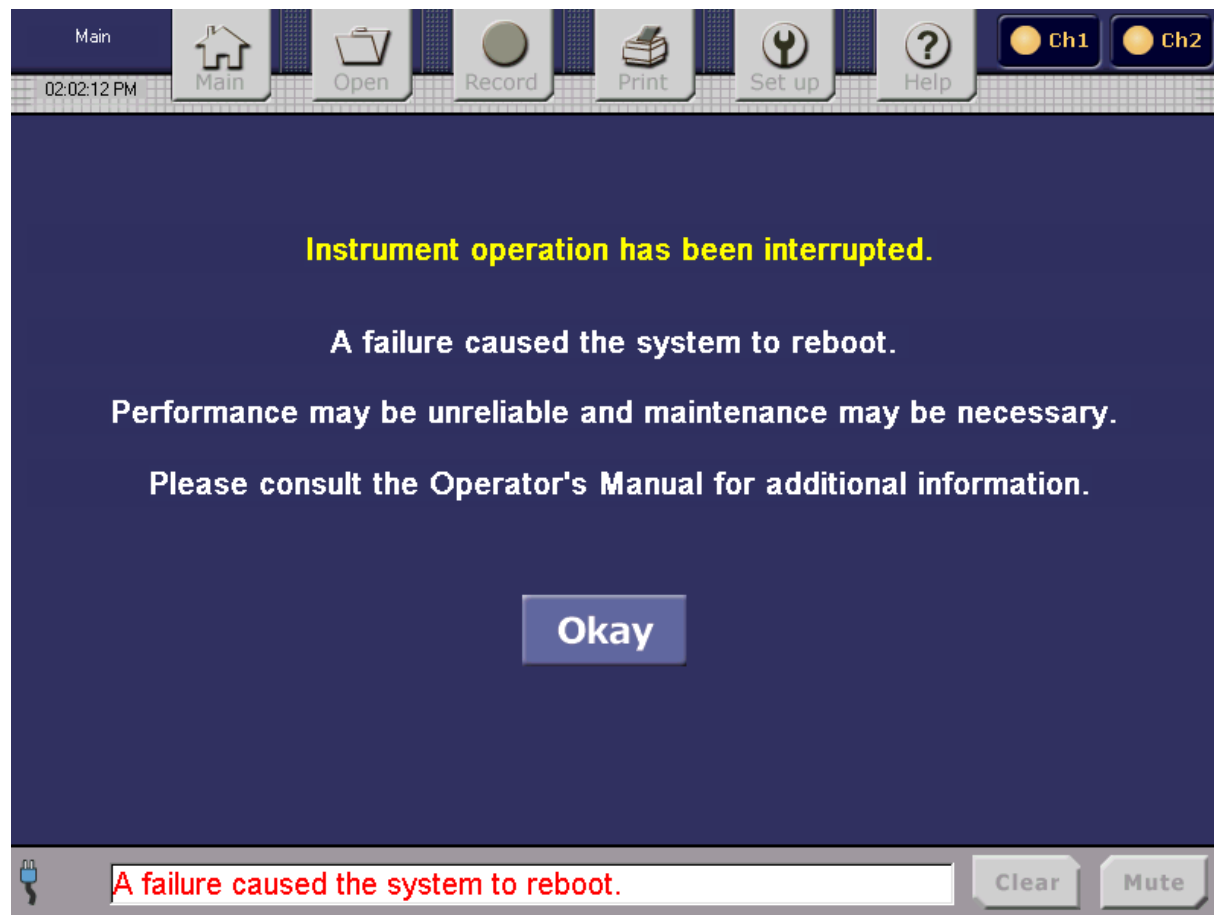


Figure 35. Reboot Recovery Screen

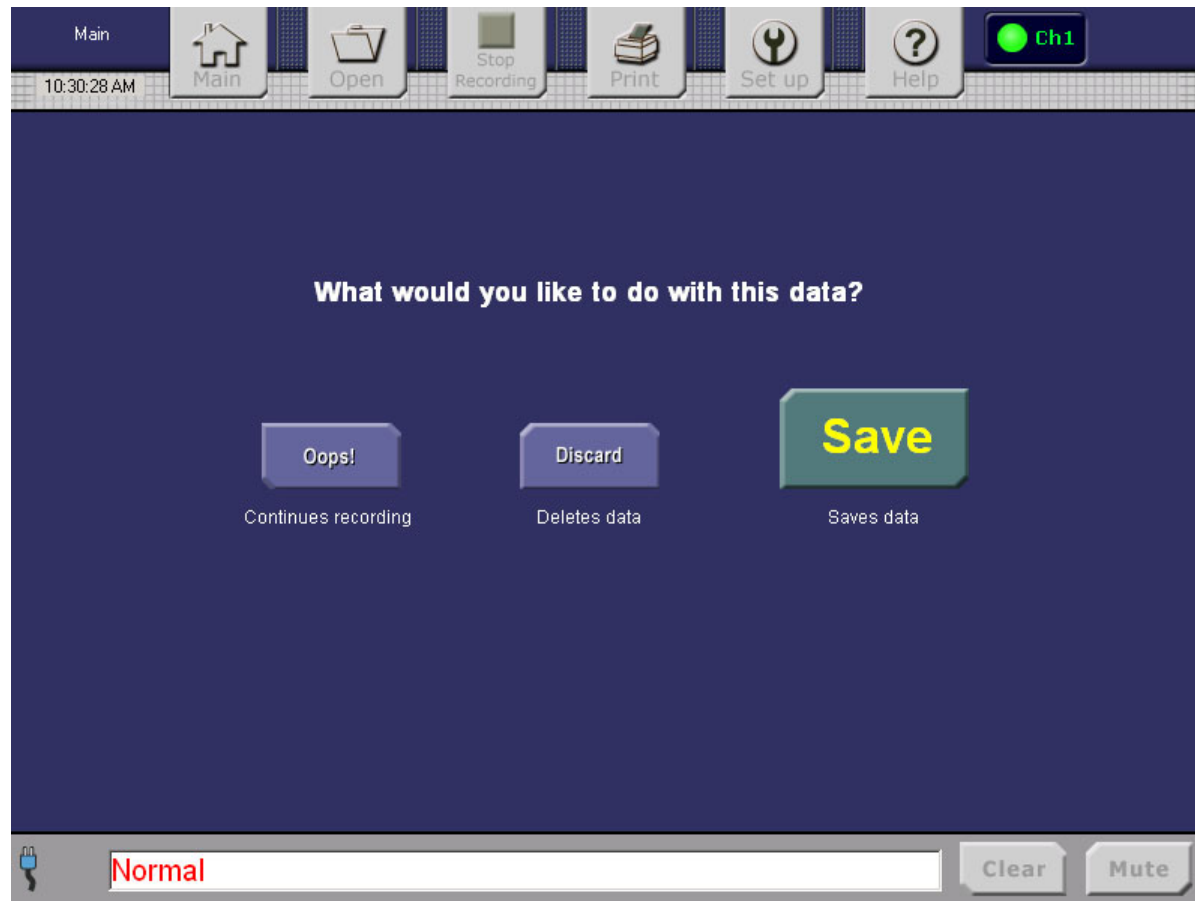


Figure 36. Sensor Data Disposal

Section V. Maintenance

Cleaning and Disinfecting:

Disposable Small-Patch Sensors

The T.Ox™ Disposable Small Patch Sensors are provided sterile in peel-open packages and are intended for single-patient one-time use. **DO NOT REUSE. DO NOT RE-STERILIZE.** Dispose of used sensors in accordance with your institution's biohazard disposal policies.

Console

Warning: Always disconnect the T.Ox™ Tissue Oximeter unit from any power sources prior to cleaning.

- To clean the LCD screen, dilute a household water-based glass cleaner with 50% water. Spray a small amount on a soft clean cloth and gently wipe the screen.
- The T.Ox™ Tissue Oximeter console exterior can be wiped down with a soft cloth dampened with water. Make sure excess water has been squeezed out.
- The connector ends should periodically be cleaned with alcohol and a soft swab.



Warning: Do not soak fiber optic sensors in any solution. Do not use harsh or caustic chemicals. Do not spray cleaner directly onto the console. Keep all liquids, including cleaning fluids, out of any electrical openings.

Section VI. Specifications

Console:

Tissue Oxygen Saturation Range	0 – 100%
Measurements and Wavelengths	
Red	690 nanometers
Infrared	830 nanometers

Ranges and Precision:








Parameter	Range	Precision	Precision (With Motion)
StO ₂	80-100%	2.7%	3.1%
	60-80%	2.3%	2.7%
	40-60%	5.2%	5.6%
	10-40%	13.3%	13.7%







System control	System will perform self-test when power is turned on.
Alarms (visual and audio)	Adjustable Low StO ₂ Adjustable High StO ₂ Adjustable StO ₂ Drop Rate <i>Low battery</i>
Alarms (visual)	Inadequate patient contact Sensor laser ON AC power ON
Alarm Volume	50 to 80 dbA at 30 cm (1 ft.)

Battery	3-cell Lithium Ion Battery, 30 minutes minimum
Operating mode	Single-channel (default) or dual-channel (applies to consoles with dual channel option when 2 sensors are attached)
Operating Power	100-120 / 200-240 V~, 50-60 Hz
Rated power consumption	50 VA
Protection	Type BF, ordinary, continuous operation. The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
<i>Transport and Storage</i>	<i>Temperature: -10 °C to 40 °C</i> <i>Humidity: 20% to 80% (non-condensing)</i>
Atmospheric Pressure	700hPa to 1060hPa
Dimensions	27.5 cm x 38.1 cm x 17.8 cm (11 in x 15 in x 7 in)
Weight	4.3 kg (9.5 lbs)
Sensors:	Available in flexible styles 5 mm x 5 mm Flexible sensors are used for continuous monitoring.
Laser System:	Two pairs of solid state diode lasers, 690 nm and 830 nm per pair, 3 mW max. output from sensor head. Laser pulse duration 140 milliseconds per laser with pulse repetition frequency of 1.538 seconds during sampling.
Wi-Fi Capability Option:	Optional internal Wi-Fi adapter, 802.11n compliant, WPA2-PSK encryption (with preconfigured SSID and pre-shared key).

Glossary of Symbols

Symbols

	<p>Sterile Disposable Small Patch Sensor –are intended for single-patient one-time use. DO NOT REUSE, DO NOT RE-STERILIZE</p>
	<p>Sterilized by Ethylene Oxide</p>
	<p>Use by expiration date stamped</p>
	<p>Fuse marking; identifies location, type and rating of safety circuit component (replacement fuse)</p>
	<p>Type BF equipment</p>
	<p>Attention, consult accompanying documents</p>
	<p>Protective Earth Ground</p>

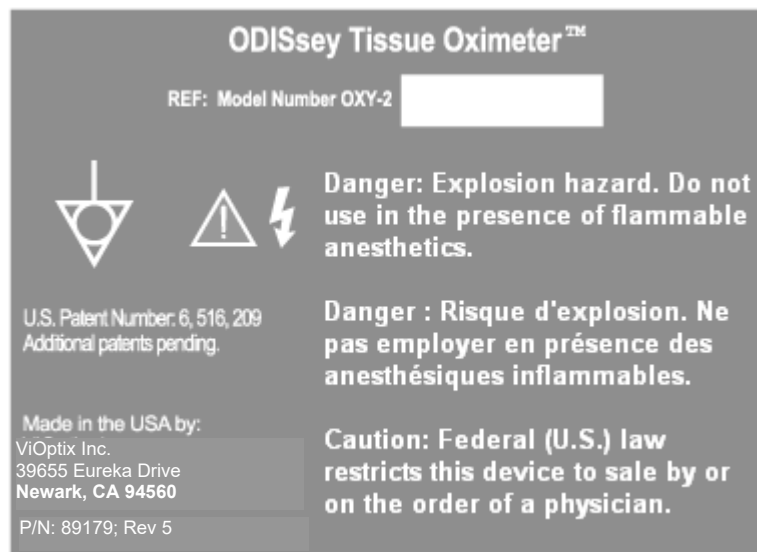
	ON/Standby Button
	Off (Power)
	On (Power)
	Non-ionizing radiation
<i>REF</i>	Model Number (Catalog Number)
	Lot Number
	DANGER: Explosion risk if used with flammable anesthetics

Labels


Laser warning labeling:



Rear Panel Product Label:




Rear Panel Fuse Label:**Sensor Channel Labels (for single channel or dual channel option, as applicable):****Front Panel Label:**



T.Ox™ Tissue Oximeter

Disposable Small Patch Sensor


5mm x 5mm



ViOptix, Inc.
39655 Eureka Drive
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ViOptix P/N: OXY-2-SPD-1 Quantity: 1/Pkg.

S/N



Use by:
YYYY-MM

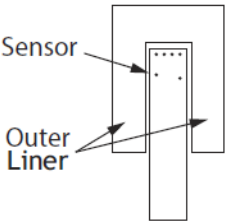
Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician



Do not re-use

STERILE

EO




Sensor

Outer Liner

Important User Information

Intra-Op use: Take care to ensure outer liner stays attached to foam pad. Keep sensor and pad dry.

Post-Op use: Ensure area and sensor head are clean, dry, and free of oils or blood before affixing sensor. Remove release liner before affixing sensor. Press firmly on foam pad to affix. Avoid repositioning sensor once pad is affixed in place. Do not allow holes on sensor face to become obstructed.



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Made in USA U.S. Patents: www.vioptix.com/patents Label P/N: 89222 Rev B

Section VII. Troubleshooting

The T.Ox™ Tissue Oximeter system provides many alarm and error messages to indicate when any problems occur. The following table displays the error, alarm or warning message, what its cause is, where it is shown on the screen, and how to correct the condition:

- Except where noted, the console will display most of the alarms, errors, and warning messages in the Status Bar's Errors & Alarms area. The message text will be flashing red on a white field.
- If more than one alarm occurs, the area will scroll to the next message, after displaying each alarm for 4 seconds.

Table 5 Alarm Messages

Alarm Messages			
Alarm Message	Cause	Message Location	Corrective Action
<i>Ch 1 Low StO₂. Exceeded alarm limit.</i>	Patient's oxygen saturation readings have exceeded the set alarm levels.	Errors & Alarms area	Numbers will be displayed in red until the alarm is cleared.
<i>Ch 1 High StO₂. Exceeded alarm limit.</i>	Patient's oxygen saturation readings have exceeded the set alarm levels.	Errors & Alarms area	Numbers will be displayed in red until the alarm is cleared.
<i>Ch 2 Low StO₂. Exceeded alarm limit.</i>	Patient's oxygen saturation readings have exceeded the set alarm levels.	Errors & Alarms area	Numbers will be displayed in red until the alarm is cleared.
<i>Ch 2 High StO₂. Exceeded alarm limit.</i>	Patient's oxygen saturation readings have exceeded the set alarm levels.	Errors & Alarms area	Numbers will be displayed in red until the alarm is cleared.
<i>Low Battery! Check AC! Console will shut down in xxx seconds.</i>	Low battery.	Errors & Alarms area	Plug the T.Ox™ Tissue Oximeter into an AC power source. Continuing to run the T.Ox™ Tissue Oximeter on battery power after the Low Battery warning has been displayed causes the system to shut down within 3 minutes.

Table 6 Error Messages

Error Messages			
Error Message	Cause	Message Location	Corrective Action
<i>No sensor detected. Check connection.</i>	No sensor connection detected.	Errors & Alarms area	Check sensor connection. Change sensors if failure persists.
<i>Channel 1: Unknown sensor type. Refer to user manual.</i>	Unable to identify sensor attached to channel 1.	Errors & Alarms area	Remove channel sensor, check for sensor pin damage. Change sensors if failure persists.
<i>Channel 2: Unknown sensor type. Refer to user manual.</i>	Unable to identify sensor attached to channel 2.	Errors & Alarms area	Remove channel sensor, check for sensor pin damage. Change sensors if failure persists.
<i>Resampling</i>	Trying another sample sequence; was unable to process returned sensor data; all 16 values might not have been returned.	Errors & Alarms area	Reposition the sensor to get a better signal; change sensors if failure persists.
<i>CH1: Inadequate signal. Check the contact/sensor.</i>	One of returned channel 1 detector readings is exactly zero, indicating a defective sensor or source.	Errors & Alarms area	Pause, if sampling. Reposition the sensor on the patient, and hold it firmly in place while sampling. Run maintenance sensor test if failure persists.
<i>CH2: Inadequate signal. Check the contact/sensor.</i>	One of returned channel 2 detector readings is exactly zero, indicating a defective sensor or source.	Errors & Alarms area	Pause, if sampling. Reposition the sensor on the patient, and hold it firmly in place while sampling. Run maintenance sensor test if failure persists.
<i>CH1: Inadequate contact. Pause, reposition sensor & resume.</i>	Cannot display channel 1 results, either calculated 0.0>StO ₂ reading >100.	Errors & Alarms area	Pause, reposition the sensor to get a better signal; change sensors if failure persists.
<i>CH2: Inadequate contact. Pause, reposition sensor & resume.</i>	Cannot display channel 2 results, either calculated 0.0>StO ₂ reading >100.	Errors & Alarms area	Pause, reposition the sensor to get a better signal; change sensors if failure persists.
<i>CH1: Unable to set power level. Check the sensor.</i>	Channel 1 returned detector voltage(s) less than the minimum level (Nmin).	Errors & Alarms area	Reposition the sensor to get a better signal; change sensors if failure persists.
<i>CH2: Unable to set power level. Check the sensor.</i>	Channel 2 returned detector voltage(s) less than the minimum level (Nmin).	Errors & Alarms area	Reposition the sensor to get a better signal; change sensors if failure persists.

Table 7 Status Messages

Status Messages			
Status Message	Cause	Message Location	Corrective Action
<i>Normal</i>	Sampling from 1 or more sensors; no errors detected.	Errors & Alarms area	Status message, no corrective action needed
<i>Paused</i>	No sampling initiated; no errors detected.	Errors & Alarms area	Status message, no corrective action needed
<i>Sampling ...</i>	Occurs after power level adjustment, returned data analyzed to determine if readings are within limits.	Errors & Alarms area	Status message, no corrective action needed
<i>CH1: Adjusting power level.</i>	Auto-adjusting power level for channel 1.	Errors & Alarms area	Status message, no corrective action needed
<i>CH2: Adjusting power level.</i>	Auto-adjusting power level for channel 2.	Errors & Alarms area	Status message, no corrective action needed
<i>Running on battery. Connect AC power.</i>	No AC connected or AC switch not ON.	Errors & Alarms area	Connect AC power or toggle AC power switch to ON position

Table 8 Other Status, Error, and Warning Messages

Other Status, Error, and Warning Messages			
Message	Cause	Message Location	Corrective Action
Alarm setting Screen			
<i>HIGH level can't be left blank.</i>	StO ₂ alarm set screen: If High required, StO ₂ High alarm-level field cannot be left empty.	StO ₂ Alarm Set screen	Enter StO ₂ High alarm level
<i>LOW level can't be left blank.</i>	StO ₂ alarm set screens: Low alarm-level field cannot be left empty.	StO ₂ Alarm Set screen	Enter StO ₂ Low alarm level
<i>HIGH level must be greater than LOW level.</i>	User input high value less than or equal to low value. StO ₂ alarm set screen: If High required, StO ₂ High alarm-level field's value must be greater than Low alarm-level field's value.	StO ₂ Alarm Set screen	Enter new StO ₂ alarm levels
Open Screen			
<i>File Format Error</i>	Device cannot open file because of formatting error.	Open File screen	File corrupted or incompatible version number. Check file header for version number.
Self-Test Screen			
<i>Self-Test. xx% has been done.</i>	Displayed during Maintenance sensor self-test.	Errors & Alarms area	Status message, no corrective action needed.

Abnormal Shutdown Screen			
<i>Sampling has been interrupted. A failure caused the system to reboot. Performance may be unreliable, and maintenance may be necessary. Please consult the Operator's manual for additional information.</i>	A failure (General Protection Fault, operating system hangup, or application software hangup) caused the system to reboot. Upon reboot by watchdog, the system should sound an audible alarm and display this visual alarm to notify that sampling has been interrupted.	Reboot screen (Figure 34)	Tap the Okay button, if sampling and recording was previously being performed the operator will be given the option (Figure 36) to save or discard the previous (pre-failure) logged data. The operator can also select Continue Logging to continue logging once the device restores its pre-failure mode.
Data Screen			
<i>Invalid new date. Please enter correct day value.</i>	From Set Up Date screen: If an incorrect or nonexistent day is selected (for example, 6/31/2003) and Done is tapped, this message will occur.	Set Up Date screen	Enter the correct day, and tap the Done button.

—End of T.Ox™ Tissue Oximeter Operator's Manual.—