MEDIAID

MODEL 3X Series

User's Manual

Pulse Oximeter with options for 24 hour Memory, Printer & USB / Infrared Ports

MEDIAID INC.

User's Manual

Model 3X Series

Pulse Oximeter with options for 24 hour Memory, Printer & USB / Infrared Ports

Models

30

34

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CHAPTER 1: PRINCIPLES OF OPERATION

INTENDED USES

The Mediaid model 3X pulse oximeters are intended to non-invasively measure arterial oxygen saturation and pulse rate in hospitals, physician's offices, emergency medical facilities, or at home. The model 34 can store data in memory for later review and documentation and also features a sleep mode for patient sleep screening.

IMPORTANT NOTE : **The Mediaid model 30 pulse oximeter can be used for spot checks only. It does not have alarm facility, storing and retrieval of data, IR, USB features.**

WARNING: **Before using the pulse oximeter, become thoroughly familiar with the information in this manual.**

WARNING: **Model 3X refered through out this manual refers to the common features of Model 30 & 34. Model 34 has more features and hence additional instructions are given throughout this manual for proper & safe use. They are marked as (For Model 34 only). Similarly specific instructions pertaining to Model 30 are marked as (For Model 30 only)**

WARNING: **The model 3X is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.**

PRINCIPLES OF PULSE OXIMETRY

The Mediaid model 3X pulse oximeter is designed to measure the percentage of functional oxygenated hemoglobin to total hemoglobin.

Noninvasive arterial oxygen saturation measurement is obtained by directing red and infra red light through a pulsating vascular bed. The pulsating arterioles in the path of the light beam cause a change in the amount of light detected by a photodiode. The pulse oximeter determines the oxygen saturation of arterial blood by measuring the ratio of transmitted red to infrared light within the pulse waveform. The non-pulsatile signal is removed electronically for the purpose of calculation. Therefore, skin, bone, and other non-pulsating substances do not interfere with the measurement of arterial oxygen saturation.

INTRINSIC CALIBRATION

The light absorption by hemoglobin is wavelength-dependent. Mediaid red and infrared LED (light emitting diode) wavelengths are tightly controlled by testing in production.

PRINCIPAL FEATURES

The Mediaid model 3X pulse oximeter is a portable, lightweight, pocket-sized instrument that monitors both functional arterial oxygen saturation (SpO_2) and pulse rate non invasively.

The principal features of the model 3X pulse oximeters are as follows:

- Displays SpO_2 percentage (%SpO_2) and pulse rate (BPM- Beats per minute) on a 3-digit, 7-segment LED Display.
- Displays Perfusion Quality (PQ) & Pulse Amplitude (PA) in bargraph displays.
- Works with any Mediaid sensors with the CompuShield® connector.
- Provides increased longevity and functionality to the pulse oximeter with the removable and replaceable sensor modules.

The Model 34

- Tags patient readings automatically with Patient number, the time and date of the reading.
- The model 34 can retain upto 136 hours of information for a single patient, making the device useful for treadmill and other long tests.
- The model 34 can be used in walk around test, storing more than 7200 data for upto 20 consecutive patients.
- The model 34 can also be used for sleep screening where data can be stored every 5 seconds for up to 18 hours.
- Enables data to be printed or transmitted to a computer via the INFRARED PORT or the USB PORT.
- Includes one button that allows for different modes of data storage and the transmission of recorded data to a printer or a computer.
- Performs approximately 24 hours of operation on a single rechargeable Lithium ion battery. (Sleep Mode)

CAUTIONS

General Cautions

- The model 3X is restricted to sale by or on the order of a physician. It is a prescription device and is to be operated by qualified personnel only.
- Become thoroughly familiar with the information in this user's manual and all the other accompanying documents before using the pulse oximeter.
- Do not attempt to modify or repair the pulse oximeter – doing so voids the warranty.

- Dispose of this instrument and its accessories according to governmental regulations.
- Adhere to all cautions, stipulations, and instructions included with the sensors used.
- Explosion hazard. Do not use model 3X in presence of flammable anesthetics or gases. Do not use model 3X in presence of any flammable agents.
- The use of equipment is restricted to one patient at a time.
- Use accessories specified by our company only, otherwise; the device may not function normally.
- The system may not meet its performance specifications if stored or used outside the specified temperature and humidity ranges.
- Do not drop the model 3X oximeter or its accessories which may result in certain damage.
- Do not use a model 3X oximeter, Charger, AC power cord, sensor, sensor cable or connector and USB Cable that appears to be damaged or broken. Failing to comply with this may result in damage or electric shock hazard to the user/operator as mechanical/electrical integrity of the monitor and/or its accessories could have been hampered.
- Use of damaged sensor or oximeter may result in erroneous or faulty readings or no alarm.
- Do not attempt to lift the oximeter by its charger cable, usb cable or sensor cable. Any attempt made to lift may result in the detachment of the cables and the fall of the oximeter resulting in damage.

Environmental Cautions

- Do not use the pulse oximeter in the presence of flammable agents or flammable anesthetics.
- Do not immerse in liquid and do not allow any liquid to penetrate the pulse oximeter's interior.
- Operate the pulse oximeter in normal light conditions.
- Avoid bright light or glare on the sensing area to ensure correct reading of the displays and indicators.
- Keep away from MRI (Magnetic Resonance Imaging) equipment.
- Move the pulse oximeter away from other electromagnetic emitting equipment if you experience interference problems. (This device complies with electromagnetic compatibility standard EN60601-1-2.)
- Keep away from the equipment that emitsm x-ray, alpha particles, beta particles, neutrons particles, or microwave emissions.

Battery Cautions

- Use only Li-ion batteries specified by Mediaid. Use of any other type of battery not specifically recommended. Use of such batteries could damage the pulse oximeter.
- Never dispose of batteries into fire, short-circuit the terminals, or attempt to disassemble or heat the battery. Doing so could damage the battery and cause a fire, injury, or environmental contamination.
- Liquid leaking from battery can cause skin burns or damage the pulse oximeter. If a battery leaks inside the instrument, return the pulse oximeter for servicing.
- Remove the battery during shipment or if the pulse oximeter will be idle for several weeks.

Sleep Screening Cautions (MODEL 34 ONLY)

Powering OFF the model 34 while it is in the Sleep Recording mode will end the sleep screening process. The next time that the pulse oximeter is powered ON (with the sensor attached) will result in recording of new sleep screening data.

- Removing the sensor from the model 34 while it is in Sleep Recording mode will power OFF the instrument after 2 minutes, ending the sleep screening process.
- When sleep screening data is gathered overnight, the sensor cord should be placed such that the patient does not become entangled. Do not attach the cord or the pulse oximeter in any permanent or semi-permanent manner to the bed or furniture. The sensor cord and the pulse oiximeter should be free to move with the patient.

> *NOTE:* When being used in the sleep mode or in continuous monitoring the sensor must be checked and repositioned once every 2 or 4 hours. Tissue damage might occur.

Preventing Device Complications and Faulty Readings

- Trim the patient's long fingernails and remove artificial nails or thick nail polish.
- Insert the patient's finger completely into the sensor.
- Fit the sensor comfortably without constricting or compressing the application site when using a sensor that is attached to the cable adaptor.
- Do not apply the sensor to anything but a well-perfused extremity.
- Cold extremities can affect readings. Warm up the extremity, or move the sensor to a different site, if necessary.
- Do not apply the sensor on extremities that have blood pressure cuffs or arterial or venous catheters.
- Avoid extremity positions that could compromise venous return.
- Check for intravascular dyes, which could affect pulse oximeter readings.

- Turn off very bright lights, such as surgical, bilirubin, fluorescent, or infrared heating lights if they interfere with sensor functioning. In cases where such lights are unavoidable, cover the sensor site with an opaque material.
- Route sensor cords carefully.
- Avoid applying excessive tension to the sensor or sensor cord.
- Consider conditions affecting the hemoglobin dissociation curve when interpreting pulse oximeter readings (such as intravascular dyes).
- Keep patient movement to a minimum.
- When not in use, do not wind the sensor cord around the pulse oximeter.

CHAPTER 2: FEATURES, INDICATORS, KEYS AND SYMBOLS

PULSE OXIMITER FRONT & BACK VIEW

Model 34   Model 30

Fig. 1

Model 34   Model 30

Fig. 2

PULSE OXIMETER SIDE & TOP VIEW

DC inlet/Battery Charger

Fig. 3

USB Port (Model 34 only)

Fig. 4

Infrared Port/Window (Model 34 only)

Sensor inlet

Fig. 5

PULSE OXIMETER VISUAL DISPLAY

%SpO$_2$ Reading

Pulse Amplitude Bar graph

Perfusion Quality Bar graph

Pulse Reading (Beats per minute)
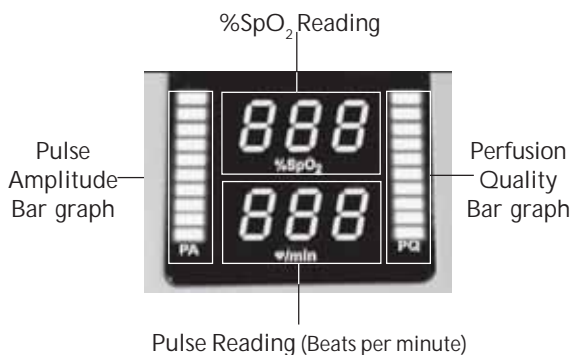
Fig. 6

SYMBOLOGY & MARKINGS

Symbol	Definition
%SpO$_2$	Oxygen Saturation Percentage
♥/min	Heart Beats per Minute (BPM)
PA	Pulse Amplitude Indicator
PQ	Perfusion Quality Indicator
(power symbol)	Power On/Off
(alarm off symbol)	Alarm Off Key and Indicator
(SEND)	Multi Function Key for Communication
▲	Increment Key
▼	Decrement Key
(RATE ALARM)	High Pulse Rate Alarm
(RATE ALARM)	Low Pulse Rate Alarm
(SAT ALARM)	High Oxygen Saturation Alarm
(SAT ALARM)	Low Oxygen Saturation Alarm
(battery symbol)	Low Battery Indicator (Blinking Red LED)
(battery symbol)	Fully Charged Battery Indicator (3 Green or Red LED)
(battery symbol)	Partially Charged Battery Indicator (2 Green or Red LED)
(USB symbol)	USB Key Symbol
(DC symbol)	DC Power Connection
⚠	Attention: Consult Accompanying Documents
(non-anesthetic symbol)	Non-anesthetic Proof
(type BF symbol)	Type BF Applied Part

KEYPADS & DEFINITIONS

Refer respective key number below in the definitions

Model 34

Model 30
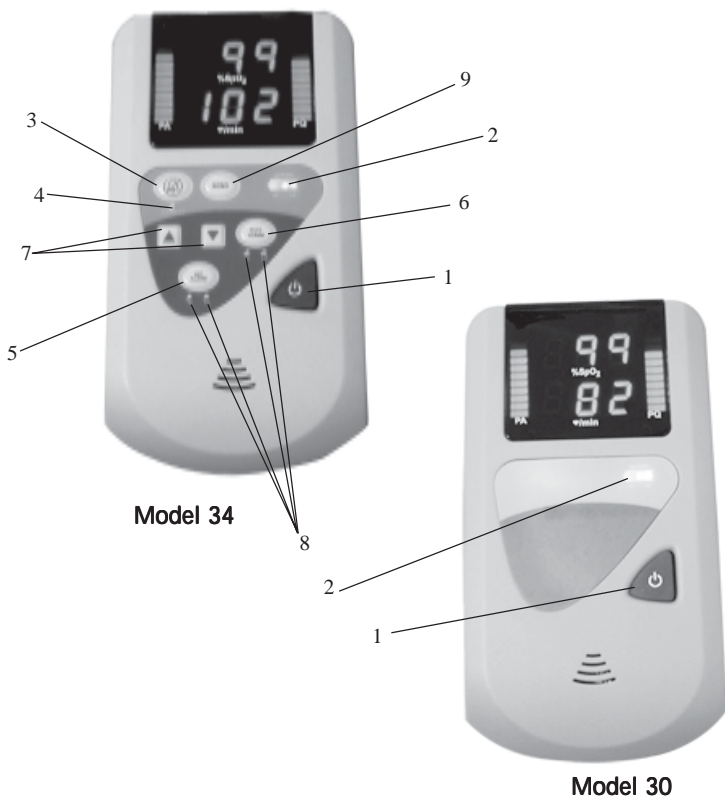
Fig. 6

1.   POWER ON/OFF KEY

The unit powers ON with a short depression of the POWER ON/OFF KEY. A one-second display and indicator test is performed automatically, and all the segments of Light Emitting Diodes (LEDs) will be illuminated. The software version number will then be displayed as "Ver" in %SpO$_2$ display area and the *version number* in ♥/min display area accompanied by a long beep.

Unit switches off automatically (auto-power off) when there is no sensor connected or no finger in sensor for more than 2 minutes.
The unit power OFF with a short-depression of the Power ON/OFF Key.

2.   **BATTERY LEVEL INDICATOR**

The Battery level indicator displays the battery level in a scale of 3. If the unit is connected to external power supply for charging (irrespective of whether the unit is ON or OFF), then the level indicator glows Green and displays the charging status. The LSB LED glows, if the charger is connected. The LSB & Middle LEDs glow, if the unit is partially charged. All 3 LEDs LSB, Middle and MSB glow if the unit is completely charged.

If the unit is operating in Battery mode, then the battery level indicator glows in Red. All three LEDs (MSB, Middle, LSB) glow if the battery voltage is between 91% to 100% voltage. 2 LEDs glow (middle & LSB) if the battery voltage is in the range of 87% to 90%. One LED (LSB) glows ON if the battery voltage is in the range of 71% to 87%.

CAUTION: Below 71% the LSB LED blinks indicating that the battery is near depletion and the unit will shut down within 5 minutes time.

3.   **ALARM OFF (MUTE) KEY**

A short depression of this key silences the alarm for a period of 60 seconds. The ALARM OFF INDICATOR illuminates and remains on constantly, and the oximeter monitors normally. Silenced alarms can be reactivated by a short depression of the ALARM OFF KEY or automatically after a period of 60 seconds regardless of new alarms. This key can be used as enter key while entering a data in model 34.

CAUTION: Do not silence the audible alarm or decrease its volume else the patient safety could be compromised

4.   **ALARM OFF INDICATOR**

The ALARM OFF INDICATOR illuminates and remains on constantly when audible alarms are silenced.

5.   **OXYGEN SATURATION ALARM KEY**

Short depression of the OXYGEN SATURATION ALARM KEY toggles the LED display between the high and low alarm settings, and respective HI/LO ALARM INDICATOR glows below the key. These alarm settings are adjusted using UP ARROW and DOWN ARROW KEYS. The alarm settings are retained in memory until reset by the user. (The default alarm settings for adult / neonate are minimum of 85% for Low limit and

100%/95% for high limit respectively.) The display reverts back to normal monitoring after six seconds of key inactivity or Mute key press. The high/low reading of Oxygen Saturation keeps blinking when the reading is above the maximum preset value and when reading is below the minimum preset value.

6. PULSE RATE ALARM KEY

Short depression of the PULSE RATE ALARM KEY toggles the LED display between the high and low alarm settings and respective HI/LO ALARM INDICATOR to glow below the key. These alarm settings can be adjusted using UP ARROW and DOWN ARROW KEYS. The alarm settings are retained in memory until reset by the user. The default pulse-rate alarm settings are as per the patient type selected (Adult/Neo): High 170 BPM and Low 40 BPM for Adult mode and High 190 and Low 90 for Neo mode. The display reverts back to normal patient monitoring after a six-second period of key inactivity or Mute key press.

CAUTION: Each time the monitor is used, check the alarm limits to ensure that they are appropriate for the patient being monitored.

7. UP & DOWN ARROW KEYS

The pulse-tone volumes are adjusted using the UP & DOWN ARROW KEYS. There are 5 levels of audible (pulse) tone volume, and "off." The pulse tone volume is increased with the UP ARROW key, and decreased or silenced with the DOWN ARROW key. Default pulse-tone volume level is 3. Alarm levels are also adjusted with these keys during alarm condition but the alarm volume is never zero. UP & DOWN arrows keys also used to scroll through the menu, during mode selection (i.e. Storage mode selection, trend values, patient number, etc.).

8. VISUAL HI/LO ALARM INDICATORS

These indicators are located close to the OXYGEN SATURATION ALARM and PULSE RATE ALARM keys; these indicators illuminate when the patient's oxygen saturation or pulse rate crosses the preset high or low alarm settings. While setting alarm limits, the appropriate indicator is illuminated. During the high or low reading of SpO_2 or pulse rate corresponding indicator would be ON.

9.   PRINT / SEND KEY   (SEND)

A long press of the SEND key transmits all the stored data to a computer through USB/IR or a printer through the IR port. In Auto Mode, short press of the SEND key starts storing the data in the memory and in Intermittent Mode, every short press of the SEND key stores the displayed data in the memory.

CHAPTER 3: INITIAL SETUP

UNPACKING AND INSPECTION

Notify the carrier if the shipping carton is damaged. Unpack the model 3X and components. If anything is missing or damaged, contact Mediaid Technical Support.

TESTING

Before using the model 3X in a clinical setting, verify that the unit functions properly by following the instructions in the section on "*Powering ON the Pulse Oximeter*" in this chapter.

Also check if any error codes are displayed.

INSTALLING THE BATTERY

The model 3X pulse oximeters are powered by a single Li-ion battery that will operate for approximately 24 hours with a fully charged battery in sleep mode.

To open the battery enclosure remove the screw indicated here

Pull out the Battery Connector

Fig. 7

To replace the battery, complete the following steps.

1. Unscrew the Battery cover on the rear of the oximeter.
2. Disconnect and Remove the battery.
3. Insert the new battery and attach the connector. Put back the rear cover and tighten the screw.

CAUTION: While replacing battery, ensure that the proper tools are used to remove/fix the screw. Using a wrong tool may result in screw head portion getting broken.

CAUTION: To ensure patient safety, do not place the monitor in any position that might cause it to fall on the patient.

CAUTION: As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

CAUTION: Explosion hazard. Do not use the model 3X handheld pulse oximeter in the presence of flammable anesthetics.

CAUTION: Follow local governing ordinances and recycling instructions regarding disposal or recycling of device components, including batteries of the model 3X.

CAUTION: Always adhere to all cautions detailed in "Battery Cautions," in Chapter 1.

CAUTION: Do not remove the battery from the pulse oximeter when it is in any of the recording modes (Automatic, Intermittent, or Sleep). Doing so can result in the loss of stored data.

CAUTION: Ensure that the battery connector is inserted correctly to avoid reverse polarity of the battery. Trying to connect the battery in reverse polarity may damage model 3X and / or its components.

CHARGING THE BATTERY

Connect Model 3X to the specified charger unit. Battery is charged by attaching the given charger to the AC inlet and turning it ON. While charging the battery level indicator glows in Green.

The Battery level indicator displays the battery level in a scale of 3LEDs. If the unit is connected to external charger for charging, then the LSB LED indicator should glow in Green and display the charging status. LSB & Middle LEDs glow, if the unit is partially charged (about 70%). All three LSB, Middle and MSB LEDs glow if the unit is fully charged.

POWERING ON THE PULSE OXIMETER

WARNING: **To ensure personal safety and proper operation of the pulse oximeter, adhere to all directions, warnings, cautions, and policies stated within this manual as well as those included with each accessory. Before each measurement, visually check and ensure that the monitor and its accessories are intact and safe for use.**

Before powering on the unit for the first time set the date and time. To adjust or set the time and date, see *"Adjusting the Time and Date Settings"* in Chapter 7.

To power on the pulse oximeter attach the sensor to the patient's finger and press the POWER ON/OFF key.

SELF TEST STATE

Model 34

Model 30

Fig. 8

After the pulse oximeter is powered on, all the segments of 7 segment LED DISPLAY, BARGRAPHS are turned ON and all LEDs in the Keypad are also turned ON for about 1-2 seconds. This is as a part of self test to ensure that all display segments are functional. On completion of visual indicator test, the software version number is displayed with a long beep for a second to ensure that the audio circuitry is functional.

MODEL 3X DISPLAYING SOFTWARE VERSION

Fig. 9

CAUTION: A non-functioning LED segment will result in an incomplete numeral and possible erroneous reading.

CAUTION: A non-functioning beeper may result in compromising of patient safety. Do not use model 3X when there is no beep sound during self-test.

The LED DISPLAY shows one of the following for 1 second: (MODEL 34 ONLY)

- *Ato*, if the pulse oximeter is in the Automatic Recording mode.
- *int*, and the patient number (from P01 to P 20) if the pulse oximter is in the Intermittent Recording mode. If a patient number has not been selected, the LED display shows P and two dashes (**P - -**).
- *SLP*, if the pulse oximeter is in the Sleep Recording mode.

Next, the pulse oximeter tests the sensor availability, internal functions, and the battery status. The LED DISPLAY of both SpO$_2$ and BPM shows three dashes (- - -) during these tests, which last for about 1-2 seconds.

When the pulse oximeter has successfully passed the power-on tests, it enters the Monitoring Mode. The battery condition is monitored continuously and the battery level indicator displays the charge on the battery. An error Code is shown if any other malfunction occurs. See "Troubleshooting", in Chapter 12, for error code interpretation.

POWERING OFF THE PULSE OXIMETER

- To power off the pulse oximeter in any mode remove the finger from the sensor and press the POWER ON/OFF key.
- Remove patient's finger from the sensor or detach the sensor cable from the oximeter, the oximeter switches off after a period of 120 seconds.

CAUTION: Powering off model 34 while it is in the sleep recording mode will end the sleep screening process. The next time that the instrument is powered on (while sensor is attached) new sleep data will be recorded. Ensure that the data recorded is transmitted to a computer using USB cable/IR as soon as the sleep screening process is completed, failing which may result in loss of stored data.

In Model 34, In the Sleep Recording mode, the LED DISPLAY will dim and beeper will automatically mute after 30 seconds without any key activity. Press any key on the pulse oximeter to re-illuminate the LED DISPLAY & activate beeper for another 30 seconds.

CHAPTER 4: MONITORING AND RECORDING

In Model 30, Pulse oximetry data can be displayed and has only Monitoring mode. In Model 34, Pulse oximetry data can be displayed in the Monitoring mode, or it can be recorded and stored in the Intermittent, the Automatic, or the Sleep recording mode.

PERFORMANCE CONSIDERATIONS

Pulse oximeter readings and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

Inaccurate measurements can be caused by:

- Incorrect application of the sensor. Incorrect application may cause tissue damage. Inspect the sensor site periodically as directed in the sensor directions for use.
- Placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- Ambient light
- Patient movement

CAUTION: Calibration cannot be performed by the user/operator. Please contact Mediaid.

CAUTION: Reusing the device/sensor without prior cleaning may result in cross contamination.

Loss of pulse signal can occur for the following reasons:

- The sensor is too tight
- A blood pressure cuff is inflated on the same extremity as the one with the sensor attached
- There is arterial occlusion proximal to the sensor

Clean and remove any substances such as nail polish from the application site. Periodically check to see that the sensor remains properly positioned on the patient.

- High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, and direct sunlight can interfere with the performance of a SpO_2 sensor. To prevent interference from ambient light, ensure the sensor is properly applied, and cover the sensor site with opaque material.
- Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

MONITORING PULSE OXIMETRY (MODEL 30 ONLY)

The model 30 can be used only for spot checks. It does not have alarm, storing and retrieval of data, IR, USB features. Do not attempt to use for continuous monitoring, as it may endanger the patient.

- The Monitoring mode is started by placing the finger in the sensor and powering on the monitor. In Monitoring mode, pulse oximetry data can be viewed on the LED DISPLAY, as follows:
- Top 3 LED DISPLAY indicates %SpO2.
- Bottom 3 LED DISPLAY indicates BPM (Beats per minute)
- Two Bar graph displays (scale of 1 to 10), Left one indicates PULSE AMPLITUDE (PA) and the right one indicates PERFUSION QUALITY (PQ).
- Powering on the LED DISPLAY shows three dashes one each for SpO2 and BPM indicators for 1-2 seconds while the pulse oximeter performs the power-on self tests.
- After the power-on tests, the following information shows on the pulse oximeter:
  - The PA Bar graph begins to blink, indicating the start of measurement. Then PQ Bar Graph starts to blink to the level of perfusion at the measuring site.
  - Both SpO_2 and BPM values are displayed.
- Record the readings if required and switch off the model 30 to save battery power.
- This completes one cycle of measurement using the model 30.
- Please follow the cleaning instructions given in the manual before making next measurement on another patient.

NOTE: If the PQ and PA don't blink adjust the sensor position.

CAUTION: When Perfusion Quality (PQ) display is showing less than 3 LED Bars, it indicates that the PQ is too low. Either change the monitoring site to an alternative location or check if the sensor is applied correctly.

CAUTION: Reusing the device/sensor without prior cleaning may result in cross contamination.

MONITORING PULSE OXIMETRY (Model 34 only)

The Monitoring mode is started by placing the finger in the sensor. In Monitoring mode, pulse oximetry data can be viewed on the LED DISPLAY, as follows:

- Top 3 LED DISPLAY indicates %SpO_2.
- Bottom 3 LED DISPLAY indicates BPM (Beats per minute)
- Left Bar graph displays (scale of 1 to 10) indicates PULSE AMPLITUDE (PA)
- Right Bar graph displays (scale of 1 to 10) indicates PERFUSION QUALITY (PQ).

To monitor pulse oximetry data without recording the data in memory (possible only in Auto & Intermittent mode without pressing the send key), complete the following steps:

1. After powering on (in Auto or Intermittent mode) the LED DISPLAY shows three dashes (- - -) for SpO_2 and BPM indicators for 1-2 seconds while the pulse oximeter performs the power-on self tests.

2. After the power-on tests, the following information shows on the pulse oximeter:
- The PA Bar graph begins to blink, indicating the start of measurement. Then PQ Bar Graph starts to blink to the level of perfusion at the measuring site.
- Both SpO_2 and BPM values are displayed.

CAUTION: When Perfusion Quality (PQ) display is showing less than 3 LED Bars, it indicates that the PQ is too low. Either change the monitoring site to an alternative location or check if the sensor is applied correctly.

RECORDING DATA IN MEMORY (MODEL 34 ONLY)

The pulse oximeter can record pulse oximetry data either intermittently (on upto 20 patients) or automatically every 1 minute for a patient. In addition it has a Sleep Recording mode that can record pulse oximetry data every 5 seconds up to 18 hours for single patient.

CAUTION: Changing the modes of operation will completely erase the previously stored data.

Recording Data Intermittently

The following conditions apply to the Intermittent Recording mode:
- Data can be manually recorded on up to 20 different patients.
- The time and date are recorded with each data entry.
- Recorded data can be either printed or transmitted to a computer.

To record data in memory, the time and the date must be set first . See *"Adjusting the Time and Date Settings"*, in chapter 7, for more information.

To record data intermittently, complete the following three procedures: *"Selecting the intermittent recording mode"*, *"Entering a patient number"*, and *"Recording the Intermittent Data"*.

Selecting the Intermittent Recording mode

1. If the oximeter is on, Power it off

2. Press the down arrow key and power ON/OFF key.

3. After 4 seconds of showing "*int*", the LED DISPLAY will show (—), indicating that all previously stored data of Auto/Sleep Mode has been erased.

Entering Patient Number

When the pulse oximeter is in the Intermittent Recording mode, the patient number from P1 to P20 shows on the LED DISPLAY at power-on, unless a patient number has not been selected.

The patient number can be adjusted or entered when the pulse oximeter is in the Intermittent Recording mode (see *"Selecting the Intermittent Recording Mode"* for more information.)

1. Power on the pulse oximeter, taking note of the patient number that appears for 1 second after power on.(if a patient number has been entered)

   If a patient number has not been entered, the LED DISPLAY will show three dashes (- - -) at power-on.

2. To increase or to enter a patient number, press the down or up arrow key.

   If a patient number has not been entered, and unit is powered on in INT mode from AUTO or SLEEP mode the display shows (**P** - -) indicating no patient number is selected.

Recording the Intermittent Data

The pulse oximeter is ready to record intermittent data when it is in the Intermittent Recording mode and a patient number has been selected (see *"Selecting the Intermittent Recording Mode"* and/or *"Entering a Patient Number"* for more information).

1. Apply the sensor to the patient.

2. Power on the pulse oximeter.

   The patient number (from *P01* to *P20)* will show briefly on the LED DISPLAY, and then the pulse oximeter will begin normal monitoring.

3. To record the data showing on the LED DISPLAY, press the send key.

   The data will flash two or three times to indicate that it has been recorded. Each time the SEND key is pressed, both oxygen saturation and pulse rate data are recorded, regardless of what shows on the LED DISPLAY.

4. To record data under a different patient number, without erasing previously stored data, enter a new patient number and repeat steps 1-3, above.

See "*Entering a Patient Number*" for more information.

The data recorded can be retrieved; either by printing or by transmitting to a computer (see Chapter 6).

Recording Data Automatically on a Single Patient

The following conditions apply to the Automatic Recording mode:

Data is recorded every **1 minute** for a single patient. The time (Hour, Min) and date (Year, Month & Date) are also recorded and the data can either be printed or transmitted to the computer.

To record data in memory the time and the date must be set first. To adjust or set the time and date, see "*Adjusting the Time and Date Settings*" in Chapter 7.

To record data automatically, complete the following two procedures: "*Selecting the Automatic Recording Mode,*" and "*Recording the Automatic Data*".

Selecting the Automatic Recording Mode

1. If the pulse oximeter is on, power it off.
2. Press the DOWN ARROW KEY, and the Power ON/OFF key simultaneously. Either *Int, Ato or SLP* (Intermittent, Automatic, or Sleep Recording mode)shows on the LED DISPLAY.
3. If *Int or Slp* shows on the LED DISPLAY press the UP/DOWN arrow key till *Ato* is displayed. After 4 seconds, three dashes (- - -) shows on both %SpO$_2$ and ♥/min displays. Indicating all previously stored data has been erased, and now the pulse oximeter is ready for monitoring in Auto mode.

Recording the Automatic Data

The pulse oximeter is ready to record automatic data when it is in the Automatic mode (Read "*Automatic Recording Mode*" for more information).
1. Apply the sensor to the patient.
2. Press the power ON/OFF key to power on the pulse oximeter. *Ato* will show briefly on the LED DISPLAY, and then the oximeter will begin normal monitoring.

3. Short press of the SEND/PRINT key would start/stop the recording process. Both the displays will flash once to indicate the commencement of recording.

Erasing stored Data

Press SAT ALARM key and RATE ALARM key together at any time when the unit is ON for about 6 seconds. Both the LED DISPLAYS will blink indicating that the memory is cleared.

CHAPTER 5: RECORDING SLEEP SCREENING DATA
(MODEL 34 ONLY)

SLEEP SCREENING SETUP

CAUTION: If data has been stored under the Intermittent or Automatic Recording modes, changing to the Sleep Recording mode will erase the stored data.

NOTE: Before starting sleep screening process charge the battery fully or use a fresh battery.

1. If the model 34 is on, power it off. Connect the sensor.
2. Press DOWN ARROW KEY & POWER ON/OFF keys together. The current mode is displayed. If **Ato** or **Int** is displayed then scroll using arrow keys till **SLP** is displayed. After about 4 seconds three dashes (- - -) are displayed both in SpO_2 and BPM indicators.
3. Data is stored every 5 seconds upto 24 hrs for a single patient. Switching off the unit in sleep mode can be done by detaching sensor and without key activity for 2 minutes switches off the unit automatically or by pressing the power button.
4. Give the model 34 and a copy of the *"Patient Sleep Screening Instructions"* to the patient for a home sleep study.
   The *"Patient Sleep Screening Instructions"* can be found on a separate sheet included with the model 34, as well as in the following section.
5. To transmit the sleep screening data to a computer, follow the instructions in*"Transmitting Data to a Computer"* in Chapter 6.

   Sleep screening data can be transmitted to a computer and then printed, but it cannot be transmitted directly to an infrared printer.

Patient Sleep Screening Instructions

Your health care provider has given you the Mediaid model 34 pulse oximeter so that you can record your oxygen saturation data while you sleep. Carefully read the following instructions.

1. Place the sensor given along with the model 34 on your right or left index finger so that the transmitting LED lies above the middle of your fingernail.
The angle of the sensor can be opened wider if the fit is too tight. Avoid any constriction of your finger.

2. Tear off a 4-5 inch strip of ¼ or ½ inch paper tape.

3. With the sensor resting comfortably on your finger, wrap the tape around your finger and the sensor.

4. Press the tape against the skin on both sides of your finger.

5. Turn the model 34 on by pressing POWER ON/OFF key.
   The model 34 will display *SLP* for a few seconds and will then start to monitor your oxygen saturation and pulse rate. After about 30 seconds, the display will dim.

6. Place the model 34 next to you while you sleep.

WARNING: **Carefully place the sensor cord so that you do not become entangled while you sleep. Do not attach the sensor cord or the model 34 to the bed or the furniture. The sensor cord and the model 34 should be free to move with you throughout the night.**

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7. Do not remove the sensor from your finger until the study is finished.

NOTE: The model 34 should be carried with you if you get up during the night. Monitoring can continue for as long as 24 hours.

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8. When the study is finished (most likely when you wake up in the morning), turn the model 34 off by disconnecting the sensor – squeeze the tabs on either side of the sensor connector and pull it away from the model 34.

9. Please ensure that the saved data is transmitted to computer/laptop.

CHAPTER 6: DATA RETRIEVAL (MODEL 34 ONLY)
VIEWING TREND

Data can be viewed on the oximeter itself by switching ON the oximeter in the following manner. Press SAT ALARM key and switch ON the oximeter using the POWER ON/OFF key together. The data is displayed depending on the modes. The arrow keys are used for scrolling between time and patient number (in case of intermittent mode).

In Intermittent mode the display is in the following order. First the patient number and the date is displayed in SpO_2 and BPM displays respectively. Next the reading is displayed. After this the time (hour and minute) when the corresponding reading was taken is shown. Arrow keys are used to scroll between readings and patient.

In Automatic mode the display is the following order. First the time (hour & minute) is displayed in SpO_2 and BPM. Next the reading is displayed. Arrow keys are used for scrolling.

In Sleep mode the display is in the following order. First the reading is shown followed by the time (hour and date). Arrow keys are used for scrolling.

> **WARNING:** **If data receiving equipment is not approved for the patient environment (not meeting the requirements of IEC 60601-1), remove the pulse oximeter from the patient environment before transmitting the data.**

Stored data can be retrieved by sending it to a computer or printer via the INFRARED PORT or USB PORT. If the data was stored in the Intermittent or Automatic Recording mode, it can be transmitted to a printer or computer. All patient information remains in memory until erased or until the recording mode is changed.

> **WARNING**: **Do not change the recording modes without first printing or transmitting stored data. Doing so will erase all data stored in memory.**

TRANSMITTING DATA TO A PRINTER

Transmitting pulse oximetry data to a printer requires the model 34 & compatible printer with IR port.

Selecting the Printer Transmission Method

The pulse oximeter has two data transmission methods. To transmit data to a printer, the Printer Transmission method must first be selected.

The pulse oximetry retains in memory the last method selected. To change, go to the Printer Transmission method, complete the following steps.

1. If the pulse oximeter is ON, power it OFF.
2. Hold down the SEND key while simultaneously powering ON the pulse oximeter. Either *Prt* (for transmission to a printer) or *CO* (for transmission to a computer) shows on the LED DISPLAY.
3. If *CO* shows on the LED DISPLAY, press the arrow keys to scroll and select between printer and computer transmission methods.

Printing Stored Data

1. With the Printer Transmission method (*Prt*) selected, power OFF the pulse oximeter, if necessary.
2. If the sensor is attached then remove the sensor.
3. Align the infrared printer to the INFRARED PORT on the model 34.
   The distance between the infrared printer and the INFRARED PORT should be no more than 6 inches.
4. Power ON the printer.
5. Power ON the pulse oximeter.
6. Send the data to the printer by pressing the SEND key on the pulse oximeter.

While data is being transmitted, the LED DISPLAY on the pulse oximeter displays *Prt,* and a printout is obtained.

CAUTION: If the INFRARED PORT on the model 34 is misaligned with the infrared receiver on the printer, data transmission will be incomplete. However, data will not be lost and can be retransmitted.

7. Transmission stops when all data has been received.

TRANSMITTING DATA TO A COMPUTER

Transmitting pulse oximetry data to a computer requires the following:

· The model 34.

· Infrared Data Converter.

· USB Port and Connector.

· A Personal Computer (PC) or Laptop running Windows 2000, ME, XP, or NT 4.0 SP3-SP6.

· Oxysoft™ software installed on the PC.

GETTING READY TO TRANSMIT DATA

Before transmitting data to a computer, make sure that the following conditions have been met.

> *CAUTION:* Do not change the recording modes without printing or transmitting stored data. Doing so will erase all data stored in memory.

● Pulse oximetry data has been stored in memory, using either the Automatic, Intermittent, or Sleep Recording modes.

● Oxysoft software has been installed. To install the software, follow the instructions on the CD package and/or the computer screen. A password is required for installation, which can be found on the back of the CD package.

● Ensure the Infrared Data Converter has been connected to the PC. Connect the serial cable from the IR Data Converter to the PC's COM port. The PC COM port is either a 9- or 25- pin D-shaped male connector, usually located on the back of the computer. It is sometimes labeled "COM1" or "COM2". Alternately a USB port can be used. A USB Cable connects the model 34 to the PC's USB port.

● The Computer Transmission method has been selected for transmitting data (see *"Selecting the Computer Transmission Method"*, in this chapter, for more information).

SELECTING THE COMPUTER TRANSMISSION METHOD

The pulse oximeter has two data transmission methods. To transmit data to a computer, the Computer Transmission method must be first selected.

The pulse oximeter retains in memory the last method selected. To change to the Computer Transmission method, complete the following steps.

1. If the pulse oximeter is ON, power it OFF.

2. Hold down the SEND key while simultaneously powering ON the pulse oximeter.

Either **Prt**(for transmission to a printer) or **CO** (for transmission to a computer) shows on the LED DISPLAY.

3. If **Prt** shows on the LED DISPLAY, press the arrow keys to scroll till **CO** is displayed. Each press of up or down arrow will toggle the pulse oximeter between the Printer and Computer Transmission methods (**Prt** & **CO**).

NOTE: Follow the insturctions of Oxysoft Softwre for proper and successful data transmission.

TRANSMITTING THE STORED DATA

To transmit data to a computer, complete the following steps:

1. Power ON the PC and start the Oxy34 program.
2. Align the infrared port on the Infrared Data Converter with the INFRARED PORT on the model 34.
   The distance between the pulse oximeter and the IR Data Converter should be no more than 6inches.
3. Alternately a USB cable can be used to connect the oximeter and the Computer.
4. On the PC, open the "File" menu, point to "Import", and then click "model 34".
   The "Import Pulse Oximeter Data, Step 1" screen appears.
5. Follow the on-screen instructions, clicking on the "Next > > " button to proceed to the next step.

When the data transmission begins, the pulse oximeter's LED DISPLAY briefly flashes **CO,** the end bars of the LED DISPLAY move from top to bottom, and the "Receive Status" box will flash "RECEIVING". When data transmission is complete, the "Receive Status" box will show "FINISHED".

NOTE: The Infrared Data Converter powers off automatically after 1 minute without any transmission activity. It might be necessary to power it back on if there is transmission delay.

NOTE: Sleep screening data can take several minutes to transfer.

6. After the transmission is completed, on the PC, click the "Exit" button on the "Import Pulse Oximeter Data" window to exit "Import".

NOTE: Data Transmission will be incomplete if the INFRARED PORT on the model 34 is misaligned with the IR receiver on the IR Data Converter or Laptop or Computer. However, data is not lost and can be retransmitted.

CHAPTER 7: CHANGING THE PULSE OXIMETER ' SETTINGS
(MODEL 34 ONLY)

ADJUSTING THE TIME AND DATE SETTINGS

To adjust the time and/or date settings, complete the following steps.

1. If the pulse oximeter is on, power it off.
2. Power on the unit while pressing UP ARROW key simultaneously.
3. Adjust the year parameter while it is displayed, to increase/decrease use the arrow keys.
4. To scroll through the remaining time/date parameters, press the SEND key. The parameters appear in the following order: Year, Month, Day, Hour and Minute.

NOTE: The model 34 uses 24 hour format for time.

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5. Adjust the remaining parameters while they are displayed using arrow keys.
   After 6 seconds without key activity, or press of alarm off key, the parameters are set in memory and the pulse oximeter resumes monitoring.

ADJUSTING THE ALARM SETTINGS

The model 34 has an alarm for low or high readings of SpO_2 or BPM which can be set to the levels as required by the user. The following describes the alarm settings.

Audible Alarm Indicators

The alarm tone is a fixed pitch, and the volume is adjustable. Alarm tones are automatically silenced when the alarm condition goes away.

- HIGH PRIORITY alarm tones sound 0.75 seconds for every three seconds. HIGH PRIORITY alarms are caused by conditions such as: low /high oxygen saturation and pulse rate; no pulse.
- MEDIUM PRIORITY alarm tones sound for 0.75 seconds every five seconds. MEDIUM PRIORITY alarms are caused by measuring problems such as No finger in sensor, or a faulty sensor.
- LOW PRIORITY alarm tones sound for one second every 10 seconds. LOW PRIORITY alarms are caused by disconnected sensor.

Alarm off Key

A short depression of this key silences the alarm for a period of 60 seconds. The ALARM OFF INDICATOR illuminates and remains on constantly, and the oximeter monitors normally. Silenced alarms shall be reactivated by a short depression of the ALARM OFF KEY.

Alarm Off Indicator

The ALARM OFF INDICATOR illuminates and remains on constantly when audible alarms are silenced.

Oxygen Saturation Alarm Key

Short depression of the OXYGEN SATURATION ALARM KEY toggles the LED display between the high and low alarm settings, and respective HI/LO ALARM INDICATOR glow below the key. These alarm settings can be adjusted using UP ARROW and DOWN ARROW KEYS. The alarm settings are retained in memory until reset by the user. Alarm setting can be minimum 85% for Low limit and accordingly 87% for High limit.

The default saturation alarm settings are

	Adults	Neo
High	100%	95%
Low	85%	85%

The display reverts back to normal monitoring after six seconds of key inactivity or Mute key press.

Pulse Rate Alarm Key

Short depression of the PULSE RATE ALARM KEY toggles the LED display between the high and low alarm settings and respective HI/LO ALARM INDICATOR glows below the key. These alarm settings are adjusted using UP ARROW and DOWN ARROW KEYS. The alarm settings are retained in memory until reset by the user.

CAUTION: Each time the monitor is used, check the alarm limits to ensure that they are appropriate for the patient being monitored.

NOTE: Changing the default settings of alarm will retain the changed values until mode (Pressing Rate Alarm and simultaneously powering on the unit, i.e. **neo** or **AdU**) is changed.

CHAPTER 8: OVERVIEW OF THE OPERATING MODES

MONITORING MODE

In the Monitoring mode, the pulse oximeter measures oxygen saturation and pulse rate. The Monitoring mode is entered after the pulse oximeter is powered on and a sensor is applied to the patient.

Intermittent Recording Mode (MODEL 34 ONLY)

In this mode, data can be manually recorded on up to 20 different patients, and a number of data recordings can be entered under each patient number. Data stored in the Intermittent Recording mode can be transmitted to either a printer or a computer via the IR port or USB port.

Automatic Recording Mode (MODEL 34 ONLY)

In this mode data is stored automatically which is started by pressing of the SEND key. The data stored in the Automatic Recording mode can be transmitted to either a printer or a computer via the IR port or USB port.

Sleep Recording Mode (MODEL 34 ONLY)

In this mode, data can be automatically recorded and stored every 5 seconds for up to 18 hours. The data stored in the Sleep Recording cannot be printed, but can be transmitted to a computer via the IR port / USB port on the model 34.

CHAPTER 9: SPECIAL KEY FUNCTIONS
(MODEL 34 ONLY)

POWER ON FUNCTION OF A KEY

Pressing Power ON/OFF key along with other keys

- **To view the stored trend values**
  Press ON/OFF + SAT ALARM KEY. The unit is in this mode till its switched off. The display of the trend values is as following,

1) If the unit is in Automatic mode

i) Hours on the LED1

ii) Minutes on LED2

  Eg: h-represents hours

  n-represents minutes

  | 23h |

  | 50n |

  This display is shown for 3 seconds.

iii) Then it shows the SpO_2 and BPM values in the respective LED position for 3 seconds. It toggles between the Hour/Minute and the data values until the UP/DOWN arrow key is pressed to scroll to the next data. Press and hold UP/DOWN arrow key (for more than 3 seconds), starts scrolling of all the data stored in the memory.

NOTE: On pressing the UP/DOWN ARROW KEY the display of SpO_2 and BPM should be shown only the changed values with respect to the previous values and respective hours & minutes.

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2) For Intermittent mode trend display, display format is given below,

i) Initially it displays Patient data & Date for 3 seconds.

  P represents Patient followed by number

  d represents date

  | P01 |

  | 24 d |

ii)   Then the Hour & Minutes is displayed for 3 seconds.

  h-represents hour

  n-represents minutes

  $$\boxed{23h}$$

  $$\boxed{52n}$$

iii) Then it displays SpO_2 and BPM values in the respective LEDs for 3 seconds.

iv) Then it displays the next reading.

3)   For Sleep mode trend display, display format is given below,

  i)   Initially the readings of SpO_2 and BPM are displayed for 3 seconds.

  ii)   Then it displays the time corresponding to the reading.

● **To change patient mode (Adult/Neonatal)**

  Press ON/OFF KEY + RATE ALARM KEY. The oximeter has two modes for SpO_2 & Rate alarm for two types of patients Adult or Neonatal. The UP ARROW key and the DOWN ARROW key can be used to select the desired setting.

● **To set the date and time**

  Press ON/OFF KEY + UP ARROW KEY. Before using the oximeter for the first time the date and time have to be set. The UP ARROW key and the DOWN ARROW key can be used to change the settings. Pressing send key stores the date/time.

● **To change the mode of operation**

  Press ON/OFF KEY+ DOWN ARROW KEY. Operation mode settings are Sleep, Automatic or Intermittent. The UP ARROW key and the DOWN ARROW key can be used to change the settings.

● **To set Transmission mode**

  Press ON/OFF KEY + PRINT/SEND key. This toggles the transmission Mode between Printer and Computer. The UP ARROW key and the DOWN ARROW key can be used to change the setting.

● **To set alarm volume**

Press ON/OFF KEY + MUTE KEY. To set the alarm volume, the UP ARROW key and the DOWN ARROW key are be used to increase or decrease the alarm. There are 5 levels. The alarm volume can never be decreased to zero. Default Alarm volume is middle level (3 in a scale of 1 to 5).

● **To initiate FUNCTIONAL TEST**

Press ON/OFF KEY + RATE ALARM KEY + SAT ALARM KEY. Turning the unit ON by simultaneously pressing the RATE Alarm key + SAT alarm key will cause the unit to enter the self test mode. Upon entry the SAT Led will show *'Tst '*and the RATE LED will show the test number "0". The test number can be manually selected using UP/ DOWN arrow keys. After 6 seconds of key inactivity or Mute key press, the corresponding testing sequences will start. The following tests will be carried out,

TEST 0   -   Global test, initiates all user assurance tests that can be run.

TEST 1   -   Display and indicator test, each icon and display segment will be activated. (Each segment will be set to ON one by one).

TEST 2   -   Sensor and circuitry test, all sensors and circuits are tested to verify correct operation.

TEST 3   -   Speaker test. This initiates alarm to sound from low volume to high volume.

TEST 4   -   Internal circuitry test, and components are tested. Upon completion, if an internal problem was detected then the display shows "Err2".

TEST 5   -   Internal memory test, tests all internal memory. If this test is passed a display of "software version number" is seen.

● **To erase stored data**

While the unit is ON, if the SAT ALARM KEY and the RATE ALARM KEY is pressed for more than 6 seconds, then all the memory data will be erased. During this time all the LED displays will blink for about two seconds.

CHAPTER 10: SPECIFICATIONS

PERFORMANCE

Heart rate
- Range: 25 to 255 beats per minute (BPM)
- Accuracy: ± 2 BPM or 2% of reading whichever is greater
- Resolution: 1 BPM
- Response time: 4 heart beats

Oxygen saturation
- Range: 0 to 100% saturation (SAT)
- Accuracy: 70 to 100%: ±2 percentage points and
                      ±3 percentage points for neonates*

                      Less than 70%: Unspecified
- Resolution: ± 1 percentage point
- Response time: 4 heart beats

* S.D.(Standard Deviation) is a statistical measure; upto 32% of the readings may fall outside these limits.

ELECTRICAL

Instrument
Power requirements
7.4V, DC power supplied by battery power only

Patient Isolation
No electrical connection to patient (inherently insulated)

Battery
Type & Capacity   Li-ion, 7.4V, 1050mAh

Sensor
Peak Wavelength   Red LED   660+/-2 nM @ 60 uW
                      IR LED   910+/-10nM @ 150uW

ENVIRONMENTAL

Operating Temperature

Instrument	0 to 40°C
Sensor	Within physiologic range for specified accuracy. Refer sensor datasheet.

Humidity

Operating	5-95% noncondensing
Storage	5-95% noncondensing over temperature range of -30°C to 65°C.

Atmospheric Pressure

770 to 282.45 mm Hg or 1026 to 377 hPa

PHYSICAL

Weight	Approx. 200 gm (with batteries installed)
Size	5.5" X 3" X 1.1" (140 X 76 X 27 mm)

EQUIPMENT CLASSIFICATION

Emission compliance	EN 55011, CISPR 11, GROUP 1, Class B
Type of Protection	Internally Powered
Degree of Protection	Type BF
Enclosure Degree of Protection	IPX 1
Mode of operation	Continuous
The equipment is designed to comply with the following additional industry standards of design and manufacture	ISO 13485:2003, ISO 9001:2000, ISO 14971:2000, MDD 93/42/EEC IEC 60601-1-2:2004, IEC 60601-1:1988, ISO 9919:2005, ISO 10993-1:2003, IEC 60601-1-4:1996, ISO 14155-1:2003 & ISO 14155-2:2003

CHAPTER 11: ACCESSORIES

CAUTION: Use of any improper accessories not authorized by Mediaid may damage the unit or cause harm to the user/patient.

SENSORS

Use only Mediaid sensors with the device. Use of other sensors may result in faulty data/injury to the user/damage to the device

S.No.	Sensor	Part Number
1	Universal Hinged Sensor, Compushield connector, 30" cable	POX050-100S
2	Universal Hinged Sensor, Compushield connector, 96" cable	POX050-105S
3	Spot Check Soft Sensor, Compushield connector, 30" cable	POX050-150S
4	Great Toe Sensor, Compushield connector, 96" cable	POX050-220S
5	Small Soft Sensor, Compushield connector, 96" cable	POX050-300S
6	Large Soft Sensor, Compushield connector, 96" cable	POX050-400S
7	Pediatric Soft Sensor, Compushield connector, 96" cable	POX050-310S
8	Earlobe Clip Sensor, Compushield connector, 96" cable	POX050-710S
9	Pediatric Adjustable Sensor, Compushield connector, 96" cable	POX050-530S
10	Tape – On Sensor, Compushield connector, 96" cable	POX050-850S
11	Adult R-Adhesive Sensor, Compushield connector, 96" cable	POX050-905S
12	Pediatric R-Adhesive Sensor, Compushield connector, 96" cable	POX050-820S
13	6 Feet Extension Cable, Compushield to Compushield connector	POX050-600S

CAUTION: Use of damaged/broken sensor may result in faulty or erroneous readings. Reuse of sensors beyond lifetime may deteriorate the performance and hence the sensors must be used within the lifetime mentioned in the sensor instructions.

CAUTION: Reuse of single patient use disposable sensors may result in cross contamination.

Biocompatibility testing

Biocompatibility testing has been conducted on Mediaid sensors in compliance with ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. The sensors have passed the recommended biocompatibility testing and are therefore in compliance with ISO 10993-1.

USB CABLE/CONNECTOR (MODEL 34 ONLY)

MEDIAID Male to Male USB Cable can be used to connect the unit to a PC.

BATTERY CHARGING/AC-DC ADAPTER

Medical Grade charger with the following specifications.

Input: 100-230VAC @ 50/60 Hz

Output: DC 9V @ 1A, 3.5A pk.

BATTERY

Single 7.4 Volt Li-ion battery with a connector.

> *WARNING:* **Please take precautions while attaching or detaching the battery. Attach the connector with correct polarity. Improper attachment could damage the device and may cause harm to the user.**

INFRARED PRINTER (MODEL 34 ONLY)

Mediaid recommends use of ACCESS IR printer for printing the data from model M34. However, any printer with IR capabilities with the following specifications can be use to print the stored data

Specifications

Print Data

Print Method	Line Thermal Dot Printing
Resolution	0.125 mm dots (8 dots/mm)
Effective Printing Area	48 mm
Paper Feeding Pitch	0.125 mm
Printing Speed	18 lines per second
Interface Conformity	InfraRed @ 9600bps

Thermal Paper

Paper Thickness	60 – 72 um
Paper Width	57.5 mm
Recommended Paper	TF60KS-E Nippon Paper
	PDI50 Oji Paper

CHAPTER 12: MAINTENANCE AND MISCELLANEOUS

CLEANING

The pulse oximeter and the sensor can be wiped clean with a soft cloth lightly dampened with isopropyl alcohol, a glutaraldehyde solution, or soap and water. Do not immerse in liquid or allow any liquid to penetrate the interior of the pulse oximeter. Avoid caustic or abrasive cleaners that could damage the case, keypad, or sensors. Use extra care in cleaning the LED DISPLAY window to avoid scratching the finish.

CAUTION: Do not attempt to clean the unit while in use. May result in damage to unit/ user. Before and after every use any excess moisture has to be wiped off.

WARNING: **In case of accidental wetting of the equipment ensure that the equipment is switched off and excess liquid/moisture is wiped off/ cleaned. Allow the unit to dry before using it again. In case of "Not Functioning" or unit not turn ON, contact local Mediaid technical support.**

WARNING: **If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the monitor is functioning correctly.**

CAUTION: Reusing the device/sensor without prior cleaning may result in cross contamination.

LED DISPLAY CODES (MODEL 34 ONLY)

The following is a list of all possible LED DISPLAY codes:

Display Codes	Explanations
Int	Intermittent Recording mode
Ato	Automatic Recording mode
SLP	Sleep Recording mode
Ptr	Transmit to printer
Co	Transmit to Computer
- - -	Memory erased / No signal
Err #	Error Code (**#** = number)

TROUBLESHOOTING

Whenever an error occurs, the pulse oximeter displays the letters *Err* (error) in % SpO$_2$ LED and displays the error code by blinking in BPM LED.

CAUTION: There are no user-serviceable parts or adjustments inside the model 34. Do not attempt to open the instrument voids the Mediaid warranty. Refer to the information in "*Mediaid Problem Correction Plan*", in Chapter 13, for service information.

ERROR CODES

Whenever an error occurs the display shows the letters "Err" and the corresponding error number.

ERROR CODE	ERROR CODE MESSAGE	SOLUTION
2	The instrument will not power off	Remove the battery and contact Mediaid Technical Support
3	The oximeter cannot detect the sensor because of sensor malfunction or sensor not properly attached	Replace/Reattach the sensor. If the error code persists, contact Mediaid Technical Support
4,5,6,7, 8,9,10,12, 13,14,15	An internal failure has occurred	Contact MEDIAID technical support

Performance Considerations

Pulse oximeter readings and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

Inaccurate measurements can be caused by:

- Incorrect application of the sensor
- Placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- Ambient light
- Patient movement

Loss of pulse signal can occur for the following reasons:

- The sensor is too tight
- A blood pressure cuff is inflated on the same extremity as the one with the sensor attached
- There is arterial occlusion proximal to the sensor clean and remove any substances such as nail polish from the application site. Periodically check to see that the sensor remains properly positioned on the patient.
- High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, and direct sunlight can interfere with the performance of a SpO_2 sensor. To prevent interference from ambient light, ensure the sensor is properly applied, and cover the sensor site with opaque material.
- Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

Chapter 13:
Mediaid Inc.
Limited Warranty
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APPLICABILITY OF WARRANTY

This warranty covers only the Mediaid Model 3X Series pulse oximeter and accessories as indicated. It is not extended to other products or components that the customer uses in conjunction with Mediaid products. This warranty shall not apply if the manufacturer determines that the product has been damaged due to abuse, misuse, misapplication, accident, negligence, tampering, or as a result of service or modification by anyone other than an authorized Mediaid Inc. service technician. Opening of the sealed enclosure or altering of the serial number voids the Mediaid Inc. Warranty. Use of equipment contrary to or inconsistent with the User's Manual will also void the warranty.

WARRANTY COVERAGE

Mediaid Inc. warrants that the Model 3X Series enclosed with this warranty will conform to the manufacturer's specifications and will be free from defects in workmanship and materials for a period of 1 year from the date of purchase. Batteries and accessories are excluded from this warranty. The Sensors are warranted according to information on their respective instruction sheets.

This warranty does not cover any damage done to the equipment during shipping, which shall be the sole responsibility of the transportation company.

There are no warranties, expressed or implied, which extend beyond the warranties set forth herein. Mediaid Inc. makes no warranty of merchantability or fitness for a particular purpose with respect to the product or parts thereof. This warranty gives you specific legal rights. You may have other legal rights which vary from state to state (or country to country). Mediaid Inc. will not be liable to the user for incidental or consequential damage or loss arising out of the user's inability to use this product.

MEDIAID INC. PROBLEM CORRECTION PLAN

Should the Mediaid product prove to be defective, contact Mediaid Inc. at:

Mediaid Inc.

17517 Fabrica Way Suite H
Cerritos, CA 90703 USA
(Tel) 714-367-2848
(Fax) 714-367-2852
E-mail: info@mediaidinc.com

Have the product and serial numbers available when calling. Mediaid Inc. will then issue a Return Authorization Number (RAN). Return the pulse oximeter securely packaged in its original shipping carton (or equivalent packaging), and include the RAN.

Mediaid Inc. will repair any faulty workmanship and will either repair or replace (at our option) any defective part with new or refurbished parts. For non-warranty repairs, the customer will be charged the current repair rate at the time of receipt by Mediaid Inc. All transportation charges shall be the customer's responsibility.

ALWAYS READ THE USER'S MANUAL CAREFULLY. The information included in the User's Manual will assist the user in preventing equipment misuse and ensuring patient safety. Operation of the equipment in a manner contrary to or inconsistent with the User's Manual voids the warranty.

OWNER'S REGISTRATION

To assist Mediaid Inc. in better serving the user, please complete the included Warranty Registration Card and return it to:

Mediaid Inc.

17517 Fabrica Way Suite H
Cerritos, CA 90703 USA
(Tel) 714-367-2848
(Fax) 714-367-2852
E-mail: info@mediaidinc.com

Chapter 14:
User References

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CONTACT/CUSTOMER SERVICE INFORMATION

For information on other Mediaid Inc. products, visit the Mediaid Inc. home page on the web at www.mediaidinc.com, or contact us at:

Customer Service & Returns Department

Mediaid Inc.

17517 Fabrica Way Suite H
Cerritos, CA 90703 USA

Telephone

714-367-2848

Fax

714-367-2852

Email

info@mediaidinc.com

PRODUCT INFORMATION

To better assist customers, Mediaid Inc. recommends writing down all pertinent product and warranty information in the spaces provided below:

Model 30 series

Product Number: POX010-30 / POX010-34

Serial Number: _____

Warranty Expiration Date: _____

Universal Hinged Sensor

Product Number: POX050-105S

Serial Number: _____

Warranty Expiration Date: _____

WARRANTY REGISTRATION FORM
Please return to Mediaid Inc. / local distributor for validation

MEDIAID INC.

17517 Fabrica Way Suite H Cerritos, CA 90703 USA
(Tel) 714-367-2848 (Fax) 714-367-2852
Email: info@mediaidinc.com   Website: www.mediaidinc.com

Model _____ Serial Number _____

Date of Purchase _____

Institution/Physician _____

Address _____

   _____

   _____

Contact Department _____

Telephone _____

Distributor _____ Phone _____

Comments _____

   _____

   _____

1007-60001-002