T3 – Clinical Manual

Version 1.1
Latest Revision 19 February 2009
Copyright© 2009
Nox Medical - All rights reserved

Manufactured by:

Nox Medical ehf
Keldnaholti
IS - 112 Reykjavik
Iceland
Website: www.noxmedical.com

Certification:

Distributed by:

Cardinal Health Germany 234 GmbH
Leibnizstrasse 7
97204 Hoechberg, Germany
Website: www.cardinalhealth.com

Cardinal Health
Respiratory Technologies
1100 Bird Center Drive
Palm Springs, California 92262-8099
Website: www.cardinalhealth.com

Copyright Notice

No part of this publication may be reproduced, transmitted, transcribed, stored in a retrieval system, or translated into any language or computer language, in any form, or by any means: electronic, mechanical, magnetic, optical, chemical, manual, or otherwise, without the prior written authorization from Nox Medical.

Disclaimer

This document may contain typographical errors or technical inaccuracies. Nox Medical does not accept any liability for the use or misuse whether direct or indirect of the products, or for damages arising out of the use of or inability to use the products. Users must accept all responsibility for any results obtained by or concluded from data obtained by the products including software from Nox Medical. All clinical conclusions and decisions that are based on the use of this product are the responsibility of the user.
# TABLE OF CONTENTS

Table of Contents ................................................................................................................. 3

Introduction ............................................................................................................................ 5
  Intended Use ......................................................................................................................... 5

The T3 Device ......................................................................................................................... 6

What's included ....................................................................................................................... 7
  Compatible 3rd Party Accessories ..................................................................................... 9

Operating the Device ............................................................................................................. 11
  Connecting the T3 device to a computer ........................................................................ 14

Hooking up the patient .......................................................................................................... 16
  Using 3rd party sensors .................................................................................................. 19

Working with Noxturnal ....................................................................................................... 23
  Installing Noxturnal ....................................................................................................... 23
  Running Noxturnal ......................................................................................................... 25
  Connecting t3 to noxturnal ............................................................................................ 26
  Starting a new Recording ............................................................................................... 27

Downloading A Recording from a t3 Device ........................................................................ 30

Recording Results Page ...................................................................................................... 31

Recording Playback ............................................................................................................ 34

Automatic Analysis ............................................................................................................. 34

Viewing Signals .................................................................................................................... 38

Working with Markers ........................................................................................................ 39

Working with Scorings ........................................................................................................ 41

Viewing Report .................................................................................................................... 42

The Recording Library ....................................................................................................... 47

Archiving Recordings ........................................................................................................ 49

data locations ..................................................................................................................... 50

scoring keyboard shortcuts ............................................................................................ 51

Recording Properties ........................................................................................................ 51
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changing Input Units</td>
<td>52</td>
</tr>
<tr>
<td>Customizing Reports</td>
<td>52</td>
</tr>
<tr>
<td>Changing reporting and Analysis Defaults</td>
<td>53</td>
</tr>
<tr>
<td>Troubleshooting</td>
<td>55</td>
</tr>
<tr>
<td>System Maintenance</td>
<td>57</td>
</tr>
<tr>
<td>Environment</td>
<td>57</td>
</tr>
<tr>
<td>Calibration</td>
<td>57</td>
</tr>
<tr>
<td>Single Use versus Reusable</td>
<td>57</td>
</tr>
<tr>
<td>Cleaning</td>
<td>57</td>
</tr>
<tr>
<td>Regulatory Information</td>
<td>59</td>
</tr>
<tr>
<td>Warnings and Cautions for Use</td>
<td>59</td>
</tr>
<tr>
<td>Guide to Device’s Symbols and Labeling</td>
<td>60</td>
</tr>
<tr>
<td>Bluetooth® Wireless Technology</td>
<td>61</td>
</tr>
<tr>
<td>Specifications</td>
<td>62</td>
</tr>
<tr>
<td>T3 Device Specifications</td>
<td>62</td>
</tr>
<tr>
<td>Abdomen Thorax Cable</td>
<td>63</td>
</tr>
<tr>
<td>Respiratory Effort Sensor</td>
<td>63</td>
</tr>
<tr>
<td>Clip Strap</td>
<td>63</td>
</tr>
<tr>
<td>Filter Tube Connector</td>
<td>63</td>
</tr>
<tr>
<td>Pulse Oximeter Module</td>
<td>64</td>
</tr>
<tr>
<td>Classifications</td>
<td>65</td>
</tr>
<tr>
<td>Certifications</td>
<td>65</td>
</tr>
<tr>
<td>EMC Information</td>
<td>67</td>
</tr>
</tbody>
</table>
INTRODUCTION

Congratulations on choosing the new T3 portable sleep recorder. The T3 is designed for recording physiological signals of patients with suspected sleep breathing disorders. The device is compact, lightweight and easy to use. Simple sensor placement, and customizable instructional diagram, makes setup quick and can be performed by the patient. The system is designed for both adult and pediatric patients.

INTENDED USE

The T3 device is intended for ambulatory recording of physiological signals during sleep. The recorded signals are then downloaded to a computer where the signals can be viewed and analyzed with the Noxturnal application.

The system is intended for use in patients greater than 2 years of age.

The T3 system is NOT intended for any patient monitoring or automatic diagnosis.

The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient’s home.

► Please read this manual carefully before use, especially sections marked with an exclamation mark.
THE T3 DEVICE

The T3 device records signals from five external sensors and three built-in sensors. The external sensors that can be used with the device are abdominal and thoracic respiratory effort sensors, pulse oximeter, and two channels of the following: ECG, EMG or EOG. The built-in sensors include a pressure transducer allowing recording of nasal/mask pressure and snoring, a three dimensional acceleration sensor for measure of patient’s position and activity, and a microphone for true audio recording capabilities. The arrangement of sensors will be determined by the type of recording. The device is worn on the patient’s chest by snapping it to the thoracic respiratory sensor and securing its position with the clip straps. The device is powered with one AA battery. The device has a display for status indication.
WHAT’S INCLUDED

The system consists of a carry bag, compact digital recorder, two respiratory effort sensors, clip straps, USB cable, abdomen thorax cable, filter tube connectors, batteries and a software application called Noxturnal, which is used for communication with the device, analyzing and reviewing of data.

Without additional 3rd party sensors the device allows for recording of respiratory effort, body position, activity and respiratory sound. By use of 3rd party sensors the T3 device is able to record additionally: snoring, nasal or mask pressure, pulse oximeter data and two channels of EOG/EMG/ECG leads. For a list of 3rd party compatible sensors that have been validated with the T3 system; please refer to the section Compatible 3rd Party Accessories.

THE T3 DEVICE

The T3 device interface consists of a display, buttons, sensor inputs/connections and an USB connector. The USB connector is placed under the battery lid making it inaccessible and tamper proof for children. It connects to the USB cable for device configuration and data download. See the figures and tables below for detailed description.

<table>
<thead>
<tr>
<th>Number</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Display.</td>
</tr>
<tr>
<td>2</td>
<td>Push button – Middle – starts/stops recording and selects display options</td>
</tr>
<tr>
<td>3</td>
<td>Push button – Forward – navigates to the next page.</td>
</tr>
<tr>
<td>4</td>
<td>Push button – Backward – navigates to the previous page.</td>
</tr>
<tr>
<td>5</td>
<td>Pressure lock – Connects to external nasal cannula/mask pressure tube via filter tube connector.</td>
</tr>
<tr>
<td>6</td>
<td>Bipolar touch proof inputs – Channel 1.</td>
</tr>
<tr>
<td>7</td>
<td>Bipolar touch proof inputs – Channel 2.</td>
</tr>
<tr>
<td>8</td>
<td>Reference ground input for channels 1 and 2.</td>
</tr>
<tr>
<td>9</td>
<td>Microphone – For recording of respiratory sounds.</td>
</tr>
<tr>
<td>10</td>
<td>Clip strap loops.</td>
</tr>
<tr>
<td>11</td>
<td>Indicator light for device status.</td>
</tr>
<tr>
<td>12</td>
<td>Battery lid – Covers the battery and the USB connector.</td>
</tr>
</tbody>
</table>
Battery compartment pin – Pressed down with a simple tool to open.

14 Metal snaps – Connects to thorax respiratory effort sensor.

15 Metal snaps – Connects to abdomen-thorax cable for abdomen respiratory effort sensor.

CLIP STRAP

The T3 device is equipped with two clip straps, which are fastened to the clothing of the patient to secure the position of the device during the night.

BATTERY

The T3 device is powered by one AA battery. The battery lasts from 8 – 16 hours.

- The recording duration depends on the quality of the battery used.
- Low quality batteries may last up to 8 hours while high quality batteries can last from 16 hours and up.

CARRY BAG

The carry bag is used to store and protect the T3 system during transportation.

RESPIRATORY EFFORT SENSOR (BELT)

The T3 device uses two identical respiratory effort sensors to measure the patient’s respiratory effort. One belt is placed around the patient’s abdomen and the other around the patient’s thorax. The belts are made out of knitted elastic with insulated wire conductor and have a plastic glider for adjustment of belt length. They are terminated with a metal snap at the ends that allows for the connection to the device.

The belts are available in two versions and are adjustable to fit patient circumference from 40cm (16in) up to 205cm (80in).

- The respiratory effort sensors should be worn over night-clothing or a T-shirt.
- The Respiratory Effort Sensor is reusable up to 5 times.

ABDOMEN-THORAX CABLE

The abdomen-thorax cable connects together the abdomen respiratory effort sensor and the T3 device via metal snaps on each end of the cable. The cable is wrapped around the abdomen end for adjustment of length.

USB CABLE

A USB cable is provided with the system and is used to connect the device to the computer.
FILTER TUBE CONNECTOR

The filter tube connector is equipped with hydrophobic filter and serves as a connector tube between the nasal cannula/mask pressure tube and the T3 device.

⚠️ The filter tube connector is single use.

NOXTURNAL DESKTOP APPLICATION

The T3 application (Noxturnal) is used to configure the device for recording, downloading, viewing and analyzing of recorded data. For information on how to use the software, refer to the section Working with Noxturnal.

COMPATIBLE 3RD PARTY ACCESSORIES

This section describes compatible 3rd party sensors and accessories that have been validated with the T3 system.

NASAL CANNULA

The nasal cannula is optional and is used for measuring of airflow pressure and snore. It connects to the pressure lock on the T3 device via the filter tube connector. The following nasal cannulas are compatible with the T3 system:

<table>
<thead>
<tr>
<th>Type</th>
<th>Catalogue Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salter Labs - Adult Cannula</td>
<td>5012</td>
</tr>
<tr>
<td>Salter Labs - Pediatric Cannula</td>
<td>5022</td>
</tr>
</tbody>
</table>

⚠️ The nasal cannula is single use.

MASK PRESSURE TUBE

The mask pressure tube is optional and is used for connection to CPAP mask for measuring of mask pressure. It connects to the pressure lock on the T3 device via the filter tube connector. The following mask pressure tube is compatible with the T3 system:

<table>
<thead>
<tr>
<th>Type</th>
<th>Catalog Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embla Systems - CPAP pressure tubing</td>
<td>1420117</td>
</tr>
</tbody>
</table>

⚠️ The mask pressure tube is single use.
PULSE OXIMETER

The Nonin pulse oximeter is an optional sensor which measures oxygen saturation levels ($\text{SpO}_2$), pulse rate, and plethysmography data. The following pulse oximeter is compatible with the T3 system:

<table>
<thead>
<tr>
<th>Type</th>
<th>Part Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonin Medical - Avant 4100</td>
<td>5166-000</td>
</tr>
</tbody>
</table>

OXIMETER SENSORS

The Nonin oximeter pulse oximetry module supports all Nonin PureLight™ pulse oximeter sensors. The following oximeter accessories are compatible with the T3 system:

<table>
<thead>
<tr>
<th>Type</th>
<th>Preferred Application Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonin’s Models Soft Sensor – Reusable</td>
<td>Fingers, Toe</td>
</tr>
<tr>
<td>Model 8000SL/SL-WO (large)</td>
<td>Fingers, Toe</td>
</tr>
<tr>
<td>Model 8000SM/SM-WO (medium)</td>
<td>Fingers, Toe</td>
</tr>
<tr>
<td>Model 8000SS/SS-WO (small)</td>
<td>Fingers, Toe</td>
</tr>
<tr>
<td>Nonin’s Models Finger Clip Sensor - Reusable</td>
<td>Index, middle or ring fingers</td>
</tr>
<tr>
<td>Model 8000AA – Adult</td>
<td>Index, middle or ring fingers</td>
</tr>
<tr>
<td>Model 8000AP – Pediatric</td>
<td>Index, middle or ring fingers</td>
</tr>
<tr>
<td>Nonin’s Models Ear Clip Sensor - Reusable</td>
<td>Ear lobe</td>
</tr>
<tr>
<td>Model 8000Q</td>
<td>Middle forehead</td>
</tr>
<tr>
<td>Nonin’s Models Reflectance Sensor - Reusable</td>
<td>Index, middle or ring fingers</td>
</tr>
<tr>
<td>Model 8000R</td>
<td>Toel, thumb, medial aspect of hand</td>
</tr>
<tr>
<td>Nonin’s Models Flex Sensor - Reusable</td>
<td></td>
</tr>
<tr>
<td>Model 8000J + 8000JW -Adult Flex Sensor and Wrap</td>
<td></td>
</tr>
<tr>
<td>Model 8008J + 8000JFW -Infant Flex Sensor and Wrap</td>
<td></td>
</tr>
</tbody>
</table>

► Nonin’s Model 8000 Reusable Sensors are indicated for spot-checking and/or continuous monitoring of patients where little sensor motion is expected.
► Refer to the labeling accompanying the oximeter sensor for detailed information.

EXG SENSORS

The T3 device is capable of recording any combination of two ExG channels, that is, EMG, EOG or ECG. The use of electrodes is optional and they connect to the bipolar touch proof inputs on the device. The following electrodes are compatible with the T3 system:

<table>
<thead>
<tr>
<th>Type</th>
<th>Catalogue Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tyco Healthcare - H92SG Kendall</td>
<td>31.1925.21</td>
</tr>
<tr>
<td>Grass Technologies - SURFACE</td>
<td>FH-ESSH-12</td>
</tr>
<tr>
<td>ELECTRODES - Ag/AgCl</td>
<td>FH-ESSH-24</td>
</tr>
<tr>
<td></td>
<td>FH-ESSH-30</td>
</tr>
</tbody>
</table>
OPERATING THE DEVICE

The device has three push buttons (Middle, Backward and Forward) located on the front panel. These buttons are used to get signal status and to view information about the recording taking place. Pressing the Forward button will navigate to the next page and pressing the Backward button will navigate to the previous page. The Middle button is used to start and stop recording. If the T3 device has been configured to View Signal Status, the signal status can be viewed by browsing through different device displays. If any internal error or warning occurs they are displayed on the device display.

MANUALLY STARTING/STOPPING A RECORDING

If you selected to manually start the recording when configuring the device in Noxturnal, you can use the Middle button to manually start a recording. Use the same method to manually stop the recording.

If you specified the duration of the recording when configuring the device the device will automatically stop after the specified duration. The device can contain as many recordings as the internal 1GB memory allows. The current recording count is displayed in the bottom left corner of the display.

STARTING A RECORDING AT A SCHEDULED TIME

If the device is configured to automatically start recording at a scheduled time the patient does not have to take any action for the recording to start. Pressing the Middle button shows the countdown to the specified start of recording.
TESTING SENSORS/GENERAL CHECKS

The indicator light on the device blinks green when recording is in progress and the device is functioning normally. When there are any device warnings the indicator light blinks orange and you can press the middle button to get more information. Warnings might include:

- Battery low
- Oximeter battery low
- Oximeter Probe not on finger

If there are any serious device errors the indicator light blinks red and you can press the middle button to get more information.

TESTING SENSORS/GENERAL CHECKS

Information about the recording and signals status is available from the device display. If the display is turned off pressing the Middle button turns it on. The display will turn itself off after 40 seconds.

When a recording is in progress pressing the middle button shows the duration of the recording. On the top right corner is the battery status and in the bottom left corner is a number showing how many recordings are on the device.
SENSOR CHECKS

If the T3 device has been configured to View Signal Status, the signal status can be viewed by browsing through different device displays. The information presented will depend on the configuration of the T3 device. Note that if the View Signal Status option is not checked the device is in simple operation and only the start page will be shown.

Pressing Forward on the display shows information about the respiratory signals.

1. Abdomen and thorax movement. The movement signals sweep over the screen showing the breathing pattern.
2. Position (Left, Right, Supine, Prone and Upright).
3. Audio, power gauge.

Pressing the Forward button again will show the actual oxygen saturation levels and pulse rate of the patient.

If communication has not been established with the selected oximeter a message is displayed that the device is trying to communicate with the oximeter with certain serial number. Make sure that the serial number of the oximeter used matches the configured serial number. If the oximeter probe is not on the finger or the values received from the oximeter are outside normal range, a message comes up on the display saying Probe not on finger.
Pressing forward button shows the ExG channels: channel 1, channel 2 and the values from the pressure transducer.

Depending on the configuration, either the mask pressure or nasal pressure is shown. The mask pressure shows the average DC value in cmH₂O ranging from 0-20 cmH₂O. The nasal pressure has its DC value removed and shows the pressure values as a signal plot that sweeps over the screen.

1. Mask Pressure or nasal pressure
2. ExG channels, sweep across the screen showing the raw signals.

CONNECTING THE T3 DEVICE TO A COMPUTER

To connect a T3 device to a computer you need to access the USB connector on the device. The USB connector is placed under the battery lid making it inaccessible and tamper proof for children. To open the battery connector, press with a pen or a similar tool on the battery compartment and slide the battery lid towards the bottom of the device. When the battery lid is open a USB connector is visible, connect one end of the supplied USB cable to the device and the other end to the computer. The battery does not have to be inserted while the device is connected to the computer.

When the T3 device is connected to the computer the display lights up and displays a message saying the device is connected to the computer. If Noxturnal is running it will automatically detect the
device. When the device has been successfully configured the message on the display changes to reflect the successful configuration.

When you are done working with the device unplug the USB connector and close the battery compartment by pressing the lid back towards the device without causing any strain, then slide it back into position, towards the top of the device.
HOOKING UP THE PATIENT

PREPARING THE PATIENT FOR A RECORDING

It is assumed that the clinician will demonstrate the use of the T3 device and applicable sensors to the patient, or in the case of pediatrics to the parents, and the hook up then takes place at home by using the T3 hookup card. In some cases the clinician may prepare the patient partly or completely.

Go through the following points with the patient:

1. Attaching device and sensors
2. Testing of sensors’ connections
3. Status indications on the display including warnings
4. Replacement of battery

It is important to remind the patient to follow the instructions given, prior to the recording.

Before sending the patient home:

1. Make sure the device has been prepared correctly
2. Make sure the carry bag contains all equipment needed to finish the recording, including batteries
3. If desired, provide the patient with a customizable hookup card printed from the Noxturnal application

Children should under no occasion hook up the system.
Do not use damaged equipment like sensors or accessories.
As with all medical equipment, carefully route cables and connections to reduce the possibility of entanglement or strangulation.

INSERTING A BATTERY TO THE T3 DEVICE

Before you start a recording you should make sure that the device has a fresh or fully charged battery. To insert a new battery do the following:
1. Open the battery compartment by pressing down the battery compartment pin with a pen or similar tool and slide the lid towards the bottom of the device.

2. Place one AA battery in the compartment aligning the battery poles as illustrated on the back of the device (the positive (+) pole is towards the battery lid).

3. Close the battery compartment by pressing the lid back towards the device without causing any strain, then slide it back into position, towards the top of the device. Make sure the lid is securely closed.

The status of the battery can be checked by turning on the device. The battery status indicator positioned in the upper right-hand corner of the device display allows you to check the battery status.

► To avoid risk of battery leakage, the T3 device should not be stored with battery inserted.
► Always use fully charged or fresh battery for each sleep recording.
► When the battery is running low during a recording the device will automatically stop the recording.

**ATTACHING THE DEVICE AND THE RESPIRATORY EFFORT SENSORS**

**Step 1:** Snap the clips to the patients shirt

**Step 2:** Snap the abdomen cable to the back of the device. Place the respiratory effort sensor around the thorax and snap its ends to the back panel of the device.
Step 3: Use the sliders to adjust the belt length. The slider is fixed by the hook/loop fastener.

![Image of adjustable belt]

Step 4: Adjust the cable length as needed by wrapping it around the abdomen connection unit. Wrap the belt around the abdomen and snap in place.

![Image of cable wrapping around abdomen]

The device is ready to be used. And the hookup should look like this:

![Image of device setup]

- The device and respiratory effort sensors (belts) should be worn over clothing.
- The belts should fit the patient snugly without being uncomfortably tight.

**RECORDING OF RESPIRATORY SOUNDS**

The device uses a built-in microphone to record the patient’s respiratory sounds.
USING 3RD PARTY SENSORS

ATTACHING THE NASAL CANNULA

**Step 1:** Place the nasal prongs gently in the nostrils  
**Step 2:** Pull the cannula tubing over the ears and then position it under the chin  
**Step 3:** Slide the fastener snugly under the chin to hold the cannula tubing securely in place

► The nasal cannula can only be connected to the pressure lock by using a filter tube connector.  
► Medical tape can be used to hold the cannula against the cheeks to secure the cannula in place if necessary.  
► The nasal cannula is single patient use.  
► The filter tube connector is single patient use.

ATTACHING ELECTRODES

The electrodes are placed on applicable locations on the body depending on the type of recording.

► Make sure the skin is clean before attaching the electrode.

PULSE OXIMETER MODULE

Choosing the Appropriate Pulse Oximeter Sensor

Use the measurements provided in the user instructions accompanying the sensor to determine which size of sensor should be used. Sensor size recommendations are based on digit height (thickness).

► Use only NONIN manufactured PureLight™ pulse oximeter sensors. These sensors are manufactured to meet the accuracy specifications for NONIN pulse oximeters. Using other manufacturers’ sensors can result in improper pulse oximeter performance.  
► To avoid the risk of confusing or misinterpreting patient data; verify that the patient module is paired with the correct T3 device.  
► This pulse oximetry system might misinterpret motion as good pulse quality. Minimize finger motion or change the type of sensor being used.
INSERTING BATTERIES INTO THE OXIMETER

The Nonin pulse oximeter requires two AA alkaline batteries.

To insert batteries:

1. Remove the battery cover of the pulse oximeter to open the battery compartment.
2. Place two AA batteries in the compartment aligning the battery poles as illustrated on the bottom of the battery cover.
3. Close the battery compartment. Make sure the cover is securely closed.

- Single use batteries last up to 120 hours of use so it is important to track the number of measurements made with the pulse oximeter. It is recommended to change the batteries after 10 recordings.
- If you are using rechargeable batteries it is recommended that you replace them at the beginning of each week.

ATTACHING THE PULSE OXIMETER MODULE AND SENSOR

Step 1: Attach the sensor to the pulse oximeter module. Press firmly to make sure the sensor is securely connected. The pulse oximeter is automatically activated when an oximeter sensor is connected.

Step 2: Secure the wristband to the patient’s wrist. Insert the selected digit (refer to the sizing recommendations in the user instruction accompanying the sensor) into the sensor. The patient’s digit must reach the end of the sensor.
Step 3: Direct the cable along the patient’s finger/toe, parallel to the arm/leg

Verify proper operation:
- The connection status LED (1) flashes green when a connection is established.
- It flashes amber if no connection is established.

The wristband can be cut in length with to accommodate a variety of patient wrist or ankle sizes.

PRECAUTIONS FOR USE OF THE PULSE OXIMETER

- Proper sensor placement is critical for good performance. If the sensor is not positioned properly, light may bypass the tissue and result in SpO₂ inaccuracies.
- Do not fasten the pulse oximeter too tightly around the wrist. Inaccurate readings and patient discomfort could result.
- To prevent the sensor from falling off secure the wire to the digit with medical tape.
- Do not use a damaged sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.
- Oximeter readings may be affected by the use of an electrosurgical unit (ESU).
- This pulse oximetry system is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin, such as methemoglobin, might affect the accuracy of the measurement.
- To prevent improper performance and/or patient injury, verify sensor and pulse oximeter compatibility before use.
A functional tester cannot be used to access the accuracy of a pulse oximeter monitor or probe.

Factors that may degrade pulse oximeter performance include the following:

- Excessive ambient light
- Excessive motion
- Electrosurgical interference
- Arterial catheter
- Blood pressure cuffs
- Infusion lines, etc.
- Moisture in the sensor
- Improperly applied sensor
- Carboxyhemoglobin
- Methemoglobin
- Artificial nails
- Incorrect sensor type
- Poor pulse quality
- Venous pulsations
- Anemia or low hemoglobin concentrations
- Cardiovascular dyes
- Sensor not at heart level
- Dysfunctional hemoglobin
- Fingernail polish

Refer to instruction for use accompanying the pulse oximeter and oximeter sensor for maximum oximeter application time at a single site.

Refer to instruction for use accompanying the pulse oximeter and oximeter sensor for additional warnings and cautions.
WORKING WITH NOXTURNAL

The Noxturnal application interacts with the T3 device. It allows the configuration of the device as well as navigating, analyzing, and archiving recordings from the device. This section describes the main features of the application and installation instructions.

INSTALLING NOXTURNAL

Before installing the Noxturnal application you should review the system requirements for running the application.

NOXTURNAL SYSTEM REQUIREMENTS

The following tables show the minimum and recommended hardware requirements needed to install and operate the software effectively. The computer used must comply with the international standard EN/IEC 60950 for the safety of Information Technology Equipment.

DESKTOP MINIMUM SYSTEM REQUIREMENTS

<table>
<thead>
<tr>
<th>Hardware Type</th>
<th>Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating System</td>
<td>Windows® XP Home or Professional with Service Pack 2</td>
</tr>
<tr>
<td></td>
<td>Windows® Vista or later versions</td>
</tr>
<tr>
<td>Processor</td>
<td>X86 based Intel or AMD</td>
</tr>
<tr>
<td>Processor Clock Speed</td>
<td>1.7 GHz or faster</td>
</tr>
<tr>
<td>Memory</td>
<td>512 MB or more</td>
</tr>
<tr>
<td>Free Hard Drive Space</td>
<td>500 MB or more</td>
</tr>
<tr>
<td>Graphics Resolution</td>
<td>1024x768 or higher</td>
</tr>
<tr>
<td>USB Port</td>
<td>Yes</td>
</tr>
</tbody>
</table>

LAPTOP MINIMUM SYSTEM REQUIREMENTS

<table>
<thead>
<tr>
<th>Hardware Type</th>
<th>Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating System</td>
<td>Windows® Vista (any version)</td>
</tr>
<tr>
<td></td>
<td>Windows® XP Home or Professional with Service Pack 2</td>
</tr>
<tr>
<td>Processor</td>
<td>X86 based Intel or AMD</td>
</tr>
<tr>
<td>Processor Clock Speed</td>
<td>1.2 GHz or faster</td>
</tr>
<tr>
<td>Memory</td>
<td>512 MB or more</td>
</tr>
<tr>
<td>Free Hard Drive Space</td>
<td>500 MB or more</td>
</tr>
<tr>
<td>Graphics Resolution</td>
<td>1024x768 or higher</td>
</tr>
<tr>
<td>USB Port</td>
<td>Yes</td>
</tr>
</tbody>
</table>

DESKTOP RECOMMENDED SYSTEM REQUIREMENTS

<table>
<thead>
<tr>
<th>Hardware Type</th>
<th>Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating System</td>
<td>Windows® XP Home or Professional with Service Pack 2</td>
</tr>
<tr>
<td>Processor</td>
<td>X86 based Intel or AMD</td>
</tr>
<tr>
<td>Processor Clock Speed</td>
<td>1.2 GHz or faster</td>
</tr>
<tr>
<td>Memory</td>
<td>512 MB or more</td>
</tr>
<tr>
<td>Free Hard Drive Space</td>
<td>500 MB or more</td>
</tr>
<tr>
<td>Graphics Resolution</td>
<td>1024x768 or higher</td>
</tr>
<tr>
<td>USB Port</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Operating System

<table>
<thead>
<tr>
<th>Operating System</th>
<th>Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Windows® Vista (any version)</td>
<td>Windows® Vista (any version)</td>
</tr>
<tr>
<td>Windows® XP Home or Professional with Service Pack 2</td>
<td>Windows® XP Home or Professional with Service Pack 2</td>
</tr>
<tr>
<td>Windows® Server 2003 with Service Pack 1</td>
<td>Windows® Server 2003 with Service Pack 1</td>
</tr>
<tr>
<td>Processor</td>
<td>X86 based Intel or AMD</td>
</tr>
<tr>
<td>Processor Clock Speed</td>
<td>2.0 GHz or faster</td>
</tr>
<tr>
<td>Memory</td>
<td>1 GB or more</td>
</tr>
<tr>
<td>Free Hard Drive Space</td>
<td>2GB or more</td>
</tr>
<tr>
<td>Graphics Resolution</td>
<td>1280x1024 or higher</td>
</tr>
<tr>
<td>USB Port</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**LAPTOP RECOMMENDED SYSTEM REQUIREMENTS**

<table>
<thead>
<tr>
<th>Hardware Type</th>
<th>Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating System</td>
<td>Windows® Vista (any version)</td>
</tr>
<tr>
<td>Processor</td>
<td>X86 based Intel or AMD</td>
</tr>
<tr>
<td>Processor Clock Speed</td>
<td>1.5 GHz or faster</td>
</tr>
<tr>
<td>Memory</td>
<td>1 GB or more</td>
</tr>
<tr>
<td>Free Hard Drive Space</td>
<td>500 MB or more</td>
</tr>
<tr>
<td>Graphics Resolution</td>
<td>1280x1024 or higher</td>
</tr>
<tr>
<td>USB Port</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**INSTALLATION INSTRUCTIONS**

1. Make sure you are logged onto the system with administrator privileges.
2. Browse for a file on the installation CD called **Setup.exe** and run it.
3. A window pops up asking for the installation language. Choose the desired language for the Noxturnal application.
4. Next a wizard opens up that guides the user through the installation. Follow the instruction to install the application.

RUNNING NOXTURNAL

To run the Noxturnal application, double click on desktop icon or click on the application icon in the windows start menu. To close the application click on the X in the top right corner or on the File menu choose Exit.

When Noxturnal starts up the workspace environment is displayed. The environment is divided into several areas: the main menu bar, the application toolbar, the task windows and the sheet windows area.

The workspace window is where you work with T3 devices and the recorded data. A workspace that has no recording open displays the Start Page which guides you through the most common tasks you can perform in the application:
**View Existing Recording**: This option opens up the recording library. The library stores a list of all recordings that have been either downloaded or manually added to the recording library. For more information see the section ‘The Recording Library’

**Start a New Recording**: To start a new recording, select this option. A configuration wizard will guide you through the configuration process. For more information see the section ‘Starting a new Recording’

**Download and View Recording**: If a T3 device is connected and it contains a recording you can download and review the recording on the device. For more information see the section ‘Downloading a Recording from a T3 Device’

**CONNECTING T3 TO NOXTURNAL**

Noxturnal is used to configure and download recorded data from a T3 device. To work with a T3 device you start by connecting it with a USB cable to the computer. Noxturnal automatically detects the device and shows information about the device in the top right corner of the start page. If the device is not detected, click, “Scan for Device”.

---

T3 Clinical Manual

---

~ 26 ~
The device information displayed is: device name, firmware version and recording status. The task you will perform on the device depends on the device status which can be the following:

- **Empty** – The device has not been configured and does not contain any recordings. Click **Start a New Recording** to schedule a new recording.
- **Ready to Record** – The device has been configured but does not contain any recordings. You can disconnect the device and initiate the recording process.
- **Ready to Download** – The device contains a recording that has not been downloaded to the computer. Click on the **Download and View Recording** button to download the recording to the computer.
- **Download Complete** – The device contains a recording that has already been downloaded. Click on **Start a New Recording** to configure the device for another recording. Click on **Download and View Recording** to download the recording again.

To upgrade the firmware on the device click on the **firmware version** link and a dialog wizard will appear. Follow the instructions presented in the wizard on how to upgrade the firmware.

When you are done working with the device click on the **Eject Device** link and unplug the device from the computer.

If a device is connected but does not show up on the start page click the **Scan for Device** link. If that does not work then refer to **Troubleshooting** for more information.

**STARTING A NEW RECORDING**

To prepare a T3 device for a new recording start the Noxturnal application and connect a T3 device to the computer. Noxturnal automatically detects the device and shows information about it on the start
Click on the **Start a New Recording** button on the **Start Page** and a wizard opens up which guides you through configuring the device.

On the first wizard page you specify which channels to record:

- Check **Snore Sound** to record patient respiratory sounds.
- Check **Allow Playback** to allow recorded sound to be played back in the application.
- Check the **Cannula** option to record Nasal Pressure. Select **Mask Pressure** if you are measuring CPAP pressure.
- You can record one or two **ExG** channels. Check **Channel 1** or **Channel 2** to record EXG signals and use the drop-down lists to select the channel type to record. Click **Edit** to create new channel types that are not in the list.
- Check **Oximeter** option to record data from a pulse oximeter. To be able to use a pulse oximeter device it needs to be paired to the T3 device. Select the appropriate oximeter serial number from the drop-down list. If the oximeter you are using is not in the drop-down list, select the entry called “new Bluetooth oximeter” and a dialog box will appear where you can add the serial number of a new pulse oximeter.
- Select the **Show Signal Status on Device** check box if you want to be able view signal status on the T3 display.

Click the **Next** button to move to the schedule recording page where you can schedule the recording time.
• If you check the **Manually Start Recording** option the user is responsible for starting/stopping recordings from the T3 device. This is done by pressing and holding the **Middle** button until the T3 device indicates the recording has started.

• Check the **Start Recording At** option to schedule a specific recording time. The device will turn itself on and automatically start recording at the specified time. If you choose to record for more than one night each recording will start at the same time each night.

• If you want the device to stop recording after a specific **duration** you can specify the **duration** to be either: **6 hours, 7 hours, 8 hours** or enter a **custom** duration. If you choose **unspecified duration** then the user is responsible for stopping the recording. This is done by pressing and holding the **Middle** button until the T3 device indicates the recording has stopped.

Click the **Next** button to continue to the subject information page where you enter information about the patient. The only required field is the patient name or the patient ID. After you have entered the information you can click the **finish button** to write the configuration to the device.

Next, a confirmation page appears confirming the T3 device is configured. The hookup instructions, customized to the options selected, can be printed out by clicking the **Print Hookup Instructions** button and the hookup card will be printed directly on the default printer.
It’s recommended, if you are done working with the device, that you check the Disconnect Device option. This will remove the device from the computer which means you can safely unplug the USB cable and start using the device.

**DOWNLOADING A RECORDING FROM A T3 DEVICE**

To download recorded data from a T3 device to the computer, ensure that Noxturnal is running and connect a T3 device that contains recorded data to a USB port on your computer.

Noxturnal automatically detects the device and shows information about it on the start page. If the T3 device is not detected, click, “Scan for Device”.

Click on the Download and View Recording button on the Start Page and Noxturnal will start downloading the recording from the device to the computer. When the download has completed Noxturnal performs the following actions:

- The recording is copied to a default **data storage location**. You can change the default data storage location on the automation tab in the tools options dialog (Tools – Options – Automation).

- The recording is automatically added to the recording library and can be reviewed any time by going to the recording library and opening it.

- The default automatic analysis is executed on the recording.

- Noxturnal opens up the recording and displays the Recording Results page which gives an overview of the whole recording and the result of the analysis. If the recording spans multiple days, a separate overview is shown for each day.
► If a download partially fails for any reason it can lead to inconclusive recording results. The user will be warned when this happens and needs to decide whether the recorded data is complete or not. It is possible to download the data from the device again. If the problem persists refer to the troubleshooting section.
► The downloaded recording is not deleted from the device until the device is configured for another recording.

RECORDING RESULTS PAGE

After downloading from a T3 device or opening an existing recording in Noxturnal the Recording Results page is shown. This page contains an overview of the most common parameters and signals. This view is automatically updated when changes are made to the existing scoring or if the automatic analysis is applied.

RESULT PAGE COMMANDS

The results page has buttons for the following actions:

- **Close Recording**: This option closes the active recording and returns to the Start Page.
- **Start a New Recording**: Starts the Configure Device wizard which allows you to configure any device which is connected to the computer via USB cable.
- **View Signals**: For browsing through the recorded signals, viewing automatically scored events and manually editing scored markers.
- **View Report**: Shows a report summarizing the recording result parameters. If more than one night has been recorded it will show you options to view a report for a specific night.
- **Print Report**: Prints a report summarizing the recording result parameters. If more than one night has been recorded it will show you options to print a report for a specific night.

PATIENT INFORMATION

The General information panel shows information about the recorded patient. You can edit the recording properties and patient information by selecting the Edit link or by pressing Ctrl+I shortcut key. Refer to Recording Properties for more detailed information.

SLEEP PARAMETERS

The Sleep Parameters panel shows the main analysis parameters and their relation to severity. AHI stands for apneas and hypopneas per hour of rest and ODI is the number of oxygen saturation drops or drops per hour of rest. The severity goes from Normal → Mild → Moderate → Severe and complies with the levels set forth by the AASM. If more than one night has been recorded then these parameters will show the average values for all nights. Refer to Automatic Analysis section for more detailed information about analysis parameters.
SIGNAL OVERVIEW:

The Signal Overview panel is a top down reviewing tool where you can efficiently review and edit recording results. The overview panel is split up into analysis parameters on the left and signal overview on the right. Analysis parameters show common analysis results such as time in bed, AHI etc. for a single night. If more than one night has been recorded then each night is represented within its own panel.

SIGNAL OVERVIEW PARAMETERS

The analysis parameters show a summary of the most common analysis parameters for a single night. Each parameter is color coded based on its severity ranging from green to red, green being a normal value while red is an indication that something might be wrong.

- Sleep quality is measured with the Time in Bed and Estimated Sleep Efficiency. Efficiency ranges from 0-100% where 0% means that the patient was moving the entire night and 100% means that there was no movement. Time in bed is where the patient is lying down and gives normal values for time in bed over 6 hours.

- Respiration is represented by indices. Indices are a method to represent analysis parameters in a standardized way. AHI, AI, HI and Oxygen Desaturation Index (ODI) represent a number of breathing related events per hour of Time in Bed. Snoring Index is the total duration of snoring episodes relative to Time in Bed.
• Quality for the oxygen saturation signal (SpO2) and the airflow signals are represented from 0-100% where 0% means that no good signal is available and 100% means that the entire signal is good.

SIGNAL OVERVIEW SIGNALS AND MARKERS

Signals and markers shown on in the overview panel give an overview of a whole night. Troubled areas are easily located as markers show breathing related events such as sleep apnea and oxygen saturation drops.

• Signals shown on the overview include activity, oxygen saturation (SpO2) and audio volume (Snoring).

• Markers in the overview are apneas (including sub classifications), hypopneas, oxygen saturation drops, snoring episodes and artifacts. Normally these markers show areas where there are breathing disorders.

Moving the mouse cursor over the Time in Bed, Movement, Apneas and Desaturation icons will show more details for the related signal or markers.

CHANGING THE ANALYSIS PERIODS

If a recording starts before the patient has added all the sensors or if the patient removes the sensors before the recording ends you can adjust the interval being analyzed by moving the analysis start and analysis stop markers to the appropriate location. All analysis parameters are updated accordingly when these adjustments are made.

To navigate into the recording use the synchronization marker. All signal sheets such as the Respiration or Pulse Oximeter sheets are synchronized accordingly. If an interesting event is occurring in the overview, drag the synchronization marker and press the View Signals button to view the raw signals.
RECORDING PLAYBACK

There are two ways to play back recorded signals in Noxturnal: **real time** or in **fast** playback mode. To playback the recording you need to switch to either a **signal sheet** or the **result page**. If you are on a signal sheet then the signals scroll across the screen as you play back the recording. If the recording has an audio signal, the audio is played back through the speakers during **real time** playback. If playback is initialized from the **results page**, the time indicator scrolls across the overview and respiratory audio is played if available. Pressing the **space** key toggles playback on and off.

If respiratory audio signal is part of the recording the playback button on the toolbar changes appearance to indicate that audio is available.

AUTOMATIC ANALYSIS

The **Automatic Analysis** analyses the recorded signals and marks sections where significant events are found. These sections are called markers. Each marker has a type, start time and duration.

ANALYSIS PROTOCOLS

An analysis protocol is a set of detectors that detects various events within the recorded signals. There are two default protocols included in the Noxturnal application:

1. **Respiratory Cannula Flow** – Detects the markers listed below. Uses the Flow derived from the Cannula Pressure signal as an input for the Apnea/Hypopnea analysis.

2. **Respiratory RIP Flow** – Detects the markers listed below. Uses the Flow derived from the Abdomen and Thorax RIP belts as an input for the Apnea/Hypopnea analysis.

These protocols detect automatically the following:

- **Apnea**: An 80% drop in flow that lasts at least 10 seconds but no more than 2 minutes.
  - **Obstructive Apnea**: Apnea that is associated with continued or increased inhalation effort throughout its entire period.
  - **Central Apnea**: Apnea that is associated with an absent inhalation effort throughout its entire period.
  - **Mixed Apnea**: Apnea that is associated with absent inhalation effort in its initial portion, followed by resumption of inhalation effort in its second portion.

- **Hypopnea**: A 30% drop in flow that lasts at least 10 seconds but no more than 2 minutes and is followed by a desaturation event. If the saturation input signal is not available or in areas where it is damaged, a hypopnea can be scored without a link to a desaturation event where there is a 60% drop in flow.

- **Desaturation**: A 4% drop in saturation.

- **Snore Train**: At least 3 consecutive increases in the audio signal or the snore signal derived from the Cannula.

- **Paradoxical Breathing**: A period where there is a phase difference between the Thorax and Abdomen belts i.e. the two are not working in harmony. This is often caused by an obstruction in airflow.
You can create and use analysis protocols that use different settings.

**CREATING A NEW ANALYSIS PROTOCOL**

You can create your own analysis protocol by selecting from the main menu bar Analysis - Analysis Protocols - New Protocol which will open up a new Analysis Protocol sheet where you can specify the new protocol. A protocol is a collection of detectors and the function of a detector is to mark areas of interest within a signal and score the areas with markers.

Start by giving the protocol a new name. You can tag the protocol and add a description.

If you want the analysis to stop if any of the detectors fail, then check that option. If that option is not checked remaining detectors will run even of one or more fails.

Now you can add detectors to the protocol. On the left side of the protocol sheet there is a list of available detectors. To add a detector to your protocol, select it and click on the Add Detector button. After adding for example the Apnea/Hypopnea detector it is added to the list on the right side. You can add any number of detectors to a protocol. To remove a detector from the protocol click on the X box in the top right corner of the detector.
The settings section for each detector consists of two tabs: General Properties and Input Signals.

**GENERAL PROPERTIES**

Within the General Properties tab you define the general settings for the detector. Settings vary between detectors and have an impact on how markers are scored. For example: settings for the Apnea/Hypopnea detector include parameters such as the Apnea drop (%), Hypopnea drop (%) and the minimum and maximum duration of these events.

**INPUT SIGNALS**

Each detector works on one or more input signals and scores markers on those signals. The following parameters can be set for each Input Signal:

- **Signal Group** – The list of potential input signals, ordered by priority, to use as an input by the detector. The signal in the group with the highest priority that exists in the recording will be used as the input by the detector.

- **Single Input Source** – Instead of using a Signal Group as input, you can specify exactly the signal that will be used.

- **Remove Artifacts** - When this option is checked, sections in the Input signal where artifacts have been scored will be ignored by the analysis.

- **Remove Invalid Data Sections** - When this option is checked, all periods that coincide with an Invalid Data marker, will be ignored by the analysis.

- **Manual Input Selection** - When this option is checked, the user will be prompted to manually select the input signal when the analysis protocol is executed.

- **Enable Sampling Rate Filter** - When this option is checked, only signals that have a sampling rate that lies within the defined range are used by the analysis.
SAVING THE ANALYSIS PROTOCOL

When you are done editing the protocol, the protocol can be saved by clicking the **Save and Close** button. The **Save and Close** button will only be enabled after the name of the protocol has been set. When the protocol has been saved it is available from the **Analysis** menu.

CREATING A NEW PROTOCOL BASED ON AN EXISTING ONE

A new protocol can be created, that is based on an existing protocol. By basing a new protocol on an existing one, you don’t have to start from scratch but at the same time you are not modifying an existing protocol. To create a new protocol based on an existing protocol, select **Analysis - Analysis Protocol - New Protocol Based on …**

Once that is selected, you will be prompted for an existing protocol to base your new protocol on

Selecting from the list and clicking **OK** will present you with a dialog where you will be prompted for a name for the new Protocol. Enter the name and click the **OK** button. A protocol sheet will open up where you can edit the protocol. Click the **Save and Close** button when you are done editing the protocol.

MANAGING THE ANALYSIS PROTOCOLS

To manage existing protocols or create new ones, select from the main menu **Analysis - Analysis Protocols - Manage Protocols**. This will present you with a dialog where you can create new protocols from scratch or based on existing ones. You can also rename, edit or remove existing protocols.
VIEWING SIGNALS

SIGNAL SHEET

A signal sheet shows one or more signals in a tab window in the workspace. Noxturnal comes with predefined signal sheet such as the Respiratory sheet and the Pulse Oximeter sheet. The user can add or create new sheet layouts by clicking on the Add Sheet button on the application toolbar. To add or remove signals in a signal sheet navigate the mouse to the Signals and Data task window located to the right of the workspace. When the mouse cursor is over this tab the Signals and Data task window will slide out. If you click on the window it will stay there until you click outside of this window. A list of all signals available is listed in the task window. A check box next to the signals determines if the signals are displayed in the sheet or not. Check/Uncheck the box to add or remove the signal from the sheet. The following signals are available:

- Thorax breathing effort (RIP).
- Abdomen breathing effort (RIP).
- Respiratory sound (Audio)
- Audio Volume
- Gravity (3D axis, x, y and z) used for scoring position and movement.
- Oxygen Saturation Levels (wireless pulse-oximeter).
- Pulse (wireless pulse-oximeter).
- Plethysmograph (wireless pulse-oximeter).
- ExG 1 (general purpose input channel).
- ExG 2 (general purpose input channel).
- Mask Pressure or Nasal Pressure, depending on setup.

Additionally some derived signals are generated by the Noxturnal application. These include:

- RIP Sum: the sum of the abdomen and thorax signals.
- RIP Phase: the phase difference between the abdomen and thorax signals in degrees (°).
- RIP Flow: flow derived from the RIP Sum signal, shows the rate of change of the RIP Sum.
- Activity: derived from the X and Y gravity axes.
- Position: derived from the X and Y gravity axes. The position is shown in degrees (°) where supine position is 0°.
- Flow: derived from the Nasal Pressure signal.
- Snore: derived from the Nasal Pressure signal.

WORKING WITH SIGNALS
1. The navigation bar allows you to quickly navigate to any time in the recording. The blue line indicates where you are located in the recording. Click on any location in the bar to jump to that time. Notice there is a moon indicating when it is night time and a sun indicating when it is day time.

2. Time axis displays the recording time and the time period in the window. Right click on the time axis to change the interval in the window; you can stretch the time axis with the mouse to change time interval in the window.

3. The synchronization marker located on the time axis is used to synchronize with other signal sheets and views. The clock on the right side of the navigation bar shows the time of day of the marker position. The synchronization marker can be dragged and moved in time.

4. Signal value axis shows the name of the corresponding plotted signal and the value axis scale. The axis can be stretched with the mouse. To change the properties of the value axis double click on axis and a dialog will appear where you can change the properties.

5. Shows the signal plot in the window. Signals can be adjusted in many ways. The user can resize the signal pane or move the signal pane around by using the mouse. To change the properties of the signal double click on the signal and a dialog will appear where you can change the signal properties.

You can also navigate in the signal sheet by pressing the Left/Right arrow keys which scroll the window half a screen page at a time. The Page-Up/Page-Down keys move whole screen pages at a time.

WORKING WITH MARKERS

Markers are used to identify areas of interest in a signal. A marker has a start and stop time and a type used to classify it. Markers can either be manually added to a signal or scored by the automatic analysis to flag areas of interest. Markers can be modified or removed by the user.

SCORING A MARKER

To score a marker go to a sheet containing signals; locate an area on a signal of interest. 1. With your left mouse button, highlight an area which you want to score the marker on. 2. Press the shortcut key for that marker. For example to score an oxygen desaturation marker press the D key.
An alternative method for scoring a marker is to highlight with the left mouse button, as before, but then right clicking on the area and selecting a marker from the list.

DELETING A MARKER

There are several ways to delete existing markers.

- Select a marker by left clicking it and then press the Delete key.
- Right click on a marker and select Remove Marker.
- Select an area with the mouse that intersects with the markers you want to delete and press the delete key.

MOVING A MARKER

To move a marker to a different location, select the marker by holding down the left mouse button and then drag the marker to the desired location. Markers can be dragged between signals as well as to a different period.

RESIZING A MARKER

To resize a marker, move the mouse cursor over the left or right boundary of a marker. The mouse cursor should change to an icon of an arrow pointing right and left. Once the icon has changed to an arrow, left click and drag the marker to the desired duration.
NAVIGATING MARKERS

There are several ways to navigate the scored markers in the recording:

- You can jump between the markers that have been scored on a signal by clicking on the signal and pressing the Tab key which jumps to the next marker in time. To jump to the previous marker in time press the Shift + Tab key.

- In the top right corner of the workspace there is a search text box which allows you to search for any markers that have been scored. Clicking on the textbox shows a dropdown list of all the marker types that have been scored. To search for markers of some type click on the marker type in the list. This shows the next marker in time with that type. Click on the navigation buttons in the drop down list to navigate the markers.

- Select View – Marker Overview to bring up an overview window that shows all the markers in a plot that have been scored in the recording. To navigate to a specific marker, click on it in the overview plot.

WORKING WITH SCORINGS

A scoring is a collection of markers that are scored signals in the recording. The actions for working with scorings are located under the Data menu and in the Scorings task window located on the right of the workspace window. The actions you can take while working with scorings are listed in the following sections.

SELECTING A SCORING

Multiple scorings can be associated with a recording. All available scorings are listed in the scorings panel. You can select the active scoring by clicking on it.
SAVE SCORING

You can save the active scoring by clicking on the Save Scoring link. You will be prompted for a name for your saved scoring. The saved scoring will be added to the scorings list.

CLEAR SCORING

If a scoring is active, this action will clear it. If the active scoring has local modifications, you will be prompted on whether you want to save your local modifications.

REVERT SCORING

If a scoring has local, unsaved modifications, these modifications can be reverted. This means that the scoring will be returned to the state it was in when it was loaded.

DELETE SELECTED SCORING

A saved scoring can be deleted by selecting it from the scoring list and clicking on the Delete Selected Scoring link. A prompt will come up, asking whether it is ok to delete the scoring.

EDIT SCORING TAGS

A scoring tag is a label that can be attached to a scoring for future use. You could for example add the tag reviewed to scorings that have been reviewed.

VIEWING REPORT

Reports show a summarized report of the analyzed data. There are two ways to run reports in Noxturnal:

1. Click on the View Report button on the start page. This will create the default report.
2. Choose a report from the Reports menu.

New reports are shown in a sheet in the workspace. Generated reports remain fixed and are not updated automatically when the analysis of the recording changes. If changes are made to the analysis another report can be generated. You can add as many reports to the workspace as necessary.

RESPIRATION REPORT

The default report that is generated when you click on the View Report button on the start page is the Respiration Report.
The Respiration report contains a summary of sleep disorder breathing parameters such as apnea and hypopnea index (AHI). The summary is broken down into events occurring during the entire recording and when in supine, since most sleep breathing disorders are more severe while the patient is sleeping supine.

RESPIRATION REPORT SECTIONS

**Patient Information**: This section contains information about the patient such as the patient name, ID, date of birth and the patient address. The units used in height and weight are displayed in cm or inches, kilogram or pounds depending on the selected unit system. Refer to Changing Input Units on how to change active unit system.

**Recording Information**: displays Information about the recording time and time in bed.

- **Recording Date** – The date of the recording. If a recording spans multiple nights the recording date of the first night is used.
- **Recording Time** – The time of the recording in hours and minutes.
- **Recording Duration** – The total duration of the recording. If a recording spans multiple nights then the duration is calculated from the start of the first night until the end of the last night.
- **Bed Time Starts** – The time the patient goes into bed, i.e. when he goes from an upright position to a horizontal position. If a recording spans multiple nights then Bed Time Starts is shown for each night. **Bed Time Ends** – The time when the patient gets out of bed, i.e. when changing from a horizontal position to an upright position. If a recording spans multiple nights then Bed Time Ends is shown for each night.
- **Time in Bed** – Duration spent in bed, indicated by the time during the night in which the patient is in a horizontal position. If a recording spans multiple nights then each **Time in Bed** is shown.

**Respiration Overview**: Overview of the most common calculated parameters from the recording. The background of the parameters is color coded, from green to red, depending on the severity.

- **AHI** – Apnea Hypopnea Index, the number of apneas and hypopneas per hour of time in bed.
- **ODI** – Oxygen Desaturation Index, the number of scored oxygen saturation drops per hour of time in bed.
- **Snore Index** – Total duration of snore episodes as a percentage of time in bed.

**Respiratory Indices**: Reports on respiratory related parameters in relation to time in bed.

- **Apnea Hypopnea Index** - Number of apneas and hypopneas per hour of time in bed and per hour of time in bed in supine position.
- **Apnea Index** – Number of apneas per hour of time in bed and per hour of time in bed in supine position.
- **Hypopnea Index** – Number of hypopneas per hour of time in bed and per hour of time in bed in supine position.
- **Snore Index** – Total duration of snore episodes as a percentage of time in bed and as a percentage of time in bed in supine position.

**Respiratory Count**: Reports on respiratory events which occur during time in bed.

- **Apneas** – The number of apneas including all subtypes, obstructive, mixed and central, which occur during time in bed and during supine position.
- **Obstructive** – The number of obstructive apneas which occur during time in bed and during supine position.
- **Central/Mixed** – The number of mixed apneas and central apneas which occur during time in bed and during supine position.
- **Hypopneas** – The number of hypopneas which occur during time in bed and during supine position.

**Pulse Oximetry**: Pulse Oximetry related events which occur during time in bed.

- **Desaturation Index** – Number of oxygen saturation drops which occur during time in bed and during supine position.
- **Average SpO2** – The average oxygen saturation value during time in bed and during supine position.
- **Average Pulse** – The average pulse or heart rate value during time in bed and during supine position.
- **Desaturation <= 90%** - The number of oxygen saturation drops where the saturation drop ends lower than or equal to 90
- **Desaturation <= 85%** - The number of oxygen saturation drops where the saturation drop ends lower than or equal to 85

**Signal Quality**: Shows overall signal quality. The signal quality ranges from 0-100% where 100% is the best quality. The table below maps the quality value to quality string.
• **SpO2 Signal** – Overall signal quality of the oxygen saturation signal. Quality is measured from the presence of signal dropouts and artifacts located during analysis.

• **Pulse Signal** – Overall signal quality of the Pulse signal. Quality is measured from the presence of signal dropouts and artifacts marked during analysis.

• **Cannula Flow Signal** – Overall signal quality of the Cannula Flow signal. Quality is measured from the presence of signal dropouts and artifacts located when no breathing is present in the pressure signal.

• **RIP Flow Signal** – Overall signal quality of the RIP Flow signal. Quality is measured from the presence of signal dropouts and artifact located where the RIP flow is flat lined.

**Position and Activity:** Shows the duration of various patient positions

• **Supine Time** – The total duration in minutes where the patient is in the supine position and in relation to the time in bed duration.

• **Non-Supine Time** – The total duration in minutes where the patient is not in supine position and is not upright. This duration is also shown in relation to the time in bed duration.

• **Upright Time** – The total duration in minutes where the patient is upright and in relation to the time in bed duration.

• **Activity Time** – The total duration in minutes of the patient movements, which exceeds a specific threshold, as defined by the analysis protocol.

**Other:** Shows a combination of different elements such as paradoxical breathing index, estimated sleep efficiency and CPAP pressure if available.

• **Paradoxical Index** – Total duration of paradoxical breathing events where the phase difference between the abdomen and thorax signals is greater than 40° (depends on the analysis protocol). The index is the total paradoxical breathing duration in relation to the total time in bed duration.

• **Est. Sleep Eff.** – Estimated sleep efficiency. The total bed time where the patient is not moving in relation to the total bed time.

• **CPAP Pressure** – If mask pressure is available the average CPAP pressure is shown for both the time in bed period and the supine time in bed period. The mask pressure has a unit of cmH2O.

**Trend Overview:** Shows the overview of signals and scored markers for the night. The overview is a combination of signals, markers as bars and markers showing their duration. Below is a summary of the overview components.

• Movement markers

• Activity signal

• Position markers (Supine, Prone, Left, Right and Upright)
- SpO2 signal or oxygen saturation signal
- Desaturation markers, oxygen saturation drops of 4% or more (depending on the analysis protocol used)
- Pulse signal
- Snore markers
- Audio Volume signal
- Paradoxical Breathing markers
- RIP Phase signal
- CPAP Pressure signal (in the Respiration Report CPAP)

**Patient Notes:** If notes have been added to the recording properties, they are displayed in this section. Refer to **Recording Properties** for more information.

**Technician Notes:** Notes added to the technician properties under the recording properties are displayed in this section. Refer to **Recording Properties** for more information.
PRINTING REPORTS

After a report has been generated you can print the report. To print a report select the report to print in the workspace tabs. Click on the Print button on the report toolbar to print out the report to a printer. A window will open where you can change the printing options. Click the Print button when the settings have been adjusted.

EXPORTING REPORTS

To export a report, select the appropriate report tab in the workspace window. When you have the report selected, click File - Export Sheet... This will open a new window to specify what file format file name. Click the Save button when done and the report will be saved to disk in the file format you specified. The available formats are:

- Pdf (default)
- Excel
- Html
- Rich text

THE RECORDING LIBRARY

The Recording Library shows and manages all the recordings that have been downloaded from T3 devices. When recordings are opened or downloaded in Noxturnal they are automatically added to the recording library.
To open a recording, select it from the list by either double-clicking on the entry or click the open recording button in the info pane.

To manually add recordings to the library do the following:

1. Go to the Library tab.
2. Click on the Add button and select the Add Recordings to Library.
3. A browse for folder dialog will open where you can navigate through your folders and files. Navigate until you find the desired folder or file then click OK.
4. The file/folder will be scanned for recordings then added to the library.

To remove recordings from the library do the following:

1. Go to the Library tab.
2. Select the recordings you wish to remove from the library.
3. Press <Delete> on the keyboard or right click and select Remove Recording.
4. If you are in a custom recording set the recording will be removed from that set.
5. If you are in the All Recordings set the recording will be removed from the library.
6. Recordings from date recording sets cannot be removed.

Removing a recording from the library does not delete the data permanently. The recording is simply removed from the library. To delete a recording permanently from the disk locate the recording in windows explorer and delete it from there.

The Search Box allows you to search for specific recordings. Enter the search criteria and the recording list will update automatically with the matching entries. You can search for most properties in the recording. Put space between search terms to search using more than one recording property.

The recording sets view shows the available recording sets. A recording set is a folder that contains one or more recordings. Click on a recording set to show the recordings in that set.

Noxturnal has the following default sets:

a. All Recordings - All the recordings that are in the library.
b. Today - The recordings that have been recorded today.
c. This Week - The recordings that have been recorded this week.
d. This Month - The recordings that have been recorded this month.
e. This Year - The recordings that have been recorded this year.
f. Older Recordings - contains all recordings that are older than one year.

You can create your own custom sets by clicking on the Add button and selecting Add New Folder. You will be prompted to give the new folder a name. When the folder is created you can drag recordings from other folders to the newly created folder. To delete custom datasets click on the dataset and press <Delete>. Please note: When adding new recordings to the library they are always added to the default recording sets and to the selected custom recording set.
The **Information Panel** shows information about the selected recording. From the information panel you can also **archive** the selected recording or **open** it.

Click on the **Home Page** button to get back to the start page view.

**ARCHIVING RECORDINGS**

Recordings stored in the recording library can be archived to a different location or to a permanent storage. To archive a recording select a recording in the library and click on the **Archive Recording** button on the **recording information** panel. The following dialog will appear guiding the user through the archiving process:

![Archive Recording Dialog](image)

1. Start by choosing between selecting a predefined **Archiving locations** or entering the path to a folder where the archive is to be stored. You can also press the **…** button to manually browse for a folder location.

To create new archive locations that will be shown in the dropdown, refer to the **data locations** section on how to create archive locations.

2. Then you choose a name for the archive. The Default name used is the recording name with the archive date added to it.

3. If you want compress all the files in the recording into a single **zip** file then check the **Compress recording to a ZIP file** option. The zip file minimizes disk space required to store a recording and is recommended if you are storing recordings on a backup media.

Click the **Next** button to move onto the next wizard page. The second page asks you which files in the recording you want to archive. By default all the files in the recording are selected. If a file should not be archived uncheck the file.
Click the Finish button to start the archiving process. A progress dialog will appear showing the progress. You can click cancel at any point during the archiving progress by clicking the Cancel button but this will leave you with an unfinished archive which needs to be manually removed.

DATA LOCATIONS

Data locations are used when archiving recordings and are used as shortcuts in the open recording dialog (File – Open Recording). To create a new data or archive location, choose Tools – Options from the main application menu. In the Option dialog that appears select the Data Locations property page.

Click on the Add Location button to add a new data location. A dialog will appear where you can choose the location. If you want the location to be an archive location, check that option. Archive locations are used within the archiving process to quickly select archiving locations.

After adding the name and location select OK. When you are done working with the data locations click OK in the Tools Options dialog.
SCORING KEYBOARD SHORTCUTS

To change keyboard scoring shortcuts select Edit – Scoring Shortcut Keys from the application main menu. A Scoring Shortcut Keys dialog appears.

To change an existing shortcut or add a new one locate the desired marker and add the shortcut to the Shortcut key input box and click the Assign Key button. To help you locate the marker quickly that you want to edit use the search edit box to find the desired marker. A shortcut key is used to score markers quickly when reviewing and analyzing the recording. As a general rule markers should only have a keyboard character as a shortcut, but a combination of Ctrl, Shift and Alt plus a keyboard character is supported.

When all desired shortcuts have been added select the OK button to finish.

RECORDING PROPERTIES

To view and edit the recording properties press Ctrl +I or select File – Recording Properties from the application main menu. The Recording Properties dialog contains several property pages to edit different aspects of the recording properties. These include:

Subject Information: On this property page you can edit the patient information, which includes the following fields:

- **ID** - The patient identifier. This could be an internal hospital number or a system identifier.
- **Full Name** – Patient full name. There are no restrictions on the patient name.
- **Social Security Number** – The social security number is different from country to country, so this field is not fixed and will accept all input.
- **Date of Birth** – The date of birth can be edited directly with the number keys (e.g. 02→02→1970 equals the 2nd of February 1970, here → stands for the right arrow key).
- **Body Metrics** – This includes weight and height. The options for system units are: US lbs. or metric. Refer to **Changing Input Units** on how to set the appropriate input units.
- **Gender** – includes male, female and unknown

**Subject Address** - On this property page you can add or **change** the existing subject address information.

**Notes** – Here you can enter information regarding the patient or the recording.

**Technician Notes** – Technicians can add comments and their name which will appear in the reports.

**Recording Info** – This page shows an overview of recording related parameters. These parameters include:

- **Path** – Location of the recording on disk.
- **Recording Start** – Start time of the recording.
- **Recording Stop** – End time of the recording.
- **Recording Duration** – Total duration of the recording, from recording start to recording stop.
- **Tags** – Tags which can added to the recording for identification. Searches for recordings in the Recording Library are based on tags.
- **Recording Format** – The data type of the recording. For T3 Noxturnal the data type is NOX.

### CHANGING INPUT UNITS

1. To change the **System Units** select **Tools – Options** from the main application menu
2. On the **General** property page locate the **System Units** drop down list
3. For kilogram and centimeter input fields select the **Metric System**. For pound and inch input fields select **US System**.
4. Select **OK** to finish.

### CUSTOMIZING REPORTS

To change the report logo and company information that is used in reports, choose **Tools – Options** from the main application menu. In the Option dialog that appears select the **User & Company** property page.
1. **User Information** – General information about the current user of the system. This can be left blank as it will not show up on the default reports.

2. **Company Information** – Information about the clinic, hospital or company publishing the report. The **Address** field can have multiple lines. Press **Alt+Enter** inside the input field to add new lines.

3. **Logo** – The reports can display a small logo on the top right margin of each page. To change the logo either type in the full path into the input field or click the **Browse** button. The optimal logo image size is 220 pixels wide and 50 pixels high. Larger images will be scaled down to fit either the optimal width or optimal height. In some cases pictures with higher resolution will give a higher quality print.

4. Select **OK** to finish.

### CHANGING REPORTING AND ANALYSIS DEFAULTS

To change the reporting and analysis defaults choose **Tools – Options** - from the main application menu. In the Option dialog that appears select the **Automation** property page.
1. **Data Location** – This field shows you the default data location where downloaded recordings are stored. To change to a new data location either type in the full path or click on the button and browse for a new location.

2. **Analysis** – Specifies the analysis protocol that is executed when recordings are downloaded from a T3 device. To change protocols choose a new one from the dropdown list or leave blank if no analysis protocol is to be executed. Refer to the Analysis Protocols section for more information on analysis protocols.

3. **Reports** – Specifies the default report that can be viewed and printed directly from the Recording Results Page.

4. Select **OK** to finish.
TROUBLESHOOTING

This section provides information on troubleshooting the system. If the system does not operate correctly after following these steps and the problems persists contact technical support.

PROBLEMS INSTALLING NOXTURNAL

• When installing the Noxturnal application the user needs to be logged into the computer with administrator privileges. This is required as some files are copied to shared locations. If you don’t have access to an administrator account, contact the administrator of the computer for assistance.
• If installing the software fails, uninstall the previous version and reinstall the software.

PROBLEMS COMMUNICATING WITH A T3 DEVICE

There are a few possible reasons that you might have problems connecting and communicating with a T3 device. Start out by checking for the following issues:

• Check cable connections. Make sure the USB cable is firmly connected to the T3 recording device, and make sure the USB cable is firmly connected to the USB port of the computer
• Perhaps the selected USB port is not providing sufficient power. Try connecting the USB cable to another port on the computer, preferably an externally powered USB hub.
• The USB cable can malfunction, try a different cable
• The T3 device works as a standard USB mass storage device when connected to the computer. There could be problems with the USB drivers on the computer. Check if other USB devices are working on the computer. If not then this is an operating system problem and you should consult the operating system manual for help on troubleshooting USB devices.

If the above does not fix the issues the file system on the device could have become corrupt. This can happen for example if the device is not properly ejected from the computer. Symptoms of this might include:

• Noxturnal fails recognize the device.
• Operating system errors occur when connecting the device.
• Problems configuring the device.
• Problems downloading recordings from the device.

There are two possible ways to fix this issue:

1. If there are any recordings on the device you should try the following first: When a T3 device is connected to the computer it appears as a standard storage disk to the operating system. Locate the disk in the operating system and run the operating system command scan and fix errors. Refer to the operating system help on how to perform this task. (Search for “chkdsk” in the windows help).

2. If that doesn’t work try to reset the device to factory settings: First, connect the T3 device to a computer and Click the forward button. You should see the following on the device display:
To format and reset the device to factory settings hold down the middle button for a few seconds and follow the instructions displayed on the device display.

![Image](image.jpg)

- Resetting the device to factory settings will erase all recordings that are on the device, and if they have not been downloaded they will be lost.

## PROBLEMS VIEWING RECORDING RESULTS

- A report might come up empty if no printer is setup on the computer. To fix this, install any printer driver and make it your default printer. The report uses the page size from the default printer to render reports.

- If recording parameters are always shown as zero (AHI, Snore Index, ODI etc), this normally indicates that the automatic analysis has not been executed successfully. To fix this try the following:
  - Select **Analysis** → **Analysis Protocols** → **Manage Protocols** and remove the **Respiratory RIP Flow** and **Respiratory Cannula Flow**. Restart the application. This will reset the analysis protocols to the installation defaults. Run either of these protocols to determine if the problem is solved.
  - Select **Edit** → **Configuration** → **Signal Types & Groups**. From the dialog that appears remove all the signal groups. Close Noxturnal and open it again. This will reset all signal groups to the installation defaults. Run either of the default protocols to determine if the problem is solved.
SYSTEM MAINTENANCE

No special maintenance of the T3 system is needed.

▶ Remove batteries if the system is not used within 30 days.

ENVIRONMENT

The T3 should be stored in a clean, dry place. Handle the T3 device with care and protect it against mechanical shocks, dirt and liquids. The device is not waterproof or splash proof. Refer to the section specification regarding detailed environmental conditions.

CALIBRATION

The T3 device is factory calibrated. No further calibration needed.

SINGLE USE VERSUS REUSABLE

The following table includes information regarding which system components and accessories are reusable and which are single use. See instructions provided by Original Equipment Manufacturer (OEM) for more detailed information. Regarding cleaning of reusable components please refer to the sections below or to the appropriate OEM instruction.

<table>
<thead>
<tr>
<th>Component/Accessory</th>
<th>Use/Reuse</th>
</tr>
</thead>
<tbody>
<tr>
<td>T3 Device</td>
<td>Reusable</td>
</tr>
<tr>
<td>RIP belts for respiratory effort (adult and pediatric)</td>
<td>Reusable up to 5 times</td>
</tr>
<tr>
<td>Filter tube connector</td>
<td>Single Use Only, Disposable</td>
</tr>
<tr>
<td>Abdomen – Thorax Cable</td>
<td>Reusable</td>
</tr>
<tr>
<td>Clip Straps</td>
<td>Reusable</td>
</tr>
<tr>
<td>USB Cable</td>
<td>Reusable</td>
</tr>
<tr>
<td>Probes or Flexi Wrap for oximetry</td>
<td>Refer to OEM Instructions</td>
</tr>
<tr>
<td>Tubing and cannula for pressure sensing</td>
<td>Single Use Only, Disposable; refer to OEM instructions</td>
</tr>
<tr>
<td>Electrodes and electrode cables</td>
<td>Refer to OEM Instructions</td>
</tr>
</tbody>
</table>

CLEANING

No part of the T3 system requires sterilization.

**T3 Device:** Clean the device with a soft cloth dampened with hospital grade cleaner that is not corrosive to plastic or metal. Do not pour or spray any liquids onto the device, and do not allow any liquids to enter any openings in the device. Allow the unit to dry thoroughly before use.

**Cables:** Clean the cables with a moist cloth using hospital grade cleaner. Do not immerse the cables in liquid and avoid contact of the cleaning solution with the connectors.
**Pulse Oximeter Module:** Clean the module with a soft cloth dampened with isopropyl alcohol. Do not pour or spray any liquids onto the device, and do not allow any liquids to enter any openings in the device. Allow the unit to dry thoroughly before use.

**Pulse Oximeter Sensor (Model 8000):** Unplug the sensor from the pulse oximeter module before cleaning or disinfecting. Clean the sensor by wiping all patient contact surfaces with a soft cloth dampened in water or a mild soap solution. To disinfect the sensor, wipe all patient contact surfaces with isopropyl alcohol (IPA).

For other types of pulse oximeter sensors refer to the sensor package inserts.

**Respiratory effort sensors:** Belts can be hand washed or machine washed in a wash bag using mild detergent. Water temperature should not exceed 30°C/86°F. Do not tumble dry.

**Nasal cannula:** The cannula is single patient use and shall not be sterilized.

**Filter tube connector:** The filter tube connector is single patient use and shall not be sterilized.

---

**Important Notes:**

- Clean the device separately from its associated sensors.
- Do not autoclave or immerse any device equipment or sensor in any kind of liquid.
- Do not use caustic or abrasive cleaning agents on the units.

**DISPOSAL**

Follow local governing ordinances and recycling instructions regarding disposal or recycling of this device and accessories, including batteries.

- According to the regulation in Europe on Waste of Electrical and Electronic Equipment (WEEE) the equipment and its’ accessories may not be disposed of as unsorted municipal waste. The equipment shall be collected separately and returned to the appropriate collection system available.
- Please contact your distributor regarding take-back or recycling of the equipment.
WARNINGS AND CAUTIONS FOR USE

► The device is **NOT CERTIFIED TO BE USED FOR CONTINUOUS MONITORING** where failure to operate can cause injuries or death of the patient. The term **CONTINUOUS MONITORING** is specified in the standard IEC60601-1.

► This system is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

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

► This system complies with international standards IEC60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of interference due to close proximity or strength of source might disrupt the device’s performance. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to information detailed in the EMC Information section of this manual.

► The T3 system does not increase the safety risk for pacemaker patients as long as the pacemakers comply with the EN50061 standard of electrical safety of medical devices. Nevertheless, prior to using the system with pacemaker patients, the operator should consult the pacemaker’s accompanying documents regarding its certifications and requirements of use or, if necessary, contact the producer.

► The device is classified as ordinary equipment regarding ingress of liquids, that is, it is not drip-proof, splash-proof or watertight. During use of the device avoid all unnecessary contact with moisture.

► The device is not defibrillator proof.

► Do not use any part of the system in an MRI (Magnetic Resonance Imaging) environment.

► The device and its accessories should be removed from the patient before download of data.

► No user serviceable parts inside the device. Serviced by authorized parties only. Warranty void if opened.
GUIDE TO DEVICE’S SYMBOLS AND LABELING

► Consult instructions for use.

► Caution, consult accompanying documents.

► Manufacturer.

► Do not reuse.

► Serial number.

► Batch code.

► Type BF applied part (patient isolation from electrical shock).

► IN COMPLIANCE WITH THE EUROPEAN DIRECTIVE ON WASTE OF ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE) 2002/96/EC, DO NOT DISPOSE OF THIS PRODUCT AS UNSORTED MUNICIPAL WASTE.

► Non ionizing electromagnetic radiation. Equipment includes RF transmitter: INTERFERENCE may occur in the vicinity of equipment marked with this symbol.

► Federal Communications Commission (FCC) logo

► CE marking indicating conformance to EC directive No. 93/42/EEC concerning medical device.

► FCC ID: V5AASDB1

Contains TX IC: 1520A-LMX9838

► Industry Canada (IC) label.

T3 ASDB1 or ASDB1US

► Brand name/Model name

Revision: XXXX

► Technical name

► Version of device

► Bluetooth® wireless technology

► Do not reuse.
The T3 device uses Bluetooth® wireless technology to receive signals from the Nonin Pulse Oximeter. The Bluetooth® wireless technology is based on a radio link that offers fast and reliable transmission of data. Bluetooth® radio uses globally available frequency range in the ISM band, intended to ensure communication compatibility worldwide and a fast acknowledgement and frequency-hopping scheme to make the link robust, even in noisy radio environments. Please refer to the Specifications section for details on RF specifications for the T3 device and Nonin Pulse Oximeter.
## T3 DEVICE SPECIFICATIONS

<table>
<thead>
<tr>
<th>Description</th>
<th>Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Function</strong></td>
<td></td>
</tr>
<tr>
<td>Storage capacity</td>
<td>1GByte</td>
</tr>
<tr>
<td>Recording time</td>
<td>Nominal 24 hours with new or fully charged battery</td>
</tr>
<tr>
<td>Number of channels</td>
<td>Eight</td>
</tr>
<tr>
<td>Internal channels</td>
<td>Thorax Respiratory Effort Sensor</td>
</tr>
<tr>
<td></td>
<td>Abdomen Respiratory Effort Sensor</td>
</tr>
<tr>
<td></td>
<td>Pressure channel</td>
</tr>
<tr>
<td></td>
<td>Respiratory sound/snoring channel</td>
</tr>
<tr>
<td></td>
<td>Two bipolar channels (EXG)</td>
</tr>
<tr>
<td></td>
<td>Position</td>
</tr>
<tr>
<td></td>
<td>Activity</td>
</tr>
<tr>
<td>External channels</td>
<td>Nonin oximeter via Bluetooth</td>
</tr>
<tr>
<td><strong>Physical</strong></td>
<td></td>
</tr>
<tr>
<td>Device Dimension</td>
<td>79mm (3.11&quot;) W, 63mm (2.48&quot;)H, 21mm(0.83&quot;) D</td>
</tr>
<tr>
<td>Weight</td>
<td>65 gram (88 gram with battery)</td>
</tr>
<tr>
<td>Bipolar inputs</td>
<td>Touch proof DIN 42-802</td>
</tr>
<tr>
<td></td>
<td>±8mV input range AC</td>
</tr>
<tr>
<td><strong>Power</strong></td>
<td></td>
</tr>
<tr>
<td>Power Source</td>
<td>One 1.5V AA battery</td>
</tr>
<tr>
<td></td>
<td>Host PC (Data Download)</td>
</tr>
<tr>
<td>Battery Type</td>
<td>- Alkaline primary</td>
</tr>
<tr>
<td></td>
<td>- Alkaline rechargeable</td>
</tr>
<tr>
<td></td>
<td>- Nickel-metal hydride (NiMH)</td>
</tr>
<tr>
<td><strong>Display</strong></td>
<td></td>
</tr>
<tr>
<td>Type</td>
<td>OLED</td>
</tr>
<tr>
<td>Display Dimension</td>
<td>19x35mm</td>
</tr>
<tr>
<td>Resolution</td>
<td>128x64 dots</td>
</tr>
<tr>
<td><strong>Environmental Condition</strong></td>
<td></td>
</tr>
<tr>
<td>Temperature</td>
<td>Operation: +5°C to +50ºC (40°F to 120º F)</td>
</tr>
<tr>
<td></td>
<td>Storage: -20°C to +50ºC (0°F to 120º F)</td>
</tr>
<tr>
<td>Rel. Humidity</td>
<td>Operation: 15-95% (non-condensing)</td>
</tr>
<tr>
<td></td>
<td>Storage: 10-95% (non-condensing)</td>
</tr>
<tr>
<td>Pressure</td>
<td>Withstands atmospheric pressures from 0.5 to 2 bar</td>
</tr>
<tr>
<td><strong>Transmitter</strong></td>
<td></td>
</tr>
<tr>
<td>Bluetooth® compliance</td>
<td>Version 2.0</td>
</tr>
<tr>
<td>Operating frequency</td>
<td>2.402-2.480 GHz</td>
</tr>
<tr>
<td>Output Power</td>
<td>&lt; 1.62 mW</td>
</tr>
<tr>
<td>Network Topology</td>
<td>Point-to-Point: Point-to-Multipoint</td>
</tr>
<tr>
<td>Operation</td>
<td>Scatter-Net Master</td>
</tr>
<tr>
<td>Antenna Type</td>
<td>Internal</td>
</tr>
<tr>
<td>Modulation Type</td>
<td>Frequency Shift Keying</td>
</tr>
<tr>
<td></td>
<td>Frequency Hopping Spread Spectrum</td>
</tr>
</tbody>
</table>
Bandwidth 1 MHz

**Material**
- Enclosure ABS/PC
- Snaps Stainless steel
- Pressure port Stainless steel

### ABDOMEN THORAX CABLE

<table>
<thead>
<tr>
<th>Description</th>
<th>Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical</strong></td>
<td></td>
</tr>
<tr>
<td>Length</td>
<td>57mm</td>
</tr>
<tr>
<td><strong>Material</strong></td>
<td></td>
</tr>
<tr>
<td>Cable jacket</td>
<td>PVC</td>
</tr>
<tr>
<td>Enclosure material</td>
<td>ABS</td>
</tr>
</tbody>
</table>

### RESPIRATORY EFFORT SENSOR

<table>
<thead>
<tr>
<th>Description</th>
<th>Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical</strong></td>
<td></td>
</tr>
<tr>
<td>Size</td>
<td>Pediatric version adjustable from 40cm to 110cm</td>
</tr>
<tr>
<td></td>
<td>Adult version adjustable from 70cm to 205cm</td>
</tr>
<tr>
<td><strong>Material</strong></td>
<td></td>
</tr>
<tr>
<td>Belt</td>
<td>Polyester</td>
</tr>
<tr>
<td></td>
<td>Latex free</td>
</tr>
<tr>
<td>Slider</td>
<td>Polypropylene (PP)</td>
</tr>
<tr>
<td>Snap wire</td>
<td>Spring steel</td>
</tr>
</tbody>
</table>

### CLIP STRAP

<table>
<thead>
<tr>
<th>Description</th>
<th>Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical</strong></td>
<td></td>
</tr>
<tr>
<td>Length</td>
<td>55mm +/-5mm</td>
</tr>
<tr>
<td><strong>Material</strong></td>
<td></td>
</tr>
<tr>
<td>Cord</td>
<td>Polyester</td>
</tr>
<tr>
<td>Clip</td>
<td>Steel</td>
</tr>
</tbody>
</table>

### FILTER TUBE CONNECTOR

<table>
<thead>
<tr>
<th>Description</th>
<th>Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical</strong></td>
<td></td>
</tr>
<tr>
<td>Filter</td>
<td>Hydrophobic Filter with Female Luer Lock Inlet - diameter of 13 mm, with a 0.2 μ filtering capability</td>
</tr>
</tbody>
</table>
### Environmental

| Storage     | Store in a cool dry place |

### Material

<table>
<thead>
<tr>
<th>Filter</th>
<th>Acryl</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tube</td>
<td>TPE/PVC</td>
</tr>
</tbody>
</table>

### PULSE OXIMETER MODULE

#### Description

| Properties |

#### Range

<table>
<thead>
<tr>
<th>Description</th>
<th>Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxygen Saturation Range (%SpO2)</td>
<td>0-100%</td>
</tr>
<tr>
<td>Pulse Rate Range</td>
<td>18-300 pulse per minute</td>
</tr>
</tbody>
</table>

#### Accuracy

<table>
<thead>
<tr>
<th>Description</th>
<th>Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Oxygen Saturation (%SpO2) ( ± 1 S.D.)</td>
<td>70-100% ± 2 digits for adults using 8000AA-WO Finger clip sensor</td>
</tr>
<tr>
<td>Pulse Rate</td>
<td>± 3%</td>
</tr>
</tbody>
</table>

#### Display

| Connection status LED | Amber or green |

#### Measurement Wavelengths and Output Power

<table>
<thead>
<tr>
<th>Description</th>
<th>Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red</td>
<td>660 nanometers @ mW nominal</td>
</tr>
<tr>
<td>Infrared</td>
<td>910 nanometers @ mW nominal</td>
</tr>
</tbody>
</table>

#### Internal Power

<table>
<thead>
<tr>
<th>Description</th>
<th>Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery</td>
<td>Two 1.5V AA batteries</td>
</tr>
<tr>
<td>Operating Life</td>
<td>Minimum 120 hours of continuous operation with new batteries</td>
</tr>
<tr>
<td>Storage Life</td>
<td>10 months</td>
</tr>
<tr>
<td>Weight</td>
<td>4.4 ounces with batteries (125g)</td>
</tr>
</tbody>
</table>

#### Environmental Condition

<table>
<thead>
<tr>
<th>Description</th>
<th>Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>Operation: 0°C to +50°C (32°F to +122°F) Storage/Transportation: -30°C to +50°C (-22°F to +122°F)</td>
</tr>
<tr>
<td>Operating Altitude</td>
<td>Up to 40,000 feet</td>
</tr>
<tr>
<td>Humidity</td>
<td>Operation: 10-90% (relative humidity, non-condensing) Storage/Transportation: 10-95% (relative humidity, non-condensing)</td>
</tr>
<tr>
<td></td>
<td>If transferred from a non-operating temperature and/or humidity condition, allow at least one hour of stabilization time before use.</td>
</tr>
</tbody>
</table>
Hyperbaric Pressure: Up to 4 atmospheres
Antenna Type: Inverted F type antenna
Antenna Gain: +2 dB (typical), +3 dB (max)

**Transmitter**

- Bluetooth® compliance: Version 1.1
- Operating frequency: 2.4-2.4835 GHz
- Output Power: < 1.1 mW
- Operating Range: 10 meter radius indoors
- Network Topology: Point-to-Point
- Operation: Slave: Model 4100
- Antenna Type: Internal
- Modulation Type: Frequency Shift Keying, Frequency Hopping Spread Spectrum
- Bandwidth: 1 MHz

**CLASSIFICATIONS**

- Degree of protection (applied part) against electric shock: The device is classified as of type BF.
- Powering of device: The device is internally powered.
- Mode of operation: The device is intended for CONTINUOUS OPERATION.
- Degree of protection against ingress of liquids: The device is classified as an ordinary equipment regarding ingress of liquids, i.e. it is not drip-proof, splash-proof or watertight.
- Use with Flammable Anaesthetics: The device is not suitable for use in presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN or NITROUS OXIDE.
- Installation/use of device: The device is classified as a portable device.

**CERTIFICATIONS**

The T3 device complies with the following directives and standards:

- Annex V of the **Medical Device Directive 93/42/EEC** and is certified by BSI to carry the CE label
- **ISO 13485:2003** Medical devices – Quality Management systems – Requirements for regulatory purposes. The manufacturing site of the T3 device is certified according to ISO 13485.
- **UL 60601-1** Medical Electrical Equipment - Part 1: General Requirements for Safety (USA)
- **CAN/CSA C22.2 NO. 601.1 - M90** Medical Electrical Equipment - Part 1: General Requirements for Safety (Canada)
<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC 60601-2-26: 2002</td>
<td>Medical electrical equipment. Part 2-26: Particular requirements for the safety of electroencephalographs</td>
</tr>
<tr>
<td>ISO 14971: 2007</td>
<td>Medical devices - Application of risk management to medical devices</td>
</tr>
<tr>
<td>ISO 15223: 2000</td>
<td>Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied.</td>
</tr>
<tr>
<td>IEC 60950-1: 2001</td>
<td>Information technology equipment – Safety - General requirements</td>
</tr>
<tr>
<td>ETSI EN 300 328 V1.7.1: 2006-10</td>
<td>Electromagnetic compatibility and Radio Spectrum Matters (ERM); Wideband Transmission systems; Data transmission equipment operating in the 2.4 GHz ISM band and using spread spectrum modulation techniques</td>
</tr>
<tr>
<td>ETSI 301 489-17 V1.2.1: 2002-08</td>
<td>Electromagnetic compatibility and radio spectrum matters (ERM); Electromagnetic compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for 2.4 GHz wideband transmission systems and 5 GHz high performance RLAN equipment</td>
</tr>
<tr>
<td>21CFR898</td>
<td>FDA PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES</td>
</tr>
<tr>
<td>EN 50371</td>
<td>Generic Standard to Demonstrate the Compliance of Low-Power Electronic and Electrical Apparatus with the Basic Restrictions Related to Human Exposure to Electromagnetic Fields (10 MHz–300 GHz) – General Public</td>
</tr>
<tr>
<td>RSS 210 of IC</td>
<td>The device complies with RSS 210 of Industry Canada (IC)</td>
</tr>
<tr>
<td>RSS-GEN Issue 1</td>
<td>The device complies with RSS-GEN Issue 1 of Industry Canada (IC)</td>
</tr>
<tr>
<td>Bluetooth® compliance (SIG)</td>
<td></td>
</tr>
</tbody>
</table>
EMC INFORMATION

► This product emits radio frequency energy, but the radiated output power of this device is far below the FCC radio frequency exposure limits. Nevertheless, the device should be used in such a manner that the potential for human contact with the antenna during normal operation is minimized.
► Caution: Exposure to radio frequency radiation.
► Portable and mobile RF communications can affect the performance of the device.
► The device should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
► Electrostatic discharges (ESD) may cause artifacts in the signal from the device. Avoid conditions where electrostatic charge can build up because of low humidity and friction against carpets, clothing and sheets made from artificial fibers.
► The use of accessories, sensors, and cables other than those listed in this manual may result in increased emission and/or decreased immunity of this device.
► This system may be interfered with by other equipment, even if that equipment complies with CISPR emission requirements.
► Refer to the tables in this section for specific information regarding the device’s compliance to the standard IEC60601-1-2

DECLARATION OF CONFORMITY WITH USA FEDERAL COMMUNICATIONS COMMISSION (FCC) AND CANADIAN MINISTRY OF HEALTH RULES FOR ELECTROMAGNETIC COMPATIBILITY

The T3 device complies with Part 15 of the FCC Rules and RSS 210 of Industry Canada. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference, including interference that may cause undesired operation of this device.

For questions regarding your product or this FCC declaration, please contact:

Cardinal Health
Respiratory Technologies
1100 Bird Center Drive
Palm Springs, California 92262-8099
Telephone: 800.231.2466 or 1.714.283.2228
Fax: 1.714.283.8493
www.cardinalhealth.com
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by tuning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the distance between the equipment and the receiver.
- Connect the equipment to outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

MODIFICATION STATEMENT

The FCC requires the user to be notified that any changes or modifications not expressly approved by Nox Medical could void the user’s authority to operate the equipment.

SPECIFIC ABSORPTION RATE (SAR)

Ministry of Health (Canada), Safety Code 6: standards include substantial safety margin designed to ensure the safety of all persons, regardless of age and health. The Specific Absorption Rate or SAR is a measure of the rate at which electromagnetic energy is absorbed into the body. The SAR limit for the general public is 1.6W/kg for the trunk and 4W/kg for the limbs.
**GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC EMISSIONS**

**Guidance and manufacturer’s declaration – electromagnetic emissions**

The T3 system is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 2</td>
<td>The T3 device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class B</td>
<td>The T3 system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/ flicker emissions</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC IMMUNITY**

**Guidance and manufacturer’s declaration – electromagnetic immunity**

The T3 device is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>±6kV contact ±8kV air</td>
<td>±6kV contact ±8kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60Hz) magnetic field</td>
<td>3A/m</td>
<td>3A/m</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of T3 device, including cables, than the recommended separation distance calculated from the equation applicable to</td>
</tr>
<tr>
<td>IEC 61000-4-8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

~ 69 ~
the frequency of the transmitter.

<table>
<thead>
<tr>
<th>Conducted RF</th>
<th>3Vrms</th>
<th>3Vrms</th>
<th>$d = 1.2\sqrt{P}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC 61000-4-6</td>
<td>150kHz to 80MHz</td>
<td>$d = 1.2\sqrt{P}$</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Radiated RF</th>
<th>3V/m</th>
<th>3V/m</th>
<th>$d = 2.3\sqrt{P}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC 61000-4-3</td>
<td>80MHz to 2.5GHz</td>
<td>$d = 2.3\sqrt{P}$</td>
<td></td>
</tr>
</tbody>
</table>

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:

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

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

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the T3 device is used exceeds the applicable RF compliance level above, the T3 device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the T3 device.

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

**RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE T3 DEVICE**

<table>
<thead>
<tr>
<th>Rated maximum output</th>
<th>Separation distance according to frequency of transmitter</th>
</tr>
</thead>
<tbody>
<tr>
<td>150kHz to 80MHz</td>
<td>800MHz to 2.5GHz</td>
</tr>
</tbody>
</table>
For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

<table>
<thead>
<tr>
<th>power of transmitter $W$</th>
<th>80MHz $d = 1.2\sqrt{P}$</th>
<th>800MHz $d = 1.2\sqrt{P}$</th>
<th>$d = 2.3\sqrt{P}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td>0.12</td>
<td>0.12</td>
<td>0.23</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
<td>0.38</td>
<td>0.73</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
<td>1.2</td>
<td>2.3</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
<td>3.8</td>
<td>7.3</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
<td>12</td>
<td>23</td>
</tr>
</tbody>
</table>