

NOX W7 LINK KITS

Instructions for Use

Introduction

The Nox W7 LINK KITS come in three different versions and can be used with the Nox recording devices when configured for an ambulatory study. Note there is a slight difference in the configuration dependent on if the Nox T3 recorder or Nox A1 recorder is used (Refer to section Instructions for Use).

• Nox W7 LINK KIT - A

To be used with:

- Resmed AirSense™10

• Nox W7 LINK KIT - R

To be used with:

- Radiometer TCM4, TCMCombIM, TCM40, TCM TOSCA
- Nonin RespSense
- Resmed S9™

• Nox W7 LINK KIT - S

To be used with:

- SenTec Digital Monitor (Software SMB07.0x and SMB08.00)

The Nox W7 LINK KIT packages include:

- Nox W7 LINK (Uncord Serial Port Plug F2M01SXA)
- Power Adapter (FW7721M/05)
- USA Plug Adapter
- European Plug Adapter
- UK Plug Adapter
- Nox USB Mini Cable
- DB9 Male to Male Mini Null Modem
- Nox User Instruction Leaflet

Intended Use

The Nox W7 LINK is a Medical Device Data System (MDDS) and allows for electronic conversion and wireless transfer of medical device data between an auxiliary medical device and a Nox recording device. The Nox W7 LINK is connected to a serial port of an auxiliary medical device. Before the data is transmitted over Bluetooth® link to the applicable Nox recording device it is converted from serial to Bluetooth format.

Scope

This leaflet is designed to instruct users on how to use the Nox W7 LINK with supported auxiliary devices.

Warnings and Cautions

- Warning: Do not use damaged equipment, sensors or accessories. This may result in bad performance of the Nox W7 LINK or patient/operator injury.
- Warning: The Nox W7 LINK is not certified to be used for continuous monitoring where failure to operate can cause injuries or death of the patient.
- Warning: The RF function of the Nox W7 LINK might influence the performance of other devices in close proximity and lead to potential serious harm.
- Warning: Only use the medical grade power adapter provided by Nox Medical as part of the Nox W7 LINK KIT package to power the Nox W7 LINK. The use of other power adapters may result in electric shock or overheating of the power adapter/burns.
- Warning: Use of the Nox W7 LINK with auxiliary devices that have not been validated by Nox Medical may result in electric shock. Always use the Nox W7 LINK with validated auxiliary devices. Auxiliary devices need to comply with applicable IEC 60601-1 safety standards for medical electrical equipment.
- Warning: Do not use the Nox W7 LINK KITS in a Magnetic Resonance Imaging (MRI) environment. That might lead to serious patient harm.

Instructions for Use

1. Preparing a Study with the Nox W7 LINK

When configuring a Nox recording device for an ambulatory study with the Nox W7 LINK in the Noxturnal software, the applicable Nox W7 LINK is added by entering its Bluetooth address in the relevant field. Two different addresses are used, depending on if the Nox A1 recorder is being used or the Nox T3 recorder:

Nox A1 Recorder: The Nox W7 LINK's Bluetooth address (BDA) is used and has 12 digits. The BDA can be found on the Nox W7 LINK's label.

Nox T3 Recorder: The Nox W7 LINK's serial number (SN) is used and has 9 digits. The SN can be found on the Nox W7 LINK's label.

2. Connecting to a Resmed S9™/AirSense™10 Device

The Nox W7 LINK is connected to the serial interface output located on the Resmed Embletta Adapter. The Nox W7 LINK has thumbscrews which can be used for more secure placement. For thumbscrews use a 4mm flat screwdriver.

Note: The supported modes are AutoSet and CPAP.

3. Connecting to a Radiometer Device

The Nox W7 LINK - R includes a DB9 male to male mini null modem. Connect the null modem to the Nox W7 LINK, use thumbscrews for secure placement. For thumbscrews use a 4mm flat screwdriver. Connect the applicable serial port extension cable (available from Radiometer) to the Radiometer device and connect the Nox W7 LINK to the serial interface located on the extension cable.

4. Connecting to a Nonin RespSense Device

The Nox W7 LINK KIT - R includes a DB9 male to male mini null modem. Connect the null modem to the Nox W7 LINK. Connect the Nox W7 Link to the serial interface output located on the side of the Nonin RespSense. Use the thumbscrews for secure placement. For thumbscrews use a 4mm flat screwdriver.

5. Connecting to SenTec Digital Monitors

The Nox W7 LINK KIT - S includes a DB9 male to male mini null modem. The null modem is connected to the serial interface output located at the back of the SenTec device. Connect the Nox W7 LINK to the null modem. Use thumbscrews for more secure placement. For thumbscrews use a 4mm flat screwdriver.

6. Starting a Study

- Connect the Nox W7 LINK to the applicable auxiliary device as instructed above (Step 2, 3, 4 or 5) and make sure the Nox Mini USB cable is connected to the NOX W7 LINK and the Power Adapter (FW7721M/05).
- Turn on the auxiliary device. The blue LED on the link starts blinking.
- Turn on the Nox recording device.
- The green LED on the NOX W7 LINK starts blinking, indicating Bluetooth connection with the Nox recording device.
Note: Establishing Bluetooth connection may take up to 2 minutes.
- Now a Bluetooth connection has been established between the Nox recording device and the auxiliary device. The auxiliary device's signals are being recorded.

States of the Nox W7 LINK's LEDs

The NOX W7 LINK is equipped with two LEDs. The green LED indicates the status of the transmission. It blinks when the device is communicating with the Nox recording device. It is steady when the device is on standby. The blue LED indicates that the auxiliary device is streaming data to the device.

Maintenance

When the Nox W7 LINK is not in use, disconnect it from auxiliary devices and store in a dry place.

Environmental Conditions

Operation:

Temperature: 0 °C to +40 °C (+32 °F to +104 °F)
Relative Humidity: 15-95% (non-condensing)
Atmospheric Pressure: 700 hPa - 1060 hPa

Storage:

Temperature: -20 °C to +70 °C (-4 °F to +158 °F)
Relative Humidity: 10-95% (non-condensing)
Atmospheric Pressure: 700 hPa - 1060 hPa



Disposal

According to the regulation in Europe on Waste of Electrical and Electronic Equipment (WEEE) the equipment 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 sales representative regarding take-back or recycling of the equipment.

Cleaning

The Nox W7 LINK tolerates cleaning with a soft cloth moistened with a mild soap solution.

Technical Specifications

Nox W7 LINK

- Physical Size: 36x17x60 (WxHxL) mm
- Voltage Range: 5-30V DC
- Current Consumption (max): 300mA
- Baud Rate: Configured up to 230400 baud/s
- Operating Frequency: 2402-2480 MHz
- Transmit Power: -8 to 16 dBm
- Sensitivity at 0.1% BER: -90 dBm
- Range: 10m in line of sight when used with Nox recording devices

Mini Null Modem

- DB9 Male to Male Mini Null Modem Adapter

Power Adapter (FW7721M/05)

- Input voltage 100 to 240 V AC (± 10%)
- Input current 200 to 100 mA
- Frequency 50 to 60 Hz
- Efficiency 80% typ. at full load
- Output 5V DC/1.5A
- Exchangeable plug system: European, UK, USA

Nox USB Mini Cable

- Mini-B plug
- Standard-A plug

Nox W7 LINK KITS

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Certifications

The Uncord Serial Port Plug F2M01SXA is certified according to CE and FCC regulations and is fully Bluetooth® certified as an end product (QDID: B012540).

Uncord Serial Port Plug F2M01SXA complies with the requirements of R&TTE Directive 1999/5/CE, the European Community Directive 73/23/EEC and 93/68/EEC

- EN 300 328
- EN 301 489-1/-17
- EN 60950

The power adapter (FW7721M/05) conforms to the following EMC standards:

- EN 55011, EN 55022/ B
- IEC 60601-1-2
- FCC 47 Part 15

- EN 61000-3-2, EN 61000-4-2, EN 61000-4-3, EN 61000-4-4, EN 61000-4-5, EN 61000-4-6, EN 61000-4-11

The power adapter (FW7721M/05) fulfils class II, SELV according to the following standards:

- ES 60601
- IEC 60601-1
- UL 2601
- Fulfills medical application class B / BF / CF

FCC Information

This Uncord Serial Port Plug F2M01SXA has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the 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 and, if not installed and used in accordance with the instructions, 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 turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

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

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

















IMPORTANT NOTE:

Radiation Exposure Statement: The Uncord Serial Port Plug F2M01SXA complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. To maintain compliance with FCC RF exposure compliance requirements, please follow operation instruction as documented in this manual.

This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter. Highest reported body SAR is: 0.581W/kg.

FCC ID: R47F2M01SX

Descriptions of Symbols and Labels

	▶ Operating instructions /Consult instructions for use
	▶ Manufacturer information
	▶ Date of manufacture
	▶ Serial number
	▶ Catalogue number / Reference number
	▶ Batch code / Lot number
	▶ Temperature limitation
	▶ Humidity limitation
	▶ Atmospheric pressure limitation
	▶ Keep dry
	▶ Fragile, handle with care
	▶ In compliance with the European Directive on Waste of Electrical and Electronical Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste
	▶ Federal Communication Commission (FCC) logo
	▶ CE marking indicating conformance to EC directives 93/42/EEC and 2007/47/EC concerning medical devices
	▶ Bluetooth® wireless technology
	▶ Unique Device Identifier (UDI): Application Identifier (01) represents the device identifier (DI) ("156943111XXXX"), the Application Identifier (11) the production date/date of manufacture ("YYMMDD", with "YY" the last two digits of the production year, "MM" the production month and "DD" the production day), the Application Identifier (21) the serial number of the device ("WWWWWWWWWWW") if applicable, and the Application Identifier (10)ZZZZZ the lot number of the device ("ZZZZZ") if applicable

(01)1569431111XXXX
(11)YYMMDD
(21)WWWWWWWWWWW

(01)1569431111XXXX
(11)YYDDMM
(10)ZZZZZ

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For distributor information go to: www.noxmedical.com

Reference number for Nox W7 LINK KIT - A is 54 40 12

Reference number for Nox W7 LINK KIT - R is 54 40 11

Reference number for Nox W7 LINK KIT - S is 54 40 10