MANUAL

nox C1

Nox C1 Manual

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www.noxmedical.com/products/nox-c1

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INTRODUCTION

Congratulations on choosing the Nox C1 Access Point. The Nox C1 is a part of the Nox Sleep System and has the main function to measure, receive, and stream physiological signals during online configuration of the Nox Sleep System. The Nox C1 is able of communicating with Nox recording devices and Noxturnal App over Bluetooth® link and with the Noxturnal PC software over Ethernet to allow configuration of the Nox recording devices and streaming of online data.

Intended Use

The Nox Sleep System is used as an aid in the diagnosis of different sleep disorders and for the assessment of sleep.

The Nox Sleep System is used to measure, record, display, organize, analyze, summarize, and retrieve physiological parameters during sleep and wake in patients greater than 2 years of age.

The Nox Sleep System allows the user to decide on the complexity of the study by varying the number and types of physiological signals measured.

The Nox Sleep System allows for generation of user/pre-defined reports based on subject´s data.

The users of the Nox Sleep System are medical professionals who have received training in the areas of hospital/clinical procedures, physiological monitoring of human subjects, or sleep disorder investigation.

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

Contraindications

The Nox Sleep System does not provide any alarms and is not intended to be used for continuous monitoring where failure to operate can cause injuries or death of the patient.

Scope

This manual covers the instructions for the Nox C1 Access Point, and how to setup and operate the device. The Nox C1 Access Point is operated by the Noxturnal PC software. For instructions on how to configure and operate the device from the Noxturnal software refer to the Noxturnal manual. The Noxturnal software and detailed user instructions are provided in electronic form at: *support.noxmedical.com*. For an online setup of the Nox Sleep System a Nox A1 recorder is also needed. For instructions on how to set up for online recording please refer to:

- Noxturnal Manual
- Nox A1 Manual

Instructions for Operators

This manual is only intended for professionals (healthcare professionals and service personnel) with relevant qualifications and skills.

Warnings and Cautions for Use

- Warning: The Nox Sleep System is **NOT certified for continuous monitoring** where failure to operate can cause injuries or death of the patient.
- Caution: U.S. federal law restricts this device to sale by, or on the order of, a

licensed medical practitioner.

- Caution: The Nox C1 access point complies with the international standard IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems. That 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 performance of the device, affecting recorded signals and therefore data analysis and resulting in possible incorrect treatment. Medical electrical equipment needs special precautions regarding Electromagnetic Compatibility (EMC), and needs to be installed and put into service according to the EMC information provided in the "EMC Information" section of this manual.
- Warning: Electromagnetic Interference (EMI) can be picked up by the analog channels of the Nox C1 access point, causing disturbed or altered signals to appear in the Noxturnal software. This may affect data analysis and result in possible incorrect treatment.
- Warning: The use of accessories and cables other than those listed in this manual may result in increased emissions and/or decreased immunity of the Nox Sleep System and cause injuries to the operator/patient.
- Warning: The Nox C1 access points should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device(s) should be observed to verify normal operation in the configuration in which it/they will be used and prevent abnormal operation which might cause injuries to the operator/patient.
- Warning: The Nox Sleep System may be interfered with by other equipment, even if that equipment complies with emission requirements of the CISPR (Special International Committee on Radio Interference) causing possible patient harm.
- Warning: The Nox C1 Access Point is not designed to give a specified degree of protection against harmful ingress of liquids. Do not autoclave or immerse the device in any kind of liquids. Ingress of liquids may result in electric shock.
- Warning: In the United States of America, only use United States Environmental Protection Agency (EPA) registered products for cleaning of the Nox C1 access point to prevent harm to the operator/patient.
- Warning: Do not use damaged equipment, sensors or accessories. This may result in bad performance of the Nox Sleep System or patient/operator injury.
- Warning: There are no user serviceable parts inside the Nox C1 Access Point. The device should be serviced by authorized parties only. Service performed by non-authorized parties may affect data analysis and result in possible incorrect treatment. The warranty is void if the Nox C1 access point is opened.
- Warning: No modification of the Nox C1 access point is allowed. Un-authorized modifications may affect data analysis and result in possible incorrect treatment.
- Warning: External equipment and all auxiliary devices intended for connection to signal input, signal output or other connectors shall comply with the relevant product safety standards, e.g. IEC 60950-1 for IT equipment and the IEC 60601 series for medical electrical equipment, to prevent electric shocks. In addition, all such combinations – systems – shall comply with the safety requirements stated in

the general standard IEC 60601-1, edition 3/3.1, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment, i.e. at least 1.5 m from the patient support. Any person who connects external equipment to signal input, signal output or other connectors has formed a system and is therefore responsible for the system to comply with the requirements. If in doubt, contact a qualified medical technician or your local representative.

- Caution: After connecting a new auxiliary signal to the Nox C1 connectors OR after modifying the connection of the auxiliary signals OR after changing the mode of the auxiliary devices signal output, always verify the correct setup by performing an actual recording, making the auxiliary device create a known signal, and monitoring the appearance and values measured in the Noxturnal software, in order to prevent signals that would lead to incorrect interpretation and possible incorrect treatment.
- Warning: All the auxiliary devices connected to the Nox C1 access point should be powered from a single power strip to ensure a common ground, avoid ground potential difference skewing or disturbing the signals and thus prevent possible incorrect treatment.
- Warning: Only use power supply **FRIWO MP115 Medical-7555M/12** with the Nox C1 access point. The use of an incorrect power supply may result in electric shock or cause the device to overheat, which may result in patient/operator harm.
- Warning: The USB channels, serial channels, and analog channels on the Nox C1 access point are signal input/output (SIP/SOP) auxiliary ports **NOT TO BE CONNECTED IN DIRECT GALVANIC CONNECTION** to the patient. This may result in electric shock.

Please read the user instructions carefully before initial use, especially sections marked with an exclamation mark.

NOX C1 DESCRIPTION

The Nox C1 is a Bluetooth® access point. It receives Bluetooth data stream from a Nox recording device, has input ports for receiving of signals originating from various auxiliary devices and internal sensors for ambient light measurement and pneumotachography. The measured/received signals are processed within the Nox C1 access point before they are streamed forward to the Noxturnal software over Ethernet.

The Nox C1 channels and built-in capabilities include the following:

- 12 analog channels; for recording of DC signals from auxiliary devices
- 2 USB channels*
- 2 serial channels; for recording of serial signals from auxiliary devices
- 2 pressure sensor channels; e.g. for recording of patient airflow at the proximal airway when using a CPAP device
- Built-in ambient light sensor
- Built-in Bluetooth® module; to support wireless connectivity allowing the device to receive signals from the Nox A1 recorder

The Nox C1 is also equipped with an Ethernet input; to support connection of the device to an Ethernet network for streaming of data and commands between the device and a remote computer.

Furthermore, the Nox C1 communicates with the Nox recording device and Noxturnal App over Bluetooth link and with the Noxturnal PC software over Ethernet to allow configuration of the Nox recording devices and streaming of data.

The Nox C1 access point is powered by a medical grade power supply providing medical grade isolation from mains.

Nox C1 Interface

The Nox C1 access point interface consists of an indicator light (LED) for device status, ambient light sensor, analog channel inputs, Ethernet cable input, factory reset button, USB input*, serial inputs, differential pressure sensor inputs and power supply connector.

The figure below shows the top view of the Nox C1, showing the device's status LED (1) and the ambient light sensor (2). For device status indicated with the LED, refer to the "Device Status" section.

* Currently the USB ports do not have any function

The figure below shows the front view of the Nox C1, showing the six analog inputs, labelled DC IN 1-12.

The figure below shows the rear of the Nox C1, showing the six inputs available. Refer to the table below for input definition.

The following table lists the Nox C1 access point inputs and the corresponding input labeling.

NUMBER	FUNCTION	INPUT/SENSOR LABEL
1	Indicator light for device status	No label on device
2	Ambient light sensor	No label on device
3	Analog inputs	DC IN 1-12
4	Ethernet cable input	LAN
5	Factory reset button	No label on device
6	USB inputs*	USB
7	Serial inputs	1 COM 2
8	Differential pressure sensor inputs	+ PRES -
9	DC power supply connector	⎓

* Currently the USB ports do not have any function

OPERATING NOX C1

The Nox C1 Access Point is only intended to be operated by professionals (healthcare professionals and service personnel) with relevant qualification in hospitals, institutions, sleep centers, sleep clinics or other test environment, not including the patient's home.

Connect to DC Power

- Warning: Only use power supply FRIWO MP115 Medical-7555M/12 with the Nox C1 access point. The use of an incorrect power supply may result in electric shock or cause the device to overheat, which may result in patient/operator harm.

The Nox C1 is powered by **FRIWO MP115 Medical-7555M/12**, a specific medical grade power supply rated with operating voltage of 12 volts and providing medical grade isolation from mains. Connect the power supply into the DC power connector on the rear of the device and have the applicable regional adapter connected to the power supply.

Verify that the LED indicator light on top of the Nox C1 access point starts blinking amber immediately after connection of the power supply and starts blinking green when the startup sequence of the device is completed and the Nox C1 is available for configuration.

FRIWO MP115 Medical-7555M/12 (FW7555M/12)

The medical grade power supply FRIWO MP115 Medical-7555M/12 is the only power supply that should be used with the Nox C1 access point to ensure safe and effective device operation. The LED indicator is the operating indicator. For detailed user instructions, product specifications and regulatory information please refer to the Nox Medical web page.

- Caution: In the case of visible damages on the housing or on the cord do not use the power supply.
- Warning: The device should never be operated or even stored at places listed below, because this could lead to operating failures:
    - Places, which are heavily exposed to moisture or where water

condensing may occur
    - Places, which are exposed to special environmental conditions
    - Places, which are subject to constant vibrations
    - Places, which are subject to high temperature fluctuations
    - Outdoors
- Caution: Always disconnect the power supply from mains during lighting storms or when not in use.
- Caution: The power supply itself is the disconnect device. Never use the cord to pull the power supply from the mains.
- Warning: The power supply is maintenance free. It must not be opened. (Risk of electrical shock).
- Warning: A modification of the power supply is not allowed.
- Warning: The device may only be repaired by authorized personnel.
- Warning: Remove from mains before cleaning. Do not clean with detergents. Clean only with a dry cloth.
- NOTE: The power supply unit is intended for supplying end medical product by its output voltage.
- Warning: The unit shall not be used for use in an oxygen rich environment.
- Warning: The unit it is not intended to be used with flammable anesthetics and not intended for use in conjunction with flammable agents.

Nox C1 Status

The Nox C1 access point has a built-in LED for device status indication. The LED is located on the top panel of the device. Refer to the table below for a description of the different states of the Nox C1 indicated with the LED.

Status Light	Description
Off	▸ Nox C1 is not connected to power and is turned off
Blinking amber	▸ Nox C1 is connected to power and is completing the startup sequence
Blinking green	▸ Nox C1 is connected to power and ready to use. A recording is not running
Solid green	▸ A recording is running
Solid amber	▸ Firmware error indication, Nox C1 is not functional ▸ Nox C1 should be factory reset (refer to section “Factory Reset”)
Alternating green and amber	▸ Firmware upgrade/factory reset is running

The LED brightness will automatically dim during a recording to ensure patient comfort.

Nox C1 Analog Inputs

- Warning: The analog channels on the Nox C1 access point are signal input/output (SIP/SOP) auxiliary ports not to be connected in direct galvanic connection to the patient. This could result in electric shock.

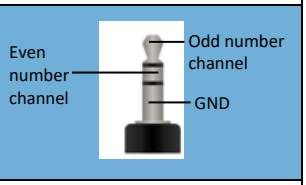
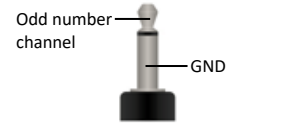
The Nox C1 access point is equipped with 12 analog channels suitable for collecting of DC signals from auxiliary devices. The channels are collected on 6 inputs, labeled DC IN from 1 to 12 on the top of the device. The analog inputs which are 3.5 mm female stereo jack and yields 2 channels each. The voltage range allows interfacing signals from -5 V to +5 V.

Auxiliary devices can be connected to the Nox C1 analog inputs using a standard 3.5 mm male stereo jack or a 3.5 mm male mono jack.

The 12 analog channels offered by the Nox C1 have six inputs labeled DC IN from 1 to 12, see the figure above. The table below addresses the channel identification.

Analog Inputs	**Analog Channels 1-12**
Analog Input 1 and 2	Channel 1
	Channel 2
Analog Input 3 and 4	Channel 3
	Channel 4
Analog Input 5 and 6	Channel 5
	Channel 6
Analog Input 7 and 8	Channel 7
	Channel 8
Analog Input 9 and 10	Channel 9
	Channel 10
Analog Input 11 and 12	Channel 11
	Channel 12

The table below lists available commercial connectors that can be used for connection to the Nox C1 analog channel inputs.

Connector Type	Channel Identification	
3,5 mm male stereo jack	▸ A stereo jack can carry two analog channels (e.g. channels 1 and 2)	
3,5 mm male mono jack	▸ A mono connector can carry one analog channel (e.g. channel 1)	

For the analog channel specifications refer to the “Specifications” section. Please refer to the Noxturnal manual for more information on how to configure and license the analog channels.

Nox C1 Differential Pressure Sensor

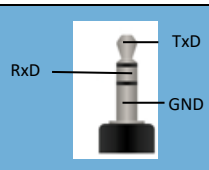
To setup the Nox C1 access point for a recording of patient airflow at the proximal airway when using a CPAP device, connect two Nox filter tube connectors to the differential pressure sensor inputs on the rear of the device, labelled + PRES -. The differential pressure sensor inputs are designed to fit directly with the filter tube connector interface from Nox Medical. The figure below shows the Nox filter tube connectors connected to the differential pressure sensor inputs.

For the differential pressure sensor specifications refer to the “Specifications” section.

Nox C1 Serial Inputs

▸ Warning: The serial channels on the Nox C1 access point are signal input/output (SIP/SOP) auxiliary ports not to be connected in direct galvanic connection to the patient. This could result in electric shock.

To record signals from auxiliary devices over a serial connection connect a 3.5 mm male stereo jack carrying the serial signal to a COM input on the rear of the Nox C1 access point. The figure below shows the rear of the device, where the serial inputs are located. The serial inputs are labelled 1 COM 2. For the serial input specifications refer to the “Specifications” section.

Connector Type	Channel Identification	
3,5 mm male stereo jack	▸ The COM stereo jacks carry one serial channel each with TxD, RxD and GND at RS232 levels.	

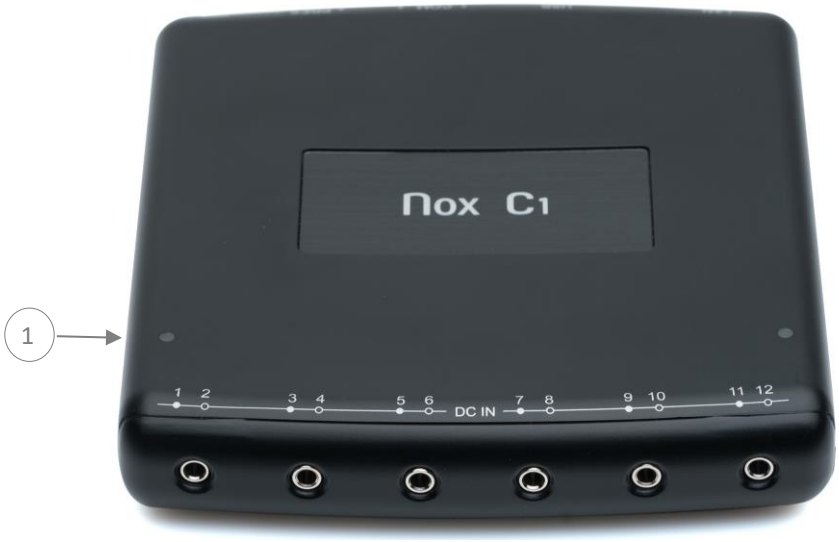
Nox C1 Serial-over-USB Inputs

▸ Warning: The USB channels on the Nox C1 access point are signal input/output (SIP/SOP) auxiliary ports not to be connected in direct galvanic connection to the patient. This could result in electric shock.

The Nox C1 access point contains USB ports that currently do not have any function within the Nox Sleep System. The USB inputs are on the rear of the device. The figure below shows the rear of the device, where the USB inputs are located. The USB inputs are labelled USB. For the USB input specifications refer to the “Specifications” section.

Nox C1 Ambient Light Sensor

The Nox C1 access point has a built-in ambient light sensor located on the top panel of the device; see the figure below (1).



The light sensor can be used for light detection in the patient room. For the light sensor to work properly make sure not to cover the light sensor on the device. For the light sensor specifications refer to the “Specifications” section.

NOX C1 NETWORK CONFIGURATION

Default Factory Configuration

The factory state of the Nox C1 access point is listed in the table below.

Nox C1 Network Configuration	**Details**
DHCP server	DHCP pool: 192.168.101.64 - 192.168.101.127

Static IP address	192.168.101.10
Universal Plug and Play (UPnP) discovery	Networking protocol that permits the Nox C1 to be discovered on a network

The Nox C1 network configuration can be managed through the Noxturnal software. Please refer to the Noxturnal manual for instructions on how to configure the Nox C1 network settings.

Factory Reset

To reset the Nox C1 access point to factory state follow the instructions below:

1. Unplug the power supply from the Nox C1 access point
2. Reset the device by performing the following:
   i. Use a sharp pin (such as a toothpick) and press and hold the reset button on the rear of the device (see figure below)
   ii. While pressing the reset button connect the power supply to the device
   iii. You can release the reset button once you see the device LED alternating between green and amber
3. The LED on the top panel will blink amber while the device is completing the startup sequence
4. After approximately 60 seconds the LED starts blinking green. This indicates that the device has been reset to factory defaults and will have the network configuration listed in the “Default Factory Configuration” section

- NOTE: Do not use a metallic item to perform the factory reset.

NOX C1 ACCESS POINT SETUP

Nox Sleep System Network Overview

Before setting up the Nox C1 access point on the network read the following.

- The Nox C1 access point should be connected to a 10/100 IP-enabled Ethernet network to transfer configuration and study data between the Nox C1 access point and the operator workstation running the Noxturnal software. The Nox C1 replies to Internet control message protocol (ICMP) echo requests and can be discovered with the Universal Plug and Play (UPnP) protocol. The Nox C1 listens on TCP port 8080 for configuration requests and on port 8888 for UPnP discovery requests.

- Any study data collected during a network outage is discarded and the user will be notified in Noxturnal if such an event occurs.
- NOTE: If the Nox C1 access point is connected to a shared network please make sure that any device connected to the network does not cause network congestion reducing the operational integrity of the Nox C1 access point.

To ensure steady operation of the Nox Sleep System please follow the recommended system setup below.

- Use a separate local area network (LAN) for each Nox C1 access point and a computer running the Noxturnal software, i.e. each patient room that includes the Nox C1 should be on a separate network.
- Use a separate Nox C1 access point for each Nox A1 recorder to be used.
  Use a separate computer running Noxturnal for each Nox C1 access point.

The table below describes the setup of the control room where the computer with Noxturnal installed is located.

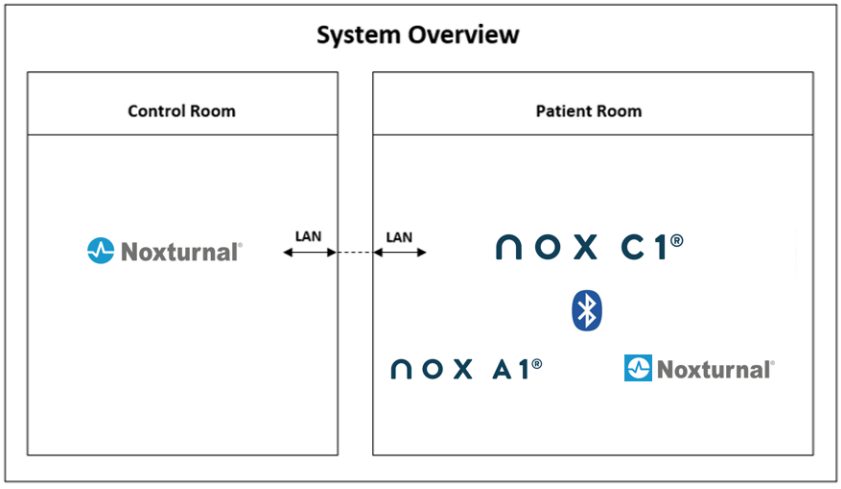
Control Room	
Item	**Connection**
PC	Connected to the same network as the Nox C1 with a network cable
Noxturnal	Installed on PC

The table below describes the setup of the patient room where the patient is sleeping during a sleep study.

Patient Room			
Item Name	**Description**	**Function**	**Setup/Connection**
Nox C1 Access Point	Bluetooth access point with analog and serial inputs and built in light sensor and differential pressure sensor	▸ Data transfer received from Nox A1 over Bluetooth connection and forwarded to Noxturnal via Ethernet ▸ Commands received from Noxturnal via Ethernet and forwarded to Nox A1 using Bluetooth connection ▸ Data transfer received from auxiliary devices connected to analog and/or serial inputs and forwarded to Noxturnal via Ethernet	Located in the patient room. Connected to the same LAN as the PC running the Noxturnal software
Nox A1	Recording device	Records physiological	Attached to the

Recorder and applicable sensors	that may be configured for different types of sleep studies	signals from built-in and attached sensors	patient in the patient room
Medical auxiliary devices	Any medical device that fits the input channel specifications of the Nox C1 Access Point. Medical devices supported by the system to be connected to Nox A1 Recorder via Bluetooth link	Depends on the auxiliary device being used	The applicable connection cable connected to the analog input/serial on the Nox C1 Access Point. Via Bluetooth link to the Nox A1 recorder
Noxturnal App	Android App	Can be used to connect to Online Rooms, review signal traces and perform bio calibration and impedance check. Can also be used to start and stop recordings	Set the App to Online Mode and connect to the applicable online room

The figure below shows the overview of the online setup for the Nox Sleep System .



The Nox C1 Access Point is operated by the Noxturnal software.

For instructions on how to configure and operate the Nox C1 Access Point and Nox A1 Recorder from the Noxturnal software refer to the Noxturnal manual.

MAINTENANCE

The Nox Sleep System is only intended to be maintained by professionals (healthcare professionals and service personnel) with relevant qualifications and skills.

The Nox C1 Access Point and accessories should be stored in a clean, dry place.

Handle the Nox C1 Access Point with care and protect it against mechanical shocks, dirt, and liquids. The device is not waterproof or splash proof.

To update the Nox C1 firmware you will need the Noxturnal software running on a computer which is on the same network as the Nox C1 Access Point. Please refer to the Noxturnal manual for more information on how to perform this task.

No regular testing of the Nox C1 access point is needed.

The service life of the Nox C1 Access Point and the FRIWO MP115 Medical-7555M/12 power supply is 5 years.

Environmental Conditions

- Note: The environmental conditions listed below apply both for the Nox C1 Access Point and the accompanying FRIWO MP115 Medical-7555M/12 power supply.

Temperature	Operation: +5°C to +40°C (41°F to 104°F) Transport/Storage: -25°C to +70°C (-13°F to 158°F)
Relative Humidity	Operation: 15-90% (non-condensing) Transport/Storage: 10-95% (non-condensing)
Pressure	Withstands atmospheric pressures from 700 hPa to 1060 hPa

Calibration

The Nox C1 Access Point is factory calibrated. No further calibration is needed.

- Warning: There are no user serviceable parts inside the Nox C1 Access Point. The device should be serviced by authorized parties only. Service performed by non-authorized parties may affect data analysis and result in possible incorrect treatment. The warranty is void if the Nox C1 Access Point is opened.
- Warning: No modification of the Nox C1 Access Point is allowed. Un-authorized modifications may affect data analysis and result in possible incorrect treatment.

Cleaning

- Warning: The Nox C1 Access Point device is not designed to give a specified degree of protection against harmful ingress of liquids. Do not autoclave or immerse the device in any kind of liquids. Ingress of liquids may result in electric shock.
- Warning: In the United States of America, only use United States Environmental Protection Agency (EPA) registered products for cleaning of the Nox C1 Access Point to prevent harm to the operator/patient

- The Nox C1 Access Point is NOT intended to be sterilized.

Clean the Nox C1 Access Point 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 on the device. Allow the unit to dry thoroughly before use.

For disinfection of the Nox C1 Access Point the following materials may be used:

- Sodium hypochlorite diluted with water at 1:500 (bleach)
- 70-90% isopropanol
- Super Sani-Cloth Plus disinfection wipes (from PDI)

For cleaning of FRIWO MP115 Medical-7555M/12 power supply only use dry cloth. Do not clean with detergents.

- Warning: Remove from mains before cleaning. Do not clean with detergents. Clean only with a dry cloth

Disposal

- According to the regulation in Europe on Waste of Electrical and Electronic Equipment (WEEE) the components labeled with this symbol may not be disposed of as unsorted municipal waste. The components shall be collected separately and returned to the appropriate collection system available.
- Please contact your sales representative regarding take-back or recycling of the components.

Follow local governing ordinances and recycling instructions regarding disposal or recycling of the Nox C1 Access Point and accessories.

COMPATIBLE DEVICES, SENSORS AND ACCESSORIES

- Warning: Do not use damaged equipment, sensors or accessories. This may result in bad performance of the device or patient/operator injury.
- Warning: External equipment and all auxiliary devices intended for connection to signal input, signal output or other connectors shall comply with the relevant product safety standards, e.g. IEC 60950-1 for IT equipment and the IEC 60601 series for medical electrical equipment, to prevent electric shocks. In addition, all such combinations – systems – shall comply with the safety requirements stated in the general standard IEC 60601-1, edition 3/3.1, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support. Any person who connects external equipment to signal input, signal output or other connectors has formed a system and is therefore responsible for the system to comply with the requirements. If in doubt, contact a qualified medical technician or your local representative.
- Caution: After connecting a new auxiliary signal to the C1 connectors OR after modifying the connection of the auxiliary signals OR after changing the mode

of the auxiliary devices signal output, always verify the correct setup by performing an actual recording, making the auxiliary device create a known signal, and monitoring the appearance and values measured in the recording software, in order to prevent signals that would lead to incorrect interpretation and possible incorrect treatment.

- Warning: All the auxiliary devices connected to the C1 device should be powered from a single power strip to ensure a common ground, avoid ground potential difference skewing or disturbing the signals and thus prevent possible incorrect treatment.

The following table includes information on accessories, sensors and devices that have been validated with the Nox C1 Access Point.

The items listed below are Nox products and have been validated for use with the Nox C1 Access Point:

NOX FILTER TUBE CONNECTORS

Type	Catalog Number
Nox Filter Tube Connector, 50 units	552110

NOX SLEEP SYSTEM COMPONENTS

Type	Catalog Number
Nox A1 System Kit	513010
Nox A1 Recorder	561410
Noxturnal CD	539010
Noxturnal	NA
Noxturnal App	536210
Nox C1 Access Point	544020

POWER SOURCE

Type	Catalog Number
FRIWO MP115 Medical-7555M/12	NA*

*The 3rd party FRIWO MP115 Medical-7555M/12 medical grade power supply has been validated with the Nox C1 Access point and is included in the C1 Kit. C1 Kit has the catalog number 544020

The items listed below are 3rd party products and have been validated for use with the Nox C1 Access Point:

ACCESSORIES FOR DIFFERENTIAL PRESSURE SENSOR

Type	Catalog Number
Mask tubing 183 cm (72 in) Female x Male	552320
Pneumoflow Sensor	552810

CLEANING

Type	Catalog Number
Super Sani-Cloth Plus Disinfection Wipes	559010

SPECIFICATIONS

Nox C1 Access Point and Power Supply

DESCRIPTION	PROPERTIES
FUNCTION	
Nox C1 Channels	▸ Ambient Light Channel ▸ Differential Pressure Channel ▸ Twelve Analog Input Channels (DC) ▸ Two USB Input Channels* ▸ Two Serial Input Channels
PHYSICAL	
Nox C1 Dimensions	▸ 135 mm x 149 mm x 26 mm (5.3″ x 5.9″ x 1.0″)
Nox C1 Weight	▸ 264 g (9.3 oz)
Nox C1 DC Inputs	▸ Number of Channels: 12 ▸ Number of Inputs: 6 ▸ Input Voltage Range: +/- 5 V ▸ Sampling: 16 bit, 250 sample/s ▸ Connector: 3.5 mm Female Stereo Jack
Nox C1 Light Sensor Input	▸ Light Range: Can distinguish between dark room and a slightly lit room ▸ Sampling: 16 bit, 250 sample/s
Nox C1 Light Indicator	▸ Number of LEDs: 1 ▸ Colors: Green and Amber for status indication

* Currently the USB ports do not have any function

Nox C1 Pressure Sensor Input	▸ Number of Channels: 1 ▸ Number of Inputs: 2 ▸ Absolute Maximum Input Pressure: +/- 7 kPa ▸ Pressure Input Range: +/- 40 cmH_2O ▸ Sampling: 16 bit, 250 sample/s ▸ Connector: Differential sensor port
Nox C1 USB Inputs *(currently nonfunctional)*	▸ Number of Channels: 2 ▸ Number of Inputs: 2 ▸ USB 2.0 compliance ▸ High Speed (up to 480 Mbit/s) ▸ Connector: USB Type A
Nox C1 Serial Inputs	▸ Number of Channels: 2 ▸ Number of Inputs: 2 ▸ RS-232 ▸ Connector: 3.5 mm Female Stereo Jack

POWER SUPPLY

Power Supply Model	▸ FRIWO MP115 Medical-7555M/12
Nominal Input Voltage	▸ 100-240 V AC +/- 10%
Nominal Input	▸ 50-60 Hz
Nominal Input Current	▸ 0.350-0.150 Arms (at max load)
Nominal Output Voltage	▸ 12 V DC +/- 5%
Nominal Output Current	▸ 0-1250 mA

COMMUNICATION

Nox C1 Bluetooth®	▸ Bluetooth® v.4.0
Nox C1 Ethernet	▸ Number of Inputs: 1 ▸ 10/100 BASE-TX ▸ Connector: RJ-45

REGULATORY INFORMATION

Performance Testing and Validation Summary

The Nox Sleep System has been tested and verified in various phases to include internal testing, verification and validation as well as external testing to assure product safety, effectiveness and reliability. The design was verified and validated, including clinical evaluation, throughout the design process, according to requirement specifications and intended use. External accredited test houses were used to conduct testing needed to comply with the applicable standards regarding EMC and patient safety as well as additional RF testing to assure compliance to Radio and Telecommunication Terminal Equipment (R&TTE) Directive (R&TTE).

Nox Medical holds a ISO 13485:2016 certified Quality Management System which complies with the requirements of the Medical Device Directive (MDD), FDA Quality System Regulation (QSR) and Canada Medical Device Regulations (CMDR).

Nox C1 Classification

- Degree of protection against electric shock: The device is classified as **class II equipment** (see the symbol to the left).
- Powering of the device: The device is powered from an **external electrical power source**.
- Degree of protection against harmful ingress of liquids and particulate matter: The Nox C1 Access Point is classified **IP20**, i.e., as defined by the standard IEC 60529 it is protected against solid foreign objects of 12,5 mm diameter and greater, but it is not protected against harmful ingress of liquids.
- Method of sterilization: The device is **NOT delivered sterile or intended to be sterilized**.
- Suitability for use in an oxygen rich environment: The device is **NOT intended for use in an oxygen rich environment**.
- Suitability for use with flammable agents and anesthetics: The device is **NOT intended for use in conjunction with flammable agents or with flammable anesthetic mixture with air or with oxygen or nitrous oxide**.
- Mode of operation: The device is intended for **continuous operation**.

Description of Symbols and Labels

- Operating instructions / Consult instructions for use

- Caution

- Manufacturer information

- Date of manufacture

- Serial number

- Catalogue number / Reference number

(01)15694311110590(11)YYMMDD(21)931XXXXXX

- Unique Device Identifier (UDI); the Application Identifier (01) represents the device identifier (DI) (“15694311110590”), 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), and the Application Identifier (21) the serial number of the device (“931XXXXXX”)

- Class II equipment

- 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 radiation. The equipment includes a RF transmitter: interference may occur in the vicinity of equipment marked with this symbol

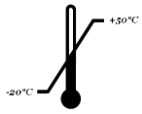
- CE marking indicating conformance to EC directives 93/42/EEC and 2007/47/EC concerning medical devices

- Bluetooth® wireless technology

- Federal Communications Commission (FCC) logo

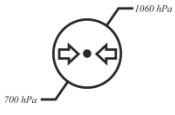
- Keep dry

- Fragile, handle with care



- Temperature limit

- Humidity limitation



- Atmospheric pressure limitation

Contains IC ID: 5123A-BGTBT111	Industry Canada (IC) ID label
Contains FCC ID: QOQBT111	Federal Communications Commission (FCC) ID label
DC IN 1-12	Analog inputs (DC)
LAN	Ethernet cable input
USB	USB inputs *(currently nonfunctional)*
$_1$ COM $_2$	Serial inputs
$_+$ PRES $_-$	Differential pressure sensor inputs
⎓	DC power supply connector

Bluetooth® Wireless Technology

The Nox C1 Access Point uses Bluetooth® 4.0 wireless technology to communicate with external Bluetooth modules.

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 industrial, scientific, and medical (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 Radio Frequency (RF) specifications for the Nox C1 Access Point.

The *Bluetooth*® word mark and logos are registered trademarks owned by the Bluetooth SIG, Inc. and any use of such marks by Nox Medical is under license. Other trademarks and trade names are those of their respective owners.

Electromagnetic Compatibility (EMC) Information

- Portable and mobile RF communications can affect the performance of the Nox C1 Access Point.
- Warning: Electromagnetic interference (EMI) can be picked up by the analog channels of the Nox C1 Access point, causing disturbed or altered signals to appear in the Noxturnal software. This may affect data analysis and result in possible incorrect treatment.
- Warning: The Nox C1 access point(s) should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device(s) should be observed to verify normal operation in the configuration in which it will be used and prevent abnormal operation which might cause injuries to the operator/patient.
- Warning: The use of accessories, transducers, sensors, and cables other than those listed in this manual may result in increased emissions and/or decreased immunity of this device and cause injuries to the operator/patient.
- Warning: The Nox Sleep System may be interfered with by other equipment, even if that equipment complies with CISPR (Special International Committee

on Radio Interference) emission requirements, causing possible patient harm.

- Refer to the tables below in this section for specific information regarding the Nox C1 Access Point's compliance to the standard IEC60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

Declarations of Conformity with the US Federal Communications Commission (FCC) and Industry Canada Regulations

USA - FEDERAL COMMUNICATIONS COMMISSION (FCC)

The Nox C1 Access Point 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, including interference that may cause undesired operation of this device.

FCC RF Radiation Exposure Statement:

This equipment 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. This transmitter meets both portable and mobile limits as demonstrated in the RF Exposure Analysis and should not be used closer than 5 mm from a human body in portable configuration. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter except in accordance with FCC multi-transmitter product procedures.

CANADA - INDUSTRY CANADA (IC)

the Nox C1 Access point complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:

(1) this device may not cause interference, and

(2) this device must accept any interference, including interference that may cause undesired operation of the device.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

COMPLIANCE WITH FCC AND INDUSTRY CANADA REGULATIONS

- The antenna(s) must be installed such that a minimum separation distance of 5 mm is maintained between the radiator (antenna) and all persons at all times.

- The transmitter module must not be co-located or operating in conjunction with any other antenna or transmitter except in accordance with FCC multi-transmitter product procedures.

MODIFICATION STATEMENT

Any changes or modifications not expressly approved by Nox Medical could void the user's authority to operate the equipment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The Nox C1 Access Point 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.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 2	The device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The device 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The Nox C1 Access Point 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.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV lines(s) to earth	± 1 kV line(s) to line(s) ± 2 kV lines(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (Continued)

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The Nox C1 Access Point 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.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6

Radiated RF
IEC 61000-4-3</td><td>3 V_{rms}
150 kHz to 80 MHz

3 V/m
80 MHz to 2.5 GHz</td><td>3 V

3 V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance

$d = 1.2\sqrt{P}$

$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

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

Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, 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.</td></tr>
</table>

[a] 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 Nox C1 Access Point is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

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

Recommended Separation Distance between Portable and Mobile RF Communications Equipment and the Nox C1 Access Point

Recommended separation distance between portable and mobile RF communications equipment and the C1 device

The Nox C1 Access Point is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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 80 MHz and 800 MHz, 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.

ABOUT

This manual and associated translations are also provided in electronic format according to Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices. They are available in electronic format on Nox Medical's website: www.noxmedical.com.

Electronic versions are provided as PDF documents and a PDF reader is required to open the documents. PDF readers are commonly available at no cost for users. Refer to the applicable system and hardware requirements for the PDF reader that is used.

Hard copies can be requested at no additional cost by emailing support@noxmedical.com. The hard copy will be sent within 7 calendar days.