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Nox C1 Manual

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www.noxmedical.com/products/nox-c1

# Table of Contents

# Introduction

Congratulations on choosing the Nox C1 access point. The Nox C1 is a Bluetooth® access point that enables measurement, receiving and streaming of physiological signals during sleep. The Nox C1 is intended to be used with the Nox A1 system to enable online functionality of the system.

## Scope

This manual covers the instructions for the Nox C1 access point, and how to setup and operate the device. This manual does not cover the software application needed for the device configuration.

## Warnings and Cautions for Use

- Warning: The C1 device is NOT certified for continuous monitoring where failure to operate can cause injuries or death of the patient.
- Caution: U.S. federal law restricts the C1 device to sale by, or on the order of, a licensed medical practitioner.
- Caution: The C1 device 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. Medical electrical equipment needs special precautions regarding 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 C1 device, causing disturbed or altered signals to appear in the PC software. This may affect data analysis and result in possible incorrect treatment.
- 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.
- Warning: The C1 device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the C1 device should be observed to verify normal operation in the configuration in which it will be used.
- Warning: The C1 device may be interfered with by other equipment, even if that equipment complies with CISPR emission requirements.
- Warning: The C1 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: Only use United States Environmental Protection Agency (EPA) registered products for cleaning/disinfection of the C1 device.
- Warning: Do not use damaged equipment, sensors or accessories. This may result in bad performance of the device or patient/operator injury.
- Warning: There are no user serviceable parts inside the C1 device. The C1 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 C1 device is opened.
- Warning: No modification of the C1 device 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 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.
- Warning: The C1 device may not be used for direct patient connections where failure to operate can cause injuries or death of the patient.
- Warning: Only use power supply FRIWO MP115 Medical-7555M/12 with the C1 device. 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 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.

## Device Description

The Nox C1 access point is a Bluetooth® access point that enables measurement, receiving and streaming of physiological signals during sleep. The Nox C1 access point communicates with the Nox A1 recorder over Bluetooth® and with the Noxturnal PC software over Ethernet to allow configuration of the recorder and streaming of data. The Nox C1 is able to measure signals from various auxiliary devices and has a built-in ambient light sensor and a differential pressure sensor. The Nox C1 offers system extension for the Nox A1 system with the integration of various auxiliary devices.

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; to support devices connected via USB
- 2 serial channels; for recording of serial signals from auxiliary devices
- 2 pressure sensor channels; for recording of differential pressure for pneumoflow recordings
- 1 built-in ambient light sensor
- 1 built-in Bluetooth® module; to support wireless connectivity allowing the device to record 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.

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

### Intended Use

The Nox C1 access point is intended for measuring, receiving and streaming of physiological signals during sleep. The Nox C1 access point communicates with Nox recorders over Bluetooth® and with the Noxturnal PC software over Ethernet to allow configuration of the recorders and streaming of data. The Nox C1 access point receives Bluetooth® data stream from Nox recorders, has input ports for measuring of signals originating from various auxiliary devices, and has 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.

The Nox C1 access point is intended for patients older than two years of age.

The intended environments are professional healthcare facilities, including hospitals, sleep centers and sleep clinics.

The Nox C1 Access Point is intended to be set-up by professionals (healthcare professionals and service personnel) with relevant qualifications and skills.

## Contraindications

The Nox C1 access point is **NOT** intended for any continuous patient monitoring or automatic diagnosis.

## Nox C1 Interface

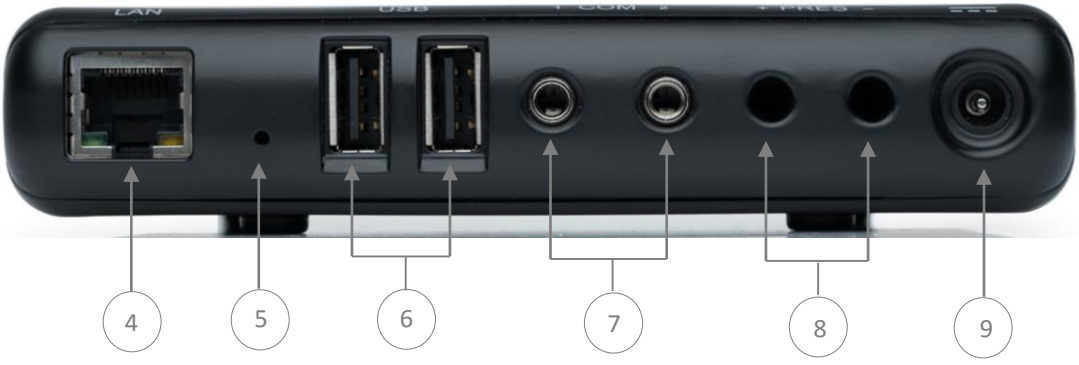
The Nox C1 access point interface consists of an indicator light (LED) for device status, ambient light sensor, analog channel inputs, Ethernet cable input, factory reset button, USB input, serial inputs, differential pressure sensor inputs and power supply connector. See the figures and tables below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

### Device Inputs and Sensors

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.


The figure on the next page 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 | ⎓ |

## Device Inputs/Sensors

The Nox C1 device 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.

- Warning: Do not use damaged equipment, sensors or accessories. This may result in bad performance of the device or patient/operator injury.
- Warning: The C1 device is NOT certified for continuous monitoring where failure to operate can cause injuries or death of the patient.
- 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.
- Warning: The C1 device may not be used for direct patient connections where failure to operate can cause injuries or death of the patient.

## Connect to DC Power

- Warning: Only use power supply FRIWO MP115 Medical-7555M/12with the C1 device. 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 device 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 to ensure safety and device operation. For user instructions, product specifications and regulatory information please refer to the product website: www.friwo-shop.de/en/power-supplies/medical-power-supplies/169/mpp15-medical?c=8970.

- NOTE: Please read user instructions before use. Always observe these instructions.
- NOTE: The LED is the operating indicator.
- 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).
- NOTE: A modification of the power supply is not allowed (Loss of warranty).
- 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.

## Device Status

The Nox C1 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 turned on<br>▸ A recording is not running |
| Solid green | ▸ A recording is running |
| Solid amber | ▸ Firmware error indication, device is not functional |
| Alternating green and amber | ▸ Device should be factory reset (refer to section “Factory Reset”)<br>▸ Firmware upgrade/factory reset is running<br>▸ Do not unplug the power source |

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

## Analog Inputs

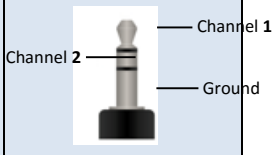
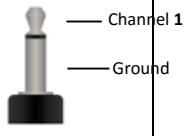
- Warning: The analog channels are signal input/output (SIP/SOP) auxiliary ports not to be connected in direct galvanic connection to the patient. This could result in electric shock.

The Nox C1 device 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. Each analog input yields 2 channels. Auxiliary devices can be connected to the Nox C1 analog inputs using standard 3.5 mm phono stereo connectors/3.5 mm mono phono connectors/3.5 mm stereo to dual mono adapters. The voltage range allows interfacing signals from -5 V to +5 V.


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 connectors that can be used for connection to the Nox C1 analog channel inputs.

| Connector Type | Channel Identification | |
|---|---|---|
| 3,5 mm stereo phono connector | ▸ A stereo connector is able to carry two analog channels (e.g. channels 1 and 2) |  |
| 3,5 mm mono phono connector | ▸ A mono connector is able to carry one analog channel (e.g. channel 1) |  |
| 3,5 mm stereo to dual mono adapter | ▸ White connector is for odd number channels (e.g. channels 1, 3, 5 etc.)<br>▸ Red connector is for even number channels (e.g. channels 2, 4, 6 etc.) |  |

Please refer to the Noxturnal software user manual for more information on how to configure the analog channels.

## Differential Pressure Sensor

To setup the Nox C1 for a pneumoflow recording, 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.

## Serial Inputs

- Warning: The serial channels 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 stereo phono connector carrying the serial signal to the serial input on the rear of the device. The figure below shows the rear of the device, where the serial inputs are located. The serial inputs are labelled $_1$ COM $_2$.


## Serial-over-USB Inputs

- Warning: The USB channels 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 device supports serial-over-USB dongles, allowing the user to connect more than two serial auxiliary devices simultaneously. 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.

## Ambient Light Sensor

The Nox C1 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 Nox C1 light sensor. For the light sensor specifications refer to the “Specifications” section.

# Network Configuration

## Default Factory Configuration

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

| **Nox C1 Network Configuration** | **Details** |
|---|---|
| DHCP server | DHCP pool: 192.168.101.64 - 192.168.135.128 |
| 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 to factory state follow the instructions below:

1. Unplug the power supply from the Nox C1 device
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.

# Setup Nox C1 Access Point with the Nox A1 System

## System Network Overview

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

- The C1 access point should be connected to a 10/100 IP-enabled Ethernet network in order to transfer configuration and study data between the C1 access point and the operator workstation. The C1 access point replies to Internet control message protocol (ICMP) echo requests and can be discovered with the UPnP protocol. The C1 access point 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 if such an event occurs.
- NOTE: If the 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 C1 access point.

To ensure steady operation of the Nox C1 with the Nox A1 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.

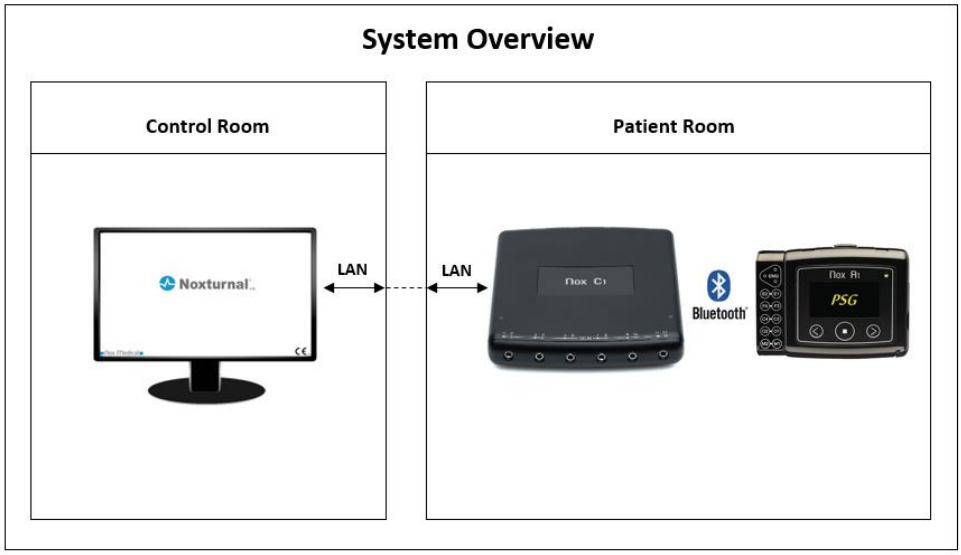
The tables below describe the patient and control room device setup.

| Patient Room | | | |
|---|---|---|---|
| **Item Name** | **Description** | **Function** | **Setup/Connection** |
| Nox C1 device | Bluetooth® access point with analog and serial inputs and built-in light sensor and differential pressure sensor | Communicates with the Nox A1 using Bluetooth®. Via Ethernet:<br>▸ Data transfer from Nox A1 to Noxturnal<br>▸ Commands from Noxturnal to Nox A1<br>▸ Data transfer from connected serial or analog channel connected auxiliary devices | Located in the patient room. Connected to the same LAN as the PC running the Noxturnal software |
| Nox A1 recorder and the applicable sensors | PSG sleep recorder | Records physiological signals from attached/connected sensors | Attached to the patient in the patient room |
| Medical auxiliary devices | Any medical device that fits the input channel specifications of the Nox C1 device (For channel specifications refer to the “Specifications” section) | Depends on the auxiliary device being used | The applicable connection cable connected to the analog/serial/USB input on the Nox C1 device |

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

## System Local Area Network Overview

The figure below shows an overview of the Nox C1 and Nox A1 network system setup.




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.

## Maintenance

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. Please refer to the Noxturnal software user manual for more information on how to perform this task.

No regular testing of the C1 access point is needed.

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

### Environmental Conditions

| | |
|---|---|
| Temperature | Operation: +5°C to +50°C (41°F to 122°F) |
| | Transport/Storage: -25°C to +70°C (-13°F to 158°F) |
| Relative Humidity | Operation: 15-95% (non-condensing) |
| | Transport/Storage: 10-95% (non-condensing) |
| Pressure | Withstands atmospheric pressures from 700 hPa to 1060 hPa |

### Calibration

The Nox C1 device is factory calibrated. No further calibration is needed.

- Warning: There are no user serviceable parts inside the C1 device. The C1 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 C1 device is opened.
- Warning: No modification of the C1 device is allowed. Un-authorized modifications may affect data analysis and result in possible incorrect treatment.

## Cleaning

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 device 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)

- Warning: The C1 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: Only use United States Environmental Protection Agency (EPA) registered products for cleaning/disinfection of the C1 device.
- The Nox C1 access point is NOT intended to be sterilized.
- Regarding cleaning/disinfection and re-use of 3rd party components and 3rd party sensors refer to the applicable 3rd party accompanying instructions.

## Disposal

Follow local governing ordinances and recycling instructions regarding disposal or recycling of this device.

- 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 distributor regarding take-back or recycling of the components.

## Compatible Sensors and Devices

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 device:

### FILTER TUBE CONNECTORS

| Type | Catalog Number |
|---|---|
| Nox Filter Tube Connector, 50 units | 552110 |

### A1 SYSTEM

| Type | Catalog Number |
|---|---|
| Nox A1 System | 513010 |
| Nox A1 Recorder | 561410 |
| Noxturnal CD | 539010 |

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

### POWER SOURCE

| Type | Catalog Number |
|---|---|
| FRIWO MP115 Medical-7555M/12 | - |

### 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 Device

| DESCRIPTION | PROPERTIES |
|---|---|
| ***FUNCTION*** | |
| **Channels** | ▸ Ambient Light Channel<br>▸ Differential Pressure Channel<br>▸ Twelve Analog Input Channels<br>▸ Two USB Input Channels<br>▸ Two Serial Input Channels |
| ***PHYSICAL*** | |
| **Nox C1 Device 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) |
| **DC Inputs** | ▸ Number of Channels: 12<br>▸ Number of Inputs: 6<br>▸ Input Voltage Range: +/- 5 V<br>▸ Sampling: 16 bit, 250 sample/s<br>▸ Connector: 3.5 mm Female Stereo Jack |
| **Light Sensor Input** | ▸ Light Range: Can distinguish between dark room and a slightly lit room<br>▸ Sampling: 16 bit, 250 sample/s |
| **Light Indicator** | ▸ Number of LEDs: 1<br>▸ Colors: Green and Amber for status indication |
| **Pressure Sensor Input** | ▸ Number of Inputs: 2<br>▸ Absolute Maximum Input Pressure: +/- 7 kPa<br>▸ Pressure Input Range: +/- 20 $cmH_2O$<br>▸ Sampling: 16 bit, 250 sample/s |
| **USB Inputs** | ▸ Number of Inputs: 2<br>▸ USB 2.0 compliance<br>▸ High Speed (up to 480 Mbit/s)<br>▸ Connector: USB Type A |

| | |
|---|---|
| **Serial Inputs** | ▸ Number of Inputs: 2<br>▸ RS-232<br>▸ Connector: 3.5 mm Female Stereo Jack |

***POWER SOURCE***

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

***COMMUNICATION***

| | |
|---|---|
| **Bluetooth®** | ▸ Bluetooth® v.4.0<br>▸ Bluetooth Classic and Bluetooth Low Energy dual mode compliant<br>▸ Operating frequency: 2.402-2.480 GHz<br>▸ Bandwidth: 2 MHz<br>▸ Transmit power: 10 mW max.<br>▸ Range: up to 35 meters in line-of-sight<br>▸ Antenna type: Internal<br>▸ Network Topology: Point-to-Point: Point-to-Multipoint<br>▸ Operation: Scatter-Net Master<br>▸ Modulation Type: Frequency Shift Keying/Frequency Hopping Spread Spectrum |
| **Ethernet** | ▸ Number of Inputs: 1<br>▸ 10/100 BASE-TX<br>▸ Connector: RJ-45<br>▸ LED Indicators: Green-Link activity, Amber-100 Mbit/s indication |

# Regulatory Information

## Performance Testing and Validation Summary

The Nox C1 access point 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 R&TTE.

Nox Medical holds a CMDCAS ISO 13485:2003 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).

## 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 device 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 Abbreviations

- Operating instructions / Consult instructions for use

| | |
|---|---|
|  | ▸ Caution |
| (01)15694311110590(11) YYMMDD(21)931XXXXXX | ▸ Unique Device Identifier (UDI); (01) represents the device identifier (DI) (“15694311110590”), (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 (21) the serial number (“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 |
| **Nox C1** | ▸ Brand name/Model name |
| **SCOM1** | ▸ Technical name |
| **REV** | ▸ Revision of the device |
| **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 |
| **LAN** | ▸ Ethernet cable input |
| **USB** | ▸ USB inputs |
| **$_1$COM $_2$** | ▸ Serial inputs |

| | |
|---|---|
| + **PRES** - | Differential pressure sensor inputs |
| ⎓ | DC power supply connector |
| Bluetooth® | Bluetooth® 4.0 wireless technology |
| FC | Federal Communications Commission (FCC) logo |
|  | Keep dry |
|  | Fragile, handle with care |

## Bluetooth® Wireless Technology

The C1 access point uses Bluetooth® 4.0 wireless technology to receive signals from 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 RF specifications for the 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.

## EMC Information

- Portable and mobile RF communications can affect the performance of the device.
- Warning: Electromagnetic interference (EMI) can be picked up by the analog channels of the C1 device, causing disturbed or altered signals to appear in the PC software. This may affect data analysis and result in possible incorrect treatment.
- Warning: The C1 device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the C1 device should be observed to verify normal operation in the configuration in which it will be used.

- 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.
- Warning: The C1 device may be interfered with by other equipment, even if that equipment complies with CISPR emission requirements.
- Refer to the tables below in this section for specific information regarding the C1 device's compliance to the standard IEC60601-1-2.

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

## USA - FEDERAL COMMUNICATIONS COMMISSION (FCC)

The C1 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, 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)

This device complies with Industry Canada licence-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

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The C1 device is intended for use in the electromagnetic environment specified below. The customer or the user of the C1 device should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions<br>CISPR 11</td><td>Group 2</td><td>The C1 device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.</td></tr>
<tr><td>RF emissions<br>CISPR 11</td><td>Class B</td><td rowspan="3">The C1 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.</td></tr>
<tr><td>Harmonic emissions<br>IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions<br>IEC 61000-3-3</td><td>Complies</td></tr>
</table>

## Guidance and Manufacturer's Declaration – Electromagnetic Immunity

| **Guidance and manufacturer's declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The C1 device is intended for use in the electromagnetic environment specified below. The customer or the user of the C1 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)<br>IEC 61000-4-2 | ± 6 kV contact<br>± 8 kV air | ± 6 kV contact<br>± 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<br>IEC 61000-4-4 | ± 2 kV for power supply lines<br>± 1 kV for input/output lines | ± 2 kV for power supply lines<br>± 1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ± 1 kV line(s) to line(s)<br>± 2 kV lines(s) to earth | ± 1 kV line(s) to line(s)<br>± 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<br>IEC 61000-4-11 | <5 % $U_T$ (>95 % dip in $U_T$) for 0,5 cycle<br>40 % $U_T$ (60 % dip in $U_T$) for 5 cycles<br>70 % $U_T$ (30 % dip in $U_T$) for 25 cycles<br><5 % $U_T$ (>95 % dip in $U_T$) for 5 s | <5 % $U_T$ (>95 % dip in $U_T$) for 0,5 cycle<br>40 % $U_T$ (60 % dip in $U_T$) for 5 cycles<br>70 % $U_T$ (30 % dip in $U_T$) for 25 cycles<br><5 % $U_T$<br>(>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 C1 device requires continued operation during power mains interruptions, it is recommended that the C1 device be powered from an uninterruptible power supply or a battery. |
| Power frequency<br>(50/60Hz)<br>magnetic field<br>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)

| **Guidance and manufacturer's declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The C1 device is intended for use in the electromagnetic environment specified below. The customer or the user of the C1 Device should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| Conducted RF<br>IEC 61000-4-6 | 3 $V_{rms}$<br>150 kHz to 80 MHz | 3 V | Portable and mobile RF communications equipment should be used no closer to any part of C1 device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>**Recommended separation distance**<br>$d = 1.2 \sqrt{P}$ |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.5 GHz | 3 V/m | $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz<br>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).<br>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]<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

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

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

The C1 device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the C1 device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the C1 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 is provided in electronic format according to Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices.

This manual is provided as a pdf document. PDF readers are commonly available at no cost for users.

This manual is also available on Nox Medical's website: support.noxmedical.com/hc/en-us/articles/207379426.

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