Neximatic's Vital Sign Streaming Solution

Nexi-7 User Manual

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Contact information
Website: www.neximatic.com
Email: info@neximatic.com

Table of Contents

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Introduction

Thank you for choosing Neximatic's Vital Sign Streaming Solution. The Neximatic's Vital Sign Streaming Solution captures and transports vital sign measurements from medical devices to electronic health record (EHR) systems, enabling new features and capabilities such as automatic charting.

Version

This document contains dynamically generated information based on the facility where the Neximatic's Vital Sign Streaming Solution is deployed. Because information of the facility could change, therefore the document is versioned. The convention of the version number is UserManual_NexiVersion_[Facility Name]_DocVersion_[Date].

Version	Change
UM_09_N7_v20230629.docx	Initial Draft

Intended use

The Neximatic's Vital Sign Streaming Solution is designed to collect vital sign measurements from medical devices and transfer the data to medical information systems only. It is not a medical device. It is not designed, and must not be used, to monitor patients, transfer vital alarms, make clinical decisions or control medical devices. It must not be relied upon for treatment of patients.

Warning

The Neximatic's Vital Sign Streaming Solution should be installed by qualitied personnels. It should be operated under documented operating conditions.

This document uses a WARNING label to indicate important information for the users. Users should review all important information.

Users should review the entire user manual before proceeding

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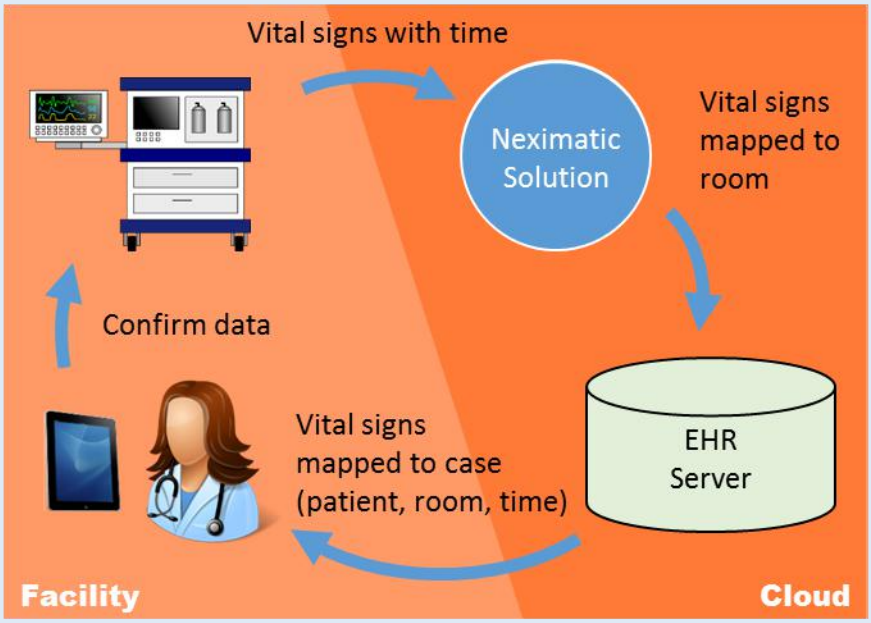
System Overview

The Neximatic's Vital Sign Streaming solution employs palm-sized vital sign transmitters, called Nexi. These transmitters are physically connected to up to four medical devices within an operating room. A Nexi collects vital sign measurements from the connected medical devices and streams the data to EHR systems. Because operating rooms can have different types of medical devices, each Nexi is configured specifically for the medical devices in that room. The cable connecting the Nexi and the medical devices is also specific. The solution relies on accurate information of its local network, whether it is Ethernet or WIFI, to stream data to the EHR systems.

Support for cloud-based and self-hosted EHRs

The Neximatic's Vital Sign Streaming Solution is designed to support cloud-based EHR systems. It can also be adapted to support self-hosted EHR systems. In both paradigms, there is no patient information with in the Neximatic's domain. Patient association is mapped at the EHRs.

Supporting a cloud-based EHR



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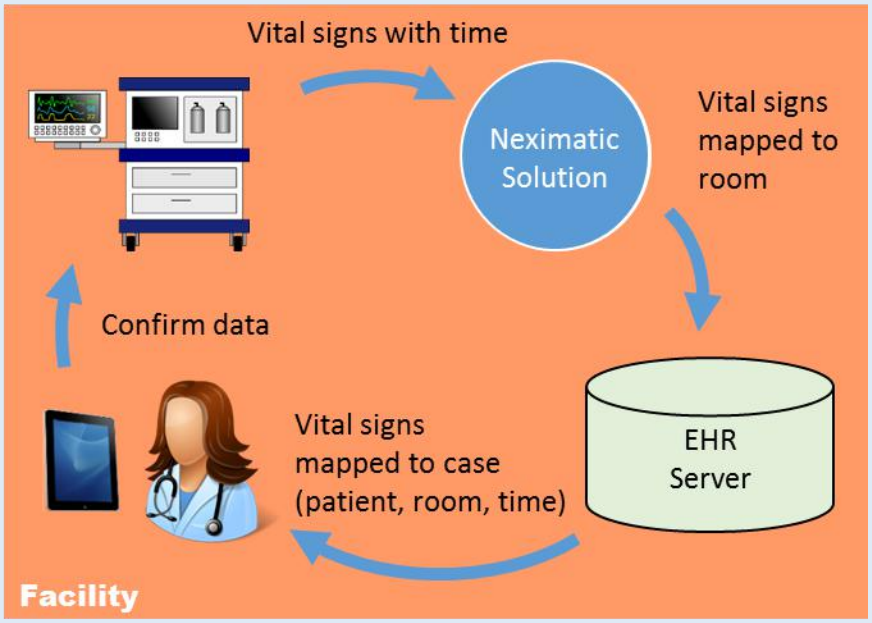
Supporting a self-hosted EHR



Facility	Implementation	Target EHR Platform

Streaming and viewing data

The Neximatic's Vital Sign Streaming Solution streams vital signs based on rooms and times. The vital sign measurements are then mapped to a patient in the EHR systems. A typical installation would have one Nexi installed in one room and is configured specific to the medical devices within the room. Users would be able to view vital signs by selecting the room on the EHR systems.

For example, if a user is in Operating Room 1 (OR1), the user should select OR1 to receive a vital sign stream on the EHR application.

If medical devices are moving in between rooms, the EHR systems would provide an alternative method for users to pick the vital sign measurements. Please consult with your EHR providers.

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Facility Information

A facility is analogous to a hospital or an ambulatory surgery center. A facility can have multiple locations such as operating room unit, emergency medical unit or intensive care unit. It is often useful to define a location that is managed by the same group of users. For example, it is reasonable to group OR and PACU in the same location where both units are managed by the same medical staff. Within a location, there are multiple rooms or bays. For example, in an operation room location, there can be three general operating rooms.

Each room requires a Nexi. A Nexi can connect up to four medical devices in the room.

Below is the current implementation of this facility.

If there is a new room that requires a new Nexi, please provide the room name and the medical devices (make and model) information to your EHR and Neximatic.

Org	Facility	Loc	Room

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Medical Devices and Nexi Assignment

Each room requires a Nexi. The Nexi is physically connected to the medical devices by a specific set of cables. The Nexi is also programmed specifically to the medical devices. Some medical devices may required additional settings on them to export data.

WARNING: Swapping Nexis between two rooms may not function because the Nexis may be programmed for different medical devices. When replacing or moving a Nexi, please contact your EHR and Neximatic if a reprogramming is required.

WARNING: The cable assembly should not be disassembled in any way. If a cable assembly is disassembled, please contact your EHR and Neximatic for support.

WARNING: Many medical devices have similar ports. The specific cable assembly must be plugged into the specific ports. If any cable is disconnected, review the Cable Assembly and Medical Device Configuration chapter and make the correct connections. If there are any questions, please contact your EHR and Neximatic.

WARNING: When a medical device is serviced or a new medical device of the same make and model is deployed, it may only have the factory settings. In both situations, review the Medical Device Configuration chapter and set any required settings of the medical devices to enable data export. If there are any questions, please contact your EHR and Neximatic.

The Nexi should be installed on the medical devices such that if the medical devices, for example an anesthesia cart with a patient monitor, are moved, the Nexi would move them. Neximatic does not track any movement of the Nexis after the initial implementation.

If the Nexi and the medical devices move between rooms, the EHR must provide a method for users to pick up the corresponding Nexi for data transmission.

Below is the room, medical devices and Nexi assignment of this facility at the time of installation. The locations of the Nexis may have changed if the medical devices move between rooms.

Room	Label	Nexi Name	MD1	MD2

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Nexi

Nexi Name

There are different generation of Nexis. A Nexi Name is a globally unique name that identifies a Nexi and its generation. The Nexi Name has a convention Nexi-X-DYYYYY, where X indicates the generation and YYYYY is a sequence number. For example, Nexi-1-D00001 where Nexi-1 is the generation and the 00001 is the sequence number.

WARNING: The deployment in this facility may employ different generation of Nexis. If information of a specific generation is missing in this document, please contact Neximatic support.

The Nexi Name can be found on a label affixed on a Nexi. The Nexi Name is used as a hostname on a network. Many network tools would report hostnames of devices on a network.

Label of a Nexi-7

Different generations of Nexi have different capabilities and features. Please refer to the relevant section of this user manual for information of the Nexi generation that is used in a facility.

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Nexi-7

Nexi-7 is the 7th generation of vital sign streaming transmitter. It operates at a 12V DC power.

It has 1 USB port and 1 Ethernet port. It also has 5 interfaces for medical device connectivity. Most of the time, the cables to the medical devices are connected to the medical device connectivity interfaces of a Nexi. Sometimes, the cable may be connected to the USB ports of a Nexi.

It has five LED indicators: Power, Internet, Service, Data Transmission and Issue.

Nexi-7 Specification	
Model	Nexi-7
Operation voltage	12V DC
Maximum current consumption	1.5A
Operation temperature	25C, in-door only
Operation humidity	5-95%
Interfaces	
Interfaces for Medical Devices	1 USB port 1 Ethernet port (Network) 5 Medical Device Interfaces
Indicators	Power Internet Service Data Transmission Issue

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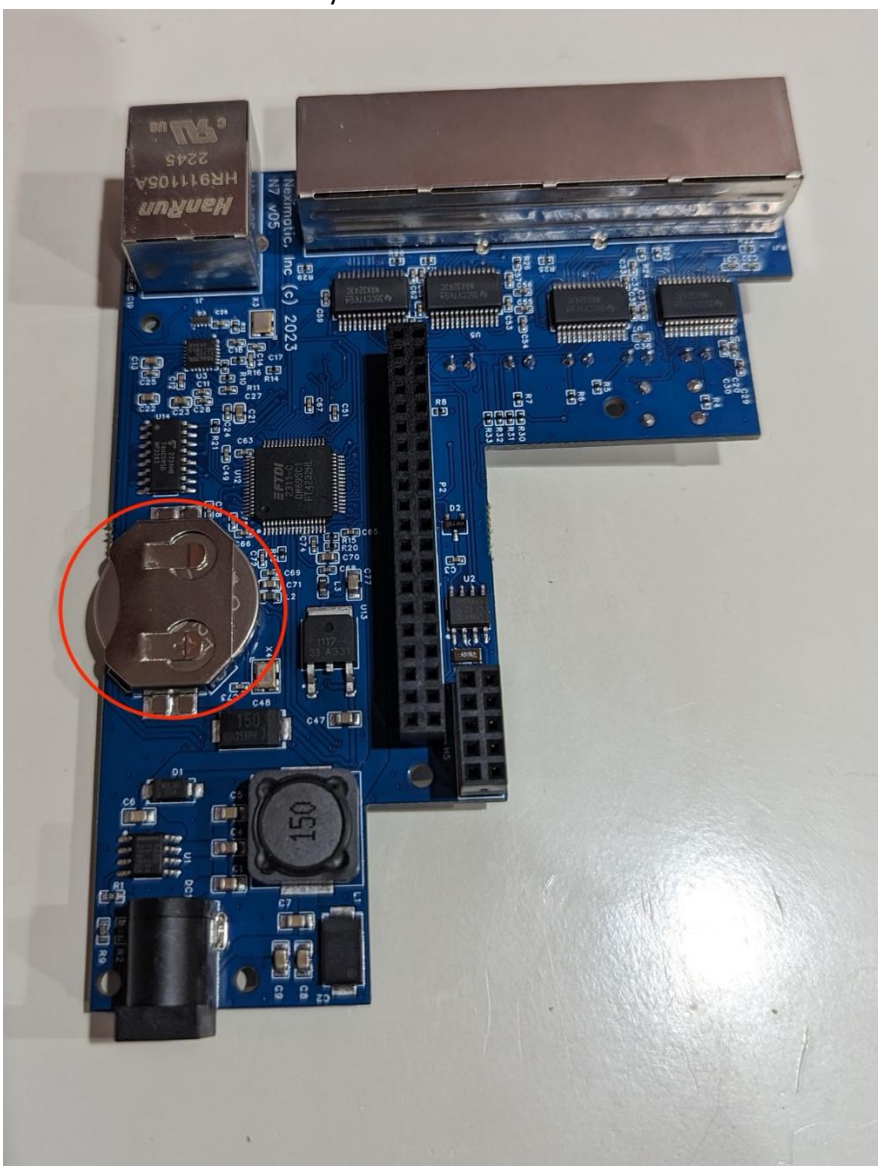
1. Insert a CR2032 coin battery to the LED Board.



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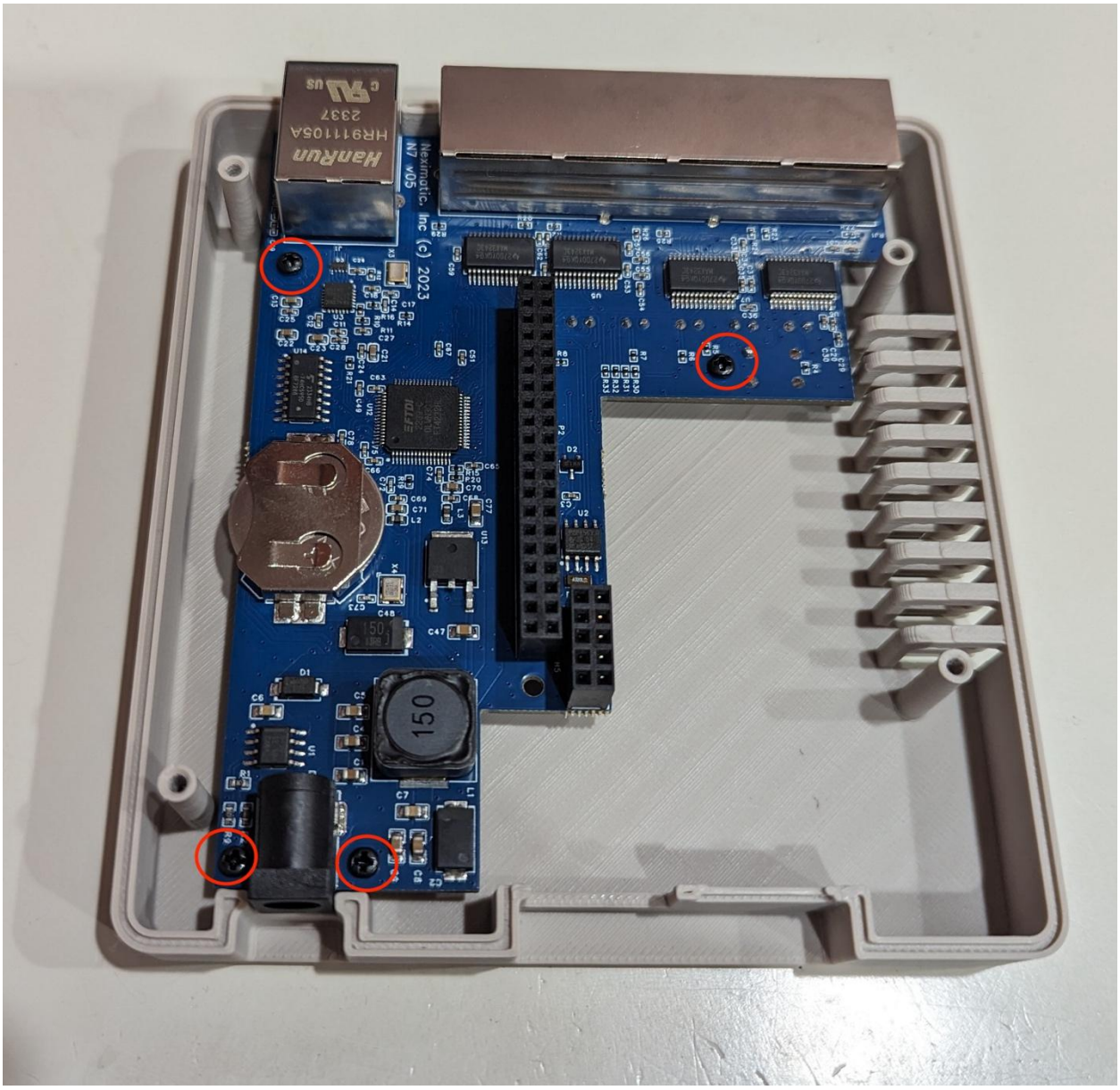
2. Use four M2.3x5mm screws to mount the LED board to the top case.



3. Remove the white tape on the antenna and stick it on the inner side of the top case, the connector should be pointing to the USB opening of the top case as shown in the picture

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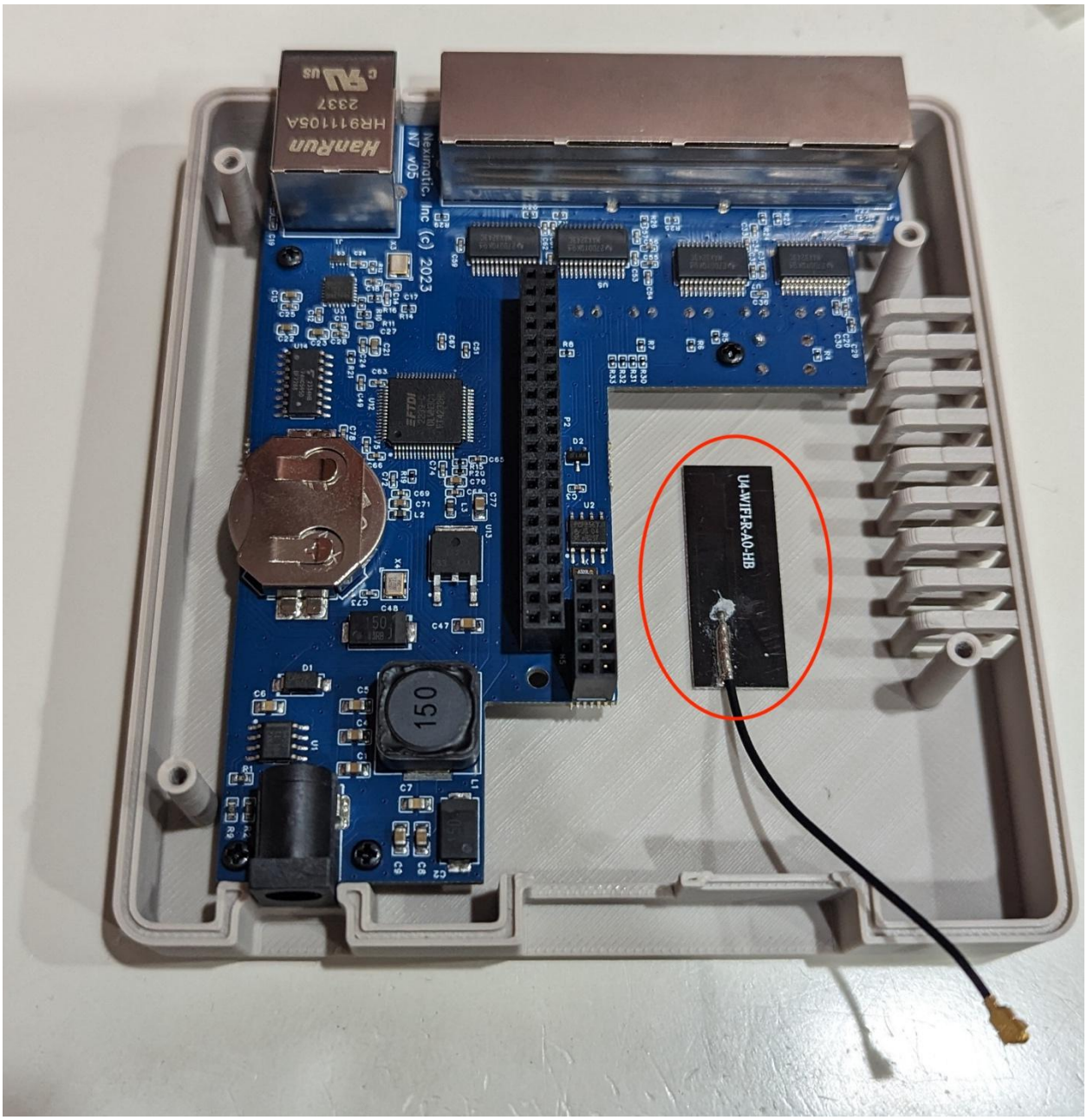
below



4. Connect the antenna connector to the NEXI-7 board and push the NEXI-7 board to connect with the 2x20 pin and 2x5 pin headers on the LED board as shown in the picture

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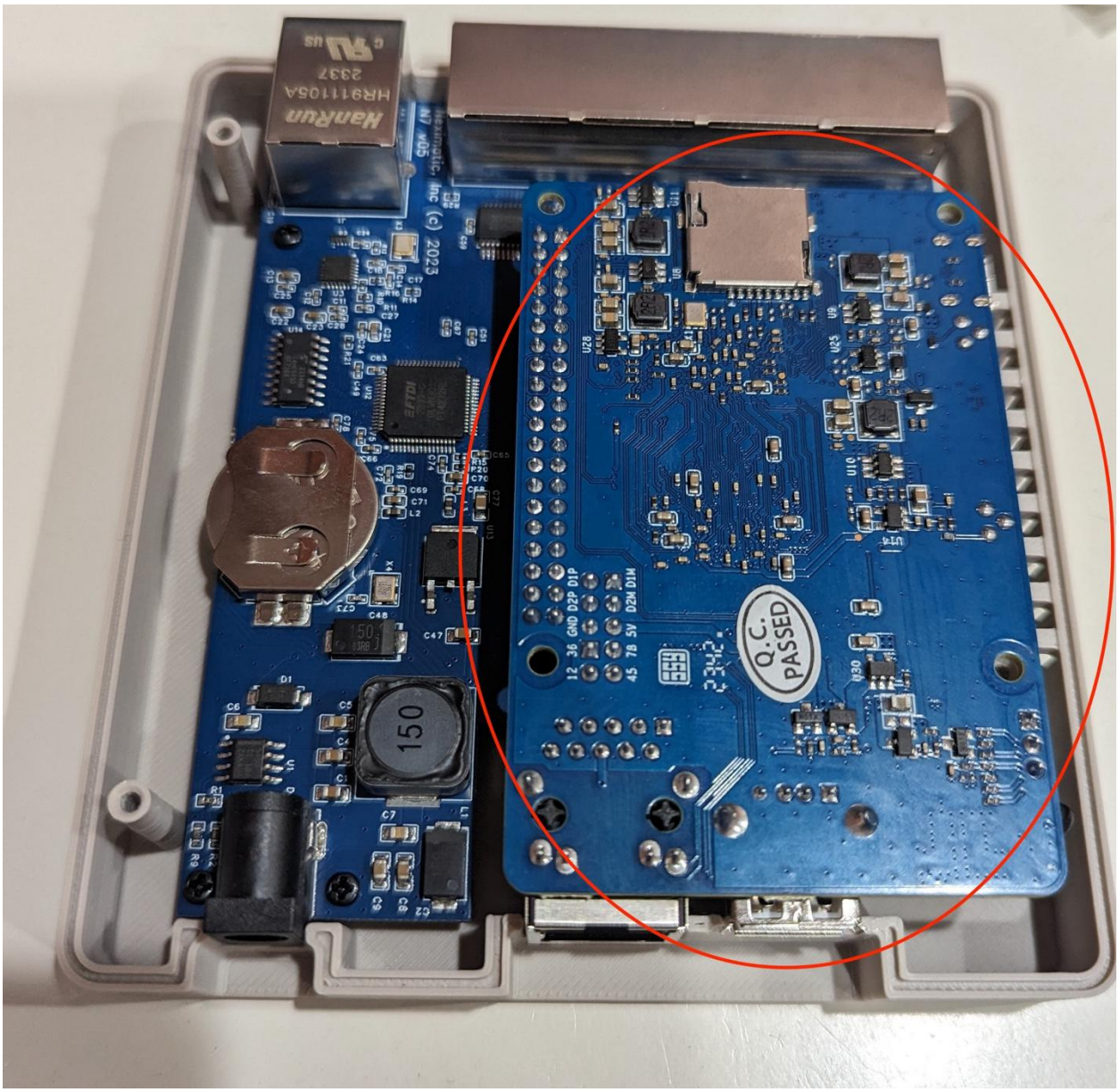
below



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5. Put the bottom case on and use four M2.3x10mm screws to secure the case.

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6. Assembly is done

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Nexi-7 supports both WIFI and Ethernet networking connectivity. It has an internal WIFI capability.

It must be used with a compatible power supply. When proper power is supplied to a Nexi-7, its Power light is on solid green.

Immediately after proper power is supplied to a Nexi-7, its indicators will turn on in some sequence. Then they will settle down.

After they settle down, the Network light, when on, indicates network connectivity. The Service light, when on, indicates the Nexi can reach the Neximatic cloud servers. The Data Transmission light, when blinking, indicates vital sign data has been captured and transmitted to the Neximatic cloud servers.

When the Issue light is on RED, there are some problems in the networking, server reachability or vital sign capture/transmission.

The Nexi-7 has an internal recovery process that attempts to correct some issues. One recovery process involves a self reboot. A self reboot is indicated by this pattern:

- All 5 lights are on
- Follow by Power and Data Transmission are on

After this sequence, a reboot is completed.

Please report any issue with the Nexi Name, date and time.

Indicators of a Nexi-7

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Nexi-7 LED Indicators

The LED indicators provide information on the operation of a Nexi.

Information: Nexi-6

- Starting a reboot sequence.

- During a reboot sequence.
- When the blue light goes off, operation begins.

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Information: Nexi-6

- Operation begins and Power light stays on.

- Regardless of WIFI or Ethernet, when there is a network connection, the Network light goes green.

- When the Nexi can reach its server, the Server light goes on green. This Server light has to be on.

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Information: Nexi-6

- When there is any issue the Issue light goes on red. The Nexi would attempt a sequence of recovery. The recovery may involve a reboot.

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Cable Assembly and Medical Device Configuration

Each room requires a Nexi. The Nexi is physically connected to the medical devices by a specific set of cables. The Nexi is also programmed specifically to the medical devices. Some medical devices may required additional settings on them to export data.

WARNING: The cable assembly should not be disassembled in any way. If a cable assembly is disassembled, please contact your EHR and Neximatic for support.

WARNING: Many medical devices have similar ports. The specific cable assembly must be plugged into the specific ports. If any cable is disconnected, review the Cable Assembly and Medical Device Configuration chapter and make the correct connections. If there are any questions, please contact your EHR and Neximatic.

WARNING: When a medical device is serviced or a new medical device of the same make and model is deployed, it may only have the factory settings. In both situations, review the Medical Device Configuration chapter and set any required settings of the medical devices to enable data export. If there are any questions, please contact your EHR and Neximatic.

Below is the information of the cable assembly and medical device configuration for this deployment.

Label	Nexi Name	MD1	MD2

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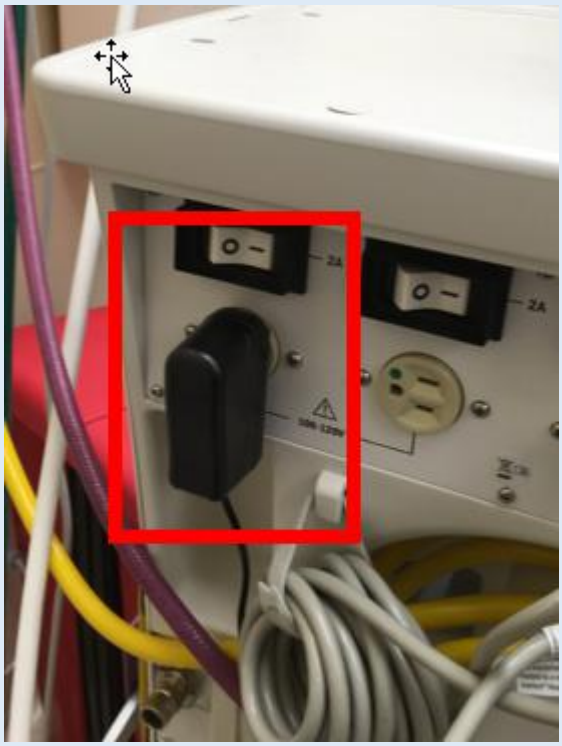
Powering and mounting the Nexi

The Nexis should be powered with the included power supply. The included power supply provides a higher current capability to support the function of the Nexi. Similar power supplies may not have enough current capability.

When sourcing power, please consider power cord management to reduce accidental yanking of the power cord or any trip hazard.

If possible, power the Nexi using the power outlet on an anesthesia delivery machine. Mount the Nexi on the anesthesia machine where the lights can be visible.

Powering from an anesthesia delivery machine



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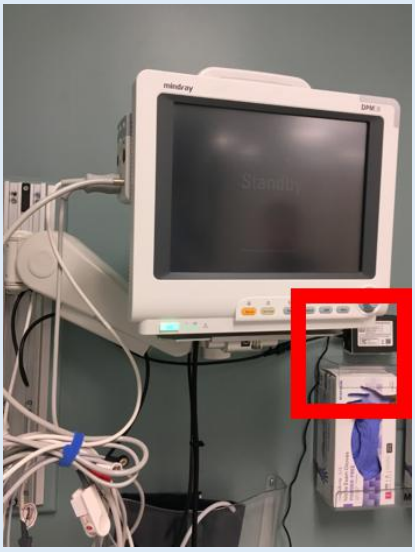
If the connected patient monitor is wall mounted, mount the Nexi on the wall. We may include a plastic bracket to house the Nexi. Allow enough slack on the cable assembly and the power cord. Mount location should be visible.

Powering from wall outlet



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If the medical device is on a wheeler, a pole outlet should be installed on the wheeler. The Nexi and the medical device should be plugged into the same pole outlet.

Powering and mounting on a wheeler

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Facility Network Information

A Nexi relies on the facility network to communicate to the EHR, regardless whether it is a cloud-based implementation or a self-hosted implementation.

WARNING: It is very important to provide up-to-date facility networking information to your EHR and Neximatic. Failure to do so could result in stoppage of vital sign streaming service.

Below is the facility networking information:

Facility Name	Network Type	DHCP	Static IP	MAC Registration

Gateway IP	Name Servers

WIFI SSID	Security Type

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Maintenance

The installed Nexis should be powered all the time.

When necessary software upgrade is available, the software would be pushed onto the Nexis and should not require local support.

During cleaning of the room or maintenance of the medical devices, please carefully disconnect any power cable, cable assembly and ethernet network connectivity. Clean the Nexi by wiping its surface with Isopropyl alcohol. After cleaning and maintenance, reconnect power and cables based on this documentation.

WARNING: Incorrect connection of the cables may cause malfunction.

WARNING: Do not disassemble the cable assembly. Disassembly and reassembling the cable assembly may cause problems in the solution.

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Trouble Shooting

Below is a step by step trouble shooting guide.

Check Power light

Connect to only compatible power supply. Observe the Power light.

Proper power supplied is indicated by a solid light on the Power light.

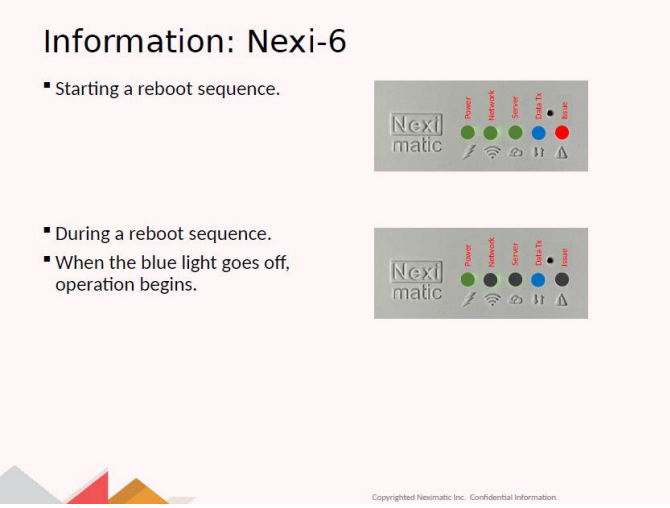
If the Power light is not on, there is a problem with the power supply or the Nexi. Please contact your EHR or Neximatic for support. Please provide the Nexi Name, date and time of the issue.

Ensure it is not in a reboot sequence

As part of an internal recovery process, a Nexi may self reboot.

The following pattern indicates a Nexi is rebooting.

The sequence completes when the Data Transmission light is turned off.



Check Network light

The Network light should be on to indicate network connectivity.

If the Nexi is to use Ethernet for networking, please ensure an Ethernet cable is connected to the Nexi and it is plugged into a wall Ethernet jack. Not all wall Ethernet jack is active. Please contact your local IT team to ensure the Ethernet jack in used is active. The local IT team may request MAC addresses. Please refer to the Installation Note chapter. Each Nexi has its MAC addresses printed on its bottom label.

If the Network light remains off and the Issue light remains on, please contact your EHR or Neximatic for support. Please provide the Nexi Name, date and time of the issue.

Check Service light

The Service light should be on to indicate server reachability.

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If the Network light is on and the Service light is off and the Issue light is on, please contact your EHR or Neximatic for support. Please provide the Nexi Name, date and time of the issue.

Check Nexi Assignment and Medical Devices Configuration

Each Nexi is programmed for a given combination of medical devices. The Medical Devices and Nexi Assignment chapter provides the information. If there is any change of medical devices for a given Nexi, please contact your EHR or Neximatic for support. Please be ready to provide the Nexi Name of the Nexi.

Check Cable Assembly and Medical Device Configuration

For a given medical device combination, a specific cable assembly is used. Please refer Cable Assembly and Medical Device Configuration and check if a correct cable assembly is available and is properly connected between the Nexi and the medical devices. Please be ready to provide the Nexi Name of the Nexi.

If a correct cable assembly is not available or if there is question on how to connect it between the Nexi and the medical devices, please contact your EHR or Neximatic for support. Please be ready to provide the Nexi Name of the Nexi.

Problem persists

After going through the above steps and the problem persists, please contact your EHR or Neximatic for support. Please be ready to provide the Nexi Name, date and time of the issue.

FCC Caution:

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

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

-- Reorient or relocate the receiving antenna.

-- Increase the separation between the equipment and receiver.

-- Connect the equipment into an outlet on a circuit different

from that to which the receiver is connected.

-- Consult the dealer or an experienced radio/TV technician for help.

To maintain compliance with FCC's RF Exposure guidelines, This equipment should be installed and operated with minimum distance between 20cm the radiator your body: Use only the supplied antenna.

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Installation Notes

Below has the MAC information of each Nexi deployed in this facility.

Nexi Name	LAN MAC	WIFI MAC

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