

**Nicolet System**

# **Nicolet**

# **EEGwireless32/64**

# **User Guide**

June, 2010



## Intended use statement

The intended use for this product is to provide the front end amplifier, which provides data acquisition for the Nicolet EEG/LTM/ICU/Sleepsystem (**hereafter in this publication referred to as Nicolet system**).

The Nicolet systems are intended for use as electroencephalography, long term monitoring, sleep studies and Intensive Care testing devices. They are designed for use in routine clinical EEG/LTMtesting and can be used in the Operating Room, ICU, ED, Sleep and during research studies.

## About the Nicolet system

The range of Multimedia EEG Nicolet systems have been designed and manufactured by CareFusion NeuroCare, which has always had an enviable reputation for innovation and quality of its products.

CareFusion NeuroCare quality management system has been certified by Kema to comply with ISO 13485:2003.

**Rx**

**CAUTION:** Federal law (U.S.A.) restricts this device to sale by, or on the order of, a physician.

**CE** 0344

## **Declaration of Conformity**

Hereby, CareFusion 209 Inc. declares that the Nicolet EEGWireless32/64, its derivatives, and its accessories are in compliance with the essential requirements and the other relevant provisions of Directive 1999/5/EC.

We, CareFusion 209 Inc, at 1850 Deming Way, Middleton, WI, USA, declare under our own responsibility that the Nicolet EEGWireless32/64 to which this declaration refers conforms with the relevant standards or other standardizing documents of EN 50371:2002 according to regulations in Directive 1999/5/EC.



Luke Thompson, 18-JUN-2010, Middleton, WI

## **Safety summary**

In this manual, two labels identify potentially dangerous or destructive conditions and procedures:



### **WARNING**

The **WARNING** label identifies conditions or practices that may present danger to the patient and/or user.



### **CAUTION**

The **CAUTION** label identifies conditions or practices that could result in damage to the equipment.

---

**NOTE:** Notes help you identify areas of possible confusion and avoid potential problems during system operation.

---



**Do NOT use cables with unattended and unsupervised children.**

**Do NOT wrap cables around your neck.**

**Batteries may explode if mistreated. Do not disassemble or dispose of batteries in fire.**

**Dispose of used batteries promptly. Keep batteries away from children.**

**Conductive parts or electrodes and their connectors, including the neutral electrode for type bf or cf electroencephalographs are not to contact other conductive parts and earth.**

## Read the safety reference guide

Please read the *Additional Information and Safety Notes for Assorted CareFusion NeuroCare Products Reference Guide* 269-594705 on CD part number 482-638702 thoroughly, paying special attention to the **Safety** information before applying power to and using your Nicolet system.

## Fixed installationguide

Please see the Fixed Installation guide for installation information.

## IT requirements

Please see the IT Requirements document for information on wired and wireless networking specifications for operation of the EEGwireless32/64

## Specification sheet

Please see Specification sheet for information regarding technical specifications of the EEGwireless32/64 amplifier.

## European authority representative

CareFusion  
Germany 234 GmbH  
Leibnizstrasse 7  
97204 Hoechberg, Germany  
Tel:( 49) 931-4972 - 308  
Email address: support.nc.eu@carefusion.com

## **Inspecting the system**

Routinely check the instrument for exterior damage.

Follow your medical facilities safety guidelines.

## **Recycling / disposal**



Many local laws and regulations consider electric equipment-related waste as hazardous or requiring special procedures to recycle or dispose of. This includes batteries, printed circuit boards, electronic components, wiring and other elements of electronic devices. Follow all of your respective local laws and regulations for the proper disposal of batteries and any other parts of your system, such as monitors, amplifiers, keyboards, electrodes, etc.

Refer to your **CareFusion** service representative for recommended instructions and addresses for proper return or disposal of electronic wastes relating to CareFusion NeuroCare products in Europe and other localities.

The contact information for the WEEE - In Europe

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USA

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# 1

## Introduction

This guide describes how to operate the amplifier in conjunction with the Nicolet EEG system and software.

## FCC Considerations

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.

## **About the Nicolet EEGwireless32/64 amplifier unit**

The amplifier is a 32/64 channel EEG amplifier that connects to a Nicolet system via wireless transmission or a standard network port. The amplifier can be used in a hospital setting without the addition of custom network infrastructure.

The amplifier:

- captures all signals needed to perform LTM monitoring, EEG, Sleep studies, Intra Operative Monitoring, Ambulatory Monitoring and ICU monitoring.
- provides low noise amplification (AC or DC recording) of physiological signals, and is designed specifically to amplify EEG and intracranial EEG signals.
- provides tethered or wireless transmission of digitized signals, which interfaces to a Nicolet Acquisition system.
- provides a quickstart feature for emergency recording situations.
- provides user configurable parameters including sampling rates and filters.
- provides built in SpO<sub>2</sub>, patient event, and provides referential, bipolar and DC recording.
- provides a small footprint and lightweight amplifier with unique garment for wearing by the patient.

The amplifier can record as a standalone device or used with Nicolet LTMsystem software for user-interface operation. It also has the ability to create electrode labels and annotations on the recorded EEG data.

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## Power Source

The amplifier can derive its operating power from either an AC outlet through the medical grade power supply, from one or two rechargeable battery packs, or from within standard, fixed installation wallplate power.

The amplifier has a second power port, which allows the plugging of either an additional battery pack for more life or a medical grade power supply. If the medical grade power supply is plugged in while a battery is also plugged into the amplifier, the battery pack will charge.

There is an onboard battery in the amplifier that allows switching of a battery pack while in the middle of a study. When the battery pack is low, it can be removed as long as it is replaced within 10 minutes of removal.

If an external battery is connected to the amplifier, the internal battery will be in the **Charge Mode**.

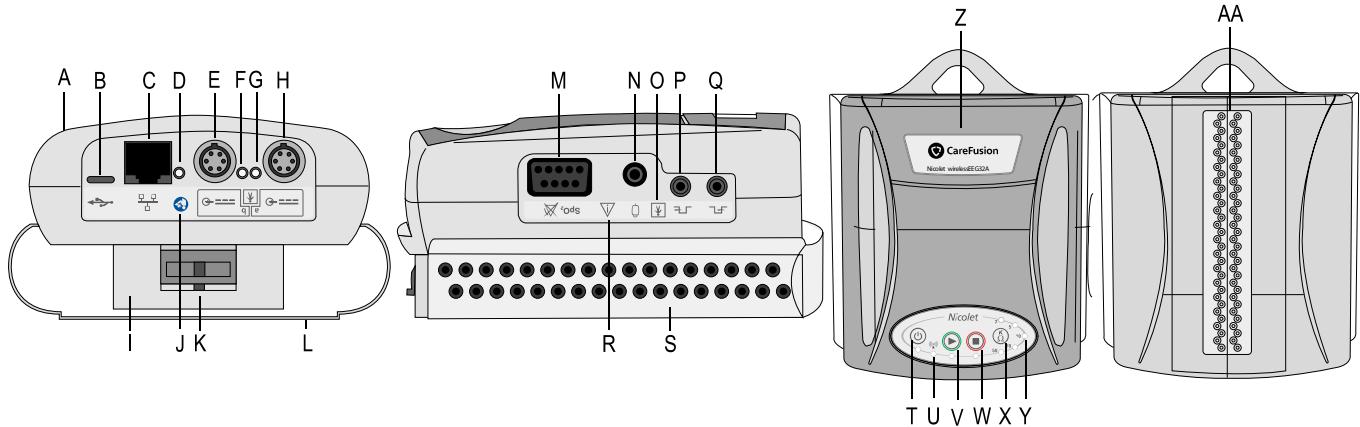
## Communication

EEG data can be transmitted to the Nicolet acquisition system either by a Ethernet cable or wirelessly using an standard 802.11 B/G access point. The amplifier is IP addressable and connects directly to the hospital network. The amplifier also provides onboard storage of EEG.

## Memory card

The amplifier has an onboard memory card used to record data. When this memory card begins to fill up, the amplifier displays an alert and the Nicolet acquisition system software indicates to the user that the memory card needs to be cleared.

## Amplifier symbols and components



|          | Symbol | Description  |          | Symbol | Description                               |           | Symbol | Description                  |
|----------|--------|--|----------|--------|---|-----------|--------|------------------------------|
| <b>A</b> | -      | Amplifier  | <b>J</b> |        | Refer to Instruction Manual ISO 7010-M002 | <b>S</b>  | -      | Electrode inputs (each side) |
| <b>B</b> |        | Diagnostic port                                    | <b>K</b> | -      | Disconnect headbox latch                  | <b>T</b>  |        | Power on/off                 |
| <b>C</b> |        | Network port                                       | <b>L</b> | -      | Electrode leads cover                     | <b>U</b>  |        | Wireless transmission on     |
| <b>D</b> | -      | LED - Ethernet connectivity                        | <b>M</b> |        | SpO2                                      | <b>V</b>  |        | Start recording              |
| <b>E</b> |        | Power input for external batteries or power supply | <b>N</b> |        | Event button input                        | <b>W</b>  |        | Stop recording               |
| <b>F</b> | -      | LED - Power connectivity                           | <b>O</b> |        | Type BF equipment                         | <b>X</b>  |        | Impedance check              |
| <b>G</b> | -      | LED - Power connectivity                           | <b>P</b> |        | Trigger output                            | <b>Y</b>  |        | LEDs - Impedance range       |
| <b>H</b> |        | Power input for external batteries or power supply | <b>Q</b> |        | Trigger input                             | <b>Z</b>  | -      | Battery door, under headbox  |
| <b>I</b> | -      | 32 or 64 headbox                                   | <b>R</b> |        | Attention, consult accompanying documents | <b>AA</b> | -      | LEDs - Impedance check       |

**NOTE:** External power from Inputs **E** and **H** are interchangeable between two external batteries and a medical power supply.

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## Activate the internal batteries

1. The first time the amplifier is used, you must pull the plastic strip out from the battery compartment (Figure 1) to activate the internal batteries for use with the amplifier.

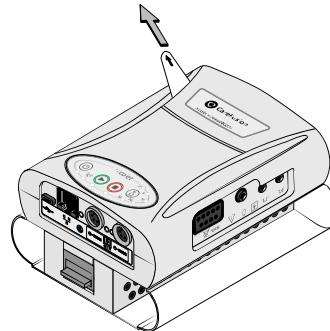


Figure 1

## Removing the electrode leads plastic cover

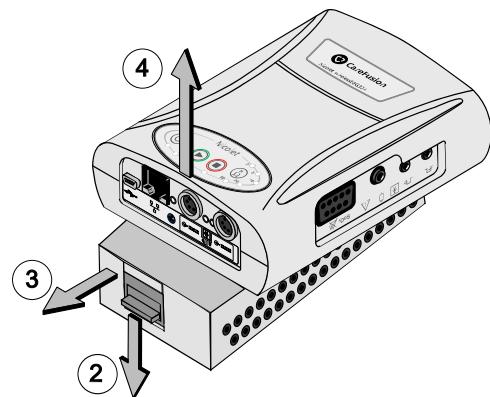
1. Grasp the plastic cover on both sides with one hand.
2. Grasp the amplifier with the other hand.
3. Carefully slide the plastic cover off the amplifier (Figure 2).



Figure 2

## Separating the headbox from the amplifier

1. Remove the electrode leads plastic cover.
2. Press downward on the release **latch** (Figure 1).
3. While firmly holding the amplifier and headbox, pull the headbox towards yourself.
4. Carefully separate the amplifier from the headbox.



*Figure 1*

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## Electrode labels

The electrode label has an area for writing customized electrode nomenclature. For temporary markings, use an **erasable** dry marker. Use **Isopropyl Alcohol** to remove the temporary markings from the labels.

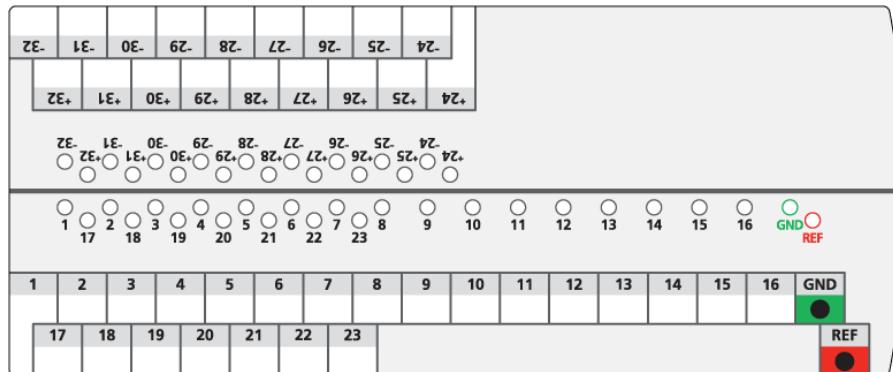


Figure 1: 32 channel electrode label.

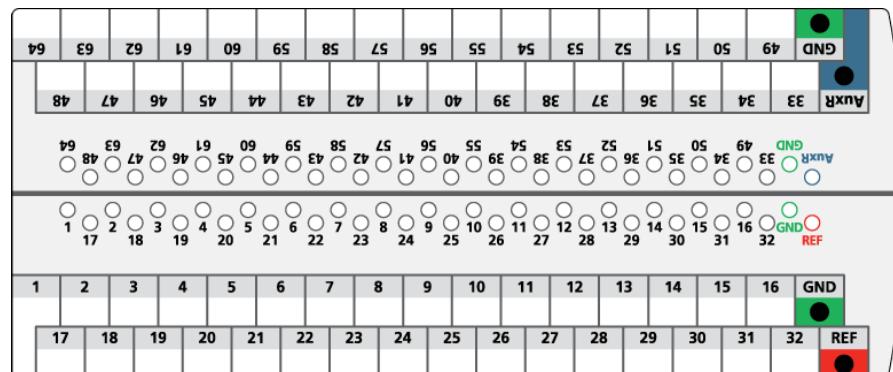


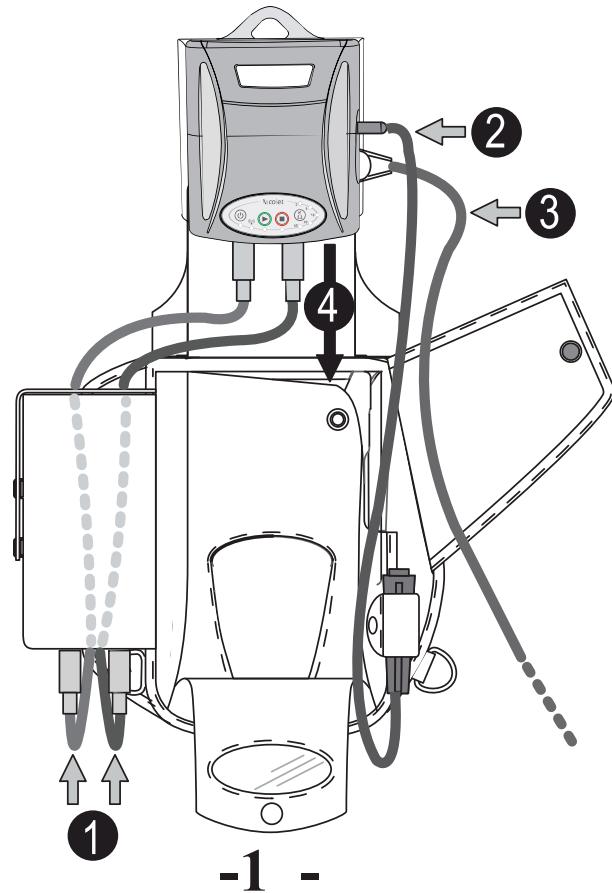
Figure 2: 64 channel electrode label.

**NOTE:** The two grounds are linked together in the amplifier. You do not need to provide two ground references.

## Cable and insert the amplifier into the carrying case

**NOTE:** See *Chapter 2* for additional cabling information.

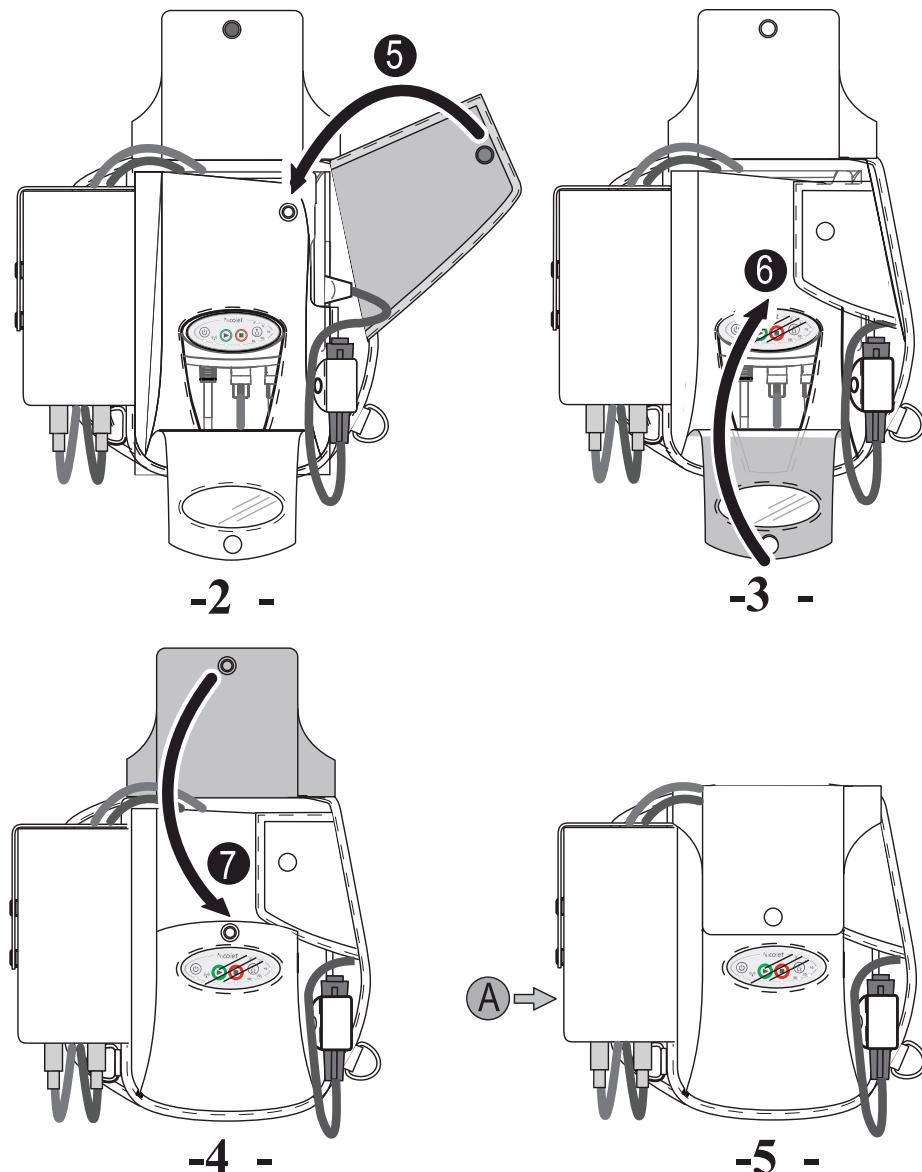
1. Connect the batteries to the amplifier (Figure 1).
2. Connect the optional Patient Event button to the amplifier.
3. Connect the optional SpO<sub>2</sub> to the amplifier. **cables** to the amplifier.
4. Insert the **amplifier** into the carrying case.



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5. Fold the **side** flap over the front and snap (Figure 2).
6. Fold the **bottom** flap up (Figure 3).
7. Fold the **top** flap down and snap to the lower flap.

**NOTE:** The battery pack (C) can be unsnapped from the carrying case and attached to the patient's belt.

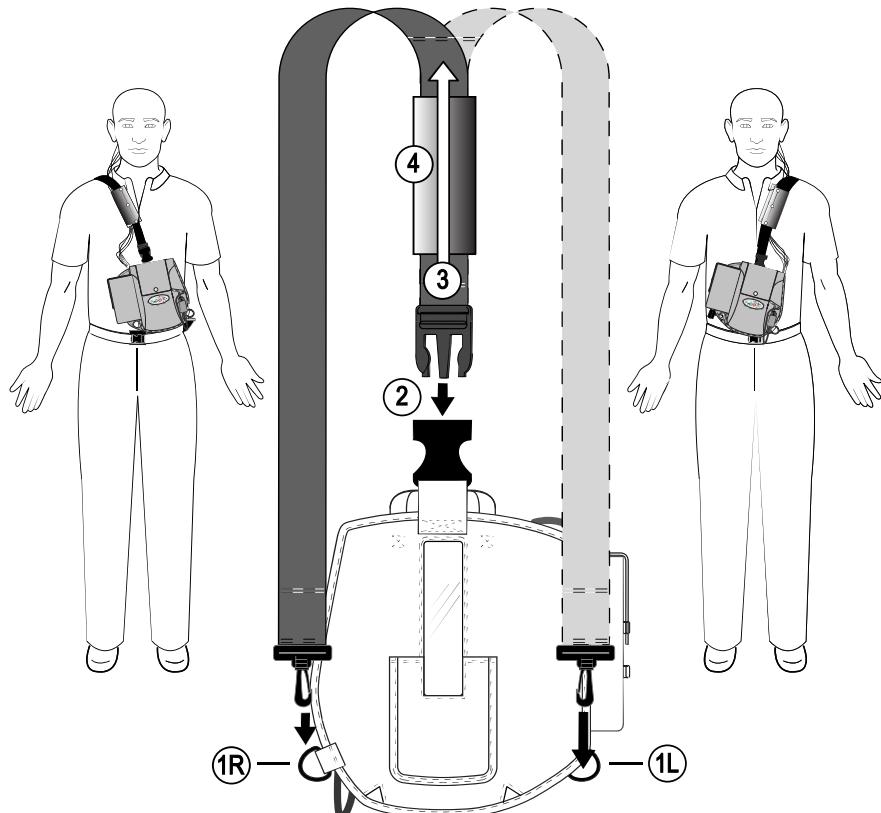


## Prepare the patient

### Option 1 - Shoulder strap

Option 1 straps the amplifier, headbox and battery pack from either the left or right shoulder.

1. Clip the shoulder strap to the bottom fastening loop; **(1R)** for the right shoulder or **(1L)** for the left shoulder (Figure 1).
2. Hang the shoulder strap assembly over the patient's shoulder and snap the other end of the shoulder strap to the top clip **(2)**.
3. Feed the electrode wires **(3)** through the electrode sleeve **(4)**.
4. Adjust the strap as necessary for a snug fit.



*Figure 1.*

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## Option 2 - Shoulder strap and belt

Option 2 straps the amplifier and headbox from either the left or right shoulder and the battery pack on the belt.

Two belts are provided with the garment, a short one (**A**) and a long one (**B**) as shown in Figure 2. Use each one individually as required or combine the two (**A** and **B**) to create a longer belt.

1. Please see the preceding page for detailed instructions for the strap.
2. Slide the belt through the belt loop (**5**) on the back of the garment.
3. Snap the belt ends together.
4. Adjust the belt as necessary for a snug fit.

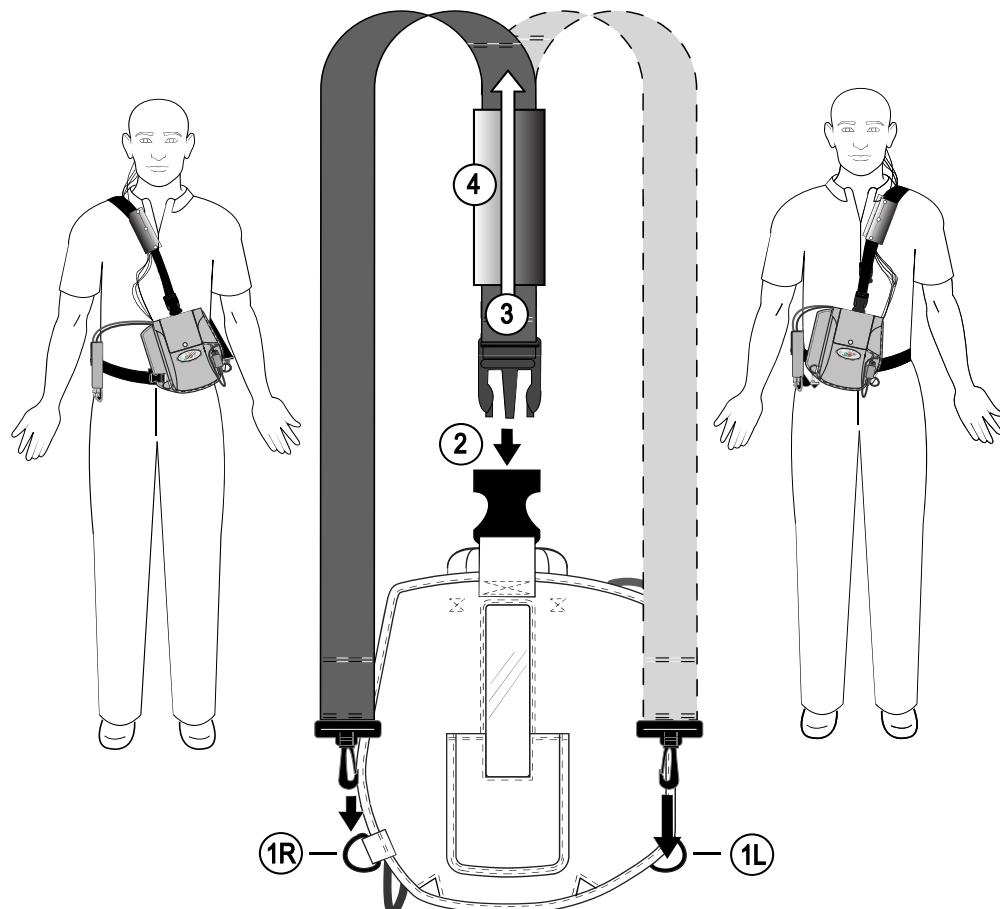


Figure 2.

## **Garment cleaning instructions**

The garment carrying case and straps are hand washable or with a delicate machine using warm water with a mild disinfectant / detergent.



**CAUTION**

**Air dry the garment only.**

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# 2

## Cabling the system

This chapter contains the cabling diagrams for the various configurations available for use with the amplifier.

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**NOTE:** Connector styles in this chapter may vary from those shown.

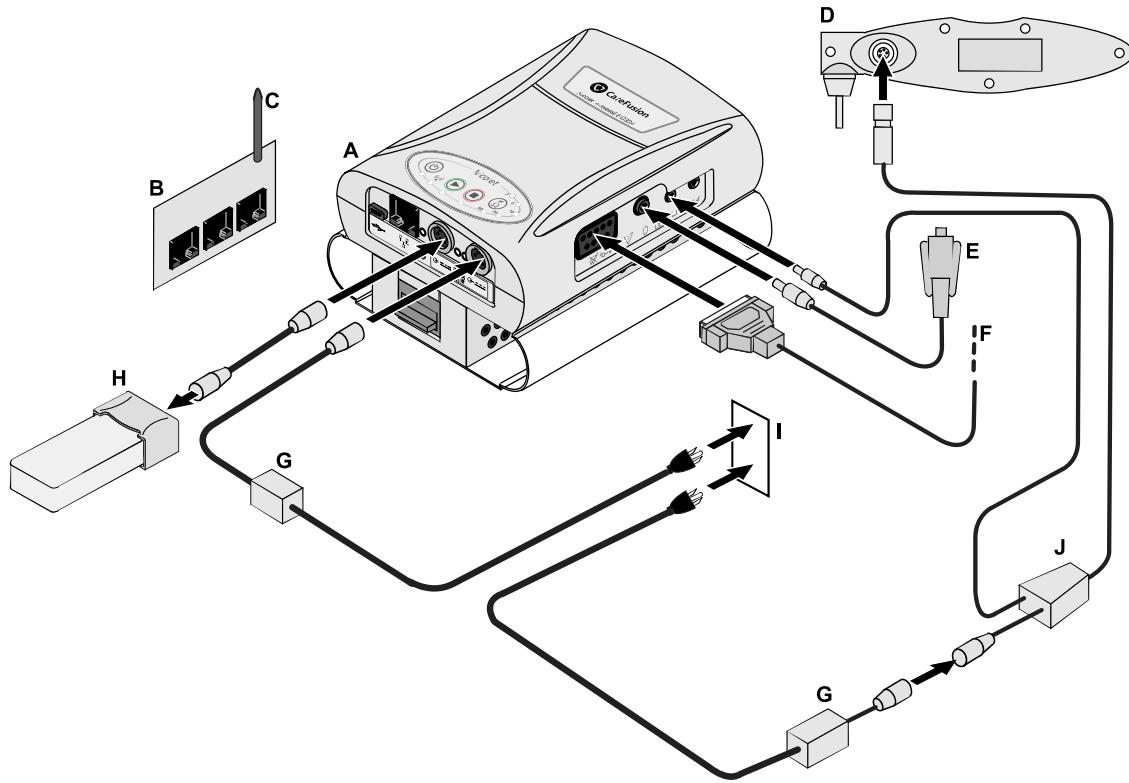
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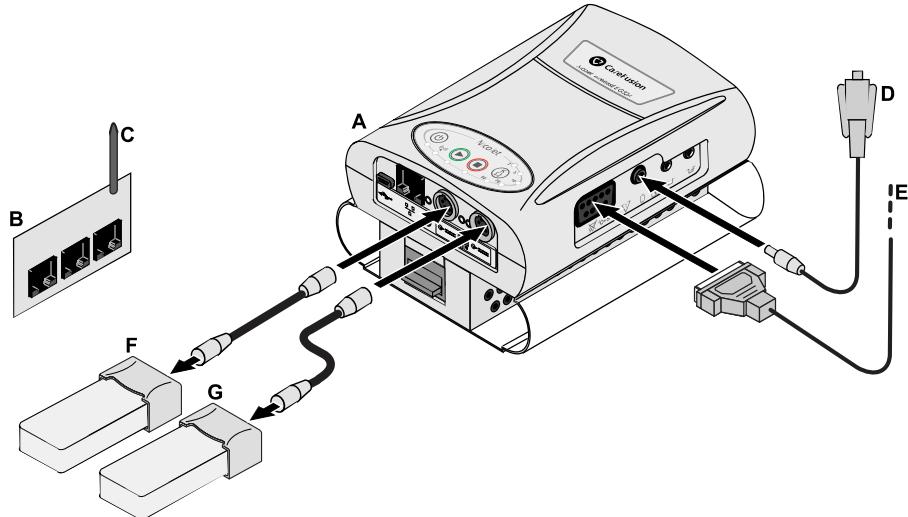
**Cabling the amplifier to be wireless with access point and hospital mains power (shown in battery charging mode, fixed install)**



| Legend   | Description                                  |
|----------|--|
| <b>A</b> | Amplifier                                    |
| <b>B</b> | Access point (connected to hospital network) |
| <b>C</b> | Antenna                                      |
| <b>D</b> | Photic strobe (option)                       |
| <b>E</b> | Event button (option)                        |
| <b>F</b> | SpO2 (option)                                |
| <b>G</b> | Medical grade power supply (PSU-EEG64)       |
| <b>H</b> | Battery with charger (Nicolet CHG1)          |
| <b>I</b> | Hospital mains                               |
| <b>J</b> | Photic cable                                 |

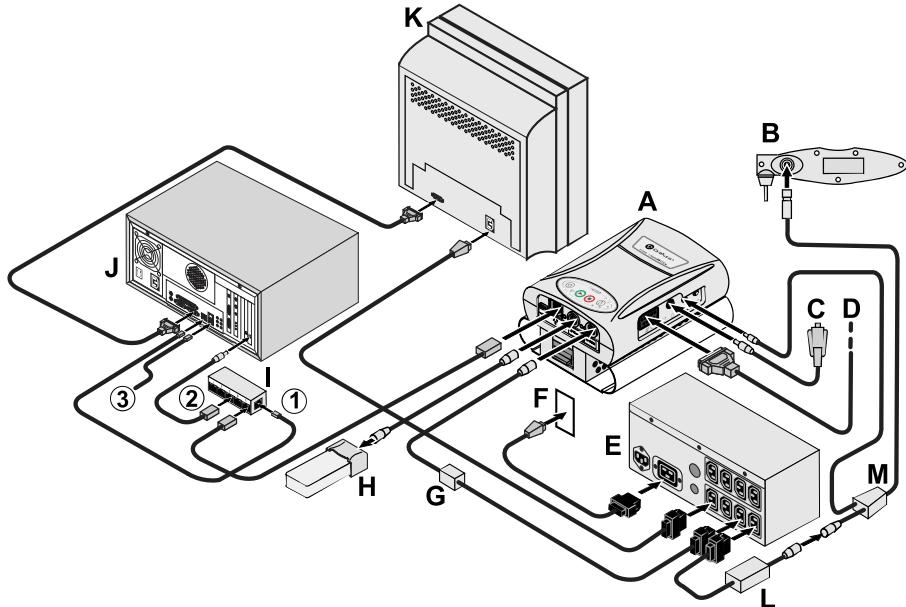
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Cabling the amplifier to be wireless with access point and Battery Power (shown with two battery packs, fixed install-roaming mode)



| Legend | Description                                  |
|--------|--|
| A      | Amplifier                                    |
| B      | Access point (connected to hospital network) |
| C      | Antenna                                      |
| D      | Event button (option)                        |
| E      | SpO2 (option)                                |
| F      | Battery with charger (Nicolet CHG1)          |
| G      | Second battery with charger (Nicolet CHG1)   |

**Cabling the cartbased system, wired network connection to a desktop computer with power supply or battery (cartmount, computer peripherals not shown)**

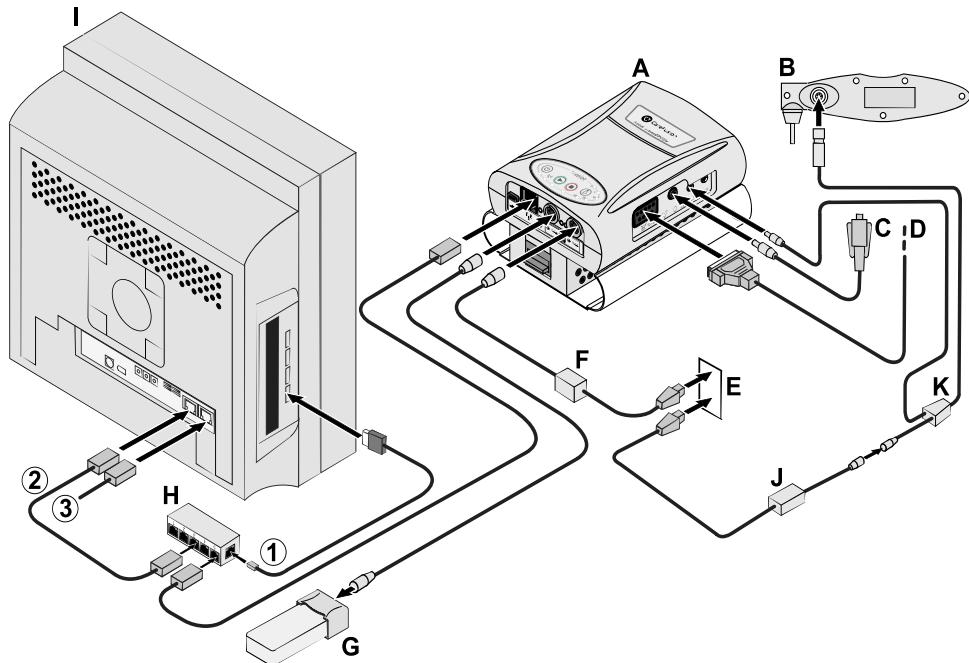


| Legend | Description  | Legend | Description  |
|--------|--|--------|--|
| A      | Amplifier  | I      | Network switch   |
| B      | Photic strobe (option)   | J      | Computer (see page 2-8 for computer and camera wiring) |
| C      | Event button (option)  | K      | Monitor  |
| D      | SpO2 (option)  | L      | Medical grade power supply (PSU-EEG64)                 |
| E      | Isolation transformer (Required with a Desktop computer in a patient room) | M      | Photic cable   |
| F      | Hospital mains   | 1      | Connect to USB Port for power                          |
| G      | Medical grade power supply (PSU-EEG64)                                     | 2      | Connect to USB Port (for switch power only)            |
| H      | Battery with charger (Nicolet CHG1)  | 3      | Output to hospital Network                             |

**NOTE:** PCI Card allows wireless connection to amplifier (optional)

# Nicolet Systems

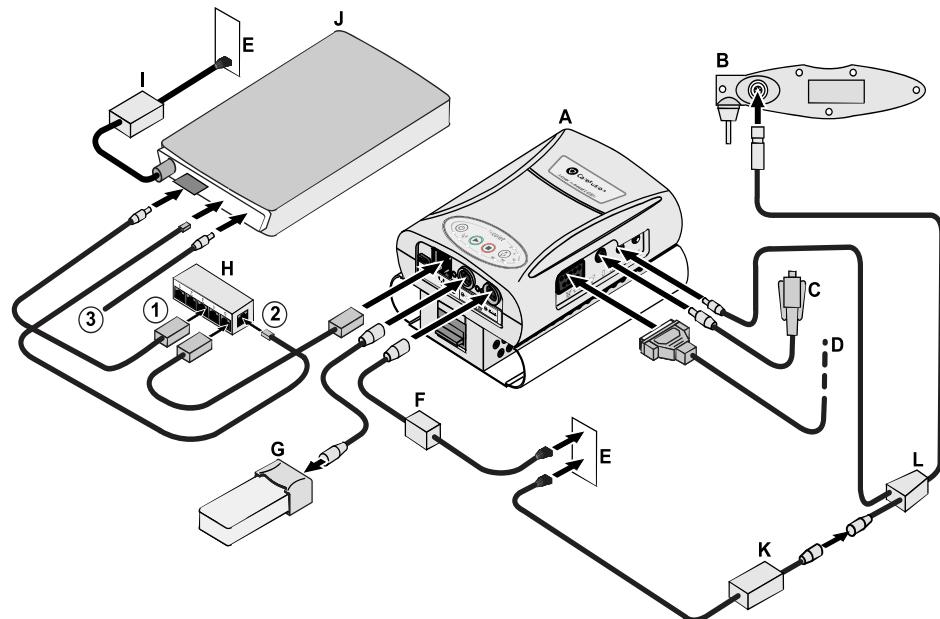
## Cabling the Panel PC with wired network communication and a supply or battery



| Legend   | Description                            | Legend   | Description                                 |
|----------|--|----------|---|
| <b>A</b> | Amplifier                              | <b>H</b> | Network switch                              |
| <b>B</b> | Photic strobe (option)                 | <b>I</b> | PanelPC                                     |
| <b>C</b> | Event button (option)                  | <b>J</b> | Medical grade power supply (PSU-EEG64)      |
| <b>D</b> | SpO2 (option)                          | <b>K</b> | Photic cable                                |
| <b>E</b> | Hospital mains                         | <b>1</b> | Connect to USB Port for power               |
| <b>F</b> | Medical grade power supply (PSU-EEG64) | <b>2</b> | Connect to USB Port (for switch power only) |
| <b>G</b> | Battery with charger (Nicolet CHG1)    | <b>3</b> | Output to hospital Network                  |

**NOTE:** US and Canada are required to only use 115VAC input power on the Panel PC Power Pack.

**Cabling the wired network communication to a laptop with power supply or battery**



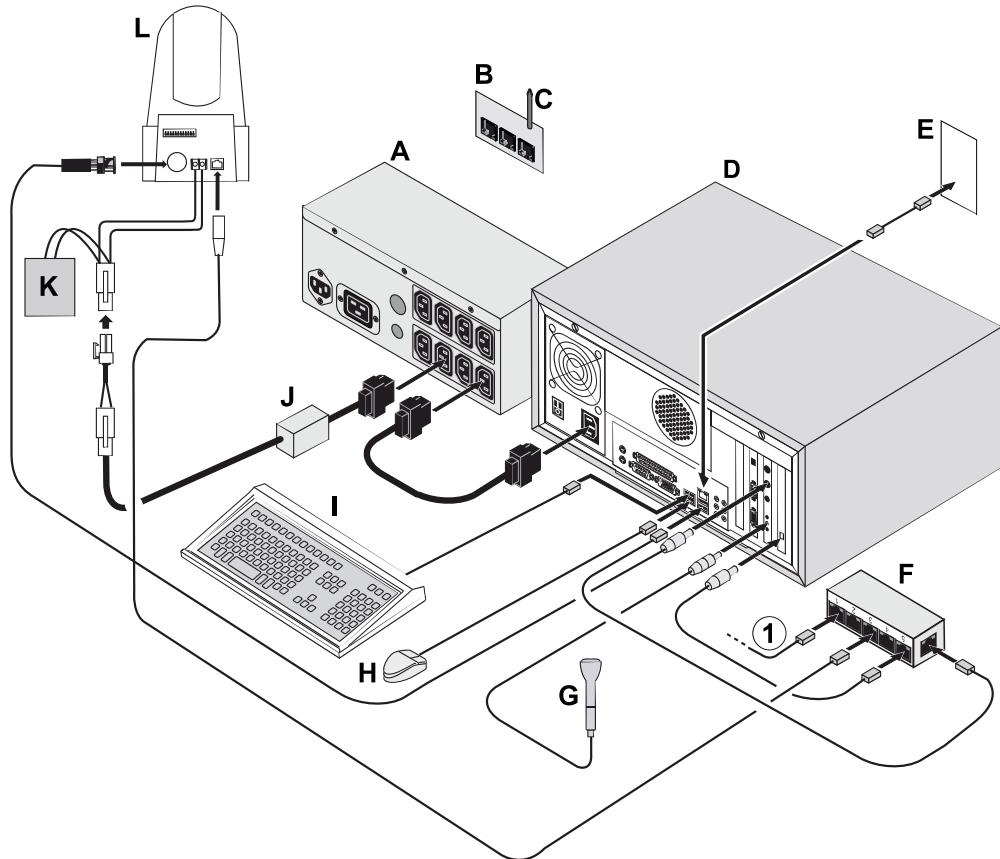
| Legend   | Description                            | Legend   | Description                                 |
|----------|--|----------|---|
| <b>A</b> | Amplifier                              | <b>I</b> | Power Supply                                |
| <b>B</b> | Photic strobe (option)                 | <b>J</b> | Laptop                                      |
| <b>C</b> | Event button (option)                  | <b>K</b> | Medical grade power supply (PSU-EEG64)      |
| <b>D</b> | SpO2 (option)                          | <b>L</b> | Photic cable                                |
| <b>E</b> | Hospital mains                         | <b>1</b> | Connect to USB Port for power               |
| <b>F</b> | Medical grade power supply (PSU-EEG64) | <b>2</b> | Connect to USB Port (for switch power only) |
| <b>G</b> | Battery with charger (Nicolet CHG1)    | <b>3</b> | Output to hospital Network                  |
| <b>H</b> | Network switch                         |          |   |

**NOTE:** PCMCIA Card allows wireless connection to amp (optional).

**NOTE:** US and Canada are required to only use 115VAC input power on the Laptop Power Pack.

# Nicolet Systems

## Cabling the computer



| Legend   | Description                                   | Legend   | Description                  |
|----------|---|----------|------------------------------|
| <b>A</b> | Isolation transformer                         | <b>H</b> | Mouse                        |
| <b>B</b> | Access point (Wireless Amplifier option only) | <b>I</b> | Keyboard                     |
| <b>C</b> | Antenna                                       | <b>J</b> | Medical grade power supply   |
| <b>D</b> | Computer                                      | <b>K</b> | IR Illuminator (option)      |
| <b>E</b> | Ethernet to hospital network wallplate        | <b>L</b> | Sony digital camera (option) |
| <b>F</b> | Network switch                                | <b>1</b> | From wired amplifier         |
| <b>G</b> | Microphone (option)                           |          |                              |

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# 3

## **NicoletEEGwireless32/64 Operation**

This chapter describes how to operate the Nicolet EEGwireless32/64 amplifier remotely.

Please see *Chapter 4* for instructions on operating the Nicolet EEGwireless32/64 amplifier connected to a Nicolet system.

## **Nicolet Systems**

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## Turn on the amplifier

1. Press the **Power** button (A in Figure 1) for 3 - 5 seconds.

When power is turned on, the **Power LED** (B) illuminates.

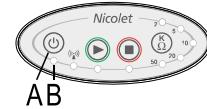


Figure 1

The number of illuminated LEDs (A in Figure 2) on the rear of the amplifier identify whether the amplifier is a 32 or 64 channel amplifier.

### Faulty communication indication

If **all** of the LEDs are flashing on the rear panel (A in Figure 2), a **communication fault** has occurred.

### Error signal indication

If **none** of the LEDs are illuminated on the rear panel (A in Figure 2), an **error signal** has occurred.

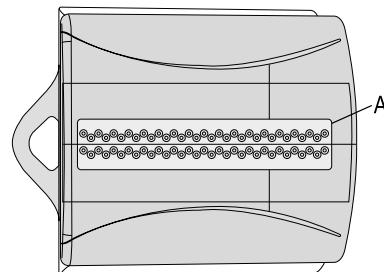


Figure 2

# Nicolet Systems

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## Perform an impedance test from the amplifier

The Headbox connects to the amplifier and provides an interface for impedance testing without using a Nicolet system.

1. Hold down the **Impedance Check** button (A in Figure 1) for 2 seconds to initiate the impedance check.
2. Press the **Impedance Check** button repeatedly until the desired impedance range: 2, 5, 10, 20, 50 Kohms LED (B) illuminates.  
**NOTE:** Range changes on release of the button.
3. Hold down the **Impedance Check** button again for 2 seconds to exit the impedance check.

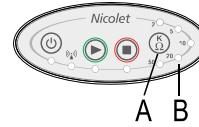


Figure 1

**Impedance indications**

The LEDs (A in Figure 1) on the back of the Headbox indicate the impedance of the connected electrodes within the range selected when the Impedance check button is pushed.

**Unlit** Impedance LEDs identify “in range” electrode impedances.

**Orange** Impedance LEDs identify “out of range” electrode impedances.

**For electrodes with ‘out of range’ impedances:**

1. Check the electrode connections to the amplifier.

**! CAUTION** Electrodes with “out of range” impedances may appear noisier than those with “in range” impedances.

2. Perform the troubleshooting steps, if desired.
3. Repeat the impedance steps.

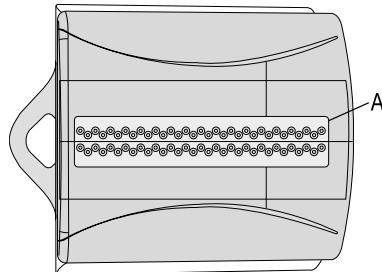


Figure 1

# Nicolet Systems

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## Start a study from the amplifier

1. Press the **Start Study (Record)** button (A in Figure 1) for 3 - 5 seconds to start a study.

The **Study Started LED (B)** illuminates when the study starts.

## Stop a study from the amplifier

1. Press the **Stop Study** button (C in Figure 1) for 12 seconds to stop a study.

The **Study Stopped LED (D)** illuminates and the **Study Started LED (B)** turns off when the study stops.

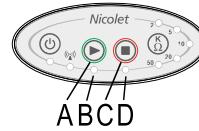


Figure 1

## Turnoff the amplifier

1. Press the **Power** button (A in Figure 2) for 12 seconds.

When power is turned off, the **Power LED (B)** turns off.

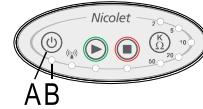


Figure 2

## Quickstart feature (starting a recording from the amplifier)

You can now start a study from the amplifier without having a Nicolet system attached. This study doesn't have patient identification until it is connected to a Nicolet system at which time you can assign patient demographic information. You can acquire multiple studies from a single patient and when connected to a Nicolet system, all data will appear with appropriate start and stop times and dates marked. To acquire data from another patient, you must first connect to a Nicolet system and download all stored data before beginning a recording on a second patient.

1. Press the **Start Recording**  button for 3 - 5 seconds to start a study.
2. The Start Recording LED illuminates when the study starts (Figure 1).



|          |                        |
|----------|------------------------|
| <b>A</b> | Start Recording button |
| <b>B</b> | Start Recording LED    |

Figure 1

**NOTE:** Currently acquired data is added to previously acquired data stored on the amplifier along with start and stop times.

# Nicolet Systems

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## Data catch up

In the event that the amplifier fails to communicate to the network or the acquisition station being used to acquire data, the amplifier stores data locally. The amplifier has onboard memory and stores all data acquired (EEG, Patient Event, Impedance Threshold Check) to its onboard memory. When the amplifier communication is restored to the network or acquisition station, the data stored locally on the amplifier is transmitted along with the current (live) data.

**NOTE:** The internal storage is not user accessible.

### **Wired to disconnected, operating on internal batteries (Mode 1)**

The following applies to an amplifier wired to the Nicolet Acquisition station (wireless capability disabled)

#### Scenario

The amplifier is acquiring data for a study and is connected either:

- directly to a Nicolet Acquisition station
  - or -
  - to a network running the Nicolet Acquisition station.
    - a. The Ethernet cable connecting the amplifier to the Nicolet Acquisition station is disconnected causing the Nicolet software to display an alert that a disconnect has occurred. Also, the medical power brick becomes disconnected.
    - b. During this time data is being stored onboard the amplifier.
    - c. The amount of time the patient can remain disconnected is a function of the charge level of the battery (see *Using the Battery* chapter). Typical times are around 20 minutes.
    - d. The amplifier is reconnected to the network or to the same Nicolet acquisition station to which it was initially connected.
    - e. The Nicolet acquisition station displays that the amplifier has been reconnected.
    - f. See the following *Data Catchup* section concerning the behavior once the amplifier is reconnected.

**Wireless to out of range, operating on external battery pack (Mode 1)**

The following applies to an amplifier operating in the Wireless mode.

The amplifier is acquiring data for a study and is connected either:

- directly wirelessly to a Nicolet acquisition station.
  - or -
- to a wireless network running a Nicolet acquisition station.
  - a. The patient moves to a location that is out of range of any wireless access point (100 feet line of sight) resulting in loss of wireless communication. The Nicolet software displays an alert that a disconnect has occurred.
  - b. During this time data is being stored onboard the amplifier.
  - c. The amount of time the patient can remain disconnected is a function of the charge level of the battery or the space of the onboard memory.
  - d. The amplifier is reconnected to the network or to the same Nicolet acquisition station to which it was initially connected.
  - e. After a moment, the Nicolet acquisition station displays that the amplifier has been reconnected.

# Nicolet Systems

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## **Data catch up (disconnected less than 10 minutes)**

The following applies to an amplifier wired to the Nicolet acquisition station with no wireless capability.

**NOTE:** If the amplifier is in range of a wireless access point, disconnecting the amplifier's Ethernet cable will not result in an interruption of data to the Nicolet acquisition station.

### **Scenario**

The amplifier is acquiring data for a study and is connected either:

- directly to a Nicolet acquisition station
  - or -
  - to a network running the Nicolet acquisition station.
    - a. The Ethernet cable connecting the amplifier to the Nicolet acquisition station is disconnected causing the Nicolet software to display an alert that a disconnect has occurred.
    - b. The disconnect lasts less than 10 minutes.
    - c. The amplifier is reconnected to the network or to the same Nicolet acquisition station to which it was initially connected.
    - d. After a moment, the Nicolet acquisition station displays that the amplifier has been reconnected.

**Data catch up  
(disconnected more  
than 10 minutes)**

The following applies to an amplifier wired to the Nicolet acquisition station or operating in the Wireless mode.

**NOTE:** If the amplifier is in range of a wireless access point, disconnecting the amplifier's Ethernet cable will not result in an interruption of data to the Nicolet acquisition station.

The amplifier is acquiring data for a study and is connected either:

- directly to a Nicolet acquisition station
  - or -
  - to a network running the Nicolet acquisition station
    - a. The Ethernet cable connecting the amplifier to the Nicolet acquisition station is disconnected, causing the Nicolet software to display an alert that a disconnect has occurred.
    - b. The disconnect lasts longer than 10 minutes.
    - c. An immediate file split occurs within the Nicolet acquisition station after the 10 minute period has elapsed. Video will not be available, when reviewing the exam, for the period of time the amplifier was disconnected.
    - d. The amplifier is reconnected to the network or to the same Nicolet acquisition station to which it was initially connected.
    - e. After a moment, the Nicolet acquisition station displays that the amplifier has been reconnected.

# Nicolet Systems

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## Memory capacity

As defined in Table1 , the amplifier has a finite amount of time it can acquire data while disconnected. When the amplifier has approximately an hour of storage left, LED 7 (see page 1-9) displays a solid light and an auditory warning sounds.

## Clearing the amplifier's onboard memory

While recording a study, the amplifier records all data collected to its onboard memory. Data may be erased from this onboard memory only with user intervention. The data must be erased before starting a new study or to continue an extended study.

### Manual memory clearing

1. In the Nicolet acquisition station acquiring data from the amplifier, click on **Options > Clear Memory**.
2. A prompt ensuring you want to clear the memory appears. Click **Yes** to clear the memory.
3. To verify the memory has been cleared, go to the Nicolet Wireless Amplifier status screen **Tools> Wireless Panel** and ensure the “Free” and “Total” onboard memory values are equal.

### Prompted memory clearing at end of a study

1. After an exam concludes, a prompt appears stating you need to clear the onboard memory.
2. Click **Yes** to clear the memory.

### Prompted memory clearing for an extended study

If a study runs for a time greater than defined in Table1 for a given sampling rate, you need to clear the onboard memory to continue.

1. A prompt appears stating you need to clear the onboard memory.
2. Click **Yes** to clear the memory.

## **Internal SpO2 operation**

3. The amplifier supports the acquisition of SpO2 data. The amplifier has a built in Nonin model [insert here] for heart rate, pleth, SpO2. To acquire SpO2 data, connect a Nonin [MODEL NUMBER OF FINGER PROBE] with optional extension cables to the amplifier. Please refer to the Nicolet Software Reference guide for instructions on using vital signs or an external SpO2 device.

## **Nicolet Systems**

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# 4

## Using the Nicolet system to setup and acquire EEG

This Chapter describes how to operate the Nicolet EEGwireless32/64 amplifier controls from the Nicolet system. Please see the previous chapter for instructions on controlling the Nicolet EEGwireless32/64 amplifier from itself.

## **Nicolet Systems**

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### Using the Nicolet system to setup and acquire EEG

This procedure describes using the Nicolet system to setup and acquire EEG. Please see *Using the amplifier to setup and acquire EEG* in this guide.

When directed to select traces in the following steps, the traces change color for easy identification.

#### Select the amplifier for the study

To start a study while connected to a Nicolet acquisition station, either directly or over a network, you must first select an amplifier from which to acquire EEG.

1. From the Nicolet acquisition station, click on **Options > Wireless Panel**. The Wireless Panel dialog appears.
2. Each amplifier has a unique identifier (Figure 1). Select the amplifier from the Wireless Panel dialog with the same identifier as your amplifier.

**NOTE:** In the event that the amplifier is still storing data from a previous exam, you will see a prompt asking you to either download the data or erase the data from the amplifier. If you choose to download the data, the amplifier will perform data catch-up. See **Data Catch-Up** in Chapter 3 for more information.

#### Select a protocol

To start an exam through Nicolet system, you must first select a protocol to run.

 **CAUTION** There are protocols specific to the amplifier that must be selected to ensure proper operation.

3. From the options menu, select **Protocols**.
4. From the dropdown list on the left, select **EEGwireless32** or **EEGwireless64** depending on the number of channels with which your amplifier is configured.
5. Click on **Apply Changes**.
6. Click **OK**.
7. The amplifier is ready to start acquiring data.

# Nicolet Systems

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## Check the impedance

**NOTE:** Skip step 8 if the **Startup in Impedance mode** checkbox was checked earlier (**Tools> Options > Acquisition tab**). Checking this box causes the Impedance window to appear automatically when you open the **Recorder software**. Please refer to the Nicolet System Software Reference Guide, **Miscellaneous Quick Steps** chapter, **Acquisition** tab for additional information.

8. Select **Impedance**  to display the Impedance Testw indow.  
**- or -**  
Select **Acquisition > Impedance**.
9. Select the acceptable impedance range, which should be **5K ohms or less**:

Click on the **Threshold** show menu  button and then select the desired **threshold value**.

**- or -**

Enter a **custom** value.

10. The measured impedance values are displayed for each electrode.
  - Electrodes with in range impedances are displayed in **green**.
  - Electrodes that are out of range are displayed in **red**. Allow time for the Impedance Testw indow to update as you work to lower impedances as necessary.
11. When the impedances are in range, select **Start**.
12. The Recorder window appears with the EEG scrolling across the screen, but not

yet being saved to the hard drive. Select **Record**  to start the recording unless the EEG was initiated using “**Quick Start**”.

The impedance threshold check can be performed either from the amplifier or from the software. To check the impedance from the amplifier see Chapter 3.

1. Click on **Options > Impedance Check**.
2. Click **Start Impedance Check**.
3. The impedances are displayed on the Nicolet Acquisiton screen.

**Start recording EEG**

4. If the Impedance Check panel was enabled to appear automatically when the Recorder application was started, the system begins recording as soon as you close the Impedance Check panel.

If the feature was not enabled, select **Record**  start recording.

**NOTE:** Select **Record**  again to stop recording EEG.

**Disconnecting from the Nicolet system**

In the event that the amplifier becomes disconnected from the Nicolet acquisition station or the network, either accidentally or intentionally, the amplifier stores its neurodiagnostic information onboard. For more information see the Catch-up section in Chapter 3.

# Nicolet Systems

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## Optional steps

The following describes how to enable/edit various features/parameters available on the Nicolet acquisition system.

### Enabling automatic impedance testing after changing the montage

The system can test the electrode impedances each time you change to a different montage.

1. Select **Settings**  and then **Misc** at the bottom of the **Editor** window.

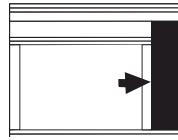
**- or -**

Select **Protocol > Settings** and then **Misc** at the bottom of the Editor window.

2. Checkmark **Automatic Impedance Test on Montage Change**.
3. Select **Save**.
4. Select **Close**.

### Edit the parameters

#### Display the Control Panel



1. Select **Panel** .
2. Select **View > Panel > Format** to display the Format palette, which lets you easily change the sensitivity, LFF, HF, F, timebase, montage and the number of channels displayed.

### **Select the montage**

1. From the Control Panel, select the **Montage** button on the **Format** palette and then select the desired **montage**.

**- or -**

Select **Format > Montage** and then select the desired **montage**.

**- or -**

Select the desired **Montage shortcut** button.

**- or -**

Right-click on the **trace labels**, select **Montage** and then select the desired **montage**.

### **Select the Sensitivity**

1. From the **Control Panel**, select the **Sensitivity** button on the **Format** palette and then select the desired **sensitivity**.

**- or -**

Select **Montage > Sensitivity** and then select the desired sensitivity.

**- or -**

Right-click on the **trace labels**, select **All Traces> Sensitivity** and then select the desired **sensitivity**.

**- or -**

Right-click on the trace labels, select **Adjust Selected** and then select the desired **sensitivity**.

### **Select the Timebase**

1. From the Control Panel, select the **Timebase** button on the **Format** palette and then select the desired timebase.

**- or -**

Select **Montage > Timebase** and then select the desired **timebase**.

**- or -**

Right-click on the **trace labels**, select **All Traces> Timebase** and then select the desired **timebase**.

# Nicolet Systems

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## Select the High Cut/Low Cut filters

1. From the Control Panel, select the **High Cut** or **Low Cut** button on the **Format** palette and then select the desired **filter settings**.

**- or -**

Select **Montage > High Cut/Low Cut** and then select the desired **filter** settings.

**- or -**

Right-click on the **trace labels**, select **All Traces**, select **HighCut/LowCut** and then select the desired **filter** settings.

**- or -**

Right-click on the **trace labels**, select **Adjust Selected**, select **HighCut/LowCut** and then select the desired **filter** settings.

## Turn the Notch filter on

1. Select **Notch** .

**- or -**

Select **Montage > Notch**.

**- or -**

Right-click on the **trace labels**, select **All Traces** and then select **Notch**.

**- or -**

Right-click on the **trace labels**, select **Adjust Selected** and then select **Notch**.

### Display the Reader window (optional)

1. Select **Review**  to display the Reader window to the left of the Record window if you want to review the EEG (or look back in the EEG) while it is being recorded.

**NOTE:** The Reader window does not update automatically. To view the latest EEG that was recorded, select **End** .

### Splitting long recordings into multiple files

You can split the recording into multiple files at a specified time or at the end of a predetermined file duration.



1. Select **Settings**  and then select **Misc** at the bottom of the Editor window.  
- or -  
Select **Protocol > Settings** and then select **Misc** at the bottom of the Editor window.

#### Splitting the recording at a specified file duration

- a. Click on the **Maximum File Duration** radio button.
- b. Select the **file duration** after which the file will close and a new file begins storing data.
- c. Select **Save**.
- d. Select **Close**.

#### Splitting the recording at a specified time

- a. Click on the **Start New File at** radio button.
- b. Select the **time of day** (AM or PM) at which you want the file to close and a new file begins storing data.
- c. Select **Save**.
- d. Select **Close**.

## **Nicolet Systems**

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# 5

## Using the EEGwireless32/64 Batteries

This chapter contains information about the internal batteries that may be used with the EEGwireless32/64.

## **Nicolet Systems**

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## Internal batteries that must be used with the amplifier

### CAUTION

The internal batteries must be replaced by only CareFusion Field Service Engineers or Hospital Biomed personnel.

Only use the following batteries with the amplifier.

- Two Panasonic #CGR14500

- or -

- Two Sanyo #UR14500P.

The internal batteries are rated for up to 400 charges in order to maintain an 80% charge.

The internal batteries can be charged with either an external battery or power supply.

## Activate the internal batteries

1. Pull the plastic strip out from the battery compartment (Figure 1) to activate the internal batteries for use with the amplifier.



Figure 1

# Nicolet Systems

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## Tenminute operation

New internal batteries can operate for up to ten minutes.

## Checking the internal batteries charges

1. Display the Wireless Panel pane in the Panel on the right side of the Acquisition window; click **View > Panel > NicoletOne Wireless Amp Panel**.
2. The percent of charge remaining is displayed in the Wireless Panel pane for **Bat 1**, **Bat 2**, and **Backup** batteries.

## Charging the external batteries

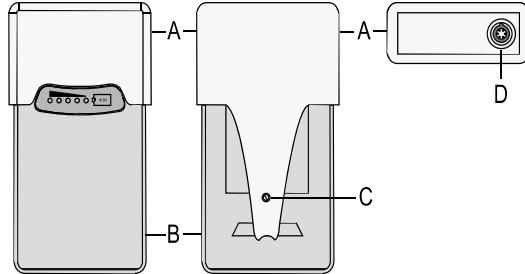


Figure 1: External battery and charger.

| Legend   | Description   |
|----------|---|
| <b>A</b> | Charger (Nicolet CHG1)  |
| <b>B</b> | Battery (Nicolet BAT1)  |
| <b>C</b> | Tool removable  |
| <b>D</b> | Connector (To amplifier or power supply for charging the battery) |

**Charging the battery  
with a medical grade  
power supply**

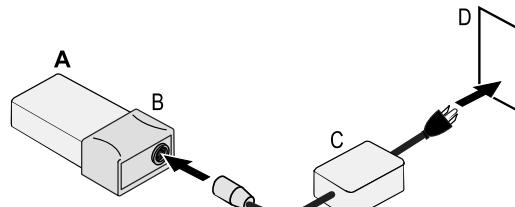


Figure 2

| Legend   | Description                      |
|----------|----------------------------------|
| <b>A</b> | Battery (Nicolet BAT1)           |
| <b>B</b> | Charger (Nicolet CHG1)           |
| <b>C</b> | Medical power supply (PSU-EEG64) |
| <b>D</b> | Wallplate- Hospital mains        |

**Charging the battery  
from the amplifier  
with a medical grade  
power supply**

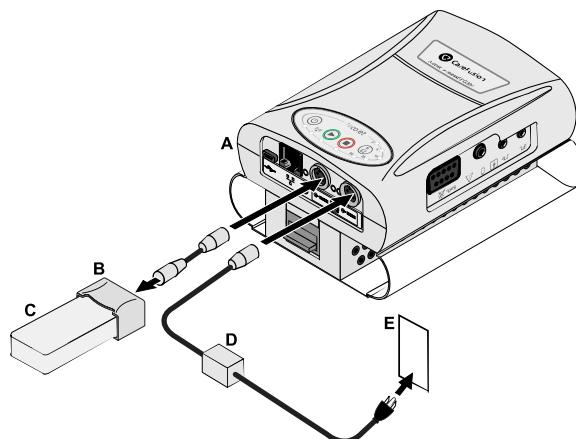


Figure 3

| Legend   | Description                      |
|----------|----------------------------------|
| <b>A</b> | Amplifier                        |
| <b>B</b> | Charger (Nicolet CHG1)           |
| <b>C</b> | Battery (Nicolet BAT1)           |
| <b>D</b> | Medical power supply (PSU-EEG64) |
| <b>E</b> | Wallplate- Hospital mains        |

# Nicolet Systems

## Replacing the internal Amplifier batteries

### Remove the electrode leads plastic shield

1. Grasp the plastic shield on both sides with one hand.
2. Grasp the amplifier with the other hand.
3. Carefully slide the plastic shield backwards off the amplifier (Figure 1) and set it aside.

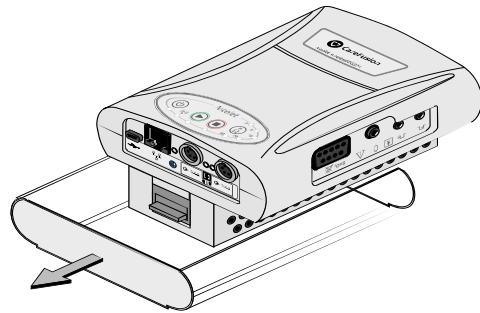


Figure 1

### Separate the headbox from the amplifier

1. Press downward on the release **latch** (Figure 2).
2. Carefully pull the amplifier and headbox apart and set the headbox aside.

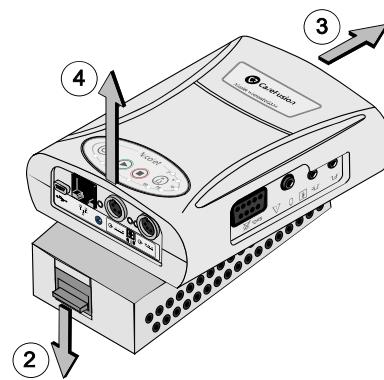


Figure 2

**Remove the battery cover securing screws**

1. Remove the two securing screws (A in Figure 3).

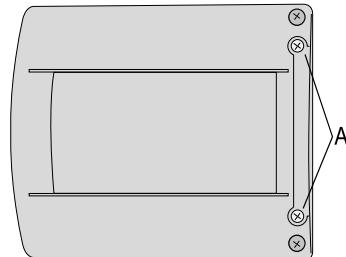


Figure 3

**Remove the battery cover**

1. Carefully separate the battery cover from the amplifier (Figure 3) and set it aside.

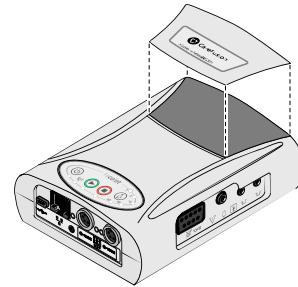


Figure 4

**Insert the batteries**

1. Insert the batteries with the anode (+) orientated as shown in Figure 5.

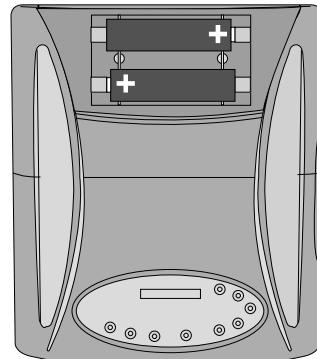


Figure 5

**Replace the battery cover**

1. Replace and secure the battery cover with the two screws removed earlier.

## **Nicolet Systems**

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# 6

## **NicoletEEGwireless32/64 OnboardMemory**

This chapter contains information about the Nicolet EEGwireless32/64 onboard memory.

## **Nicolet Systems**

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## Onboard memory

The amplifier has 32GB onboard memory that records neurodiagnostic information. In the event that the amplifier fails to communicate to the network or the Acquisition station being used to acquire data, the amplifier stores data locally. The onboard memory stores all data acquired (EEG, Patient Event, Impedance Threshold Check). When the amplifier communication is restored to the network or Acquisition station, the data stored locally on the amplifier is transmitted along with the current (live) data.

The data on this memory persists through power cycles. The amplifier can be disconnected for approximately the amount of time shown below, for a given channel count and sampling rate.

If you fail to communicate for a period of more than 10 minutes (factory set) when performing data catchup, you will not have video with the EEG data.

### Storage at 12kHz

| Number of EEG Channels | Estimated Data Storage for 1 Hour (Gbytes) | Estimated Storage Time with 32GB SD Card (Hours) |
|------------------------|--|--|
| 32                     | 2.8  | 11.292   |
| 64                     | 5.5  | 5.563  |
| 96                     | 8.3  | 3.653  |
| 128                    | 11.1                                       | 2.698  |
| 160                    | 13.8                                       | 2.125  |
| 192                    | 16.6                                       | 1.743  |
| 224                    | 19.4                                       | 1.470  |
| 256                    | 22.1                                       | 1.266  |

# Nicolet Systems

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## Storage at 10kHz

| Number of EEG Channels | Estimated Data Storage for 1 Hour (Gbytes) | Estimated Storage Time with 32GB SD Card (Hours) |
|------------------------|--|--|
| 32                     | 2.3  | 13.583   |
| 64                     | 4.6  | 6.708  |
| 96                     | 6.9  | 4.417  |
| 128                    | 9.2  | 3.271  |
| 160                    | 11.5                                       | 2.583  |
| 192                    | 13.8                                       | 2.125  |
| 224                    | 16.1                                       | 1.798  |
| 256                    | 18.4                                       | 1.522  |

## Storage at 8kHz

| Number of EEG Channels | Estimated Data Storage for 1 Hour (Gbytes) | Estimated Storage Time with 32GB SD Card (Hours) |
|------------------------|--|--|
| 32                     | 1.8  | 17.021   |
| 64                     | 3.7  | 8.427  |
| 96                     | 5.5  | 5.563  |
| 128                    | 7.4  | 4.130  |
| 160                    | 9.2  | 3.271  |
| 192                    | 11.1                                       | 2.698  |
| 224                    | 12.9                                       | 2.289  |
| 256                    | 14.7                                       | 1.982  |

## Storage at 4kHz

| Number of EEG Channels | Estimated Data Storage for 1 Hour (Gbytes) | Estimated Storage Time with 32GB SD Card (Hours) |
|------------------------|--|--|
| 32                     | 0.9  | 34.208   |
| 64                     | 1.8  | 17.021   |
| 96                     | 2.8  | 11.292   |
| 128                    | 3.7  | 8.427  |
| 160                    | 4.6  | 6.708  |
| 192                    | 5.5  | 5.563  |
| 224                    | 6.5  | 4.744  |
| 256                    | 7.4  | 4.130  |

**Storage at 2kHz**

| <b>Number of EEG Channels</b> | <b>Estimated Data Storage for 1 Hour (Gbytes)</b> | <b>Estimated Storage Time with 32GB SD Card (Hours)</b> |
|-------------------------------|---|---|
| <b>32</b>                     | 0.5   | 68.583  |
| <b>64</b>                     | 0.9   | 34.208  |
| <b>96</b>                     | 1.4   | 22.750  |
| <b>128</b>                    | 1.8   | 17.021  |
| <b>160</b>                    | 2.3   | 13.583  |
| <b>192</b>                    | 2.8   | 11.292  |
| <b>224</b>                    | 3.2   | 9.655   |
| <b>256</b>                    | 3.7   | 8.427   |

**Storage at 1kHz**

| <b>Number of EEG Channels</b> | <b>Estimated Data Storage for 1 Hour (Gbytes)</b> | <b>Estimated Storage Time with 32GB SD Card (Hours)</b> |
|-------------------------------|---|---|
| <b>32</b>                     | 0.2   | 137.333   |
| <b>64</b>                     | 0.5   | 68.583  |
| <b>96</b>                     | 0.7   | 45.667  |
| <b>128</b>                    | 0.9   | 34.208  |
| <b>160</b>                    | 1.2   | 27.333  |
| <b>192</b>                    | 1.4   | 22.750  |
| <b>224</b>                    | 1.6   | 19.467  |
| <b>256</b>                    | 1.8   | 17.021  |

**Storage at 512Hz**

| <b>Number of EEG Channels</b> | <b>Estimated Data Storage for 1 Hour (Gbytes)</b> | <b>Estimated Storage Time with 32GB SD Card (Hours)</b> |
|-------------------------------|---|---|
| <b>32</b>                     | 0.1   | 268.388   |
| <b>64</b>                     | 0.2   | 134.111   |
| <b>96</b>                     | 0.4   | 89.532  |
| <b>128</b>                    | 0.5   | 66.972  |
| <b>160</b>                    | 0.6   | 53.544  |
| <b>192</b>                    | 0.7   | 44.592  |
| <b>224</b>                    | 0.8   | 38.198  |
| <b>256</b>                    | 0.9   | 33.403  |

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## Storage at 256Hz

| Number of EEG Channels | Estimated Data Storage for 1 Hour (Gbytes) | Estimated Storage Time with 32GB SD Card (Hours) |
|------------------------|--|--|
| 32                     | 0.1  | 536.943  |
| 64                     | 0.1  | 268.388  |
| 96                     | 0.2  | 178.870  |
| 128                    | 0.2  | 134.111  |
| 160                    | 0.3  | 107.255  |
| 192                    | 0.4  | 89.352   |
| 224                    | 0.4  | 76.563   |
| 256                    | 0.5  | 66.972   |

## Storage at 128Hz

| Number of EEG Channels | Estimated Data Storage for 1 Hour (Gbytes) | Estimated Storage Time with 32GB SD Card (Hours) |
|------------------------|--|--|
| 32                     | 0.0  | 1074.052   |
| 64                     | 0.1  | 536.943  |
| 96                     | 0.1  | 357.906  |
| 128                    | 0.1  | 268.388  |
| 160                    | 0.1  | 214.677  |
| 192                    | 0.2  | 178.870  |
| 224                    | 0.2  | 153.293  |
| 256                    | 0.2  | 134.111  |

## Example modes of operation

### Mode 1: Wired to disconnected

You are wired and the patient wants to use the restroom. Use the internal battery (see *Using the Batteries* in Chapter 5) along with the *Data Catchup* in Chapter 3.

You want to change the sheets and need to disconnect the patient for a period of time.

### Mode 2: Wireless to out of range

You are wireless and need to go to a different floor for an ancillary procedure, which does not have wireless access. You can use this mode.

### Mode 3: Wired to wireless

You are tethered and want the patient to become mobile, but still want to see the data. Untether the amplifier and connect it to a wireless access point.

### Mode 4: Wireless to wired

You are operating the amplifier wired and the amplifier begins to run low on batteries. Reconnect the amplifier to AC power and the data to the wired ethernet.

Patient wants to go to sleep.

Doctor decides to increase the sampling rate beyond the 4K limitation.

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# 7

# Configuration Utility

This chapter describes the configuration utility, which is a piece of software independent of the Nicolet system. The purpose of the configuration utility is to allow you to troubleshoot the amplifier in the event of erroneous operation.

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## **Setup**

The configuration utility is installed separately from the Nicolet system. To install it, follow the instructions that came with the amplifier.

**NOTE:** The Configuration Utility displays in the **read only** mode.

The amplifier uses a micro USB to USB cable to connect to a computer running the configuration utility. The USB cable is supplied with the amplifier. The computer can be connected to a Desktop Computer, PanelPC, or Laptop as shown in Chapter 2 of this guide.

After the amplifier is connected to the computer, you can start the application.

1. Click **Windows > Start > Config Utility**.
2. When the utility launches, you will be prompted for a **password**. See the password that was supplied with the amplifier.

### **Configuration Utility dialog**

The following information can be viewed from the Configuration Utility dialog.

#### **IP Address / Ports**

This section displays the current IP address of the amplifier and the port on which it is operating.

#### **MAC Addresses**

This section displays the Media Access Control addresses. These are globally unique identifiers assigned to network hardware.

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## **Status**

The Status section displays the current power level of the amplifier and the remaining memory. The memory is displayed in GB, and the power level is displayed as a percentage of the remaining battery life or as “Connected” if the amplifier is connected to AC power.

## **Access Points**

The Access Points section displays the access points that are currently available and in range of the amplifier. The strength of the connection is also displayed.

## **DHCP / Static IP**

The DHCP section indicates if the amplifier is operating in the DHCP or Static IP mode. In the **Static IP** mode, the IP address is fixed. In the **DHCP** mode, the IP address of the amplifier is determined by the network.

## **SSID**

This section displays the Service Set Identifier. This is the identifier that determines the wireless local area network to which the amplifier is connected.

## **Sampling Frequency**

The Sampling Frequency section displays the default sampling frequency of the amplifier. This is the sampling frequency that is used if a study is started from the amplifier without first connecting to a Nicolet acquisition station.

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# 8

## Electromagnetic Compatibility (EMC)

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## **NicoletEEGwireless32/ 64Amplifier -Electromagnetic Compatibility (EMC)Information**

Portable and mobile RF communications equipment can affect the amplifier. Install and operate the amplifier according to the EMC information presented on this page and the next 4 pages.

The amplifier has been tested for EMC emissions and immunity as a standalone instrument. Do not use the amplifier adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.

| <b>Guidance and manufacturer's declaration- electromagneticemissions</b>   |                                       |   |
|--|---------------------------------------|---|
| <b>The amplifier is intended for use in the electromagnetic environment specified below. The customer or the user of the amplifier should assure that it is used in such an environment.</b> |                                       |   |
| Emissions Test   | Compliance                            | Electromagnetic environment - guidance  |
| RF emissions CISPR 11  | Group 1                               | The amplifier uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.                          |
| RF emissions CISPR 11  | Class A (Desktop)<br>ClassB (Laptop)  | The amplifier is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2  | Class A (Desktop)<br>Class B (Laptop) |   |
| Voltagefluctuations / flicker emissions<br>IEC 61000-3-3   | Complies                              |   |

## Recommended separation distances between portable and mobile RF communication equipment and the amplifier

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

| Rated Maximum output power of transmitter<br><br>W | Separation distance according to frequency of transmitter<br><br>m |  |   |
|--|--|--|---|
|  | 150 kHz to 80 MHz<br>$d = 1.17 \sqrt{P}$                           | 80 MHz to 800 MHz<br>$d = 1.17 \sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 2.23 \sqrt{P}$ |
| 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 higher frequency range applies.

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

| <h2>Guidance and Manufacturer's Declaration- Electromagnetic Immunity</h2>   |  |  |  |
|--|--|--|--|
| <p>The amplifier is intended for use in the electromagnetic environment specified below. The customer or the user of the amplifier should assure that it is used in such an environment.</p> |  |  |  |
| Immunity Test  | IEC 60601 Testlevel  | Compliance Level   | Electromagnetic Environment-Guidance   |
| <b>Electrostatic Discharge (ESD)</b><br><br><b>IEC 61000-4-2</b>   | ±6 kV contact<br><br>±8 kV air   | ±6 kV contact<br><br>±8 kV air   | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be less than 30%.   |
| <b>Electrical fast transient/burst</b><br><br><b>IEC61000-4-4</b>  | ±2 kV for power supply lines<br><br>±1 kV for input/output lines   | ±2 kV for power supply lines<br><br>±1 kV for input/output lines   | Mains power quality should be that of a typical commercial or hospital environment.  |
| <b>Surge</b><br><br><b>IEC 61000-4-5</b>   | ±1 kV differential mode<br><br>±2 kV common mode   | ±1 kV differential mode<br><br>±2 kV common mode   | Mains power quality should be that of a typical commercial or hospital environment.  |
| <b>Voltage dips, short interruptions and voltage variations on power supply lines</b><br><br><b>IEC 61000-4-11</b>   | < 5% UT<br>(>95% dip in UT) for 0.5 cycle<br><br>40% UT<br>(60% dip in UT) for 5 cycles<br><br>70% UT<br>(30% dip in UT) for 25 cycles<br><br><5% UT<br>(>95% dip in UT) for 5 sec | < 5% UT<br>(>95% dip in UT) for 0.5 cycle<br><br>40% UT<br>(60% dip in UT) for 5 cycles<br><br>70% UT<br>(30% dip in UT) for 25 cycles<br><br><5% UT<br>(>95% dip in UT) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the amplifier requires continued operation during power mains interruptions, it is recommended that the amplifier be powered from an Uninterruptable power supply or its battery. |
| <b>Power Frequency (50/60 Hz)</b><br><br><b>IEC 61000-4-8</b>  | 3 A/m  | Not applicable   | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.  |
| <p><b>Note:</b> UT is the a.c. mains voltage prior to application of the test level.</p>   |  |  |  |

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## Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The amplifier is intended for use in the electromagnetic environment specified below. The customer or the user of the amplifier 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 Vrms 150 kHz to 80 MHz | 3V               | Portable and mobile RF communications equipment should be used no closer to any part of the Nicolet EEGwireless32/64 amplifier, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>Recommended separation distance<br><br>$d = 1.17 \sqrt{P}$<br><br>$d = 1.17 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$  |
| Radiated RF<br>IEC 61000-4-3  | 3 V/m 80 MHz to 2.5 GHz  | 3 V/m            | $d = 2.23 \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$<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><br>Field Strengthens from fixed RF transmitters, as determined by an electromagnetic site survey, (a* on the next page) should be less than the compliance level in each frequency range. (b* on the next page)<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br><br> |

**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.

(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 amplifier is used exceeds the applicable RF compliance level above, the amplifier should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the amplifier.

(b\*) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1} V/m.

### Notes

Maximum constant current, as listed in the product specifications, will not be achievable with load impedances **greater than 4K**.

Maximum constant voltage, as listed in the product specifications, will not be achievable with load impedances **less than 4K**.

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