

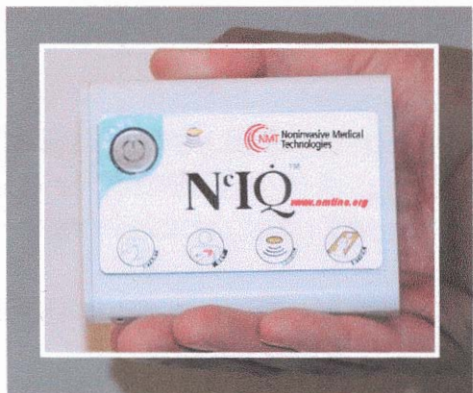


**Noninvasive Medical
Technologies**

N^cIQTM




USER MANUAL

**NONINVASIVE TECHNOLOGIES
ACROSS THE CARE CONTINUUM**



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	Consult the operator's manual for more details
	NclQ is a Class II Medical Electrical Equipment in which protection against electric shock does not rely on BASIC INSULATION only, but in which additional safety precautions such as DOUBLE INSULATION or REINFORCED INSULATION are provided, there being no provision for protective earthing or reliance upon installation conditions.
	NclQ uses Class BF applied parts

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

NclQ is a prescription device to be used on or by, the order of a Doctor or licensed health care professional.

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Introduction

The NclQ is a transportable Non-Contact Hemodynamic Monitor that provides measurement of:

- Heart Rate
- Respirations
- Cardiac Output

As the monitor tracks these assessment parameters, a Life Score number is assigned based on the change in trend over time.

NclQ is a monitor that uses bioimpedance technology to provide quick easy vital sign assessment in any environment. The NclQ is NOT a medical diagnostic device. The doctor or a designated clinical professional is responsible for interpreting what action may be required as a result of the NclQ reported values.

Indications

NclQ can be used for:

- Trauma assessment

Precautions

- Pacemakers
- Internal Cardiac Defibrillators

Contraindications

NclQ should not be used:

- Directly on the skin when individuals have skin sensitivities to adhesive material
- Directly over metallic materials such as Kevlar, aluminum, etc.

The NclQ Kit

The NclQ Kit contains the following:

- NclQ Monitor – 1
- NclQ Battery – 2
- NclQ Backers – 5
- NclQ Receiver – 1
- NclQ Receiver Software – 1

NclQ Physical Features

Description

The front of the NclQ has one Start Button (1) and one yellow light that flashes (2) when the device is searching for a good signal. The yellow light glows constant without flashing when a good signal is found, indicating that the NclQ should be left in place.



1. Start Button

2. Signal Acquisition
Light

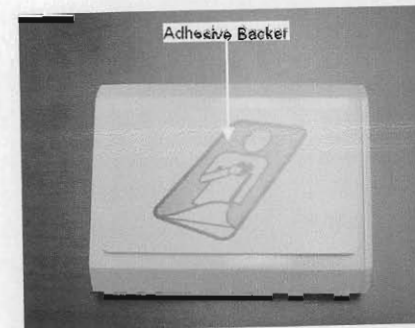
Front of the NclQ

On the front of the NclQ are a series of four label icons that depict how to use the NclQ:

- Start
- Set
- Signal
- Stick

These are part of the label instruction, and not buttons for use.

The back of the NclQ has a peel off adhesive backer (3) that attaches to textiles, clothing or the skin.



3. Adhesive Backer

How to Use the NclQ

NclQ means Noncontact IQ and can be used on the outside of regular clothes to monitor important vital signs, or apply directly to the skin.

1. **START**– Press the start button. Depress the start button down until it clicks and a green light will appear under the start button.
2. **SET**– When the NclQ is turned on, the yellow signal acquisition light will begin to blink. At this time the NclQ is searching for an adequate signal to measure. Hold the NclQ on the center of your chest over your clothing, or directly on the skin. When the yellow light is flashing the NclQ is still looking for a signal to measure. You will also feel one small buzz which also indicates that the NclQ is searching for a good signal.



3. **SIGNAL**– When the yellow light changes to a solid steady light, then the NclQ has found the correct placement for signal acquisition. You will also feel three small buzzes or vibrations from the NclQ which means that you need to leave the NclQ in one spot.

4. **STICK**– When the yellow light quits flashing and becomes solid, and you feel the three vibrations, indicating that you have found the correct NclQ placement, then gently allow the NclQ to come away from your chest and peel back the adhesive backer. The adhesive backer can be placed on the outside of clothes or directly on the skin



Note

If the NclQ loses signal acquisition the yellow light will flash again and one short buzz or vibration can be felt. Return the NclQ to the spot where you last received signal acquisition and then wait for the yellow light to turn solid and feel three short buzzes.

5. **SENDING** - Within minutes the NclQ is sending your measurement parameters to the NclQ receiver designated by the healthcare professional. See back page for NclQ receiver downloading instructions.

Power

Battery Install

- Slide open the battery door on the bottom of the NclQ.
- Insert the battery pack as shown in the picture below.



- Replace the battery door
- Test the unit after replacing each battery.

Maintenance

Batteries

- Only NclQ batteries can be used to power up the NclQ. These custom batteries can be obtained from a certified distributor or directly from Noninvasive Medical Technologies.
- NclQ batteries should last for eight continuous hours of use.
- The battery charge is becoming low when the green Start button light begins to blink. Dispose of batteries at designated battery disposal locations only.

Cleaning

- The outside surface of the NclQ may be cleaned with a soft pad soaked in alcohol (95%). A new adhesive backer should be replaced in between patient use.

Technical Specifications

Power: Disposable alkaline manganese dioxide - AAAA- 9 cells in series parallel combination. Delivers 4.5 volts and the cell thickness is 8.3mm.
Provides approximately 1700 milli amperes
Cell nominal voltage - 1.5 volts
Operating temperatures -0F to 130F
Shelf life - 5 years at 21C

Enclosures: Molded painted medical grade ABS plastic

Dimensions: (L) 3.9", (W) 3.0", (D) 0.9"

Weight: 5.6 ounces

Adhesive Backer: Disposable hypoallergenic

Measurement Current: 210 milliamps

Inputs: 915 mHz

Output: 2.4 GHz wireless transmission

Hemodynamic Parameters Measured and Reported

- Cardiac Output
- Heart Rate
- Respiration

Troubleshooting

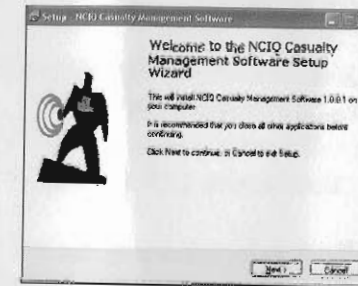
Problem	Possible Causes	Solutions
Green Start button Does not light up	Low battery	Replace battery
Signal Search vibration does not occur	Low battery	Replace battery
NciQ receiving software Does not display any results	Low battery in Comms node	<ul style="list-style-type: none"> • Replace comms node battery • Communications frequency interference may Prevent the data transmission at 2.4 GHz., try moving the comms node closer to the NciQ .
NciQ software displays Unbelievable results	Incorrect chest placement	<ul style="list-style-type: none"> • Wait for software Numbers to repopulate <p>The window one more time, If the results are still unbelievable, Then reposition the NciQ over the Center of the chest per instructions and wait for the next set of values to repopulate the software window.</p>

NciQ Software Installation Instructions

In order to monitor NCIQs with the NCIQ Casualty Management software, follow these steps.

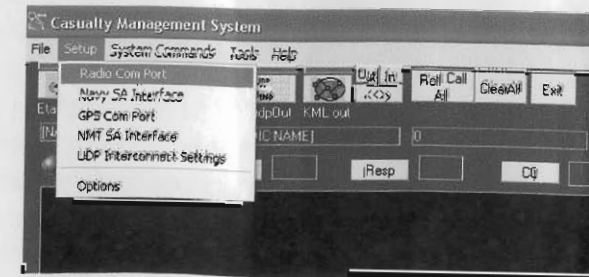
Installing the software

Insert the NCIQ Casualty Management Software CD into your computer and complete the Setup Wizard.

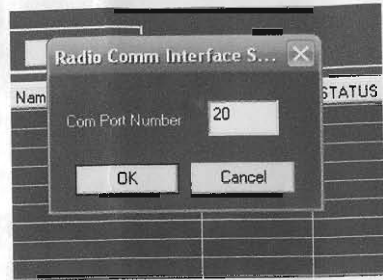


Setting up the software

To setup the program, the proper Serial Port needs to be entered into the program under Setup. Select [Radio Com Port] in the [Setup]



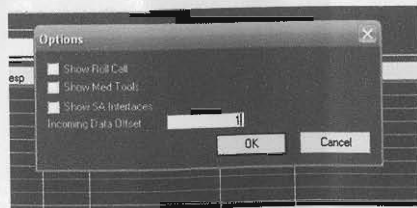
A dialog box will be brought up, enter the Serial Port connecting the Relay, then press [ok].



Now exit the program to save the new setting. The program only saves settings upon exit.

Operating the software

Ensure that the Relay is powered on. Start the application, then press the first icon on the toolbar, the green LED style indicator above the button will light up. Now turn the NCIQ on, it should appear as [Present] in the application.



After changing the data offset to "1" in the Options window, click "OK". Then close the application by clicking the "X" in the top right corner of the application window. When you reopen the application, the data will be aligned properly.

"This equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC (EN 55011 Class II & EV 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, 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 device.
- Increase the separation between the equipment.
- Consult the manufacturer or field service technician for help."

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.



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