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ECG Excellence

NR SERIES
INSTRUCTIONS FOR USE

IFU VERSION: 3.5

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General Information

NR Series. Instructions for Use.
For device models: NR-302/314/314-T/314-P/1207/1207-3/1207-E
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Copyright Information

Manufacturer and Contact Information

Manufactured by:
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The NR Series digital Recorders fulfill the requirements of the MDD 93/42/EEC.

Caution

Federal Law restricts this device to sale by or on the order of a licensed physician or healthcare provider.

Disclaimer

This system is intended as a decision support system for persons who have received appropriate medical training and should not be used as a sole basis for making clinical decisions pertaining to patient diagnosis, care, or management. Any application of medical information from the program, other than the original design or intended use thereof, is not advised and considered a misuse of the software product.

Norav Medical offers a limited warranty

Norav Medical products are warranted to be free from manufacturing and material defects for a period of one (1) year from the date of shipment from Norav Medical or the dealer to the original purchaser.

Excluded from this warranty are expendable supply items including, but not limited to, electrodes, lead wires, patient cables, and batteries. This warranty does not apply to any product that Norav Medical determines that it has been modified or damaged by the customer.

Except for the express warranties stated above, Norav Medical disclaims all warranties including implied warranties of merchantability and fitness. The stated express warranties are in lieu of all obligations or liabilities on the part of Norav Medical for damages, including but not limited to, special, indirect, or consequential, arising out of or in connection with the use or performance of Norav Medical products.

Any action for breach of warranty shall be commenced within one (1) year of said breach or be forever barred. Any repairs made to the product that are not covered by the warranty shall be billed to the customer.

For service or technical support contact your local supplier or Norav Medical.

Contents

Symbols and Notations Used in this Manual

WARNING

Warnings call attention to possible hazards involving potential damage or injury to persons.

Caution

Cautions refer to practices necessary to protect against potential damage or loss of equipment. Pay careful attention to the instructions.

Note

Notes provide supplemental information to optimize software performance or to highlight steps or procedures requiring special attention.

Device Label Symbols

Symbol	Description
	Applied part, type BF
	Defibrillator-proof applied part, type CF
	Indicates defibrillation protection of the patient cable when the defibrillation-proof feature is integrated into the cable
	Caution
	Refer to the Instructions for Use
	IP protection class
	Device Serial Number
	Device Reference Number
	Manufacturer
	Date of manufacture
	Use AA (R6) batteries.
	Contains an FCC certified Bluetooth module

	Disposal of the device in accordance with the EU Directive 2002/96/EC (WEEE). Device containing an internal lithium battery that may be recycled at the end of life. This device and all other accessories should be disposed of according to local ordinances.
	Indicates the proper orientation of the battery to be installed
	**By prescription only.** U.S. Federal Law restricts this device to sale by or on the order of a physician.
	Contains an MIC-certified Bluetooth module
	Contains an RCM-certified Bluetooth module
	Unique Device Identification (UDI) information
	Medical device
	Model Number

General Description

The NR Series Models, hereinafter referred to as "**NR**" are battery-powered *Digital Recording Devices* that allow the continuous acquisition, digitization, and real-time storage of ECG waveforms from a Patient's heart during normal daily activities, via disposable ECG Electrodes applied to the Patient's chest. The different NR Models enable different signal processing for the respective diagnostic examinations, such as Resting-ECG, Cardiac Stress Test, or Ambulatory ECG Monitoring (so-called Holter-ECG) and some can also be configured for more than one type of examination. The NR device can also detect Pacemaker Spikes and store the information together with the ECG data. For easy setup of the NR device, it is possible to make a voice recording (for Patient Demographic information). Other signals, such as *Patient Body Movement* (via Acceleration Sensors) or *Thoracic Impedance Respiration,* can also be recorded as additional valuable diagnostic information.
The NR device is part of a conventional ambulatory ECG system in which the data is recorded on an *SD Flash Memory Card* that may be removed from the device after the recording is complete. The memory card is then placed in a card reader that is connected to the Computer Analysis System. Optionally, the NR can be connected directly to the Computer Analysis System via a special USB cable; however, data transfer is slow.

NOTE: NR Models shall only be connected to computers that are in compliance with Standard EN60950-1 and are running a Microsoft® Windows™ operating system (Windows 7 or newer).

Following the instructions provided with the accompanying Norav Medical software, the recorded ECG data is downloaded onto the computer system and analyzed.

NR Feature Matrix

The following table shows the available features depending on the device model.

Note

The features shown in the Matrix also require Norav Software Applications to process the ECG data provided by the NR devices:

PC-ECG 1200	Resting-ECG and Cardiac Stress Test (including all options)
NH-301	Advanced Ambulatory ECG Monitoring (Holter-ECG)
NM-700	Telemetry ECG (rehabilitation measures)

Each Norav Software Application is delivered with its specific Instructions for Use.

	Number of ECG Channels	Type of Patient Input Cable (No. of leads)	12-Lead Resting-ECG	12-Lead Cardiac Stress Test	Ambulatory ECG Monitoring (Holter ECG)	Ambulatory Event Recording	Telemetry ECG	Pacemaker Pulse Detection	Derived Respiration Signal	Accelerometer (Body Movement)	High Resolution Color Graphic Display	Voice Recording	Built-in USB Interface	Built-in Bluetooth Interface
NR-302	3	3, 5, 7	-	-	●	-	-	●	-	-	●	-	●	-
NR-314	3	3, 5, 7	-	-	●	●	-	●	●	●	●	●	●	●
NR-314-T	6	4, 5	-	-	-	-	●	●	-	-	●	-	-	●
NR-314-P	3	3, 4, 5	-	-	●	●	-	●	-	●	-	-	●	●
NR-1207	3, 12	3, 5, 7, 10	-	-	●	●	-	●	●	●	●	●	●	●
NR-1207-3	3, 6, 12	3, 4, 5, 7, 10	●	●	●	●	●	●	●	●	●	●	●	●
NR-1207-E	6, 12	4, 5, 10	●	●	-	-	-	●	-	-	●	-	-	●

Intended Use/Purpose

Overview

Electrocardiography is the creation of an *Electrogram*, a recording of the electrical activity of the human heart. This is an *Electrocardiogram* (ECG or EKG) in which the *Voltage* of the heart's electrical activity, derived from electrodes attached to the Patient's chest, is plotted against *Time*. These electrodes sense the small electrical changes that result from the *depolarization* of the heart muscle and subsequent *repolarization* during each cardiac cycle (heartbeat).

An Electrocardiogram is carried out to check the heartbeat. It shows how fast or how slow the heart is beating. ECG test results can help the Cardiologist to diagnose:

- Irregular heartbeats, so-called *Arrhythmias*.
- A previous Heart Attack or *Myocardial Infarction*.
- The cause of *Chest Pain*. It may, for example, show signs of blocked or narrowed *Heart Arteries*.

Intended Use of NR Series Models

Patients may need an ECG examination if they have:

- Chest Pain (Myocardial Ischemia)
- Dizziness, lightheadedness, or confusion
- Pounding, skipping, or fluttering heartbeat
- Fast pulse
- Shortness of breath
- Weakness or fatigue
- Reduced ability to exercise
- Family history of Heart Disease (even if there are no symptoms yet)

Electrocardiograms are also carried out very frequently for the following reasons:

- ECG evaluation to document therapeutic interventions
- Evaluation of the response of a Patient after resuming Occupational or Recreational Activities (for example, after Myocardial Infarction or Cardiac Surgery)
- Evaluation of how well a Pacemaker or other Heart Disease Treatments are working
- Analysis of changes in the *ST Segment* in the ECG
- Analysis of *Time- and Frequency-Domain Heart Rate Variability (HRV)*

- Analysis of *Late Potentials* in the ECG
- Analysis of QT Interval parameters
- Clinical and Epidemiological Research Studies

Intended Purpose of NR Series Models

The NR Models are intended for Patients who require:

- *Ambulatory ECG Monitoring (Holter ECG)*
  If symptoms tend to come and go, a regular ECG may not detect a change in the heartbeat. Patients are then asked to wear an NR Series Model for several days (up to 14) during normal daily activities.
- *Cardiological diagnostics in the Cardiologist's Office by medical professionals:*
  - *12-Lead Resting ECG*
    Using Bluetooth communication for an instant assessment of the Patient's ECG Signal at rest to disclose either a normal condition or patterns of *Arrhythmia*, *Myocardial Ischemia*, *Rate Abnormalities*, or features of *Prognostic Value*.
  - *Cardiac Stress Test ECG*
    Using Bluetooth communication for an instant assessment of the Patient's ECG Signal to check the contractile capability of the heart muscle in response to a controlled, increasing exercise of the Patient (on a *Treadmill* or *Ergometer*).
  - *Telemetry ECG*
    Using Bluetooth communication for monitoring ECG Signals during rehabilitation measures before resuming Occupational or Recreational Activities (for example, after *Myocardial Infarction*, other *Heart Failures* or *Cardiac Surgery*).

Intended Patient Population

The NR Models are intended for the following Patient Population:

Age:	10 years of age and older, no upper limit
Weight:	Above 10 kg
Gender:	No restriction
PATIENT is User:	NO

Use Environment and Intended Users of NR Series Models

Use Environment

- All NR Models are **non-sterile** devices.
- All NR Models are reusable devices (standard disposable ECG electrodes, purchased separately as consumables, are used with the devices).
- The NR Models are also designed for use in the home environment to carry out Ambulatory ECG Monitoring (Holter-ECG). Refer to the Principle of Operation.

Intended Users

- The use of an NR Series Model should generally be prescribed and supervised only by a qualified Healthcare Professional.
- NR devices are NOT intended for use by laypeople (i.e. Patients).

Essential Performance

Within the intended use and environment, the performance elements critical to the NR Recorder ECG system remain to be the accurate, safe acquisition of the ECG signal, correct data processing, and generation of the ECG report. These functionalities shall not be degraded or negatively impacted by electromagnetic or electrical interference, or by environmental conditions that the system is designed to withstand.

Failures of the system and other included equipment do not create an unacceptable level of risk, even if they cause early termination or interruption of a test protocol. Such events do not necessarily preclude the patient from receiving additional therapy in a timely manner, and therefore do not negatively affect the essential performance of the ECG system.

Similarly, transmission of the ECG report/ECG raw data is not considered an essential performance element under environmental disturbances. The test procedure is observed by a qualified clinician as mandated by hospital protocols. Loss of data due to an interruption of the exam is covered by the previous statement dealing with early termination. A

report for the test is generated and stored when the testing has been completed**.** Failure to transmit the data is a recoverable error, and delayed transmission does not result in additional unacceptable risk to the patient.

Clinical Benefits for Patients

Clinical Benefit	Measurable outcome parameters	Benefits expected by Patient	Discussion
The device should accurately measure the heart rate	It should measure the heart rate between 60 and 100 beats per minute (bpm). However, it should also measure lower than 60 bpm (bradycardia, i.e., ≤60 bpm) and it should also measure higher than 100 bpm (tachycardia, i.e., ≥100 bpm)	Assessing the heart rate is a quick and simple method of determining overall health. It can be used to track the general level of fitness and to identify potential heart conditions.	The study reveals that the median heart rate on Holter ECG Monitoring was 95 bpm. Further, the subject device is also a Holter ECG Monitoring device, therefore this benefit is achieved with the subject device as well.
The device provides continuous ECG recording, which is beneficial over intermittent recording	Continuous ECG recording should provide better (at least two-fold) atrial fibrillation (AF) detection compared to intermittent recording.	Continuous ECG recording is used to help diagnose intermittent and infrequent cardiac arrhythmias over a long period of time. It can be used for 24 hours, 48 hours, or up to 1 week. It records the heart rhythm over longer periods of time to greatly increase the odds of capturing and recording intermittent but significant arrhythmia, which can eventually help provide adequate treatment to the patient.	The clinical literature shows that continuous event recording identified three times more AF than intermittent ECG. The subject device also measures continuous ECG, therefore this benefit is achieved with the subject device as well.
Holter monitors are better than wristband devices in Heart rate variability (HVR) measurement.	More inter-beat interval (IBIs) should be measured by a Holter device compared to a wristband (at least 10 % more).	One way to determine the autonomic nervous system's (ANS) condition is by assessing HRV. Low heart rate variability (HRV) has been linked to cardiovascular illnesses, including hypertension, while high HRV is associated with greater cardiac fitness. One of the best ways to evaluate how different factors, such as the environment, emotions, thoughts, feeling, etc., affect the nervous system, and how the nervous system responds appropriately, is to be aware of HRV.	The clinical study shows that far more IBIs were available from the Holter (M = 96,791.69, SD = 31,196.40) compared to the wristband (M = 43,604.15, SD = 19,674.02). The subject device is also used in Holter monitoring, therefore this benefit is achieved with the subject device as well.

Contraindications and Potential Adverse Effects

There is no risk of electric shock during an Electrocardiogram. The disposable adhesive electrodes, applied to the chest of a Patient, only sense the small electrical changes that result from the activities of the heart muscle during each cardiac cycle (heartbeat). NO electrical energy is delivered to the Patient.

There are no known contraindications or adverse effects for the application of the NR Model in Ambulatory ECG Monitoring (Holter ECG).

Report any adverse events to the manufacturer.

Warnings and Precautions

Note

- Only use Norav Medical -certified SD Flash Memory Cards for recording.
- It is the responsibility of the End User to properly configure the NR Series Model with settings that are compatible with the relevant ECG Analysis Software.
- False-positive results can be caused by a poor electrode connection to the Patient or by strong electrical interference from nearby objects. Pacemakers set for bipolar pacing may produce false-negative results due to a weak pacemaker pulse signal at the Patient's skin.
- The NR Series Models are not designed for emergency use, such as Intensive Care or Intermediate Care.

WARNING

- The NR Series Models are not intended for use on infants weighing less than 10 kilograms (22 pounds).
- The NR Series Models are not applied directly to the heart.
- The NR Series Models (NR-302, NR-314, NR-1207, and NR-314-P) are **NOT** protected against high-energy shocks from Cardiac Defibrillators. Remove those NR Series Models from the Patient BEFORE using a Cardiac Defibrillator.
- Some of the NR Series Models (NR-314-T, NR-1207-E, NR-1207-3) are protected against high-energy shocks from Cardiac Defibrillators when a **Defibrillation-Protected Patient Cable** is used. To avoid the possibility of injury or hazardous situations when using a Cardiac Defibrillator, a Defibrillation-Protected Patient Cable must always be used. To avoid the possibility of injury while using a Cardiac Defibrillator, do not touch the device or the Patient Cable. Proper placement of defibrillator paddles in relation to the electrode placement is also required to minimize potential harm to the Patient.
- The NR Series Models are not protected against High-Frequency Surgical Equipment. Remove the NR Series Model from the Patient BEFORE using such High-Frequency Surgical Equipment.
- The NR Series Models must not be used in areas where combustible or flammable gases or liquids, such as anesthetic gas, oxygen, or hydrogen, are present.
- The power supply of the NR Series Models (Battery) and the Patient Circuit are not distinctly isolated. Only batteries specified for the operation of the device may be used. Under no circumstances should you operate the device with a mains adapter, as this could threaten the life of the Patient.
- Any attempt to operate NR Series Models in an area where an MRI is operating will cause mutual negative effects.
- The NR Series Models should be safely stored away from children.
- Before each recording and before attaching sensors or electrodes to the Patient, check the housing and the ECG patient cable for damage that may have been caused, for example, by mechanical overload, a fall from a great height, or wear and tear (chafing areas on the cable). Do not use the device or the cable if you notice any cracks, melted spots, or other signs of damage to the cable or the housing.
- Ensure that the connector (plug) of an electrode lead never comes into contact with live parts. Do not operate the recorder near exposed live parts.
- For your safety and best performance, only connect the NR Series Model to specified equipment.
- Avoid contact between the snap terminals and leadwires of the NR Series Model and other conductive parts or earth, as this may damage the NR Series Model.
- False positive or false negative Pacemaker Spike detection events can occur in recordings with Pacemakers.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment, and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NR, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The NR requires special precautions regarding EMC and needs to be installed and put into service according to the specific instructions for maintaining basic safety and essential performance with regard to electromagnetic disturbances for the expected service life provided in the section “Electromagnetic Emissions and Immunity Information” of Operation Manual.

Caution

- Store the NR Series Models in an area free of water and humidity.
- Avoid areas with high humidity, poor ventilation, or direct sunlight. Store the NR Series Models in a place free of the harmful effects of ambient air containing dust, sodium, or sulfur.
- Do not store the NR Series Models in an area where chemicals are kept, or that is exposed to chemical fumes or vapors.
- Never attempt to modify or disassemble the NR Series Models.
- Do not open the NR Series Model housing. The housing may only be opened by Norav service personnel.
- Ensure that electrodes are correctly and safely applied to the Patient.
- Consult a qualified service technician for proper handling when using the NR Series Model in combination with any other equipment.
- When changing the batteries (except the NR-314-P), ensure that they are inserted with the correct polarity. The polarity is indicated in the battery compartment.
- Do not leave the batteries in the NR Series Model (except the NR-314-P) when it is not in use. Corrosion or battery leakage can severely damage the NR Series Model.
- Although the NR Series Models are protected against the ingress of liquids (IP22), they should not be exposed to liquids during recording. The NR Series Models are not suitable for use in the bathtub or shower.
- Ensure that, during recording, the cable lead wires are not caught by the moving parts of a machine or sports equipment. This could lead to damage or injury (e.g. if loops are formed in the cable lead wires).
- Take care to prevent chemicals or liquids from entering the connectors or internal parts of the NR Series Model.
- Any attempt to use a cleaner containing an organic solvent, thinner, toluene, or benzene for cleaning the NR Series Model will severely damage its housing.
- To clean an NR Series Model, wipe it with a damp cloth soaked in a mild soap diluted in water.
- Do not polish the housing with abrasive or a chemical cleanser.
- Under no circumstances insert objects into the Connector for the Patient Input Cable, SD Flash Memory Card slot, or the Battery Compartment other than the specified NR Series Model ECG Cable Connector, SD Flash Memory Cards, or appropriate Batteries. This may severely damage the NR Series Model and thus threaten the life of the Patient.

Possible Hazards for Patient (acceptable Residual Risk)

Possible Hazard (acceptable Residual Risk) *--- Direct Physical Harm ---*	**Possibly caused by**
Skin irritations	Allergic reaction to electrodes, biocompatibility issues, biocontamination
Infection of Patient	Cross-infection --- hygiene safety not observed
Overheating	Exposure to heat radiation
Bruising or cutting	Breakage of parts --- damaged hardware
Electrical Shock	Live parts; exposure to mains voltage, ESD, or lightning

Possible Hazard (acceptable Residual Risk)	Possibly caused by
--- Lack of Medical Data ---	
No output, or irregular or incorrect output, from the chest module or a wireless handheld device	Impaired equipment operation or equipment failure due to a design flaw.
Failure to detect Pacemaker Spikes	Noise level too high – above normal.
RF transmission failed	Insufficient wireless coexistence with: - Wi-Fi 802.11b emitter: (PC) - Other BT device - DECT cordless telephone - Cell phone with BT enabled (Nokia) Electromagnetic interference
Lost study data	Database storage failure
Failure to record, interruption of data flow, or partial/complete failure of the update function	- Battery power low - Interruption of communication - Disconnection of electrode(s) - Recording trigger did not work

Device Controls and Indicators

Models: *NR-302, NR-314, NR-314-T, NR-1207, NR-1207-3, and NR-1207-E*

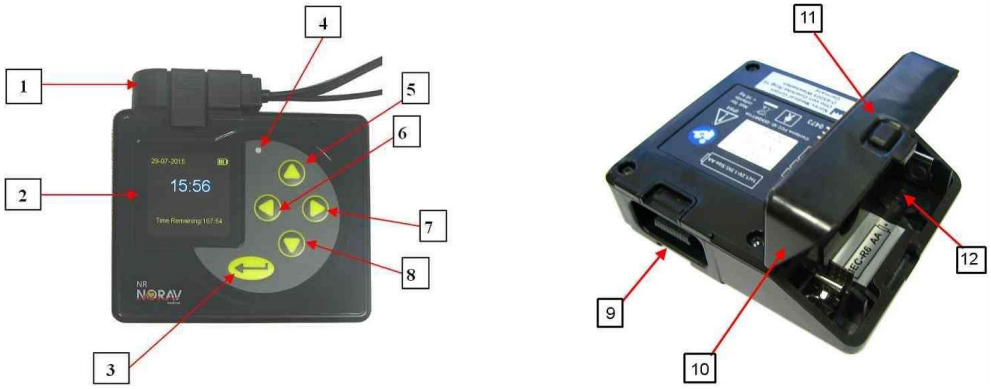


Fig. 3: ***Devices Front and Back***

Position	Description
1	Patient ECG Cable input connector
2	High-Resolution Color Graphic Display for interaction
3	Enter Button and Patient Event Button
4	Green LED indicator for Voice Recording Microphone
5, 6, 7, 8	Navigation Buttons: Up, Left, Right, Down
9	Patient ECG Cable input connector slot
10	Battery and SD Flash Memory Card compartment door
11	Battery and SD Flash Memory Card compartment door latch
12	Battery and SD Flash Memory Card compartment

Model NR-314-P

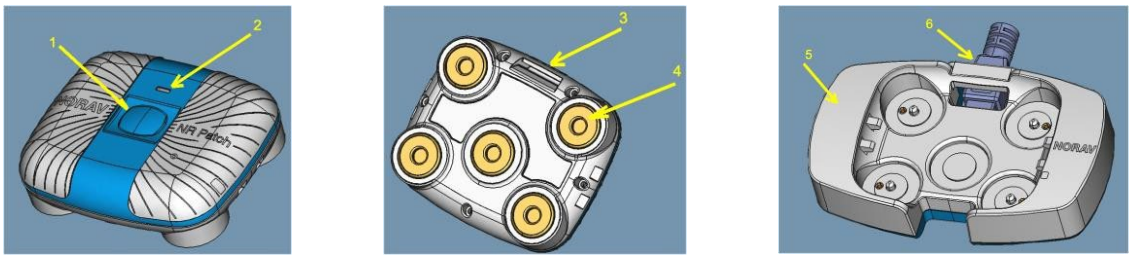


Fig. 4: ***Device Front, Back, and Docking Station***

Position	Description
1	Push button for *Power ON/OFF* and *Patient Event*
2	LED indicator light
3	Mounting eyelet for Neck Strap
4	5 Snap Sockets for standard disposable Electrodes
5	Docking Station
6	Detachable USB Cable – USB-Mini to USB-A

NR-314-P Main Battery and Docking Station Overview

NR-314-P features an internal, non-user-replaceable, rechargeable Lithium-Polymer Battery. It includes a Docking Station and USB cable for PC connection, recharging, and Holter data upload. The battery fully recharges in approximately 3.5 hours. Docking the NR-314-P during Holter recording stops and closes the recording. A fully charged battery supports up to 14 days of Holter recording, but charging before hooking up the next Patient is recommended.

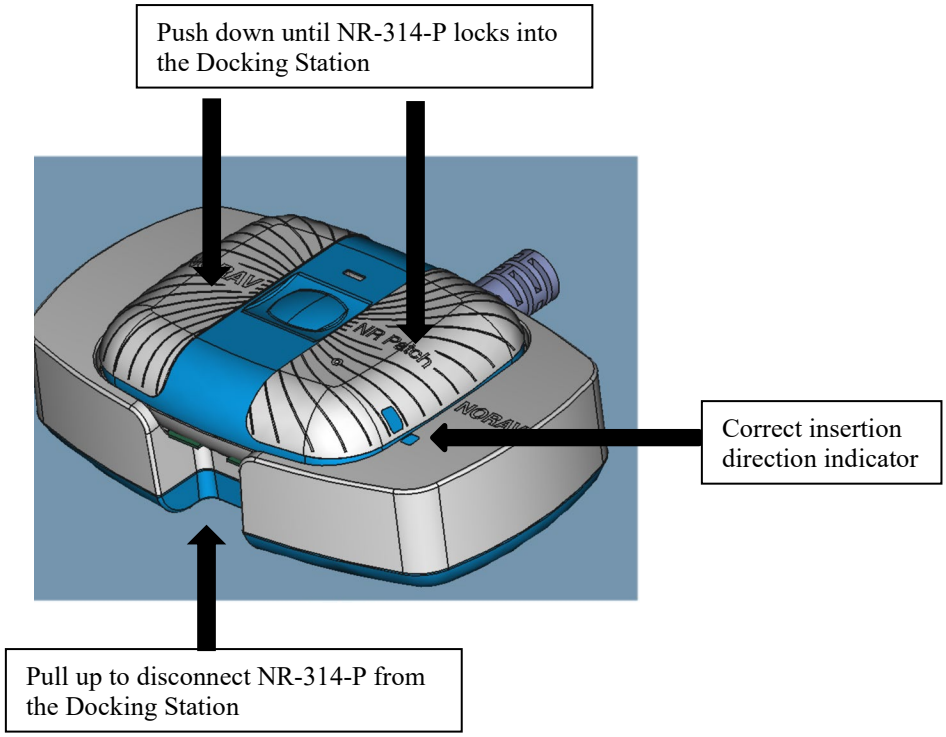
Frequent users can keep the NR-314-P docked between uses. For less frequent use, remove the NR-314-P from the Docking Station once it is charged, and reconnect shortly before the next study for a quick recharge.

The NR-314-P flashes its LED indicator blue during charging. After the NR-314-P internal battery is fully charged, the LED is solid blue. After disconnection of the NR-314-P from the Docking Station or removal of USB power, the NR-314-P turns OFF automatically.

!

Caution

- The Docking Station shall be connected only to computers that are compliant with Standard EN 60950-1

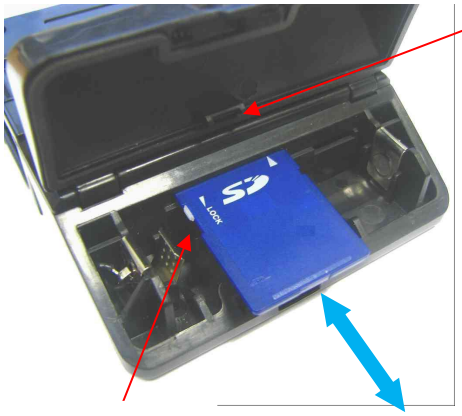


Memory Card Usage (SD card)

Models: *NR-302, NR-314, NR-1207, and NR-1207-3*

The SD (Secure Digital) card, formatted for recording biological information, is an IC card with electrically erasable, non-volatile flash memory. This ensures data retention without power, eliminating the need for backup batteries.

Open the battery compartment cover by moving the battery-compartment cover latch Left and Up.



The memory card slot is a "push-push slot." Insert the memory card by pushing it into the slot until it locks. To remove, push the card 1-2 mm into the slot to unlock it. Remove the battery before inserting or removing the SD card. The battery compartment cover includes a retainer to secure the memory card during recording.

Caution

- The NR device is mechanically protected against incorrect insertion of the memory card. Do not force the card into the slot.
- Using memory cards with other instruments (digital cameras, MP3 players, etc.) can lead to incorrect functioning and/or data loss.
- If the memory card is not completely locked inside its slot, the card retainer (part of the battery compartment cover) will not allow the cover to close. Do not push the cover forcefully when closing; it can damage the card and/or the card slot.

Note

- When looking at the SD card from the top, on the left side there may be a write-protection notch. If the notch is not in the Unlocked state, slide the tab upward (toward the contacts) to enable read/write.
- If the storage space runs out during a recording, the recording is stopped automatically and the device switches off.

Note

- Use only a Norav Medical certified SD card for recording.
- The NR device supports only SD cards formatted as follows: FAT (FAT16), cluster size = 64KB, for SD cards ≤ 4G; or FAT32, cluster size = 64KB, for SD cards > 4G.

Main Battery

Models: *NR-302, NR-314, NR-314-T, NR-1207, NR-1207-3, and NR-1207-E*

The NR is powered by one 1.5-volt alkaline battery, size AA (IEC-LR6), one 1.2-volt rechargeable nickel-metal hydride (NiMH) battery, size AA (IEC-HR6), or one 1.5-volt lithium iron disulfide (Li-FeS2) battery, size AA (IEC-FR6). Although battery life may last longer than a recording, batteries should not be reused for a second Patient. After one use, they should be disposed of in accordance with local regulations.

How to Insert Battery

Insert a fresh AA-size battery as indicated in the illustration. First insert the negative terminal. Pay special attention to the correct polarity of the battery.

As indicated in the illustration, close the battery-compartment cover and press it until the latch snaps into the base.

Caution	• Check that the NR device settings show the correct battery type in the NR device setup.

Caution	• Do not leave the battery in the NR device for extended periods (more than two weeks) when the NR device is not in use. • If you use rechargeable batteries, the battery charger should be kept out of the Patient environment and hookup area. • Dispose of used batteries carefully, using environmentally friendly methods wherever possible, following state recycling laws or your facility's recycling policy.

RTC Backup Battery

Models: *NR-302, NR-314, NR-314-T, NR-1207, NR-1207-3, and NR-1207-E*

The NR Real-Time Clock is maintained by an internal, rechargeable lithium cell, charged from the main battery during recording. With a full charge, the clock is maintained for at least 4 months after the main battery is removed. The clock cell is not user-replaceable, and in the case of suspected failure, the NR should be returned to Norav Medical for service.

Electrode Application Guide

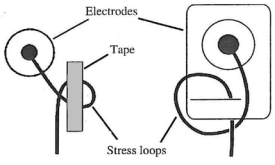
Note	Many ECG adhesive electrodes are suitable for use. As ECG electrodes from different manufacturers have different electrical properties, the choice of ECG electrodes can considerably affect measurement results and quality. Ensure that only high-quality electrodes are used. Wet gel electrodes are recommended. Always refer to the ANSI/AAMI EC12:2000 Standard for safety, performance, and labeling requirements for disposable electrodes, and guidelines for reliable patient connections.

Prepare the patient's skin prior to applying the electrodes. Skin is a poor conductor of electricity, so skin preparation is important in achieving good electrode-to-skin contact.

- If necessary, clip hair at the electrode sites (or shave, if needed).
- Clean and abrade the skin at the electrode sites to remove oil and dead skin.
- Wash the skin thoroughly with soap and water and ensure the electrode placement sites are dry.

Attaching Electrodes

- Attach the leads and the electrodes before placing the NR device on the patient.
- Snap the lead connectors onto the electrodes before placing them on the patient's chest.
- Apply the electrodes by peeling them, one at a time, from the protective backing and adhering them firmly to the patient's skin.
- The offset connector tab should be positioned in the same direction as the lead wires, toward the equipment.
- **For NR-314-P model only**: optionally use the neck strap to prevent the device from falling during recording.
- Place the electrode on the skin by gently pressing around the edge. **For wet gel, always avoid pressing down the center of the electrode**. If in doubt, refer to the directions on the reverse of the pouch.



If you use lead lock or clip lock electrodes, be sure to use the lock or clip to relieve stress on each lead wire. Otherwise, tape each lead wire into a stress loop to help prevent movement of the electrode.

WARNING

- As you attach electrodes, be careful not to let any unattached electrode come into contact with other conductive objects, including ground.
- Leave 1.5 meters (5 feet) of open area around the patient during NR device hookup and removal.
- Do not connect external devices to the NR device. Connect patient lead wires only to patient electrodes.
- Keep the NR device and patient cable clean, especially the components that touch patients.
- Do not use electrodes for adults on children.
- Before each recording and before attaching sensors or electrodes to the patient, check the housing and the ECG patient cable for damage that may have occurred, for example, due to mechanical overload, a fall from a great height, or wear and tear (chafed patches on the cable). Do not use the device or the cable if you notice cracks, melted areas, or any other signs of damage to the cable or housing.

Caution

- Verify that dates on applicable accessories have not expired.
- ECG electrodes can cause skin irritation. Examine skin for signs of irritation or inflammation and avoid placing electrodes in those areas. If skin irritation occurs during the procedure, advise the patient to remove the electrodes and contact their healthcare provider as soon as possible.
- All electrodes should be of the same brand and type to minimize noise.

Note

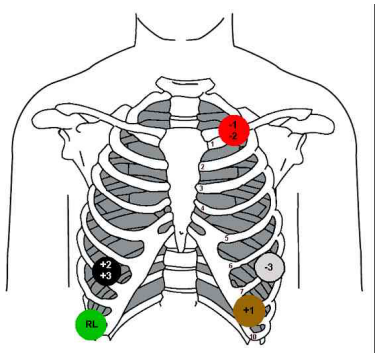
Excessive sweating can cause the electrodes to slide, become loose, fall off, and shorten wear time. It is recommended to shower briefly with the patient's back to the water, and to avoid any activities that cause excessive sweating.

Electrode Placement Scheme

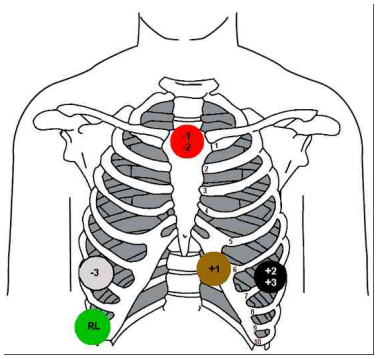
Suggested electrode placements for NR devices, except the NR-314-P model, are shown in the diagrams below. However, the physician makes the final placement determination. The NR device's ECG display or the Computer Analysis System (via Bluetooth) can be used to verify proper patient hookup.

Caution

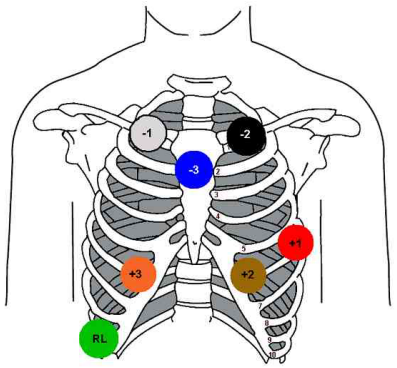
- Do not rely on the NR device's LCD display for diagnostic purposes.



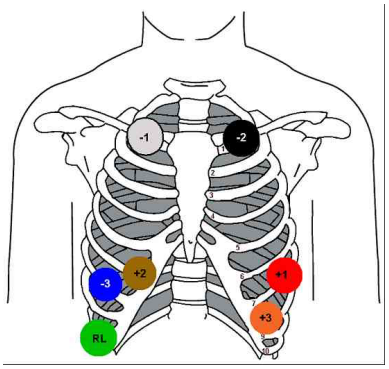
3-channel application with 5 leads
Option 1



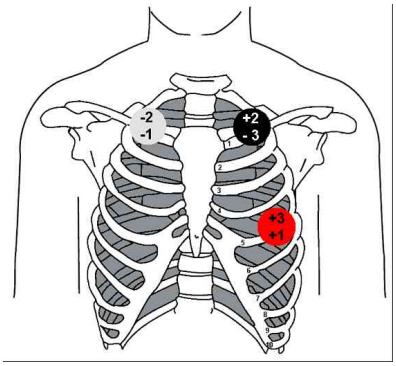
3-channel application with 5 leads
Option 2



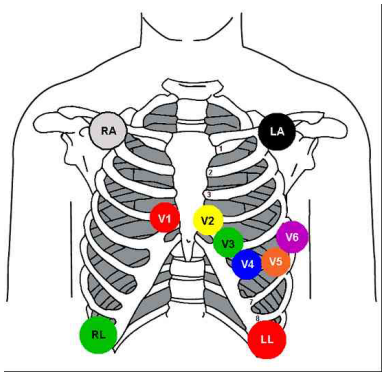
3-channel application with 7 leads
Option 1



3-channel application with 7 leads
Option 2



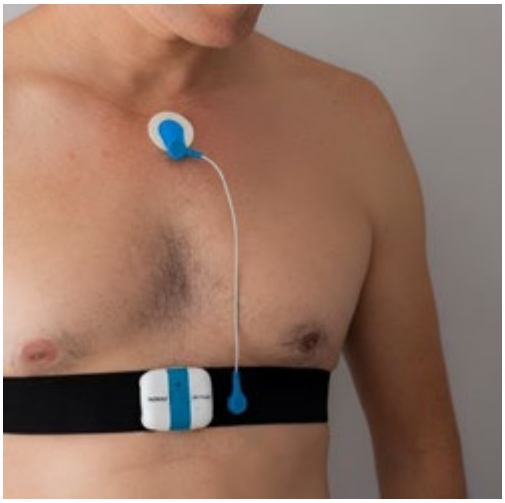
3-channel application with 3 leads



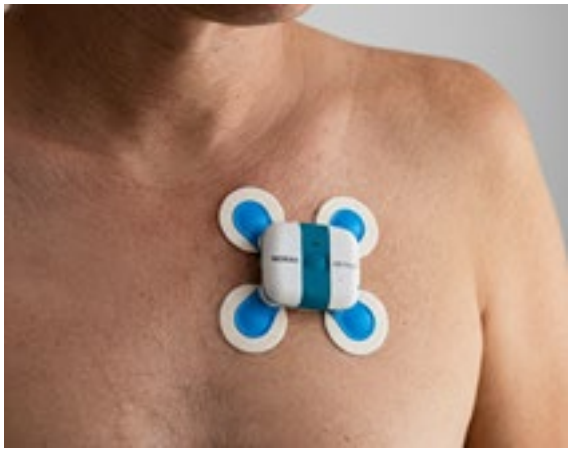
12-channel application with 10 leads

Model NR-314-P

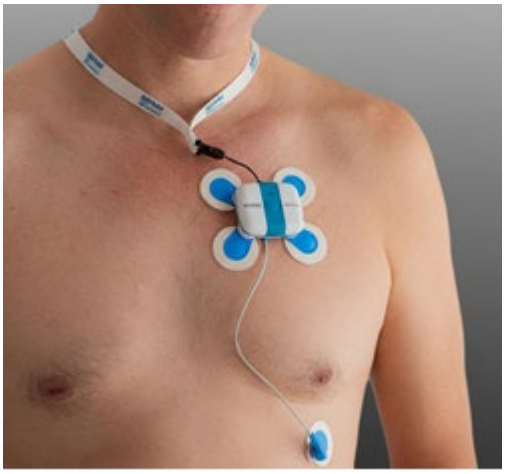
Suggested electrode placements for the NR-314-P model are shown in the figures below. However, the physician makes the final placement determination. The Computer Analysis System (via Bluetooth) can be used to verify proper patient hookup.



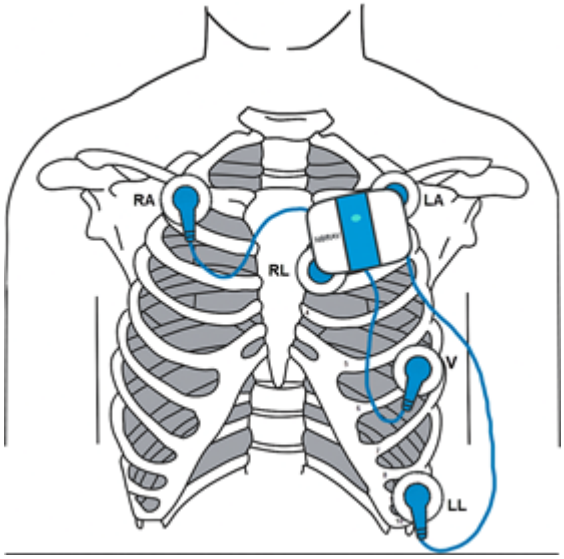
4-electrode, 3-channel, for Holter ECG
(belt unit + 1 extender wire)



4-electrode, 3-channel, for Holter ECG
(4 directly attached electrodes)



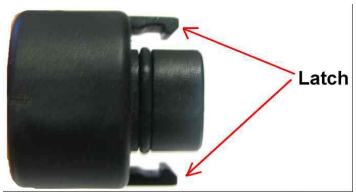
5-electrode, 3-channel, for Holter ECG
(4 directly attached electrodes + 1 extender wire)



5-electrode, 3-channel, for Holter ECG
(2 directly attached electrodes + 3 extender wires)

Patient Cable Connection

Models: *NR-302, NR-314, NR-314-T, NR-1207, NR-1207-3, and NR-1207-E*



Connecting:

Insert the Patient ECG Cable connector into the ECG cable-connector slot of the NR unit, as shown in the figure. Make sure to push the Cable connector fully in until there is no space between the Cable connector and the unit.
Make sure that the two latches on the Cable connector engage with the unit.

Disconnecting:

Remove the Patient ECG Cable connector by squeezing the two side latches on the Cable connector head and pulling it away from the connector slot of the NR unit.

Caution

- Be careful not to connect the Patient ECG Cable connector upside down or at an angle into the ECG cable slot on the NR unit. This may result in damage to both the Cable connector and the ECG Cable input slot of the unit.
- Do not insert anything other than the Patient ECG Cable connector into the ECG Cable slot on the NR unit. This may damage both the ECG Cable input slot and the Patient ECG Cable connector..
- Always check for the presence and condition of the sealing O-ring on the Patient ECG Cable connector. The O-ring protects the NR unit against ingress of splashing water when the Patient ECG Cable connector is fully fitted into the unit..
- During recording, make sure that the cable lead wires are not caught by the moving parts of a machine or sports equipment. This could lead to damage or injury (e.g., if loops are formed in the cable lead wires).
- NEVER pull on the cable itself, because this can easily break the wire inside the insulation. Pulling on the cable also can cause a noisy and intermittent ECG recording.

Note

NR hardware includes Cable-connection sensing. If the NR device does not detect a connected Cable, it will display a warning message with a buzzer beep and a diagram of the unit with the Cable connector not connected.

Screen Navigation

Models: *NR-302, NR-314, NR-314-T, NR-1207, NR-1207-3, and NR-1207-E*

The NR device features menus for setting preferences and entering patient data, navigated using four keys: Left, Right, Up, and Down. Selections are made with the Enter key. The device operation involves a sequence of steps: setting Record Mode, checking/setting Date & Time, entering Patient Identification, checking ECG signal quality, and starting Recording. Users interact with the NR device via on-screen menus on the LCD and five push buttons.

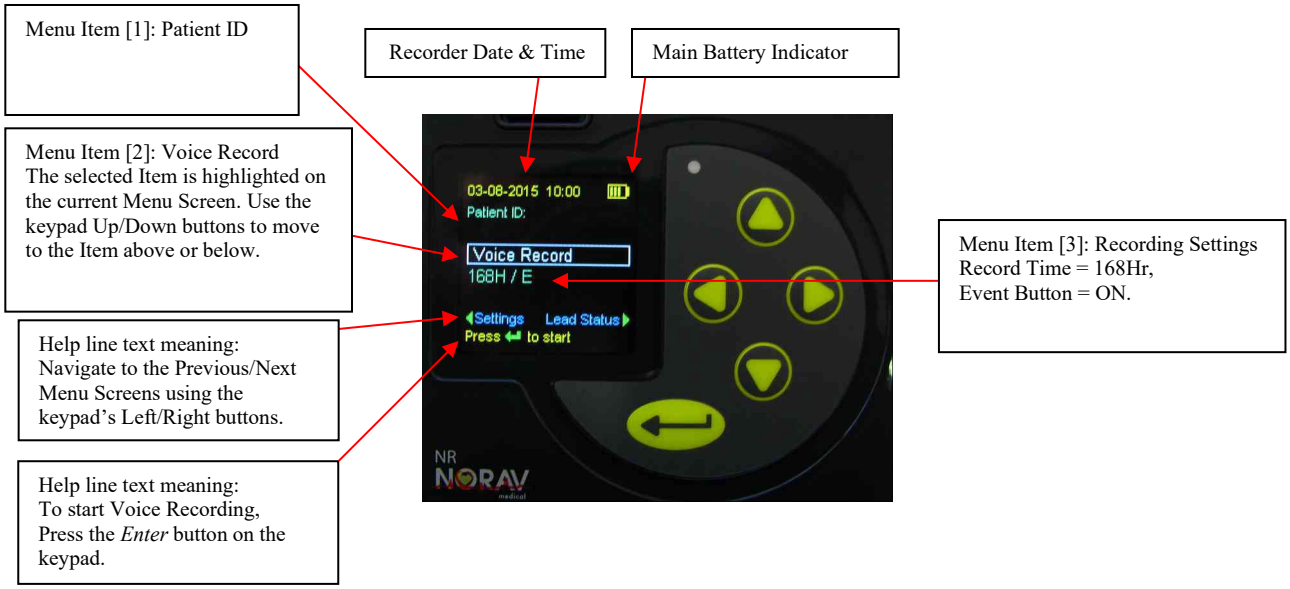
Caution

- To prevent possible damage to the keypad, do not use sharp or hard objects to press keys.

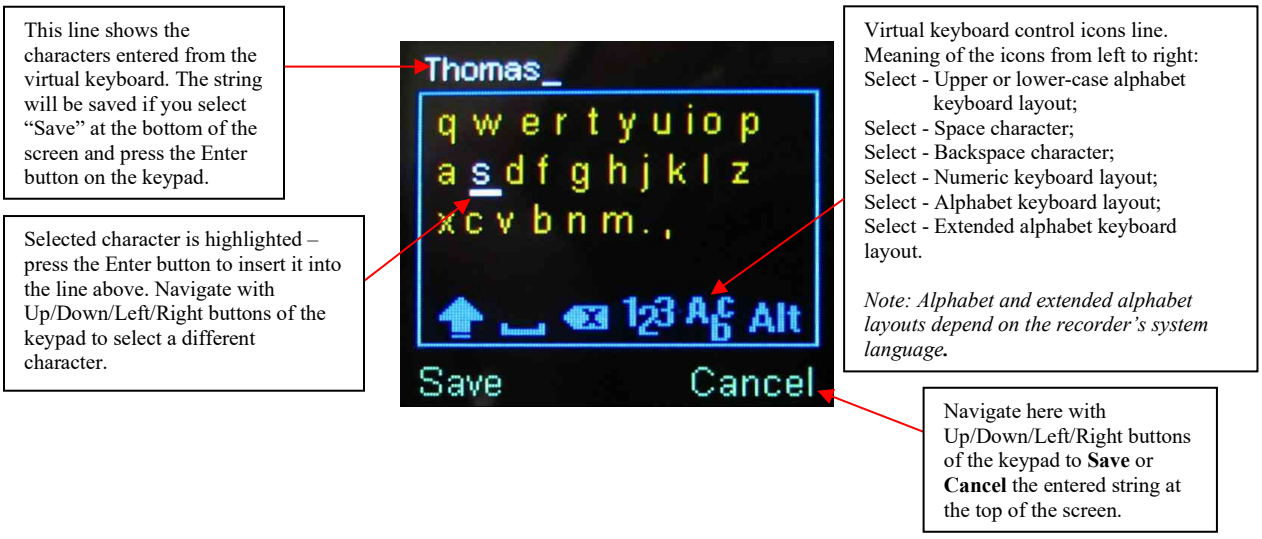
Screen	Description
Main	Displays Current date\time, Main battery level, and the following Menu items: • Patient Data *(Display Patient data – ID or Name)* • Voice Recording *(Record operator voice message - up to 20 seconds)* • Recording Settings *(Display enabled recording settings)* xxxH = Record time in hours \E = Event button enabled \P = Pacemaker detection enabled \R = Respiration enabled \A = Acceleration sensor enabled
Settings	Displays Menu items: • Patient Settings ➢ ID *(Change via Virtual keyboard screen)* ➢ First Name *(Change via Virtual keyboard screen)* ➢ Last Name *(Change via Virtual keyboard screen)* ➢ Birthday *(Change via Virtual keyboard screen)* ➢ Clinic ID *(Change via Virtual keyboard screen)* ➢ Display Format ***Patient ID***, ***Clinic ID***, ***Name*** *(Select patient data field to display on the Main screen)* • Record Settings ➢ Record Time ***24,48,72,96,120,168,336 hr*** *(336 hours option is limited to 3 channel mode with 3, 4, 5, 7-lead cable, 250 sample rate and Lithium battery only)* ➢ Sample Rate (of ECG) ***250, 500,1000*** *(samples per second)* ➢ Pacemaker detection ***ON*** *or* ***OFF*** *(OFF by default. Once turned ON remains active within the current recording only)* ➢ Accelerometer ***ON*** *or* ***OFF*** ➢ Respiration ***ON*** *or* ***OFF*** *(always OFF when Pacemaker detection is ON)* ➢ Diary ***OFF***, ***Event button***, ***Symptom list***, ***Voice note*** *(in Holter/Holter+ mode)* ■ *Event button – Save an Event for each button press* ■ *Symptom list – Select a symptom from list on the Display* ■ *Voice note - Record a Voice note* ➢ Voice note ***ON*** *or* ***OFF*** *(When ON - allow to record a Voice note) (for NR-1207-3 model in ECG+ mode)*

Screen	Description
Settings *(continue)*	• System Settings ➢ Date\Time ■ Date *(Month,Day,Year)* ■ Date Format *(MM/DD/YYYY, YYYY/MM/DD, DD/MM/YYYY, YYYY/DD/MM)* ■ Time *(Hour and Minute)* ■ Time Format *(12 or 24 hr)* ➢ Display ■ Contrast *(20-90%)* ■ Rotation *(0, 90, 180, 270 deg.)* ➢ Battery ■ Alkaline ■ NiMH ■ Lithium ➢ Language ■ English ■ Español ■ Deutsch ■ Français ■ Italiano ■ Português ■ Nederlands ■ Polski ■ Русский ■ Ελληνική ■ Türk ➢ Mode *(for NR-1207-3 model only)* ■ Holter ■ Holter+ ■ ECG ■ ECG+ • Save as default (press Enter to save current settings as the default) • About (press Enter to view NR device information – model, serial number, etc.)
Lead check	Displays the connection status of each lead
ECG CH1,CH2,CH3 or I,II …. V6	Displays real-time ECG signal, pacer pulse marks, and gain setting. Change the gain using the keypad's up/down buttons; available settings are 0.5, 1.0, 2.0, 4.0, and 8.0. Gain affects only the screen display, not the recording, which is always at 1.0x gain. At 1.0x, grid size is 10 mm/mV (two boxes = 1 mV). With Pacemaker Detection ON, pacer pulse marks appear below the trace for each detected pacer pulse.
Start	After configuring or reviewing all the settings, select the Start screen and press *Enter*. This will start the recording. During recording, the NR device displays the current time and the time remaining for the recording.
Info	During recording, the NR device displays the date, current time, battery level indicator, and the time remaining for the recording.

"Main" menu screen - explanation of menu navigation using keypad buttons, similar across other menu screens.



"Virtual Keyboard" menu screen (alphabet layout with lower case shown), used to enter Patient Data such as ID, First Name, etc. Use Up/Down/Left/Right buttons of the keypad to navigate the virtual-keyboard screen items.



Common Modes and Workflows

Holter mode (*for NR-302/314/1207/1207-3, and NR-314-P Models*)

A basic workflow for the "classic" Holter recording procedure:

- Prepare the NR device.
- Enter patient information (optional).
- Hook up the patient.
- Check ECG lead quality.
- Start recording.
- While recording continues, the patient may enter diary events.
- When the patient returns the NR device, stop the recording.
- Download the ECG recording file to the computer.
- Preview and analyze the ECG in the Holter software interface.

Holter+ mode (*for 1207-3 and NR-314-P Models*)

An advanced workflow that allows acquiring live ECG traces while the Holter recording continues:

- Prepare the NR device.
- Enter patient information (optional).
- Hook up the patient.
- Check ECG lead quality.
- Start recording.
- Acquire live ECG as needed *(the patient must be near the acquisition workstation).*
- While recording continues, the patient can enter diary events (optional).
- When the patient brings the NR device back, stop the recording.
- Download the ECG recording file to the computer.
- Preview and analyze the ECG in the Holter software interface.

ECG mode (*for NR-314-T/1207-E/1207-3 Models*)

Standard workflow for PC-live ECG acquisition via PC software or a mobile application:

- Prepare the NR device.
- Hook up the patient.
- Run the ECG software (PC-ECG 1200 or NM-700 Telemetry) or the Mobile ECG application and enter patient information.
- Check ECG lead quality.
- Acquire live ECG.

ECG+ mode (*for 1207-3 Model only*)

An advanced mode that continuously records ECG traces in the NR device memory, regardless of whether live ECG is being acquired. It allows storage of ECG records for more than one patient on the same memory card:

- Prepare the NR device.
- Enter patient information.
- Hook up the patient.
- Check ECG lead quality.
- Start ECG recording on the NR device memory card.
- As needed, launch the PC-ECG-1200 software or the Mobile ECG application, and acquire live ECG.
- At the end of testing for the current patient, stop (pause) the ECG recording.
- Hook up the next patient, then continue recording on the NR device memory card.
- When the NR device memory card is full, download the full-disclosure ECG data to the computer.

ECG Recording Procedure: Detailed Instructions

Models: *NR-302, NR-314, NR-314-T, NR-1207, NR-1207-3, and NR-1207-E*

Starting New Test

1. Prepare NR device

- Open the NR device battery compartment door.
- Insert an SD card into the NR device (skip this step when using models NR-1207-E and NR-314-T).
- Insert a new battery and close the battery compartment door. The keypad green LED flashes once per second.
- Prepare the patient (the patient should already be connected to the electrodes and patient leads) and connect the ECG cable connector to the NR device unit.
- Turn ON the NR device by pressing the Enter button on the keypad.

2. Enter Patient Information (for Holter, Holter+, and ECG+ modes)

If the NR device contains an SD card with the Patient Data/Recording Settings file, it will load this data. Verify patient data (ID, Name, etc.) on the LCD screens. If data is incorrect or missing, enter it via LCD menu screens and keypad. For voice-record-enabled models, record patient data using the voice record option on the "Main" screen for clear identification (up to 20 seconds). Ensure the microphone (indicated by the green LED on keypad) is near your mouth and speak at a normal volume. Check and modify recording settings as needed.

3. Check ECG Leads

Verify each channel's signal quality and amplitude on ECG screen menus. If ECG waveforms are unsatisfactory, reposition electrode sites with new electrodes as described earlier in this manual. Instruct the patient to stand, sit, and lie down to check the ECG signals. Have the patient walk in place and ensure that no artifacts or muscle noise appear on the NR device LCD screen. If issues persist, inspect stress loops and re-prepare hookup sites with new electrodes.

4. Start Recording (for Holter, Holter+, and ECG+ mode)

- Start the ambulatory ECG recording from the "Start" screen by pressing the Enter button.
- The LCD displays the "Recording" screen, showing date, time, battery level, and time remaining. If inactive, the screen blanks and reactivates upon button press.
- Secure the NR device on the patient in a pouch or holster, ensuring only electrodes and some lead wires are in direct contact with the skin. Position the device for easy access to the Enter button and clear view of the LCD.
- Inform the patient to keep the NR device and electrodes dry, and to avoid showering, bathing, or swimming during the test.
- Teach the patient to use the Enter button for noting symptoms or important activities. For diary entries, use the Up/Down arrows for selection, or Voice Record for voice-enabled models.

Acquire ECG Online (for Holter+, ECG and ECG+ mode)

In Holter+ mode, the NR-1207-3 device transmits live ECG traces. Use the PC-ECG 1200 Resting ECG software or the Mobile ECG app for Android OS, following the respective user manual.

Enter Diary Event (for Holter, Holter+ mode)

Press and hold the Enter button on the NR device. Follow the configuration to select a symptom from the list or add a voice note.

Add New Patient Marker (for ECG+ mode only)

During an ECG Recording ("REC" flashing on the Lead Check screen), press and hold the Enter button to increase the patient counter and add a voice note if enabled.

Stop/Pause/Restart ECG Recording (for ECG+ mode only)

During an ECG Recording, press both Left and Right arrow buttons simultaneously. In the record control menu, choose:

- "**Stop ECG**" - to pause the recording (finish for current patient).
- "**Overwrite Record**" - to erase the memory card and restart recording.
- "**Shutdown**" - to turn OFF the NR device before removing the memory card and downloading the ECG recording to the computer.

Stop Holter Recording (for Holter and Holter+ mode)

Automatic shutoff occurs when recording duration is complete or battery is low. To stop manually, press both Left and Right arrow buttons for 3 seconds..

Data Downloading

After session completion:

1) Remove the electrodes from the patient.
2) Remove the battery from the NR device.

For ECG data analysis:

1) Remove the memory card and transfer data using a card reader of the Computer Analysis System in accordance with that system's manual.
2) Optionally, download directly via USB without removing the card. Replace the Patient Cable with the USB cable, ensuring the card is in the NR device. Connect the USB to a computer; the NR device functions as a card reader.

After data transfer, erase ECG data from the memory card for reuse.

Note

- If the NR device has a battery and SD card installed, is turned ON, and the ECG Cable connector is connected to the unit, and no key is pressed for 10 minutes, it will start the test automatically (for Holter and Holter+ modes). This feature helps prevent the operator from forgetting to start the test.
- If the NR device has a battery and SD card installed, is turned ON, and the ECG Cable connector is connected to the unit, and it detects a recording on the memory card that has not yet been downloaded by the Computer Analysis System, it will display a warning message and offer an option to erase the old record and prepare the device for a new record on the same memory card.
- If the batteries run down during a recording, replace them with fully charged batteries within 1 hour. If the batteries are replaced in time, the NR device will resume the recording. However, the device will not continue the test if the batteries are not replaced in time. The data recorded before the battery runs down are stored on the memory card and can be accessed and analyzed after download by the Computer Analysis System.
- The NR device will only allow you to select settings for a recording that will fit on the SD Flash card. There is a relationship between record time, sample rate, and number of channels. By choosing a higher value in one setting, you may have to choose a lower value in another setting. It is best to set the lowest desired value first, then the next, and so on.

Model NR-314-P

Start New Recording

To start a new recording, connect the NR-314-P to the Docking Station and use the Setup Software on the Computer Analysis System to enter patient demographics and recording parameters. After downloading the settings to the NR-314-P, disconnect it from the Docking Station and power it ON. Observe the LED change from fast flashing to solid green, indicating that initialization is complete. To begin recording, press and hold the button for 3 seconds until the LED blinks green slowly, then release. Recording starts after 30 seconds; after a further 60 seconds, the LED turns OFF.

Recording in Progress: Available Actions

A short press on the button lights the LED blue for 2 seconds. Press and hold the button for 3 seconds to record a user event; the LED stays blue for 15 seconds before turning OFF.

Stop Recording

Recording stops automatically when the set duration is reached or the battery is low. To stop manually, press and hold the button for 15 seconds.

Data Downloading

After recording, remove the electrodes, disconnect the NR-314-P, and place it on the Docking Station. The flashing blue LED indicates the device is in card-reader mode. Transfer the ECG data as you would from a removable disk drive, then erase the NR-314-P's internal memory before using it with the next patient.

Switching Device ON/OFF

To turn ON the NR-314-P, press the button for 2 seconds and release; the LED flashes green rapidly. When initialization is complete, the LED turns solid green. To turn OFF, press and hold the button for 15 seconds until the LED turns OFF.

Note

- If the NR-314-P is ON and no button is pressed for 10 minutes, it starts recording automatically.
- If the NR-314-P is ON and detects an undownloaded recording in memory, the LED turns solid RED for 5 seconds, then turns OFF.

Bluetooth Pairing Options

This section guides you through the pairing process for various NR device models. Depending on the default pairing method of the specific NR Recorder, you may need to follow one of the sequences described below.

Pairing NR-314-P Device Model

Note

The NR-314-P device model is compatible **only with Bluetooth Low Energy (BLE) dongles.** Other device models may support both standard and low-energy dongles.

Note

To connect the NR-314-P recorder to the computer via Bluetooth, make sure the device is undocked from its docking station.

To connect the NR-314-P Recorder via Bluetooth:

1. Press the NR-314-P button to turn the device ON, then wait until initialization is complete (the LED indicator turns solid green).
2. On your computer, go to **Settings > Bluetooth & devices**.
3. Click **Add device**.
4. Select **Bluetooth**, then click **Show all devices** (if available).
5. In the **Add a device** list, click the **NRpXXXXX** entry (or a similar name). When prompted, enter the PIN code.
6. Enter the following PIN code: **120474**.
7. Click **Connect** to initiate pairing. If this PIN code is not accepted, contact the Support Team.
8. When the **Connected** message appears on your computer, the pairing is complete and you can click **Done**. If the device does not connect, repeat from Step 1 or consult the device manual.

Pairing Norav Recorders Using Various Pairing Options

Some NR Recorder models provide three device-computer pairing options:

- **Auto**
- **Manual**
- **Passcode**

Devices that support these three pairing options include a dedicated **Pairing** item in the **Settings** menu (for Manual and Passcode modes) and a separate **Bluetooth** item in the **System Settings** menu, allowing you to switch between these pairing methods.

Pairing in Auto mode:

1. Press the **Enter** button on the Recorder to turn the device ON.
2. On your computer, go to **Settings > Bluetooth & devices**.
3. Click **Add device**.
4. Select **Bluetooth**, then click **Show all devices** (if available).
5. In the **Add a device** list, click the **NR Recorder** entry (or a similar name).
6. When the **Connected** message appears on your computer, the pairing is complete and you can click **Done**. If the device does not connect, repeat from Step 1 or consult the device manual.

Pairing in Manual mode:

1. Press the **Enter** button on the Recorder to turn the device ON.
2. On the Recorder, go to the **Settings** menu.

3. Select **Pairing**. The **"Wait for pairing"** message appears on the Recorder's Bluetooth Pairing screen.
4. On your computer, go to **Settings > Bluetooth & devices**.
5. Click **Add device**.
6. Select **Bluetooth**, then click **Show all devices** (if available).
7. In the **Add a device** list, click the **NR Recorder** entry (or a similar name).
8. When the **PAIRED** message appears on the Recorder's screen and the **Connected** message appears on your computer, the pairing is complete. On your computer, click **Done**. If the device does not connect, repeat from Step 1 or consult the device manual.

Pairing in Passcode mode:

1. Press the **Enter** button on the Recorder to turn the device ON.
2. On the Recorder, go to the **Settings** menu.
3. Select **Pairing**. The **"Waiting for passcode"** message appears on the Recorder's Bluetooth Pairing screen.
4. On your computer, go to **Settings > Bluetooth & devices**.
5. Click **Add device**.
6. Select **Bluetooth**, then click **Show all devices** (if available).
7. In the **Add a device** list, click the **NR Recorder** entry (or a similar name).
8. Follow the on-screen instructions on your computer.
9. Press the **Enter** button on the Recorder and click **Connect** in the **Add a device** window on your computer to confirm the connection. You may perform these actions in any order.
10. When the **PAIRED** message appears on the Recorder's screen and the **Connected** message appears on your computer, the pairing is complete. On your computer, click **Done**.If the device does not connect, repeat from Step 1 or consult the device manual.

Pairing Norav Recorder via PIN-Based Connection

Some NR Recorder models support pairing with the computer by entering a PIN code on the computer. Unlike models that offer three pairing options (Auto, Manual, and Passcode), these devices do not have a **Pairing** item in the **Settings** menu and do not have a **Bluetooth** item in the **System Settings** menu.

To pair the Recorder with your computer:

1. Press the **Enter** button on the Recorder to turn the device ON.
2. On your computer, go to **Settings > Bluetooth & devices**.
3. Click **Add device**.
4. Select **Bluetooth**, then click **Show all devices** (if available).
5. In the **Add a device** list, click the **NR-XXXX-XXXX** entry (or a similar name). When prompted, enter the PIN code.
6. Enter the following PIN code: **12345**.
7. Click **Connect** to initiate pairing. If this PIN code is not accepted, contact the Support Team.
8. When the **Connected** message appears on your computer, the pairing is complete, and you can click **Done**. If the device does not connect, repeat from Step 1 or consult the device manual.

Ingress Protection Instructions

These instructions explain to lay users how to interpret the IP rating of the device and what safety measures to take to ensure proper functioning.

IP22 Instructions

Models NR-302, NR-314, NR-314-T, NR-1207, NR-1207-3, and NR-1207-E have an IP22 rating when the ECG Cable connector is fully seated, the battery-compartment door is closed, and all seals (O-rings) are correctly installed and undamaged.

- **Avoid dust:** Keep the device clean, as it is not dust-tight.
- **Keep dry:** An IP22 device can withstand light vertical drips only. Protect the device from rain, sprays, splashes, and moisture. Always keep it dry.

IP64 Instructions

Model NR-314-P has an IP64 rating.

- **Dust-resistant:** Fully protected against dust ingress.
- **Water-resistant, not waterproof:** Resists splashing water but must not be submerged. Avoid swimming, bathing, and hot tubs. Showering is permissible; face away from the spray and avoid directing water onto the device.

Maintenance and Cleaning

Cleaning and Disinfection for devices and patient lead wires

Before the Cleaning and Disinfection process, remove the battery.

WARNING

Before cleaning any part of the equipment, disconnect the equipment from the power supply, and disconnect the device from any other equipment or external devices.

Caution

- For all NR Series Models except NR-314-P, remove the battery before cleaning the device.
- Take care to prevent chemicals or liquids from entering the connectors or internal parts of the device.
- The battery contacts must not come in contact with soap or water.
- Do not polish the housing with abrasive or chemical cleansers.
- Use of alcohol, acetone, alkyl dimethyl benzyl ammonium chlorides, or methyl ammonium chloride is NOT recommended to clean the recorder unit and holster. Use of alcohol or acetone on lead wires could cause the lead wires to stiffen and the insulating plastic to crack. Use of methyl ammonium chloride (commonly found in many consumer wipes) on the device unit and accessories could cause the plastic to deteriorate.
- The device and patient lead wires must NOT be autoclaved or sterilized with steam.

Note	For all NR Series Models except NR-314-P, if liquid penetrates the device, i.e., during cleaning or operation, this may interfere with correct functioning. Switch the device OFF and remove the patient cable, the memory card, and the battery. Leave the device in a warm, dry room with the battery door open for 48 hours. If functioning is still affected, contact Customer Support.

ECG Device Surfaces/Patient Cables/Leadwires

Level of Reprocessing	Low-level disinfection.
When	Immediately after use.
Pretreatment	Wear disposable gloves.
Manual Cleaning 	1. Use a soft, non-abrasive, damp cloth with tap water; wipe the device for at least 30 seconds, repeating as necessary until no residual soil or dirt remains. 2. Prepare a neutral / mild-pH enzymatic detergent according to the manufacturer's instructions at the lowest recommended concentration. Effective cleaning can be achieved using Deconex Power Zyme prepared at a concentration of 1% (20 mL per 2 liters of water) with tap water. 3. Moisten the soft, non-abrasive cloth with the prepared detergent, then wipe the device for at least 30 seconds. Repeat as necessary until no residual soil or dirt remains. 4. Finally, use isopropanol 70% wipes to clean the device for at least three (3) minutes.
Disinfection 	After the cleaning procedure is completed, perform the disinfection procedures as follows: Use Isopropanol 70% wipes to disinfect the device for at least three (3) minutes. Repeat as necessary.
Drying	Dry for ten (10) minutes.

Maintenance

Before using the NR device, perform a unit check in accordance with the specified procedure. If any item is found to be noncompliant, the unit shall be classified as rejected. Apply corrective measures to resolve the noncompliant items. The NR device may be used only after all items meet the acceptance criteria. The unit check must be carried out by the medical institution, Norav Medical personnel, a representative agent, or an authorized third party. For further information, please contact your dealer or Norav Medical personnel.

Details of the check	Check Method	Criteria
Operation manual	Check that the operation manual is kept in a predetermined place.	Should be kept in a predetermined place.
Cracks and distortion of the NR device enclosure	Visually check the NR device enclosure for cracks and distortion.	Must be free from cracks and distortion.
Keypad buttons	Check whether the keypad buttons provide tactile feedback when pressed.	Must provide tactile feedback.
Battery contacts in the battery compartment	Visually check the battery contacts for strain, skew, and corrosion.	Must be free from strain, skew, and corrosion.
Battery compartment door latch	Check that the spring is loaded in the battery door latch.	Spring must be loaded.
Battery compartment	Check that no dirt or hair has accumulated between the battery compartment and its door.	Must be free from dirt or hair.
SD card	Visually check for scratches and damage.	Must be free from scratches and damage.
ECG snap buttons	Visually check for damage and corrosion.	Must be free from damage and corrosion.

Storage

Before storage, make sure to remove the main battery and an SD card from the NR device and close the battery-compartment door tightly. Store the NR device in the provided storage case.

! **Caution**	• Store the NR device in an area free from water and humidity. • Avoid areas with high humidity, poor ventilation, and direct sunlight; store the NR device away from adverse effects of ambient air containing dust, sodium, or sulfur. • Do not store the NR device in an area where chemicals are kept or that is exposed to chemical fumes or vapors.

NR-314-P Storage Directions
The NR-314-P must be stored within a temperature range of −5 °C to 35 °C.

If the NR-314-P device is stored for more than 3 months, the environmental conditions should be: temperature 23 ± 5 °C, humidity 60 ± 25% RH.

Store the NR-314-P at the specified temperature and recharge the device every 3 months during storage.

Service

If there is a problem with the NR device, review the Troubleshooting section for a list of problems and solutions. If additional assistance is required, contact Customer Support via phone, fax, or email listed in this manual. Contact Customer Support before returning the NR device to arrange shipping.

All repairs on products under warranty must be performed or approved by Norav Medical. Unauthorized repairs void the warranty. In addition, whether covered under warranty or not, any product repair shall be performed exclusively by Norav Medical certified service personnel.

When calling, please be prepared to provide:

- Product name and complete description of the problem.
- Serial number of your product.

In case a return cannot be avoided, the representative will record all necessary information and will provide a Return Material Authorization (RMA) number, as well as the appropriate return address. An RMA number must be obtained prior to any return.

If you have to return goods for service, follow these recommended packing instructions:

- Remove all cables, sensors, and ancillary products (as appropriate) before packing, unless you suspect they are associated with the problem.
- Wherever possible, use the original shipping carton and packing materials.
- Include a packing list and the Norav Medical Return Material Authorization (RMA) number.

It is recommended that all returned goods be insured. Claims for loss or damage to the product must be initiated by the sender.

Calibration

The device does not require calibration.

Troubleshooting

Models: *NR-302, NR-314, NR-314-T, NR-1207, NR-1207-3, and NR-1207-E*

Symptom	Solution
No display or NR device does not power on	■ Ensure the battery is inserted with correct polarity. ■ Install a new AA battery.
Low battery (*message*)	■ Install a new AA battery. ■ Inspect the battery compartment, and clean contacts if necessary.
No Cable (*message*)	■ Ensure the Patient Cable (lead set) is connected to the NR device. The NR device will not allow you to proceed past this screen unless a cable is connected. ■ Check that the NR device side connector is not damaged. Check that the cable connector pins are not broken or bent / damaged.
Noise artifacts on ECG signal	■ Ensure you have prepared the patient's skin according to the instructions. ■ Ensure the electrodes are properly applied to the patient. ■ Ensure the leads are making proper contact with the electrodes. ■ Replace the Patient ECG cable.
Lead OFF (*message*)	■ Ensure you have prepared the patient's skin according to the instructions. ■ Ensure the electrodes are properly applied to the patient. ■ Ensure the leads are making proper contact with the electrodes. ■ Replace the Patient ECG cable.
SD Card Error (*message*)	■ Ensure the memory card is Norav Medical certified. ■ Ensure the memory card is not write-protected (small switch on the SD Card) ■ Reformat the memory card or replace it with a new Norav Medical certified memory card.
Previous recording found (*message*)	■ Download the ECG data with the Computer Analysis System, or delete it from the SD card using the Left and Enter buttons.
Set Date/Time (*message*)	■ The internal battery that runs the real time clock may not be fully charged. This battery is built into the NR device and is not user-replaceable. It is recharged each an AA battery is inserted. If the NR device is unused for an extended period, the internal battery can become discharged. To fully recharge the internal real time clock battery, insert a fresh AA battery into the NR device and let the NR device charge for 12 hours.
SD card too small (*message*)	■ Check that the Record Time setting on the Record Settings screen is set for the desired number of hours. The memory card has capacity only for the recording durations available as valid selections in the Record Settings menu..

Model NR-314-P

Symptom	Solution
NR device does not power on	■ Ensure that the NR-314-P is fully charged.
RED LED is ON when not connected to Docking Station	■ Ensure the previous recording file has been downloaded to the Computer Analysis System and removed from the NR-314-P internal memory. ■ Ensure the RTC is set correctly via the Computer Analysis System.
RED LED is ON when connected to Docking Station	■ Use only the Norav Medical USB cable; try replacing the USB cable. ■ Try connecting the USB cable to another USB port or to another computer.
BLUE LED is OFF when connected to Docking Station	■ Use only the Norav Medical USB cable; try replacing the USB cable. ■ Ensure the USB cable is connected to a powered-on computer ■ Ensure the NR-314-P is connected correctly to the Docking Station
Connected to Docking Station, but NR device drive is not visible on the computer	■ Use only the Norav Medical USB cable; try replacing the USB cable. ■ Try connecting the USB cable to another USB port. ■ Ensure the NR-314-P is connected correctly to the Docking Station.

Technical Specifications

Models: *NR-302, NR-314, NR-314-T, NR-1207, NR-1207-3, and NR-1207-E*

	Conditions	Unit	min	typical	max
Dimensions					
Width	without Patient Input Cable	mm		92	
Height	without Patient Input Cable	mm		75	
Depth	without Patient Input Cable	mm		23	
Weight	without Battery	g		103	
Protection against water penetration	with Patient Input Cable plugged in, Battery Door closed and Sealing installed.	-		IP22	
ECG					
Channels		-	3		8
Input Impedance		MOhm	>10		
CMRR		dB	>90		
Frequency Response HPF	Recording	Hz		0.05	
Frequency Response LPF	Recording	Hz	65		260
Dynamic Range	Recording, Peak-to-Peak	mV		10	
A/D Bit Resolution	Recording	bit		12	
Sampling Rate	Recording	Hz	250		1000
Pacemaker Detection	Analogue Detection in 2 Channels				
Amplitude		mV	2		700
Pulse-Width		ms	0.1		2
	Conditions	**Unit**	**min**	**typical**	**max**
Accelerometer					
Channels		-		3	
Dynamic Range	Recording, Peak-to-Peak	g		4	
Derived Respiration					
Channels	Sensing Electrodes Ch1(+) & Ch1(-)	-		1	
Excitation Current		µA		27.3	
Excitation Frequency		kHz		64	
Power					
Supply Voltage	1 x Battery, size AA	V	1.0	1.5	2.7
Internally provided Voltage		V		2.8	13
In RMS Current during Recording	V_{Batt} = 1.5V	mA	10		150
Operating Environment					
Temperature		°C	+10		+45
Humidity (non-condensing)		%RH	10		95
Atmospheric Pressure		hPa	700		1060
Storage Environment					
Temperature		°C	-20		+60
Humidity (non-condensing)		%RH	10		95
Atmospheric Pressure		hPa	700		1060

Requirements applicable to ME equipment that intentionally receive RF electromagnetic energy include the following information:

- each frequency or frequency band of reception;
- the preferred frequency or frequency band, if applicable, and
- the bandwidth of the receiving section of the ME equipment for those bands.

Requirements applicable to ME equipment that include RF transmitters: the technical description shall include the frequency or frequency band of transmission, the modulation type and characteristics, and the effective radiated power (ERP).

Wireless capabilities
The recorder receives and transmits electromagnetic energy to meet its intended purpose. The characteristics of the transmitter and receiver are specified below.

Parameter	Description
Working frequency	2402-2480MHz , 2.4GHz ISM band
Wireless standard	Dual mode BLE and BR/EDR V4.2
Data transmission rate	BR (1 Mbps), EDR (2 or 3 Mbps), LE (1 Mbps)
Modulation Type	GFSK, π /4-DQPSK, 8DPSK
Radiation Power	11 dBm

Conformance with Technical Standards

Standards:	▪ IEC 60601-1 ▪ IEC 60601-1-2 ▪ IEC 60601-2-25 ▪ IEC 60601-2-47 ▪ IEC 60601-1-11
Classification:	▪ Type BF Applied Part ▪ (*NR-302, NR-314, NR-1207*) ▪ Type CF Applied Part, Defibrillator-Proof (*NR-1207-3, NR-1207-E, NR-314-T*) ▪ Internally powered Medical Device ▪ Device for continuous operation
Communication:	▪ USB 2.0 HS ▪ Bluetooth 2.1 + EDR Class 1

Model NR-314-P

ECG	
ECG Channels	3 Channels
Recording capacity	2 GByte
Input Impedance	>10 MOhm
CMRR	>90 dB
Dynamic Range	10mV Peak-to-Peak
Maximum DC Input	800mv
A/D Bit Resolution	12 Bit (24 Bit Acquisition)
Pacemaker Detection	Analogue Detection, 2 to 700 mV at 0.1 to 2 ms
Sampling Rate	128, 256, 512, and 1024
Frequency Response	128 Sampling Rate: 0.05 to 25 Hz 256 Sampling Rate: 0.05 to 51 Hz 512 Sampling Rate: 0.05 to 102 Hz 1024 Sampling Rate: 0.05 to 204 Hz
Recording Time (maximum)	128 Sampling Rate: 14 days 256 Sampling Rate: 9 days 512 Sampling Rate: 7 days 1024 Sampling Rate: 4 days
Accelerometer	
Channels	3 Channels

Dynamic Range	4 g Peak-to-Peak
Physical	
Dimensions	47 x 55.5 x 17.8 mm
Weight	41 g
Protection against water penetration	IP64

Power	
Battery Type	Lithium-Ion Polymer Accumulator (rechargeable battery)
Battery Capacity	700 mAh
Nominal Voltage	3.7 V
Charging Voltage	4.2 V
Battery Life	500 Charging Cycles
Operating Environment	
Temperature	+5 to +45 °C
Humidity (non-condensing)	10 to 95 %RH
Atmospheric Pressure	700 to 1060 hPa
Storage Environment	
Temperature	-5 to +35 °C
Humidity (non-condensing)	10 to 95 %RH
Atmospheric Pressure	700 to 1060 hPa

Conformance with Technical Standards

Standards:	▪ IEC 60601-1 ▪ IEC 60601-1-2 ▪ IEC 60601-2-47 ▪ IEC 60601-1-11
Classification:	▪ Type BF Applied Part ▪ Internally powered Medical Device ▪ Device for continuous operation
Communication:	▪ USB 2.0 HS ▪ Bluetooth Low Energy (BLE 5.0)

ECG Cables and Accessories

Models: *NR-302, NR-314, NR-314-T, NR-1207, NR-1207-3, and NR-1207-E*

Item	Part Number	NR Compatibility	Application	Defib. protected
ECG Cables				
3 Lead Patient Cable, Snap, AHA	C3-S-U-EI C3-S-U-EI-07/08	302, 314, 1207, 1207-3	Holter	No
4 Lead Patient Cable, Clip, AHA	C4-C-U-EI-07/08	314-T, 1207-3, 1207-E	Telemetry, Stress	Yes
4 Lead Patient Cable, Clip, IEC	C4-C-E-EI-07/08	314-T, 1207-3, 1207-E	Telemetry, Stress	Yes
5 Lead Patient Cable, Snap, AHA*	C5-S-U-EI C5-S-U-EI-07/08	302, 314, 1207, 1207-3	Holter	No
5 Lead Patient Cable, Clip, IEC	C5-C-E-EI-07	1207-3, 1207-E	Rest	Yes
5 Lead Patient Cable, Clip, IEC	C5-C-E-EI-08	1207-3, 1207-E	Rest	Yes
5 Lead Patient Cable, Clip, AHA	C5-C-U-EI-07	1207-3, 1207-E	Rest	Yes
5 Lead Patient Cable, Clip, AHA	C5-C-U-EI-08	1207-3, 1207-E	Rest	Yes
7 Lead Patient Cable, Snap, AHA*	C7-S-U-EI C7-S-U-EI-07/08	302, 314, 1207, 1207-3	Holter	No
7 Lead Patient Cable, Snap, IEC*	C7-S-E-EI C7-S-E-EI-07/08	302, 314, 1207, 1207-3	Holter	No
10 Lead Patient Cable, Snap, AHA	C10-S-U-EI C10-S-U-EI-07/08	1207, 1207-3	Holter	No
10 Lead Patient Cable, Snap, IEC	C10-S-E-EI C10-S-E-EI-07/08	1207, 1207-3	Holter	No
10 Lead Patient Cable, Clip, AHA	C10-C-U-EI-07	1207-3, 1207-E	12-lead ECG	Yes
10 Lead Patient Cable, Clip, IEC	C10-C-E-EI-07	1207-3, 1207-E	12-lead ECG	Yes
10 Lead Patient Cable, Banana, AHA	C10-B-U-EI-07/08	1207-3, 1207-E	12-lead ECG	Yes
10 Lead Patient Cable, Banana, IEC	C10-B-E-EI-07/08	1207-3, 1207-E	12-lead ECG	Yes
10 Lead Patient Cable, Trunk, Banana, AHA	C10-B-U-TEI-08	1207-3, 1207-E	12-lead ECG	Yes
10 Lead Patient Cable, Trunk, Banana, IEC	C10-B-E-TEI-08	1207-3, 1207-E	12-lead ECG	Yes
Accessories				
USB 2.0 HS Cable, 1.5m	C-USBA-1.5M-EI C-USBA-1.5M-EI-07/08	302, 314, 1207, 1207-3		
NR device Holster	ENC-MLD-HLD-NR-1	302, 314, 1207, 1207-3, 1207-E		
NR device Pouch	NR-POUCH-01	302, 314, 314-T, 1207		
NR device Pouch	NR-POUCH-02	1207-3, 1207-E		
Certified NR SD Memory Card 2GB	MEM-SD-2GB-01	314, 1207, 1207-3		
Certified NR SD Memory Card 512MB	MEM-SD-0.5GB-01	302		

* - To record the respiration signal, utilize either these 5-lead or 7-lead cables, as it cannot be captured with a 10-lead cable.

Model NR-314-P

Item	Part Number
NR-314-P Docking Station	NRP-USB-DOCKING-03
NR-314-P neck strap	NECK-LANYARD-NRp-01
USB Cable A-to-B(mini) 1.5m	C-USB-AB(mini)1.5
3 ECG lead wires set, Snap, F-to-M, 25/45/65cm	L3-S-MF-NRP-1-08

Electromagnetic Emissions and Immunity Information

Refer to the following tables for specific information regarding NR device compliance to IEC 60601-1-2.

Models: *NR-302, NR-314, NR-314-T, NR-1207, NR-1207-3 and NR-1207-E*

Table 1: Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.		
RF Emissions CISPR 11	Group 1	This device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	N/A	

Table 2: Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.			
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	±5% U_T (>95% dip in U_T) for 0.5 cycle ±40% U_T (60% dip in U_T) for 5 cycles ±70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage before application of the test level.			

Table 3: Guidance and Manufacturer's Declaration—Electromagnetic Immunity Homehealth

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.			
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	E = 10 V/m	$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

NOTES:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 4: Recommended Separation Distances

The following table details the recommended separation distances between portable and mobile RF communications equipment and NR device.

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Users of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to maximum output power of the communications equipment.			
	Separation Distance According to Frequency of Transmitter(m)		
Rated Maximum Output Power of Transmitter **W**	**150 kHz to 80 MHz** $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
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.

NOTES:
- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Model NR-314-P

Table 5: Electromagnetic Emissions

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group1 Class B	The NR-314-P 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.
Harmonic emissions IEC 61000-3-2	Class A	The NR-314-P is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the ME EQUIPMENT or shielding the location.
Voltage Fluctuations and Flicker IEC 61000-3-3:2013	Complies	

Table 6: Electromagnetic Immunity

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output to earth	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ME EQUIPMENT requires continued operation during power mains interruptions, it is recommended that the ME EQUIPMENT be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 7: Guidance and Manufacturer's Declaration—Electromagnetic Immunity

IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	6 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 10V/m, 80MHz to 2.7GHz, 80% AM at 1kHz	6 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 10V/m, 80MHz to 2.7GHz, 80% AM at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the [ME EQUIPMENT including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. D Interference may occur in the vicinity of equipment marked with the following symbol: 
Proximity magnetic fields IEC 61000-4-39	8 A/m (30 kHz, CW) 65 A/m (134.2 kHz, pulse modulation 2.1 kHz) 7.5 A/m (13.56 MHz, pulse modulation 50 kHz)	8 A/m (30 kHz, CW) 65 A/m (134.2 kHz, pulse modulation 2.1 kHz) 7.5 A/m (13.56 MHz, pulse modulation 50 kHz)	ME EQUIPMENT containing magnetically sensitive components or circuitry where a separation distance of those components or circuitry of at least 0,15 m from the field sources specified in table below, is ensured by the ENCLOSURE, or by the physical design of an attached ACCESSORY during INTENDED USE, need not be evaluated further for IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz.

Table 8: Recommended Separation Distances

The following table details the recommended separation distances between portable and mobile RF communications equipment and NR-314-P NR device.

Recommended separation distances between portable and mobile RF communications equipment and the [ME EQUIPMENT or ME SYSTEM]				
Rated maximum output. power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{12}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{23}{E_1}]\sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment				
Test frequency (MHz)	Band (MHz)	Service	Modulation	Immunity Test level (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	27

450	430 to 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28
710 745 780	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
810 870 930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
1720 1845 1970	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900. DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
2450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5240 5500 5785	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields		
Test frequency	**Modulation**	**Immunity Test Level (A/m)**
30 kHz	CW	8
134,2 kHz	Pulse modulation 2.1 kHz	65
13,56 MHz	Pulse modulation 50 kHz	7.5

FCC Information

WARNING

For patients with a pacemaker, maintain a minimum distance of 15 cm (6 inches) between the NR device and the pacemaker. If you suspect the NR device has affected the pacemaker, turn the device OFF immediately and provide appropriate patient care. The Health Industry Manufacturers Association recommends a minimum distance of 15 cm (6 inches) between a wireless radio and a pacemaker, which is consistent with recommendations from Wireless Technology Research.

Models *NR-302, NR-314, NR-314-T, NR-1207, NR-1207-3, and NR-1207-E* contain FCC ID: QOQBT121. *Model NR-314-P* contains FCC ID: QOQ13.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits 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 radiates 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 the 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.

ISED Information

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

CAN ICES-003 (B)/NMB-003(B) / CAN ICES-001/NMB-001

Usage Conditions:
It must be used only with the holster or pouch provided by Norav Medical in the package. The device must be used while installed parallel to the patient's body.

Limitations of usage:
Use of the product must be done exactly, as per the usage conditions and relevant statements provided by the manufacturer. Minimum separation distance between the human body and the product must be at least 7 mm (including holster or pouch).