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The NR Series digital Recorders fulfill the requirements of the Regulation (EU) 2017/745 (MDR) of the European Parliament and of the Council on Medical Devices as well as the requirements of the Regulation UK MDR 2002 (Statutory Instruments 2002 No. 618 Consumer Protection), as amended.



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

Caution

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 GmbH offers a limited warranty

Norav Medical GmbH 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 GmbH 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 GmbH determines that it has been modified or damaged by the customer.

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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 GmbH.

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Symbols and Notations Used in this Manual



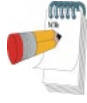
Warnings call attention to possible hazards involving potential damage or injury to persons.

WARNING



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












Caution












Notes provide pertinent information to help obtain optimum performance from the software or signify an important step or procedure that requires special attention.

Note

Device Label Symbols

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

	Contains 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 end of life. This device and all other accessories should be disposed of according to local ordinances.
	Indicates the proper orientation of battery to be installed
	By prescription only. U.S. Federal Law restricts this device to sale on order of a physician only.
	Contains MIC certified Bluetooth module
	Contains 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 the 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 a part of a conventional ambulatory ECG system where the data is recorded on a *SD Flash Memory Card* that may be removed from the device after the recording has completed. The memory card is then placed in a card reader that is connected to the Computer Analysis System. Optionally the NR can be directly connected to the Computer Analysis System via special USB cable (but data transfer is slow).

NOTE: NR Models shall only be connected to computers which are in compliance with the Standard EN60950-1 and running a Microsoft® Windows™ operating system of Win 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.

 <p>Note</p>	<p>The features shown in the Matrix also require Norav Software Applications to process the ECG data provided by the NR devices:</p>
	<p>PC-ECG 1200 Resting-ECG and Cardiac Stress Test (incl. all Options) NH-301 Advanced Ambulatory ECG Monitoring (Holter-ECG) NM-700 Telemetry ECG (Rehabilitation Measures)</p>
	<p>Each Norav Software Application is delivered with its specific Instructions for Use.</p>

	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 how well a Pacemaker or other Heart Disease Treatments are working
- Analysis of changes in *ST Segment* in the ECG
- Analysis of *Time- and Frequency Domain Heart Rate Variability (HRV)*

- Analysis of *Late Potentials* in 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 find a change in the heartbeat. Patients are then asked to wear a NR Series Model for several days (up to 14) during the normal daily activities.
- *Cardiological diagnostics in the Cardiologist Office by medical professionals:*
 - *12-Lead Resting ECG*
Using the BlueTooth communication for an instant assessment of the Patient's ECG Signal at rest to disclose either normal condition or patterns of *Arrhythmia*, *Myocardial Ischemia*, *Rate Abnormalities*, or features of *Prognostic Value*.
 - *Cardiac Stress Test ECG*
Using the 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 the 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 that must be purchased separately as consumables are used with the devices).
- The NR Models are also designed for use in the home area for being able to carry out Ambulatory ECG Monitoring (Holter-ECG). Refer to Principle of Operation.

Intended Users

- The use of an NR Series Model should generally only be prescribed and supervised 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 remains to be the accurate, safe acquisition of ECG signal, as well as correct data processing, and generating of the ECG report. These functionalities shall not be degraded or negatively impacted by electromagnetic, electrical interference, or environmental conditions that the system is designed to withstand.

Failures with that and other included equipment does not result in a creation of an unacceptable level of risk even in early termination or an interruption of a test protocol which does not necessarily preclude the patient from receiving additional therapy in a timely fashion, and therefore does not negatively affect the essential performance of the ECG system.

Similarly, transmission of the ECG report / ECG row 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 in 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 of the data 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 the 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 too is a Holter ECG Monitoring device. Hence this benefit is achieved in subject device too.
The device provides continuous ECG recording which is beneficial over intermittent recording	Continuous ECG recording should provide better (At least twice) atrial fibrillation (AF) detection as 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 this intermittent, but significant, arrhythmia, which can eventually help in providing adequate treatment to the patient.	The clinical literature shows that continuous event recording identified three times more AF than intermittent ECG. The subject device too measures continuous ECG, hence this benefit is achieved in subject device too.
Holter monitors are better than wrist band devices in Heart rate variability (HVR) measurement	More inter-beat interval (IBI) should be measured by holter device as compared to wrist band (At least 10 % more)	One way to determine the ANS's (autonomic nervous system) condition is by HVR. 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 things, such as the environment, emotion, 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 wrist band (M = 43,604.15, SD = 19,674.02). The subject device too is used in Holter monitoring, hence this benefit is achieved in subject device too.

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 for an Ambulatory ECG Monitoring (Holter-ECG).

Report any adverse events to the manufacturer.

Warnings and Precautions



Note

- Only use Norav Medical GmbH certified SD Flash Memory Cards for recording.
- It is the responsibility of the End User to properly configure the NR Series Model with settings 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 purposes (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 directly applicable to the heart.
- The NR Series Models (NR-302, NR-314, NR-1207) 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-314-P, 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/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 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** going to use 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 operate the device with a mains adapter – this could threaten the life of the Patient.
- Any attempt to operate NR Series Models in an area where an MRI is operating, will mutually generate 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.
- 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.
- NR needs 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 Section Electromagnetic Emissions and Immunity Information of Operation manual.

Caution

- Store the NR Series Models in an area free from water or humidity.
- Ensure to avoid areas with high humidity, poor ventilation, and direct sunlight. Store the NR Series Models in a place free from the harmful effects of ambient air containing dust, sodium, and sulfur.
- Do not store the NR Series Models in an area where chemicals are kept, or which is exposed to chemical fumes or vapors.
- Never attempt to modify or to disassemble the NR Series Models.
- Do not open the NR Series Models 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 correct 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 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), it 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 a recording the cable lead wires are not caught by the moving parts of a machine or sport equipment. This could lead to damage or injury (e.g. if loops are formed in the cable lead wires).
- Take care to prevent chemicals\liquids from entering the connectors or internal part of the NR Series Model.
- Any attempt to use a cleaner containing 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 with a mild soap diluted with water.
- Do not polish the housing with abrasive or chemical cleanser.
- Under no circumstances insert objects in 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 Patients.

Possible Hazards for Patient (acceptable Residual Risk)

Possible Hazard (acceptable Residual Risk) <i>--- Direct Physical Harm ---</i>	Possibly caused by
Skin irritations	Allergic reaction to electrodes, bio incompatibility, bio contamination
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, Lightning

Possible Hazard (acceptable Residual Risk)	Possibly caused by
--- Lack of Medical Data ---	
No output, irregular or incorrect output from chest module or 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 failed
Failure to record, interruption of data flow, partial/complete failure of 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

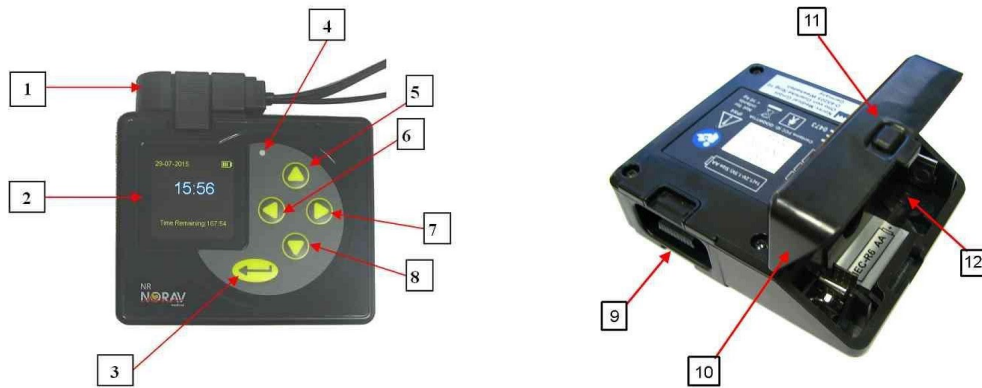


Fig. 3: Devices Front and Back

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 light 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 card compartment door
11	Battery and SD Flash card compartment door latch
12	Battery and SD Flash card compartment

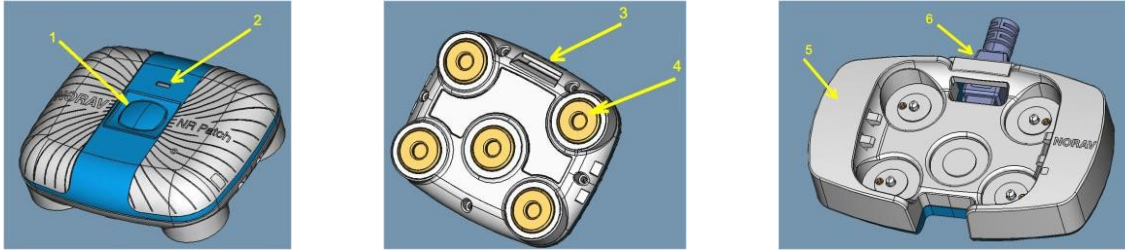


Fig. 4: Device Front, Back, and Docking Station


Position	Description
1	Push button <i>Power ON/OFF</i> and <i>Patient Event</i>
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

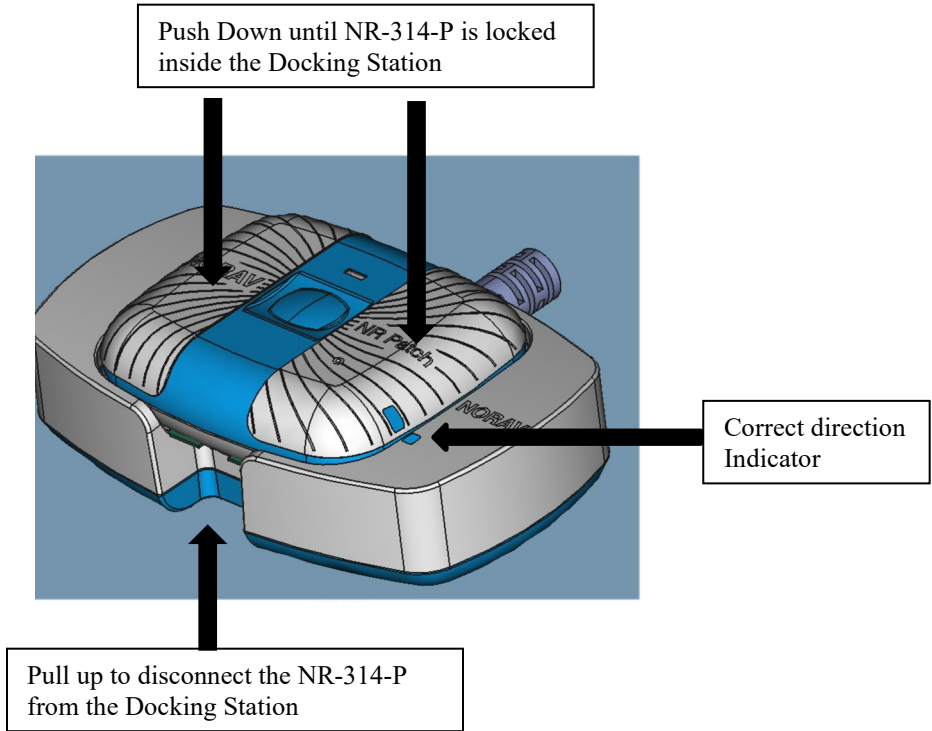
NR-314-P Main Battery and Docking Station Overview

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 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 advised.

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 charged and reconnect shortly before the next study for a quick charge refreshment.

NR-314-P will flash its LED indicator in blue during charging. After NR-314-P internal battery is fully charged the LED will be solid blue light. After disconnection of NR-314-P from the Docking Station or removing USB power, the NR-314-P will turn OFF itself.

	<ul style="list-style-type: none"> The Docking station shall connect only to computers that are compliant with EN60950-1
Caution	



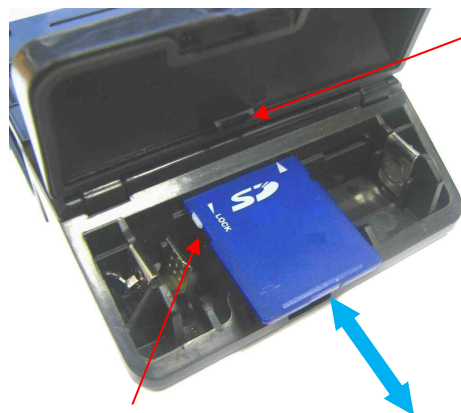
Memory Card Usage (SD card)

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




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 from an incorrect insertion of the memory card. Do not force the card into the slot.
- Using the memory cards with other instruments (digital cameras, MP3 players, etc.) can lead to incorrect functioning and/or data loss.
- If memory card is not completely locked inside its slot, the card retainer (part of battery compartment cover) will not allow to close the cover. Do not push the cover when closing with force; 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 notch is not in Unlocked state, slide the tab upward (Toward the contacts) to declare the card read/write enabled.
- If the storage space runs out during a recording, the recording is stopped automatically and the instrument switches off.



Note

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



Main Battery

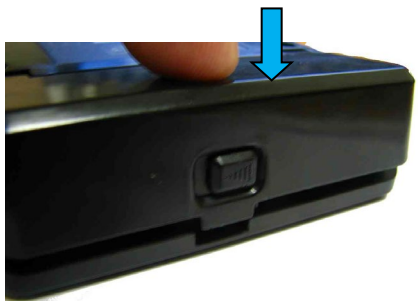
Models: NR-302, NR-314, NR-314-T, NR-1207, NR-1207-3 and NR-1207-E

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 Li-FeS2 Lithium battery, size AA (IEC-FR6). Although battery life may last longer than a recording, batteries should not be re-used for a second Patient. After one use, they should be disposed in accordance with the local regulations.

How to Insert Battery



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



As indicated in the illustration, close battery compartment cover and press on it until the latch snaps in to the base part.

**Caution**

- Check that NR device settings showing a correct Battery type in the setup of the NR device.

**Caution**

- Do not leave 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 recharger should be kept out of the patient environment and hook-up area.
- Dispose of used batteries carefully, using environmentally friendly methods wherever possible following the state's recycling laws or your facility's recycling policy

RTC Back up 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 during recording from the main battery. With a full charge, the clock is maintained for at least 4 months after the main battery is removed. The clock cell is not replaceable by the user, and in the case of suspected failure the NR should be returned to Norav Medical GmbH 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 the measurement results and quality. Ensure that only high-quality electrodes are used. Wet gel electrodes are recommended.

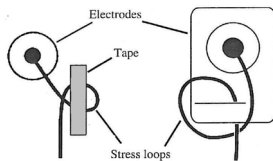
Always refer to the ANSI/AAMI EC12:2000 Standard for safety, performance, and labeling requirements for the disposable electrodes, and guidelines for reliable patient connections.

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 sites, 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 to dry the electrode placement sites.

Attaching Electrodes

- Attach the leads and the electrodes before placing the NR device on the patient.
- Snap-on the lead connectors to 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 sticking them firmly to the patient's skin.
- The offset connector tab should be positioned in the same direction as the lead wires, towards the equipment.
- **For NR-314-P model only:** Optionally use neck strap to prevent the device fall 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 to not let any unattached electrode come in 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 NR device. Connect patient lead wires only to patient electrode.
- 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 casing and the ECG patient cable for damage which may have occurred, for example, due to mechanical overload, falling from a great height or wear and tear (chafed patches on the cable). Do not use the instrument or the cable if you detect 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 placement of electrode in those areas. If skin irritation occurs during the procedure advise the patient to remove the electrodes and contact the health service 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 showering briefly with patient back to the water and avoid any activities that cause excessive sweating.

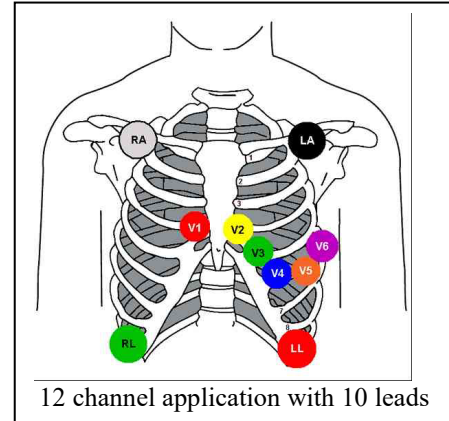
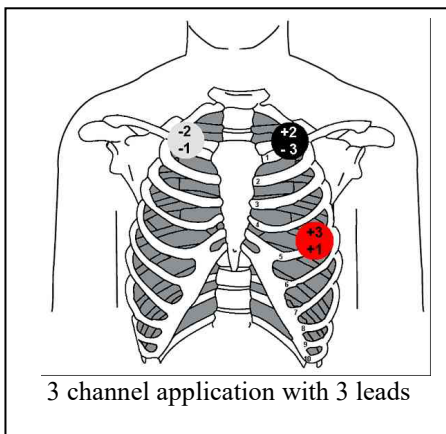
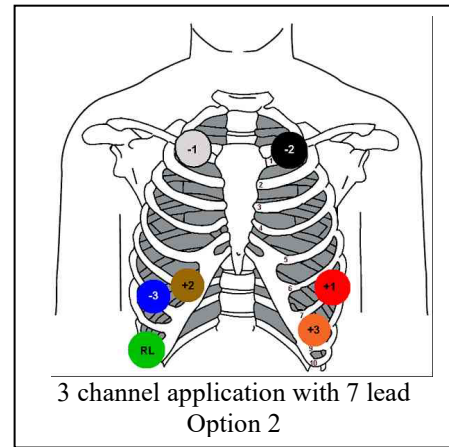
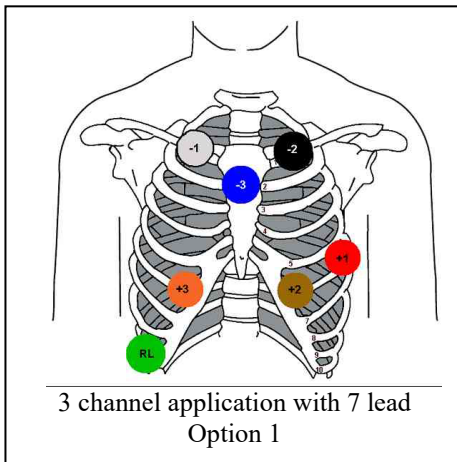
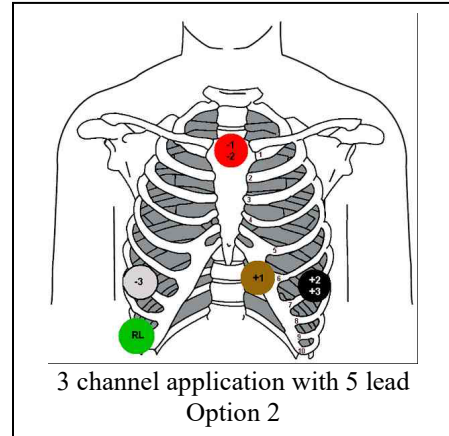
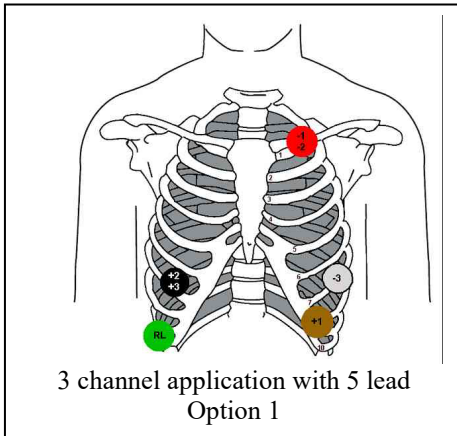
Electrode Placement Scheme

Suggested electrode placements are shown in the diagrams below. However, it is up to the physician to make the final placement determination. The NR device’s ECG display screen or Computer Analysis System that used Bluetooth communication can be used to verify a proper patient hookup.



Caution

- Do not rely on the NR device LCD display as a diagnostic tool.



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 ECG cable connector slot of the NR unit, as shown on the picture. Make sure to insert the Cable connector until there is no space between the Cable connector and the unit.

Make sure that two latches of the Cable connector are latching with the unit.

Disconnecting:

Remove the Patient ECG Cable connector by squeezing the two side latches on the head of the Cable connector and pulling 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 into the ECG Cable slot on the NR any other than the Patient ECG Cable connector. Damage can result to the both the ECG Cable slot input connector and Patient ECG Cable connector.
- Always check the presence of sealing O-ring on Patient ECG Cable connector and its quality. O-ring sealing 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 sport 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 connected sense. If NR device will not detect connected Cable, it will display warning message with buzzer beep and show diagram of unit with not connected Cable connector.

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 various LCD screens and five push-buttons.

	<ul style="list-style-type: none"> To prevent possible damage to the keypad, do not use sharp or hard objects to depress keys.
Caution	

Screen	Description
Main	Displays Current date/time, Main battery level, and following Menu items : <ul style="list-style-type: none"> • Patient Data <i>(Display Patient data – ID or Name)</i> • Voice Recording <i>(Record operator voice message - up to 20seconds)</i> • Recording Settings <i>(Display enabled recording settings)</i> xxxH = Record time in hours \E = Event button enabled \P = Pacemaker detection enabled \R = Respiration enabled \A = Acceleration sensor enabled
Settings	Displays Menu items: <ul style="list-style-type: none"> • Patient Settings <ul style="list-style-type: none"> ➤ ID <i>(Change via Virtual keyboard screen)</i> ➤ First Name <i>(Change via Virtual keyboard screen)</i> ➤ Last Name <i>(Change via Virtual keyboard screen)</i> ➤ Birthday <i>(Change via Virtual keyboard screen)</i> ➤ Clinic ID <i>(Change via Virtual keyboard screen)</i> ➤ Display Format Patient ID, Clinic ID, Name <i>(Select patient data field to display on the Main screen)</i> • Record Settings <ul style="list-style-type: none"> ➤ Record Time 24,48,72,96,120,168, 336 hr <i>(336 hours option is limited to 3 channel mode with 3, 4 , 5, 7 lead cable , 250 sample rate and Lithium battery only)</i> ➤ Sample Rate (of ECG) 250,500,1000<i>(samples per second)</i> ➤ Pacemaker detection ON or OFF <i>(OFF by default. Once turned ON remains active within the current recording only)</i> ➤ Accelerometer ON or OFF ➤ Respiration ON or OFF <i>(always OFF when Pacemaker detection is ON)</i> ➤ Diary OFF , Event button, Symptom list, Voice note <i>(in Holter/Holter+ mode)</i> <ul style="list-style-type: none"> ■ Event button - Save 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 <i>(When ON - allow to record a Voice note) (for NR-1207-3 model in ECG+ mode)</i>

Screen	Description
Settings (<i>continue</i>)	<ul style="list-style-type: none"> • System Settings <ul style="list-style-type: none"> ➤ Date\Time <ul style="list-style-type: none"> ■ Date <i>(Month, Day, Year)</i> ■ Date Format <i>(MM/DD/YYYY, YYYY/MM/DD, DD/MM/YYYY, YYYY/DD/MM)</i> ■ Time <i>(Hour and Minute)</i> ■ Time Format <i>(12 or 24 hr)</i> ➤ Display <ul style="list-style-type: none"> ■ Contrast <i>(20-90%)</i> ■ Rotation <i>(0, 90, 180, 270 deg.)</i> ➤ Battery <ul style="list-style-type: none"> ■ Alkaline ■ NiMH ■ Lithium ➤ Language <ul style="list-style-type: none"> ■ English ■ Español ■ Deutsch ■ Français ■ Italiano ■ Português ■ Nederlands ■ Polski ■ Русский ■ Ελληνική ■ Türk ➤ Mode <i>(for NR-1207-3 model only)</i> <ul style="list-style-type: none"> ■ Holter ■ Holter+ ■ ECG ■ ECG+ • Save as default (Press Enter to save as default current settings) • About (Press Enter to see 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, 8.0. Gain affects only screen display, not 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 <i>Enter</i> . This will start the recording. During recording, the NR device displays the current time and time remaining to record.
Info	During recording NR device will display the date, current time, battery level indicator and time remaining for the recording.

“Main” menu screen - explanation of menu navigation by using keypad buttons almost the same for the others menu screens.

The screenshot shows the main menu with the following elements and callouts:

- Menu Item[1]: Patient ID**: Points to the 'Patient ID:' label.
- Recorder Date&Time**: Points to the date and time '03-08-2015 10:00'.
- Main Battery Indicator**: Points to the battery level icon.
- Menu Item[2]: Voice Record**: Points to the 'Voice Record' option, which is highlighted. The text below explains: 'Selected Item is highlighted in current Menu Screen. Navigate to above or below menu Item by using up/down buttons of the keypad.'
- Menu Item[3]: Recording settings**: Points to the '168H / E' value. The text below explains: 'Recording settings Record Time = 168Hr, Event Button = On'.
- Help line text meaning:** 'Navigate to the Next/Previous Menu screens by using left/right buttons of the keypad' points to the left and right arrow keys.
- Help line text meaning:** 'To start Voice Recording Press Enter button of the keypad' points to the 'Press Enter to start' instruction.

“Virtual Keyboard” menu screen (alphabet layout with lower case shown), used to enter Patient Data like ID, First Name etc. Use up/down/left/right buttons of the keypad to navigate via the virtual keyboard screen items.

The screenshot shows the virtual keyboard screen with the following elements and callouts:

- Entered characters**: The string 'Thomas_' is shown at the top. The text below explains: 'This line shows entered characters from the virtual keyboard. This character string will be saved if select item "Save" at the bottom of the screen and pressing Enter button of keypad.'
- Selected character**: The character 's' in 'Thomas_' is highlighted. The text below explains: 'Selected character is highlighted – press Enter button of keypad to insert it to the string at line above. Navigate with up/down/left/right buttons of the keypad to select different character'.
- Virtual keyboard control icons line**: A row of icons for keyboard layout selection. The text below explains: 'Virtual keyboard control icons line. Meaning of the icons from left to right: Select - upper or lower case alphabet keyboard layout, Select - Space character, Select - Backspace character, Select - Numeric keyboard layout, Select - Alphabet keyboard layout, Select - Extended alphabet keyboard layout'. A note states: 'Note: Alphabet and extended alphabet layout depends on system language of the recorder'.
- Navigation**: The 'Save' and 'Cancel' buttons are at the bottom. The text below explains: 'Navigate here with up/down/left/right buttons of the keypad to Save or Cancel the entered string at the top of the screen'.

Common Modes and Workflows

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

A basic workflow for “classic” Holter recording procedure.

- Prepare NR device.
- Enter patient information.
- Hookup patient
- Check ECG leads quality.
- Start recording.
- While recording continues, the patient can enter diary events.
- When patient bring the NR device back stop the recording.
- Download the ECG recording file to the computer.
- Preview/Analyze the ECG in Holter software interface.

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

Advanced workflow allowing to acquire the ECG traces online while Holter recording is continues.

- Prepare NR device.
- Enter patient information.
- Hookup patient
- Check ECG leads quality.
- Start recording
- Acquire the live ECG every time when it is necessary
(*patient must be near to the acquisition workstation*)
- While recording continues, the patient can enter diary events (optional).
- When patient bring the NR device back stop the recording.
- Download the ECG recording file to the computer.
- Preview/Analyze the ECG in Holter software interface.

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

Standard workflow for PC-ECG acquisition.

- Prepare NR device.
- Hookup patient.
- Check ECG leads quality.
- Run the PC-ECG or Mobile ECG software application and enter patient information.
- Acquire the live ECG.

ECG+ mode (for 1207-3 Model only)

Advanced mode for record continuously the ECG traces in the NR device memory independently to live ECG is acquiring or not. Allows to store ECG records for more than one patient on the same memory card.

- Prepare NR device.
- Enter the patient information.
- Hookup the patient.
- Check ECG leads quality.
- Start ECG recording to the NR device memory card.
- Every time when it need - launch the PC-ECG or Mobile ECG software and acquire the live ECG.
- At the end testing of current patient – stop (pause) the ECG recording.
- Hookup the next patient and then continue the recording in the NR memory card.
- When NR memory card is filled – 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 NR device battery compartment door.
- Insert an SD card into NR device. *(Skip this step when use models NR-1207-E and NR-314-T.)*
- Insert a new battery and close the battery compartment door.
(Green LED of the keypad will start flashing 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 of the keypad.

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

If the NR device is loaded with an SD card containing 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. Recordings can last up to 20 seconds. Ensure the microphone (indicated by 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 through the 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 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 recording time left. If inactive, the screen blanks out but 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; 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 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 NR device transmits live ECG traces online. Use the Resting ECG software of PC-ECG 1200 or 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 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 clean 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. Manually stop by pressing both keypad 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 and transfer the ECG data according to the manual of this System.
- 2) Optionally, download directly via USB without removing the card. Replace the patient cable with 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

- The NR device with installed battery and SD card, turned ON and ECG cable connector connected to the unit; and is left for 10 minutes without pressing any button on keypad, will start the test automatically (*for Holter and Holter+ modes*). This feature of the device shall eliminate the risk that the operator forgets to start the test.
- The NR device with installed battery and SD card, turned ON and ECG cable connector connected to the unit; and detects a recording saved on the memory card which has not yet been downloaded by the Computer Analysis System, will show warning message screen and will 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 flat during a recording, it is necessary to 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 in the test, if the batteries are not replaced in time. The data recorded before the battery runs flat are stored in the memory card and can be freely accessed and analyzed after download by Computer Analysis System.
- The NR device will only allow you to select settings for a recording what will fit on the SD flash card. There is a relationship between the record time, sample rate, and number of channels. By choosing a higher value in one setting, you may have to choose a lower value than you want in another setting. It is best to first set the lowest setting you desire, then the second highest, 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 settings to the NR-314-P, disconnect it from the Docking Station and power it on. Observe the LED changing from fast flash to solid green, indicating completion of the initialization. To begin recording, press the button for 3 seconds until the LED starts slow flashing, then release. Recording starts after 30 seconds, and the LED turns off after 60 seconds.

Recording in Progress: Available Actions

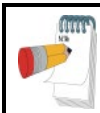
A short press on the button will light the LED blue for 2 seconds. Holding the button for 3 seconds records a user event; the LED stays blue for 15 seconds before turning off.

Stop Recording

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

Data Downloading

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

**Note**

- The NR-314-P turned ON; and is left for 10 minutes without pressing button, will start recording automatically.
- The NR-314-P turned ON; and detects a recording saved on the memory which has not been downloaded to the computer yet, will turn ON LED solid RED for 5 sec and turns OFF.

Switching Device ON/OFF

To turn on the NR-314-P, press the button for 2 seconds and release it; the LED will fast flash green. Once the NR-314-P finishes internal initialization, the LED turns solid green. To turn off, press and hold the button for 15 seconds until the LED turns off.

Ingress Protection Instructions

Ingress Protection instructions explain to lay users how to understand the IP rating of a specific device and which safety measures to take to ensure proper functioning of the device.

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 is connected, the battery door is closed, and the sealing is properly installed.

- **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.
- **Water-resistant, not waterproof:** Resists splashes but must not be submerged. Avoid swimming, bathing, or hot tubs. You may shower but avoid directly spraying water onto the device. Face away from the shower spray.

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.
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 Caution	Take care to prevent chemicals/liquids from entering the connectors or internal part of the device. The battery contacts should 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	If liquid penetrates the device, i.e., during cleaning or operation, this may interfere with correct functioning. Switch the device OFF and remove the battery. Leave the device in a warm, dry room with the battery door open for 48 hours. If the functioning is still affected, contact the 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 sec., repeat as necessary or until there are no residues of soil and dirt on the device. 2. Prepare a neutral/mild pH enzymatic detergent, according to the manufacturer's instructions (in the lowest recommended concentrations). Effective cleaning can be achieved by using Deconex Power Zyme, prepared using concentration of 1% (20 ml per 2 liters of water) with tap water. 3. Immerse the soft non-abrasive damp cloth with the prepared detergent, then wipe the device for at least 30 sec. Repeat as necessary or until there are no residues of soil and dirt on the device. 4. Finally, use Isopropanol 70% wipes to clean the device for at least three (3) minutes.

 <p>Disinfection</p>	<p>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.</p>
<p>Drying</p>	<p>Dry for ten (10) minutes.</p>


Maintenance

Before using the NR device, perform a unit check in accordance with the specified check procedure. If any item is found to be non-compliant, the unit shall be classified as rejected. Apply corrective measures to resolve the non-compliant items. The NR device may only be used once all items meet the acceptance criteria. The unit check must be carried out by the medical institution, Norav Medical GmbH personnel, a representative agent, or an authorized third party. For further information, please contact your dealer or Norav Medical GmbH 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 have tactile feedback when pressed	Must get 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 spring loaded in the battery door latch.	Spring must be loaded.
Battery compartment	Check whether dirt or hair is not 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 damages.
ECG Snap Buttons	Visually check for damage and corrosion	Must be free from damages 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.

 <p>Caution</p>	<ul style="list-style-type: none"> • Store the NR device in an area free from water or humidity. • Take care to avoid areas subject to high humidity, poor ventilation and direct sunlight; store the NR device in an area free from any adverse effects of surrounding air containing dust, sodium, and sulfur. • Do not store the NR device in an area where chemicals are kept, or which is exposed to chemical fumes or vapors.
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Service

If there is a problem with the NR device, review the Troubleshooting section for a listing of problems and solutions. If additional assistance is required, contact customer support via phone, fax or e-mail listed in this manual. Call customer support before returning an NR device to make shipping arrangements.

All repairs on products under warranty must be performed or approved by Norav Medical GmbH. Unauthorized repairs void the warranty. In addition, whether covered under warranty or not, any product repair shall exclusively be performed by Norav Medical GmbH 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 GmbH 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 need any 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	<ul style="list-style-type: none"> ■ Ensure battery is inserted with correct polarity. ■ Install a new AA battery.
Low battery (<i>message</i>)	<ul style="list-style-type: none"> ■ Install a new AA battery. ■ Inspect battery compartment, clean contacts if necessary.
No Cable (<i>message</i>)	<ul style="list-style-type: none"> ■ Ensure patient cable (lead set) is connected to the NR device. The NR device will not pass the screen unless a cable is connected. ■ Check that the NR device sided connector is not damaged. Check that the cable connector pins are not broken or bent / damaged.
Noise artifacts on ECG signal	<ul style="list-style-type: none"> ■ 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 (<i>message</i>)	<ul style="list-style-type: none"> ■ 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 (<i>message</i>)	<ul style="list-style-type: none"> ■ Ensure the memory card is Norav Medical GmbH Certified. ■ Ensure the memory card is not write protected (small switch on the SD Card) ■ Reformat the memory card or replace the card with a new Norav Medical GmbH certified memory card.
Previous recording found (<i>message</i>)	<ul style="list-style-type: none"> ■ Download the ECG data with Computer Analysis System, or delete it from the SD card using left and enter buttons.
Set Date/Time (<i>message</i>)	<ul style="list-style-type: none"> ■ 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 every time you insert an AA battery. If the NR device is unused for an extended period of time, 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)	<ul style="list-style-type: none"> Check that Record Settings screen is set for the desired number of hours. Memory card has only enough memory capacity to run for the number of Hours which are available as valid selections in the Record Settings menu.

Model NR-314-P

Symptom	Solution
NR device does not power on RED LED is ON when not connected to Docking Station	<ul style="list-style-type: none"> Ensure that the NR-314-P is fully charged Ensure previous record file downloaded to Computer Analysis System and Removed from the internal memory of the NR-314-P. Ensure RTC set correctly via Computer Analysis System
RED LED is ON when connected to Docking Station BLUE LED is OFF when connected to Docking Station	<ul style="list-style-type: none"> Use only Norav Medical GmbH USB cable, try replacing USB cable. Try connecting USB cable to other USB port or to another computer Use only Norav Medical GmbH USB cable, try replacing USB cable. Ensure USB cable is connected to powered-on computer Ensure NR-314-P connected correctly to the Docking Station
Connected to Docking Station but NR device drive not visible on the computer	<ul style="list-style-type: none"> Use only Norav Medical GmbH USB cable, try replacing USB cable. Try connecting USB cable to other USB port Ensure NR-314-P 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 of reception,
- the preferred frequency or frequency band, if applicable, and
- the bandwidth of the receiving section of the ME equipment in those bands

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

Wireless capabilities

The recorder receives and sends electromagnetic energy so as to meet its intended purpose. The characteristics of the sender 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:	<ul style="list-style-type: none"> ▪ IEC 60601-1 ▪ IEC 60601-1-2 ▪ IEC 60601-2-25 ▪ IEC 60601-2-47 ▪ IEC 60601-1-11
Classification:	<ul style="list-style-type: none"> ▪ 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:	<ul style="list-style-type: none"> ▪ USB 2.0 HS ▪ BlueTooth 2.1 + EDR Class 1

Model NR-314-P

ECG	
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<i>ECG Channels</i>	3 Channels
<i>Recording capacity</i>	2 GByte
<i>Input Impedance</i>	>10 MOhm
<i>CMRR</i>	>90 dB
<i>Dynamic Range</i>	10mV Peak-to-Peak
<i>Maximum DC Input</i>	800mv
<i>A/D Bit Resolution</i>	12 Bit (24 Bit Acquisition)
<i>Pacemaker Detection</i>	Analogue Detection, 2 to 700 mV at 0.1 to 2 ms
<i>Sampling Rate</i>	128, 256, 512, and 1024
<i>Frequency Response</i>	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
<i>Recording Time (maximum)</i>	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 Accu
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	-25 to +70 °C
Humidity (non-condensing)	10 to 95 %RH
Atmospheric Pressure	700 to 1060 hPa

Conformance with Technical Standards

Standards:	<ul style="list-style-type: none"> ▪ IEC 60601-1 ▪ IEC 60601-1-2 ▪ IEC 60601-2-47 ▪ IEC 60601-1-11
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Classification:	<ul style="list-style-type: none"> ▪ Type BF Applied Part ▪ Internally powered Medical Device ▪ Device for continuous operation
Communication:	<ul style="list-style-type: none"> ▪ 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	302, 314, 1207, 1207-3	Holter	No
4 Lead Patient Cable, Clip, AHA	C4-C-U-EI-07	314-T, 1207-3, 1207-E	Telemetry, Stress	Yes
4 Lead Patient Cable, Clip, IEC	C4-C-E-EI-07	314-T, 1207-3, 1207-E	Telemetry, Stress	Yes
5 Lead Patient Cable, Snap, AHA*	C5-S-U-EI	314-T	Telemetry	No
5 Lead Patient Cable, Snap, AHA*	C5-S-U-EI	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	302, 314, 1207, 1207-3	Holter	No
7 Lead Patient Cable, Snap, IEC*	C7-S-E-EI	302, 314, 1207, 1207-3	Holter	No
10 Lead Patient Cable, Snap, AHA	C10-S-U-EI	1207, 1207-3	Holter	No
10 Lead Patient Cable, Snap, IEC	C10-S-E-EI	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	1207-3, 1207-E	12-lead ECG	Yes
10 Lead Patient Cable, Banana, IEC	C10-B-E-EI	1207-3, 1207-E	12-lead ECG	Yes
Accessories				
USB 2.0 HS Cable, 1.5m	USBA-1.5M-EI	302, 314, 1207, 1207-3		
NR device Holster	NR-HOL	302, 314, 1207, 1207-3, 1207-E		
NR device Pouch	NR-P	302, 314, 1207, 1207-3, 1207-E		
Certified NR SD Memory Card 2GB	NR-2G-SD	314, 1207, 1207-3		
Certified NR SD Memory Card 512MB	NR-512M-SD	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
<i>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.</i>		
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
<i>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.</i>			
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% UT (>95% dip in UT) for 0.5 cycle ±40% UT (60% dip in UT) for 5 cycles ±70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) 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: UT 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
<i>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.</i>			
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.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Recommended Separation Distance $d = 1.17 \sqrt{P}$ $d = 1.17 \sqrt{P}$ 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: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	E = 10 V/m	

- 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.

<i>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.</i>			
Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter(m)		
	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	6 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	6 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	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: $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{12}{V_2} \right] \sqrt{P}$ $d = \left[\frac{12}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{23}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$
Radiated RF IEC 61000-4-3	10V/m, 80MHz to 2.7GHz, 80% AM at 1kHz	10V/m, 80MHz to 2.7GHz, 80% AM at 1kHz	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	150 kHz to 80 MHz in ISM bands	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$	$d = \left[\frac{12}{V_2} \right] \sqrt{P}$	$d = \left[\frac{12}{E_1} \right] \sqrt{P}$	$d = \left[\frac{23}{E_1} \right] \sqrt{P}$
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	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870				
930				
1720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900. DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
1845				
1970				
2450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5240	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5500				
5785				

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

 <p>WARNING</p>	<p>For patients with a pacemaker, maintain a minimum of 15 cm (6 inches) between the NR device and pacemaker. Turn the NR device off immediately and provide appropriate patient care if you suspect the NR device affected the pacemaker. The Health Industry Manufacturers Association recommends a minimum 15 cm (6 inches) distance between a wireless radio and a pacemaker, which is consistent with the recommendations of Wireless Technology Research.</p>
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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 communication. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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).