

NR Recorder

Model NR-1207-E



Installation and Operation Guide (for iOS Devices)

Copyright

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Standards Compliance

The interference generated by the device was tested according to the EMC 89/336/EEC and found compliant with the standard.

The NR Recorder conforms to Medical Devices Directive 93/42 EEC Annex II.

 Complies with the Medical Device Directive of the European Union: NB. 2797

CAUTION	
	CAUTION: <i>US Federal Law restricts this device to sale by, or on the order of, a physician.</i>

The NR Recorder is tested and certified for the following standards:

- EN60601-1
- EN60601-2-47
- IEC60601-11
- Protection type and class: BF, Internally powered
- Defibrillation protection: yes, with Banana cable only.

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 product.

Norav Limited Warranty

The Norav limited warranty guarantees products free from manufacturing and material defects for a period of one (1) year from the date of shipment from Norav 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 determines that it has been modified or damaged by the customer.

Except for the express warranties stated above, Norav 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 for damages, including but not limited to, special, indirect, or consequential, arising out of or in connection with the use or performance of Norav 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 the local supplier or Norav Medical.

Document History

Rev.	Description of Revisions	Date
A	Initial release	01/02/2018
1.4	Norav Mobile ECG for iOS, Version 1.4	03/01/2019
1.4(9)	Norav Mobile ECG for iOS, Version 1.4(9)	28/02/2019
1.4(10)	Norav Mobile ECG for iOS, Version 1.4(10)	24/04/2019
1.4(11)	Norav GmbH new address	25/11/2019
2.0	Norav Mobile ECG for iOS, Version 2.0	16/12/2019



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Document Conventions

Notes and Cautions

Pay particular attention at specific points in a procedure when one of the following messages appears:

	<p style="text-align: center;">WARNING</p> <p>WARNING: Warnings call attention to possible hazards involving potential damage or injury to persons.</p>
	<p style="text-align: center;">CAUTION</p> <p>CAUTION: Cautions refer to practices necessary to protect against potential damage or loss to equipment. Pay careful attention to instructions.</p>
	<p style="text-align: center;"> NOTE</p> <p>NOTE: Notes provide pertinent information to help obtain optimum performance from the software or signify an important step or procedure that requires special attention.</p>





Safety

	<p style="text-align: center;">WARNING</p> <p>WARNING: The NR Recorder device uses batteries as the main power supply. It is also sensitive to electrical interference. To prevent possible injury, read this page carefully prior to installing the device.</p>
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- Other devices which are part of the system must meet the requirements of the Standard for Information Technology Equipment (IEC 60950) and the Standard for Electrical Medical Devices (IEC 60601-1)
- The computer system should be approved to the appropriate safety standard for non-medical electrical equipment (IEC 60950, or its national variants).
- Computers and printers used with Medical Devices should be evaluated for EN 60950-1, EN 60601-1 or equivalent safety standard to maintain the safety of Medical Devices.
- Accessory equipment connected to the analogue and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of the standard IEC/EN 60601-1-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the standard. Use only the original data cable/power adaptor assembly.
- Magnetic and electrical fields can have an influence on the function of instruments. Ensure that all non Norav Medical equipment which is operated nearby complies with the EMC requirements (regulations for Electro Magnetic Compatibility). X-Ray, CTs, etc. can cause interference to other equipment, as a result of their authorized higher emission of electromagnetic interference.
- **Pacemaker** – It is recommended that a minimum separation of 15 cm (6 inches) be maintained between the wireless NR Recorder and a pacemaker to avoid potential interference with pacemaker. Some studies have shown that wireless devices might interfere with implanted cardiac pacemakers if used within eight inches of the pacemaker. Pacemaker users may want to avoid placing or using a wireless device this close to their pacemaker. Patients with a pacemaker:
 - Should always keep the wireless NR Recorder unit at least 30 cm from their pacemaker when the NR Recorder unit is turned on.
 - Should not carry the NR Recorder in their breast pocket.

If you have any reason to suspect that interference is taking place, turn off the ECG immediately.

- Use only the recommended battery type as instructed in the technical specifications to operate the NR Recorder (1 x AA alkaline or NiMH rechargeable battery).
- Do not use batteries with expired dates.
- Remove batteries from the unit (NR Recorder) when it is not in use.
- In the event of apparent changes in the performance of the device, discontinue use immediately. Do not resume use until the device is approved by the manufacturer or by a representative of the manufacturer.
- Defibrillation protection is guarantee only with original Norav supplied ECG cable (“banana” ends).
- Operate the unit only at clinics and hospitals. Do not use at home.
- Operation only by trained medical staff.
- Use only with battery compartment closed.
- This NR Recorder complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
 - (1) This product may not cause harmful interference.
 - (2) This product must accept any interference received, including interference that may cause undesired operation.

	<div style="text-align: center;">  NOTE </div> <p>NOTE: <i>The manufacturer is not responsible for any Radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user’s authority to operate the equipment.</i></p>
	<div style="text-align: center;">  NOTE </div> <p>NOTE: <i>Install hardware only after software installation.</i></p>

Intended Use

In conjunction with Norav Mobile ECG App the NR Recorder is intended to acquire multi-channel ECG signals from adult and pediatric patients from body surface ECG electrodes and to record, display, analyze, and store these ECG signals for review by the user. It is to be used by trained healthcare professionals. Analysis of the ECG signals is accomplished with algorithms that provide measurements, data presentations, graphical presentations, and interpretations for review by the user.

The interpreted ECG with measurements and interpretive statements is offered to the clinician on an advisory basis only. It is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings.

Indications for Use

ECG device is to be used to disclose either normal condition or patterns of arrhythmia, myocardial ischemia, rate abnormalities, or features of prognostic value in adults and pediatric populations in the following cases:

- Patients with suspected cardiac abnormalities.
- Populations of patients at an age or period in which a routine baseline evaluation of ECG characteristics is desired.

Contraindications for Use and Adverse effects

The device has no contraindications or adverse events.

Unpacking

Open the device package and verify the following package content:

P/N	Description
NR1207E-D-00E-02	NR Recorder, model NR-1207-E
C10-B-E-EI	10 lead ECG cable for NR Recorder, banana ends, IEC, EI
C-USB-EXT-2M	USB cable 2M
C-ADAPT-BANANA-SNAP-01	Banana to Snap adapters pack of 10
BAT-ALK-P-AA-EN91	Battery, Alkaline Primary, 1.5V, Size AA
ADAPTOR-BTUSB-UD100-01	Bluetooth USB Adapter (for MS Windows PC)
ANT-2.4-RPS-MAF94028-1	Detachable antenna for Bluetooth adapter (for MS Windows PC)
SW-CD-PCECG1200-01	Software PC-ECG 1200 CD (for MS Windows PC)
SW-CD-NR-OMINS-i-01	Installation and Operation Manual for Norav Mobile ECG iOS app (on CD)
SW-CD-NR-OM-01	NR Recorder Operation Manual (on CD)

Installing the Norav Mobile ECG App

The following Apple products running iOS 12.1 or later are supported:

iPhone XR
iPhone X
iPhone 7 Plus
iPhone SE

iPad Pro (12.9-inch) 2nd generation
iPad (5th generation)
iPad Air 2
iPad Air
iPad mini 2

To install the Norav Mobile ECG app on the iOS mobile device:

1. On your iPhone or iPad go to the App Store following below link:
<https://apps.apple.com/us/app/norav-medical-mobile-ecg/id1453815696>
2. When the 'Norav Mobile ECG' app description appears- tap Get. You might need to sign in with your Apple ID and password or use Touch ID or Face ID if you have them set up.



Installing the NR Recorder

1. Attach the Patient Cable:

Insert the ECG cable connector into the slot on top of the NR-1207-E unit. Make sure to insert the cable connector until both of two latches of the cable connector are locked on the unit.



2. Install the battery:

Open the battery compartment cover by moving left and up the cover latch.



Insert a fresh AA battery. First insert from the negative terminal. Ensure that the battery's removal ribbon goes behind the battery.




Close battery compartment cover and press on it until latches into the base part. Make sure that the ribbon is completely hidden under the cover.




3. Press the button on the NR Recorder to turn it ON





4. Configure the Bluetooth settings in the NR Recorder:

Press the  button to enter the Settings screen.



Open the System Settings with press the  button




Navigate with the  button down to the **Bluetooth** setting then press the  button to open the Bluetooth Pairing options.




Navigate with the  button down to the **Passcode** option then press the  button to apply the selection.



Press the  button to return to the Settings screen.




Select the **Save as Default** option the Bluetooth setting then press the  button to save the changes.



Pairing the NR Recorder with iOS Mobile Device

The pairing procedure establishes a connection between the iOS mobile device and the NR Recorder.

 1.	<p style="text-align: center;">NOTE</p> <p>NOTE: This pairing procedure is only necessary for initial setup of a mobile device and ECG acquisition module.</p>
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1. On NR Recorder:

select the **Pairing** command on the Settings screen then press

the  button to start pairing



NR Recorder will show the Waiting for Passcode screen



2. On iOS mobile device:

open **Settings**



select Bluetooth



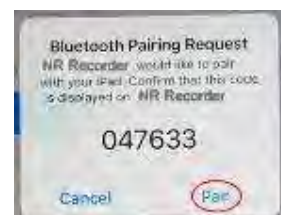
make sure it's turned ON



select the **NR Recorder** name
in the found Bluetooth accessory list



tap **Pair** on the Bluetooth Pairing Request message



3. On NR Recorder:

validate the pairing code is same as on the iOS device then

press the  button to confirm the pairing



4. On iOS mobile device:

Make sure that the NR Recorder is **Connected**

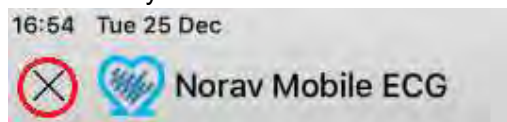


First Time the Norav Mobile ECG App Settings

1. Tap the **Norav Mobile ECG** shortcut. When the App screen will appear—open **Settings**.



2. Enter the Physician and Clinic information then exit to App main screen by tap the **X** icon



Performing the ECG test

This chapter reviews the tasks associated with running a test

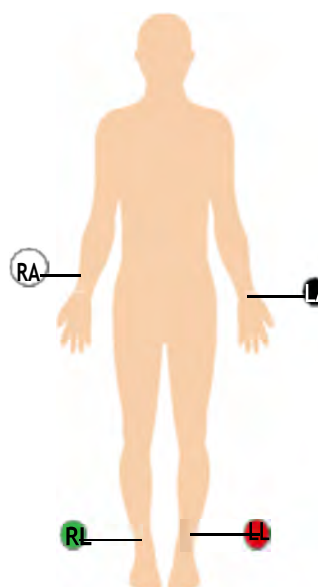


NOTE

NOTE: Make sure the NR Recorder is turned ON

■ Hook up the Patient

Connect the LIMB leads:



Connect the CHEST leads



■ Entering Patient Information

Tap **Start New Test**

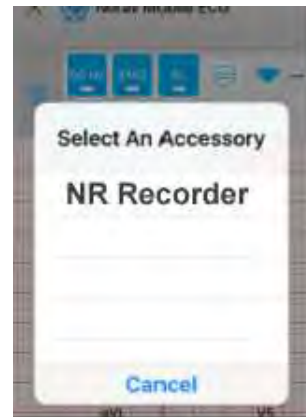


Enter Patient Details then tap **Start**



■ Recording the ECG

If **Select An Accessory** message appears tap the NR Recorder name.

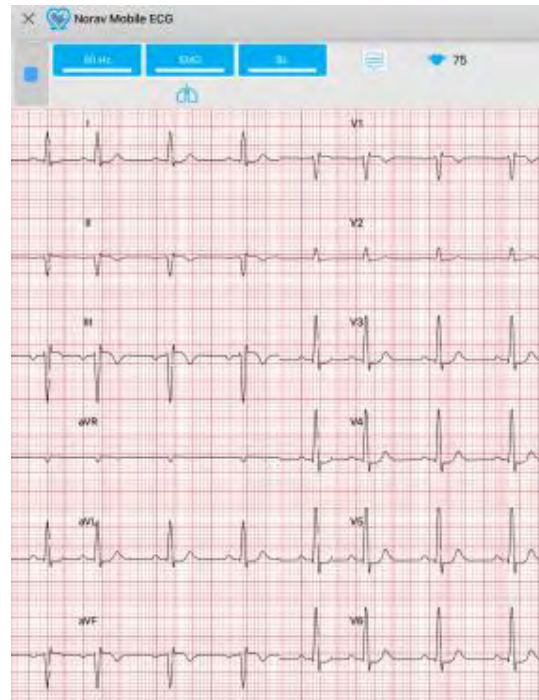


The iOS device will start running the ECG traces

Wait about 10 secs you will see the **Stop** button flashes (means it's ready to save).



Tap **Stop** button to save the test and to enter **Report Mode**.



Saving Test Results and Generating Report

Report View controls:

To add/edit remarks tap the Edit Remark button

Share report to EMAIL

Upload report to FTP server and to Norav cloud

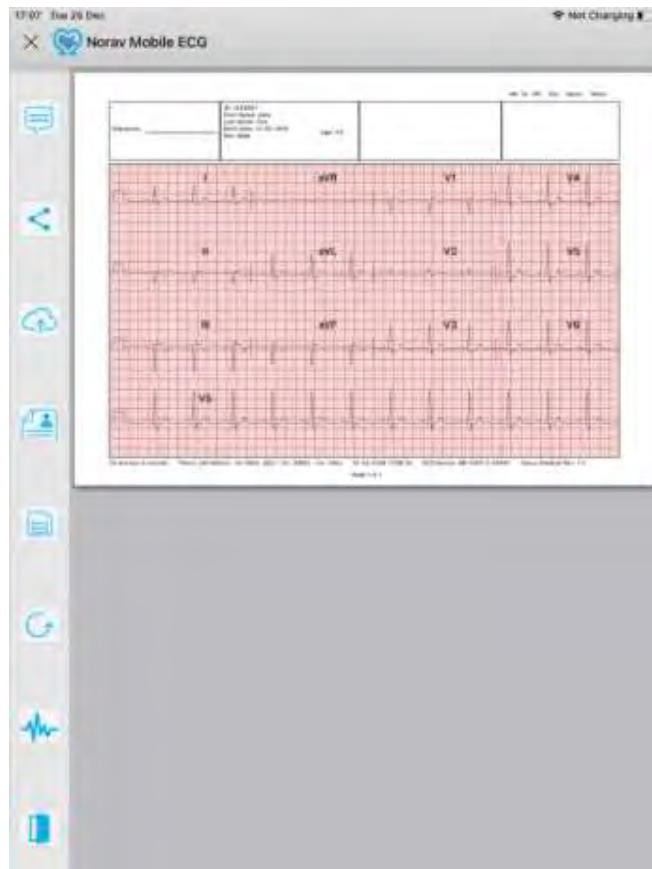
Get Automated Measurement & Diagnostics
(after uploading the report to Norav cloud)

Enter other measurements such as Blood Pressure, SpO2, Body Temperature and Glucose

Back to the main screen

Record new ECG for same patient

Return back to the app main screen



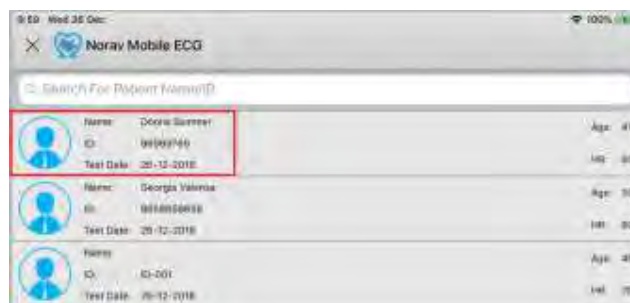
Tests Archive

Tap the Test Archive on the app main screen



Here you will see all the tests you have made ordered by last date.

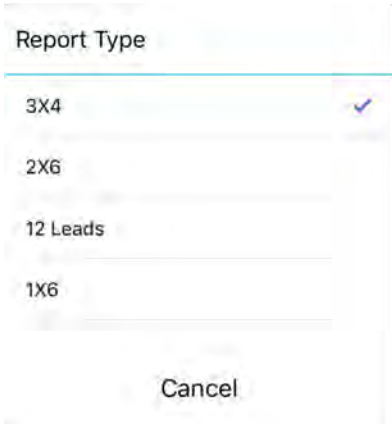




To access the test report—tap the selected patient row.

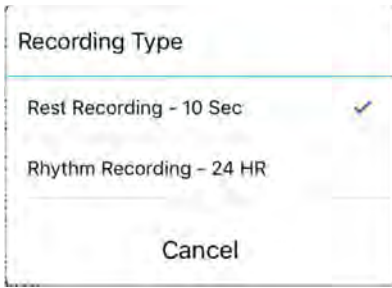


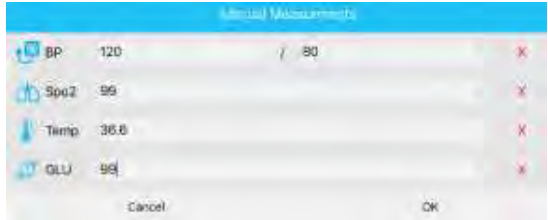
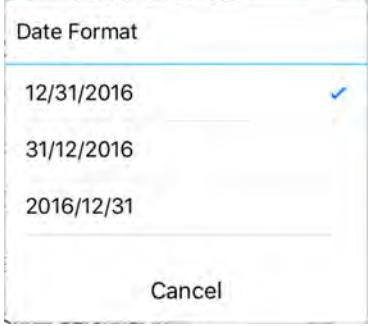
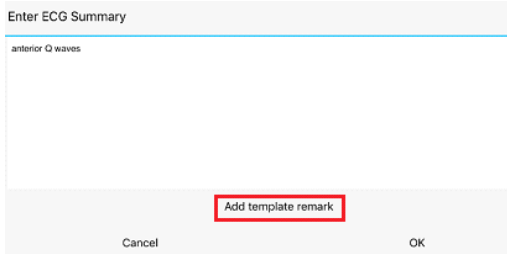




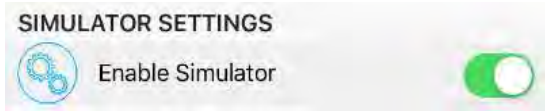
To search patient by ID or by Name enter the looking value in the Search input field

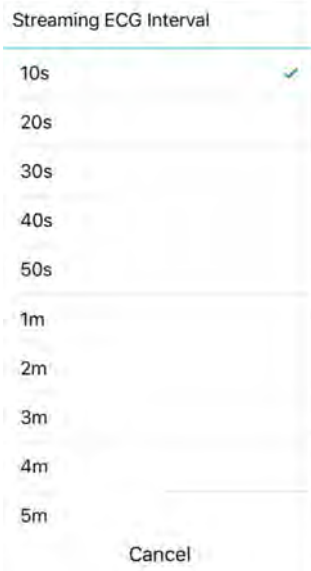
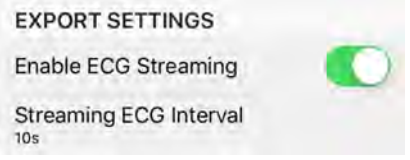
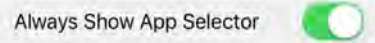


Enhanced Features

Parameter	Optional Values	Description
Horizontal Scale	12.5, 25, 50, 100	Set Real Time ECG Graph horizontal progress rate in mm/sec
Vertical Scale	5, 10, 20, 40	Set Real Time ECG Graph vertical height in mm/mV
Report Types		<p>To select report type:</p> <ol style="list-style-type: none"> 1. Open Settings 2. Select Report Type 3. Choose needed report format <p>3x4 report type is successive and show all leads from 1-5 sec except lead strip from 1-10 sec</p>  <p>2x6 report type is successive and show all leads from 1-5 sec except lead strip from 1-10 sec</p>  <p>12 Leads report showing all 1-10 sec.</p>  <p>1x6 report showing 1-10 sec of limb leads (I, II, III, aVR, aVL, aVF).</p> 

Recording Type		<p>The app is supporting long recording option. Long recording means that when you start new test it will save right from the start (not just the last 10 sec) and it will stop when the user will stop it.</p> <p>To activate long recording:</p> <ol style="list-style-type: none"> 1. Open Settings 2. Select Recording Type 3. Choose Rhythm Recording 24HR
Constant Email Recipients		<p>Set Constant Email Recipient when sending test results via email.</p> <p>To add new email recipient/s:</p> <ol style="list-style-type: none"> 1. Open Settings 2. Select Email To 3. Enter recipients <p>* You can add multiple recipient using the ; sign separator</p>
Life Measurements Support + Email	<p>life measurement can be added in manually by clicking manual measurement button</p> 	<p>BP = Blood Pressure (Systolic/Diastolic) Spo2 = oxygen saturation measured in % Temp = Body Temperature (Celsius). GLU = Glucose (Blood sugar) level (mg/dl).</p> 
Multiple Date Format Support		<p>Adding support for multiple date formats:</p> <ol style="list-style-type: none"> 1. mm-dd-yyyy [month – day – year] 2. dd-mm-yyyy [day – month – year] 3. yyyy-mm-dd [year – month – day] <p>To change date format:</p> <ol style="list-style-type: none"> 1. Open Settings 2. Click Date Format 3. Choose the needed format
Ready template ECG editable remarks		<p>In order to save time to the technician or the doctor, we've added ready remarks template (for ECG). The remarks are editable and managed.</p> 

		<ol style="list-style-type: none"> 1. Open report preview screen. 2. Click remarks on the button:  3. Click on 'Add template remark' button. 4. Select remark from the list, for example 'normal' 5. You will see the select remark inside the textbox. 6. Click OK.
Manageable Remarks		<p>The user can also manage the remarks in the settings screen.</p> <ol style="list-style-type: none"> 1. In Settings screen, select 'Edit ECG remarks.' 2. Remarks Editor Screen will open  3. To Edit the existing remark: <ol style="list-style-type: none"> a. Select the remark you want to edit (it will be gray) b. Click on Edit button c. Enter The new Remark d. Click OK button 4. To Delete the existing remarks: <ol style="list-style-type: none"> a. Select the remark you want to edit (it will be gray) b. Click on delete button 5. To Add new remark: <ol style="list-style-type: none"> a. Click on Add button b. Enter The new Remark c. Click OK button
Simulator Mode		<p>Simulator mode gives you the ability to run the App with simulated Hardware which connected to human body. This operation runs ECG waves in real time, so you can complete the full process for testing and playing with this App.</p>  <p>*Simulator mode will be labeled as Hazards in: ECG leads, summary report and database.</p>

<p>Auto Save PDF (Streaming)</p>		<p>Function to save ECG for 10 seconds, which has been taken automatically send PDF Report via FTP. Note : FTP Server must be defined.</p> <p>Action:</p> <ol style="list-style-type: none"> 1. Enter Settings screen 2. Go to Export Setting > check ECG Streaming 3. Select Streaming ECG Interval. 
<p>App selector</p>		<p>App Selector gives the user to choose other options to export the PDF Report (e.g. other App).</p>  <p>When this option is disabled and email recipients is defined (in the 'Email To' fields) it will open the default email client.</p>