



Norav Users Guide PC-ECG 1200

NV-54/PCECG1200 Revision 2111303 21.12.2023

Document Title:	No	orav Users Guide PC-E	CG 1200	NORAV medical
Document	NV-	Document Rev.:	Document Date:	Page 2 of 53
No.:	54/PCECG1200	211130	21.12.2023	Fage 2 01 33

Norav Users Guide PC-ECG 1200

For Models: 1200S/M/HR/W, Blue-ECG, NR-1207-E and NR-1207-3, software version: 5.97x

Copyright © Norav, November 2021.

All rights reserved.

Document Number: NV-54/PCECG1200 Revision 211130.

No part of this publication may be reproduced in any material form (including photocopying or storing it in any medium by electronic means whether transiently or incidentally to some other use of this publication) without the prior written permission of the copyright owner, or under the terms of a license issued by the copyright owner.

The information contained in this document is subject to change without notice. Norav is neither responsible for nor liable to anyone in connection with this document.



Manufactured by:

Norav Medical GmbH Christof-Ruthof-Weg 10 55252 Mainz-Kastel

Germany

Telephone: +49 (0) 6134-567983-0 Fax: +49 (0) 6134-567983-14

E-Mail: <u>info@norav.com</u>

United Kingdom [UK Representative]:

Physiological Measurements Ltd.

The Old Malt House

Willow Street

Shropshire, SY11 1AJ United Kingdom Tel: (+44) 1691 676496

Mail: info@pml.tel

Standards Compliance

The software complies with Standards for Analysis of Ventricular Late Potentials Using High Resolution or Signal Averaged Electrocardiography, published in 1991 by the Task Force Committee of the European Society of Cardiology, the American Heart Association, and the American College of Cardiology.



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

Cau

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 Limited Warranty

Norav 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 or the dealer to the original purchaser.

Excluded from this warranty are expendable supply items including, but not limited to, electrodes, leadwires, patient cables, and batteries. This warranty does not apply to any product that Norav determines 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 your local supplier or Norav Medical.

Document Title:	No	orav Users Guide PC-E	CG 1200	NORAV medical
Document	NV-	Document Rev.:	Document Date:	Page 3 of 53
No.:	54/PCECG1200	211130	21.12.2023	rage 3 01 33

Table of Contents

Norav Users Guide PC-ECG1200	
INTRODUCTION	
Manual Organization	
Document Conventions	
Indications for Use of the PC-ECG 1200	
Contraindications for Use and Adverse Effects	
OVERVIEW	
Package Contents	
Programs	
PC-ECG Models	
Safety Warnings and Precautions	
Classification of Equipment	
EMC Specifications according to IEC 60601-1-2	
MAINTENANCE	
SOFTWARE INSTALLATION	
System Requirements and Prerequisites	
Installing or Updating PC-ECG 1200 Software	
Installing Model 1200S and Model 1200M	
Installing Model 1200HR	
Installing Model 1200W	
Installing Models NR-1207-E and NR-1207-3	
Connecting an Exercise Device	2
ACCESSORIES INSTALLATION	2
Installation of the Tango M2 Automatic BP Unit	2
PATIENT PREPARATION	
RESTING ECG	
STRESS ECG	
LATE POTENTIAL SIGNAL AVERAGING	
HEART RATE VARIABILITY (HRV)	4
MEASUREMENTS/ INTERPRETATION (MEANS)	
TECHNICAL SPECIFICATIONS	
TROUBLESHOOTING	

¹ - Throughout this document, "Monitoring" is used as a part of the names for certain applications and devices and does not imply monitoring features.

Document Title:	No.	rav Users Guide PC-E	CG 1200	NORAV medical	Ì
Document	NV-	Document Rev.:	Document Date:	Dog 4 of 52	ì
No.:	54/PCECG1200	211130	21.12.2023	Page 4 of 53	ì

INTRODUCTION

Manual Organization

This manual explains in detail how to install and use the PC-ECG 1200.

At the beginning of each application chapter, there is a **Quick Start** section, which is a brief explanation of how to carry out a study, including the keyboard short-cuts for the main functions. If you are familiar with ECG procedures, you can use this **Quick Start** section to get up and run quickly. The software must be installed before the hardware.

Document Conventions

Notes and Cautions

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



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



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

Cau



Note

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

Document Title:	No	rav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Dogg 5 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 5 of 53	

Abbreviations and Acronyms

Abbreviation	Meaning
BP	Blood pressure
ECG	Electrocardiogram
HRV	Heart Rate Variability
ID	Identification
LP	Late Potential
LQTS	Long QT Syndrome
METS	Metabolic Stress Estimation
SN	Serial Number
USB	Universal Serial Bus

Document Title:	No.	rav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Page 6 of 53	
No.:	54/PCECG1200	211130	21.12.2023	rage 0 01 33	

Equipment Symbols

Equipment Symbols			
Symbol	Description		
<u>†</u>	TYPE BF APPLIED PART		
	TYPE CF APPLIED PART		
★	DEFIBRILLATION-PROOF TYPE BF APPLIED PART		
-{ W	DEFIBRILLATION-PROOF TYPE CF APPLIED PART		
	Class II equipment		
CE	Complies with the Medical Device Directive of the European Union		
$\Big(\big((\underbrace{\bullet} \big) \big) \Big)$	Non-ionizing radiation		
Car.	Refer to instruction manual / booklet. NOTE On ME EQUIPMENT "Follow instructions for use."		
\triangle	Caution		
Not for infants < 10 kg	The recorder is not suitable for measurements conducted on children weighing less than 10 kg (formation of loops in the patient cable!).		
IP22	IP protection class		
SN	Device Serial Number		
REF	Device Reference Number		
M	Date of manufacture		
Z.	Disposal of the device in accordance with the EU Directive 2002/96/EC (WEEE).		
2x1.5V Mignon AA 2x1.2V NiMH ACCU	Use this battery/accumulator rating.		
141.27/190(May **	Use this battery/accumulator rating.		
IEC-R6 AA	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 RCM certified RF module.		
(Contains MIC certified RF module.		
FCC ID:	Contains FCC certified RF module.		

Indications for Use of the PC-ECG 1200

ECG Intended Use

ECG is intended 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

Document Title:	No	rav Users Guide PC-E	CG 1200	NORAV medical	
Document		Document Rev.:	Document Date:	Page 7 of 53	
No.:	54/PCECG1200	211130	21.12.2023	1 4.80 / 61 66	

Oppulations of patients at an age or period in which a routine baseline evaluation of ECG characteristics is desired.

QT Analysis is useful in the assessment of long QT syndrome (LQTS). QT analysis is also used to measure QT dispersion, a measure of the homogeneity of ventricular repolarization.

The PC-ECG 1200 contains the Heart Rate Variability software. The clinical significance of Heart Rate Variability measures should be determined by a physician. The PC-ECG 1200 contains Late Potential software.

The clinical significance of Late Potential measures should be determined by a physician.

Stress Testing Intended Use

Stress testing is the most widely used method to decide whether this chest pain is related to myocardial ischemia, and thus to coronary artery disease.

In Stress testing, the contractile capability of the heart muscle is collected by ECG during patient exercise. Patients exercise using bicycle, treadmill, or other means while the ECG is continuously recording. Exercise loads are determined by predefined protocols.

ECG signals are recorded for the rest, exercise, and recovery phases of the exercise protocol. The changes in ECG waveforms are compared with the resting ECG records.

ST segment evaluation aids in assessing myocardial ischemia in patients with confirmed or suspected coronary artery disease. The ST segment algorithm has been tested for accuracy of the ST segment data, and a database is used as a tool for performance testing. The significance of the ST segment changes **must** be determined by a physician.

Contraindications for Use and Adverse Effects

The device has no contraindications or adverse events.

OVERVIEW

Package Contents

The PC-ECG 1200 package contains the following elements:

- Acquisition box one of the following device models:
 - ♦ PC-ECG 1200S / 1200M
 - ♦ PC-ECG 1200HR
 - ♦ PC-ECG 1200W
 - ♦ Blue-ECG
 - ♦ NR-1207-E / NR-1207-3
- SD memory card (for NR-1207-3 model only)
- Patient cable
- Data USB cable or wireless RF adaptor (for 1200W) or Bluetooth USB transmitter (for Blue-ECG, NR-1207-E and NR-1207-3)
- Software installation media with the PC-ECG 1200 package, including:
 - ♦ Resting ECG
 - ♦ Measurements and Interpretation
 - ♦ Stress ECG
 - ♦ "Monitoring" ECG
 - ♦ HRV

Document Title:	No	rav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Dogg 9 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 8 of 53	

LP

Software key (if optional software is included)

ProgramsEach program has a specific purpose.

Resting ECG	Records and measures short ECG tests on patients in resting position (up to 10 seconds)
Stress ECG	Records and measures ECG tests on patients under stress conditions using a pre-defined test protocol.
"Monitoring" ECG	Works with an ECG device to record, trace and save a prolonged ECG test in rest condition
HRV	Tests according to time how patient pulse and heart rate varies with load, medication, etc.
LP	Predicts tendency to ventricular tachycardia

PC-ECG Models

1200S	USB connected ECG acquisition to perform examinations during stress or rest condition.
1200M	USB connected ECG acquisition to perform examinations during rest condition.
1200HR USB connected ECG data acquisition to perform examinations during stress or rest constant of Stationed on table/cart. In addition to stress and rest testing may be used for advanced to the stress and rest testing may be used to the stress and rest testing may be used for advanced to the stress and rest testing may be used for advanced to the stress and rest testing may be used for advanced to the stress and rest testing may be used for advanced to the stress and rest testing may be used for advanced to the stress and rest testing may be used for advanced to the stress and rest testing may be used for advanced to the stress and rest testing may be used for advanced to the stress and rest testing may be used for advanced to the stress and rest testing may be used for advanced to the stress and rest testing may be used for advanced to the stress and res	
1200W	Wireless RF connected ECG acquisition to perform examinations during stress or rest condition.
Blue-ECG	Wireless Bluetooth connected ECG acquisition to perform examinations during rest condition.
NR-1207-E	Wireless Bluetooth connected ECG acquisition to perform examinations during rest or stress condition. Includes a color LCD screen to verify the applied ECG electrodes connection status and to configure the device settings.
NR-1207-3	Wireless Bluetooth connected ECG acquisition with recording function on internal memory card. Dedicated for examinations during rest or stress condition. Includes a color LCD screen to verify the applied ECG electrodes connection status and to configure the device settings.

Document Title:	No.	Norav Users Guide PC-ECG 1200		NORAV medical
Document	NV-	Document Rev.:	Document Date:	Dogg 0 of 52
No.:	54/PCECG1200	211130	21.12.2023	Page 9 of 53

Safety Warnings and Precautions



- ELECTROSURGERY There is a risk of burns and injury to the patient. If an electro surgery device is used, disconnect the ECG cable from the device.
- CABLES Cables present a possible strangulation hazard. To avoid possible strangulation, route all cables away from patient's throat.
- CONDUCTIVITY Electric shock or device malfunction may occur if electrodes
 contact conductive materials. Keep the conductive parts of lead electrodes and
 associated parts away from other conductive parts, including earth. Also make
 sure that no contact to other conductive parts is possible if the electrodes loosen
 during recording.
- GENERAL DANGER TO THE PATIENT Instructions listed in this manual in no way supersede established medical practices concerning patient care. Perform the established medical practices under all circumstances.
- EXPLOSION HAZARD—Do not use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.
- DEFIBRILLATION Device is defibrillation protected when the original Norav Medical patient cable is used. However, as a safety precaution, when possible, remove the electrodes before defibrillation.
- GENERAL DANGER TO THE PATIENT The device is not designed. for direct cardiac application.
- INFECTION RISK Reuse of disposable parts that come into contact with patients pose a risk of infecting patients. Do not reuse disposable parts that have had direct contact with the patient, such as ECG electrodes.
- INTERPRETATION HAZARD Computerized interpretation is. only significant when used in conjunction with clinical findings. A qualified physician must over read all computer-generated tracings.
- MAGNETIC AND ELECTRICAL INTERFERENCE Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason, make sure that all external devices operated in the vicinity of the device comply with the relevant EMC requirements. X-ray equipment or MRI devices are possible sources of interference as they may emit higher levels of electromagnetic radiation.
- OPERATOR Medical technical equipment such as this system must only be used by qualified and trained personnel.



PATIENT SAFETY

- A patient undergoing a test must be at a distance of at least (relates to the wired models only):
 - 1.5 meters from the computer, printer, and other peripherals, and
 - 2.5 meters from the ceiling.
- If such conditions cannot be fulfilled, the entire system needs to be connected to the A/C power supply through an Isolation transformer meeting the IEC/EN 60601-1 standard.

OPERATION WITH OTHER DEVICES

- Other devices which are part of the system must meet the requirements of the Standard for Information Technology Equipment (IEC/EN 60950-1) and the Standard for Electrical Medical Devices (IEC/EN 60601-1)
- The personal computer should be approved to the appropriate safety standard for non-medical electrical equipment (IEC/EN 60950-1, or its national variants). Also, the use of additional protective earth ground or an isolation transformer is required for the electric power circuit to which the PC-ECG 1200 System is connected to satisfy the IEC/EN 60601-1 safety standard.
- Computers and printers used with Medical Devices should be evaluated for IEC/EN 60950-1, IEC/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 60950-1 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.

Document Title:	No.	av Users Guide PC-ECG 1200		NORAV medical	
Document		Document Rev.:	Document Date:	Page 10 of 53	
No.:	54/PCECG1200	211130	21.12.2023	Č	

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.

The PC-ECG 1200 controls exercise machines.

Any treadmill used with the PC-ECG 1200 must contain a manual control to allow the user to stop the operation of the treadmill in case of emergency.

When using PC-ECG 1200 in combination with any other equipment, refer to a qualified service technician for correct handling



• DAMAGE TO THE DEVICE THROUGH BATTERY LEAKAGE –

Batteries may leak if left in an unused device for prolonged periods. If you intend to store the device for longer than one week, remove the battery from it.

- CABLE DAMAGE Bending or wrapping the cable can damage it.
 When attaching and affixing the ECG cable, make sure not to bend it excessively. Avoid coiling the ECG cable around the device, as this can damage the cable.
- DAMAGE TO THE DEVICE You may only open the battery compartment of the recorder. Do not use force when handling the recorder.
- SAFETY ONLY WITH APPROVED ACCESSORIES Safe and Reliable operation of the device is only possible when using the supplied and approved accessories.
- DIFFICULTIES FINDING CAUSES FOR MALFUNCTIONS To find and repair a malfunction, both
 device and ECG cable are needed. Remember to include the ECG cable when returning the device for service
 or repair. (Avoid wrapping the ECG cable around the device, as this can damage the cable.) Always use the
 same ECG cable with a device. If an institution has several devices and ECG cables, try to ensure that each
 device is matched with a specific ECG cable. In this way, cable or recorder failures can be isolated and
 eliminated faster.
 - 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.
- DAMAGE TO DEVICE AND ACCESSORIES Unauthorized personnel do not have the proper training to repair the device. Repairs carried out by unauthorized personnel could result in damage to the device or accessories. Send the device for inspection to an authorized facility if you find or even suspect a malfunction. Please add a detailed description of the observed malfunction.
- DAMAGE TO THE DEVICE Take care to prevent chemicals\liquids from entering the connectors or internal part of the device.



Pacemaker. It is recommended that a minimum separation of 15 cm (6 inches) be maintained between the wireless models Blue-ECG/NR-1207- E/NR-1207-3/1200W 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 Blue-ECG/NR-1207-E/NR- 1207-3 unit at least 30 cm from their pacemaker when the ECG unit is turned on.
- Should not carry the Blue-ECG/NR-1207-E/NR-1207-3 in their breast pocket.

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



- If audio is playing on the PC, the ECG shows interference. Do not run an audio CD on the PC while running an ECG test via the USB connection.
- Operate the unit only at clinics and hospitals. Do not use at home.

Document Title:	No.	av Users Guide PC-ECG 1200		NORAV medical	Ì
Document	NV-	Document Rev.:	Document Date:	Dogg 11 of 52	ì
No.:	54/PCECG1200	211130	21.12.2023	Page 11 of 53	ı



• **Power supply** - The PC-ECG 1200 uses mains power supply (unless connected via the USB port). The wireless PC-ECG 1200W transmitter uses battery power supply. PC-ECG 1200WR receiver uses Power supply via USB port. The wireless Blue-ECG, NR-1207-E and NR- 1207-3 uses battery power supply.

Use only the recommended battery type as instructed in the technical specifications to operate the 1200W, Blue-ECG, NR-1207-E and NR-1207-3 (AA size alkaline or NiMH rechargeable batteries).

Do not use batteries with expired dates.

Remove batteries form the unit (1200W/Blue-ECG/NR-1207-E/NR-1207-3) when it is not in use.

- For 1200W Use only while device is worn on patient with its strap.
- Use only with battery compartment closed.



The device (1200W/Blue-ECG/NR-1207-E/NR-1207-3) complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference and
- (2) This device must accept any interference received, including interference that may cause undesired operation.



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.



Install hardware only after software installation.

Note

Classification of Equipment

According to the type of protection against electric shock: CLASS II

INTERNALLY POWERED EQUIPMENT (1200W, Blue-ECG, NR-1207-E and NR-1207-3)

 According to the degree of protection against electric shock: TYPE CF APPLIED PART

TYPE BF APPLIED PART (NR-1207-E and NR-1207-3)

 According to the degree of protection against ingress of water: ORDINARY EQUIPMENT

IPX2 (NR-1207-E and NR-1207-3)

- According to the degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide: EQUIPMENT NOT SUITABLE FOR USE IN THE PRESENCE OF A FLAMMABLE ANAESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE.
- According to the mode of operation: CONTINUOUS OPERATION

EMC Specifications according to IEC 60601-1-2

Please, refer to the Norav NR Series Instruction for Use for detailed information about EMC Specifications according to IEC 60601-1-2 (including electromagnetic emissions, immunity, and recommended separation distances).

or

or

or

Document Title:	No.	Norav Users Guide PC-ECG 1200		NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Page 12 of 53	
No.:	54/PCECG1200	211130	21.12.2023	rage 12 01 33	

MAINTENANCE



Caution

- The device is not waterproof. Never immerse any part of the equipment including device, cables or leadwires in any liquid. Maintain in a dry place.
- ELECTRICAL HAZARD Improper handling during inspection or

cleaning could result in electrical shock. To avoid potential shock, always observe the following guidelines:

- Before inspecting or cleaning the system, turn it off, unplug it from AC pow er, and remove the battery.
- Do not pour or spray any liquid directly on cables or leadwires or permit fluid.

to seep into connections or openings.

- Never use conductive solutions, solutions that contain chlorides, w ax, or w ax compounds to clean
 device, cables or leadwires.
- Never autoclave or steam clean cables or leadwires.
- Never use solutions or products that contain the following:
 - o Any type of Ammonium Chloride such as, but not limited to:
 - Dimethyl Benzyl Ammonium Chloride
 - Quaternary Ammonium Chloride solutions
 - o Abrasive cleaners or solvents of any kind
 - Acetone
 - o Ketone
 - Betadine
 - o Alcohol-based cleaning agents
 - o Sodium salts
- Cleaning products to be avoided, including but not limited to:
 - o Sani-Cloth® Wipes
 - Ascepti® Wipes
 - o HB Quat
 - o Clorox® Wipes (they do not contain bleach).
 - o Over-the-counter detergents (e.g. Fantastic®, Tilex®, etc.).
 - $\circ\,$ Products that contain active ingredients like above listed
- Improper cleaning products and processes impact/results:
 - Product discoloration
 - Metal part corrosion
 - o Brittle wires
 - o Brittle and breaking connectors
 - o Reduced cables and leadwires life
 - Unit malfunction
 - Void warranty

Perform a visual inspection daily, preferably before the equipment's first use each day. During the inspection, verify that the device meets the following minimum conditions:

- The device case is free of cracks and other damage.
- All plugs, cords, cables, and connectors are free of kinks, frays, and other damage.
- All cords and connectors are securely seated.
- All keys and controls operate properly.

If you notice any items that need repair, contact an authorized service representative to make the repairs. Discontinue using the device until the appropriate repairs can be made.

Cleaning the Device

Cleaning and Disinfection for devices and patient leadwires

* Before the Cleaning and Disinfection process, remove the battery.

Document Title:	No	av Users Guide PC-ECG 1200		NORAV medical	Ì
Document	NV-	Document Rev.:	Document Date:	Dogg 12 of 52	ì
No.:	54/PCECG1200	211130	21.12.2023	Page 13 of 53	ı



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

Caution !	Take care to prevent chemicals/liquids from entering the connectors or internal part of the device. The battery contacts should not encounter 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 reorder unit and holster. Use of alcohol or acetone on leadwires could cause the leadwires 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 leadwires 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 Cabels/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.
Disinfection	After the cleaning procedure is completed, perform the disinfection procedures: Use Isopropanol 70% wipes to disinfect the device for at least three (3) minutes. Repeat as necessary.
Drying	Dry for ten minutes.



Wring excess disinfectant from wipe before using.



Drying times may vary based on the environmental conditions.

Note

- Do NOT immerse either end of a cable or leadwire connector. Immersing or "soaking" the connector ends may corrode metal contact ends and affect signal quality.
- Wipe off cleaning solutions with a clean, lightly moistened cloth.
- Dry thoroughly with a dry lint-free cloth and let air dry for at least 30 minutes.

Document Title:	No.	av Users Guide PC-ECG 1200		NORAV medical	
Document		Document Rev.:	Document Date:	Page 14 of 53	
No.:	54/PCECG1200	211130	21.12.2023	C	ı

- Take care not to let fluid "pool" around connection pins. If this should happen, blot dry with a soft, lint-free cloth.
- DO NOT use excessive drying techniques, such as oven, forced heat or sun drying.

Calibration

The device does not need any calibration.

SOFTWARE INSTALLATION

System Requirements and Prerequisites



Install the software before installing the hardware. If the device is connected to the PC, disconnect the device before installing the software.

Note:

PC Minimum Configuration

Applica	ation	CPU performance	RAM amount (GB)	Disk free space (GB)	Free USB Ports (*a)
Resting	ECG	Intel i3 or similar	1.0	2	1 (*b)
"Monitoring" ECG		Intel i3 or similar	1.0	20	1 (*b)
LP		Intel i3 or similar	1.0	2	1 (*b)
HRV		Intel i3 or same	1.0	2	1 (*b)
	ECG Device only	eadmill/Ergometer		20	1 (*b)
Stress	Treadmill/Ergometer		2.0		+1(*c)
ECG	Blood pressure device	inter is or similar	2.0		+1(*c)
	MP 200 Thermal printer				+1(*d)

^{*}a – a port for a standard local printer or for a LAN printer not included in the required free port calculations

^{*}d - use a USB-to-LPT adapter or direct to the LPT port instead of USB port



The computer must meet the requirements of the Standard for Information Technology Equipment (IEC/EN 60950-1)

Printers

Application	Technology	RAM Memory (MB)	Driver
Resting ECG	LASER/INK	2	Vendor / MS
"Monitoring" ECG	LASER/INK	2	Vendor / MS
LP	LASER/INK	2	Vendor / MS

^{*}b - old model 1200M/S device might require a 1200USB adapter

^{*}c - use a USB-to-COM standard adapter or a direct RS232 port instead of the USB port

Document Title:	No	av Users Guide PC-ECG 1200		NORAV medical	
Document		Document Rev.:	Document Date:	Page 15 of 53	
No.:	54/PCECG1200	211130	21.12.2023		

HRV	LASER/INK	2	Vendor / MS
Stress ECG	Fast LASER	8	Vendor / MS

Thermal Printer

A thermal printer can be supplied by Norav (MP200, 8 inch). This printer requires a dongle with the P1 license permission.

Installing or Updating PC-ECG 1200 Software

The software package works under Microsoft Windows operating systems: Windows 8/10/11.

To Install PC-ECG 1200

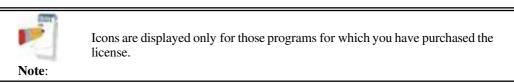
• Insert the installation media in the CD drive or to the USB slot. If

installation will not start automatically run the

program from the installation disk root.

• Follow the instructions on-screen.

After you have completed installation, a group icon called PC-ECG 1200 is added to the desktop. Double-click the group icon to display the following program icons:



Icon	Explanation
	Heart Rate Variability
<u> </u>	Late Potential Signal Averaging
	"Monitoring" ECG
W	Resting ECG
4	Stress ECG

Resting ECG is the basic software package. It does not require a software key. The following are optional and require software keys:

- ♦ Measurement and interpretation functions for Resting ECG
- ♦ Heart Rate Variability
- ♦ Late Potential
- ♦ "Monitoring" ECG
- ♦ Stress ECG

You can activate optional packages that have no key by selecting **Simulator** in Setup.

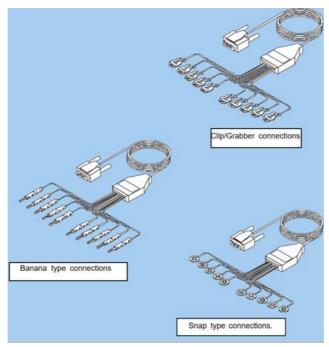
If you have purchased the **S2 Advanced Stress** option and would like to use remote viewing, install the **Remote View** program from the **Remote View** directory on the CD. This program enables a remote viewer for an ECG study. The image is displayed in JPEG format.

Document Title:	No.	rav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Dogg 16 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 16 of 53	

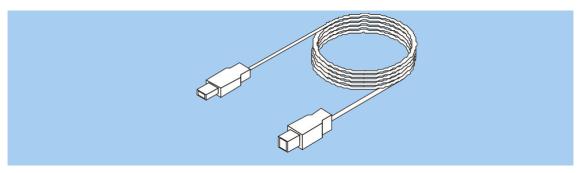
Installing Model 1200S and Model 1200M

The PC-ECG 1200S or PC-ECG 1200M kit contains the following items:

- ♦ Acquisition box
- ♦ Patient cable
- ♦ USB cable
- ♦ PC-ECG 1200 software installation package on CD or USB flash drive.
- ♦ Software license key (if optional software is included)



Patient Cable



USB Cable

To Connect Via USB

- Connect the A-type connector of the USB cable to the PC.
- Connect the B-type connector of the USB cable to the input of the 1200S unit.
- A wizard for installing the new hardware driver might appear. Wait until the driver is installed and the green light is illuminated on the 1200S unit.

Document Title:	No	rav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Dogg 17 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 17 of 53	

- Verify that the ON light is illuminated on your PC-ECG 1200M/S device.
- Connect the patient cable to the 15-pin plug of the PC-ECG 1200M/S device side.
- If the optional software key is included, connect it to the computer.
- If a printer is connected, plug the printer cable into the key.
- Connect the electrode leads to the patient, starting with RL.

To Verify the Connections

- Run the Resting ECG application.
- Press **F1** for a new test.
- Insert patient details in the dialog and then click **OK**.
- Verify that traces are acquired and displayed on the screen.

Installing Model 1200HR

The PC-ECG 1200HR kit contains the following items:

- ♦ Acquisition box
- ♦ Patient leads
- ♦ Built-in USB cable
- ♦ PC-ECG 1200 software installation package on CD or USB flash drive.
- ♦ Software license key (if optional software is included).

To Connect Via USB

- Connect the USB A-type connector of the USB cable to the PC.
- If the optional software key is included, connect it to the computer.
- Wait until the driver is installed and the green light is illuminated on the 1200HR.
- Connect the patient cable to the 15-pin plug of the PC-ECG 1200HR.

To Connect to the Patient and the Computer

- Verify that the indication LED on the front is ON.
- Connect the electrode leads to the patient, starting with RL.

To Verify the Connections

Refer to the same subsection in the previous section.

Installing Model 1200W

The PC-ECG 1200W kit contains the following items:

♦ Acquisition box

Document Title:	No	rav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Dog 19 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 18 of 53	

- ♦ Patient leads
- ♦ USB cable
- ♦ Antenna
- ♦ 1200WR receiver
- ♦ PC-ECG 1200 software installation package on CD or USB flash drive.
- ♦ Software license key (if optional software is included).

1200W Battery Installation



Step 1

Insert the first battery and slide it to the right.

Step 3

Place the battery cover.

Step 2

Insert the second battery and push it to the left and down with the same movement.

Step 4

Push the battery cover down until get click.

To Connect Via USB

- Connect the Antenna to the connector on 1200WR Receiver.
- Connect the A-type connector of the USB cable to the PC.
- Connect the B-type connector of USB cable to the USB port of the 1200WR Receiver.
- Wait until the driver is installed and the green light is illuminated on the 1200WR Receiver.
- Plug the 10 patient leads to the PC-ECG 1200W according to the labels on the lead sockets.

Document Title:	No	rav Users Guide PC-l	ECG 1200	NORAV medical	
Document No:		Document Rev.: 211130	Document Date: 21.12.2023	Page 19 of 53	

- Insert 2 x AA alkaline or NiMH rechargeable batteries into the battery compartment of the PC-ECG 1200W unit.
- Switch on the PC-ECG 1200W and verify that the ON light is illuminated.
- If the optional software key is included, connect it to the computer.
- Connect the external hardware via the appropriate cable(s) to one or more BNC connectors on the 1200W Receiver (valid for **S2 Advanced Stress** option): TTL Trigger out for blood pressure device synchronization, couple analog outputs using the ECG lead, heart rate or for drive of the analog controlled treadmill/ergometer.



To Verify the Connections

- Fasten the PC-ECG 1200W device to the patient body with a belt.
- Connect the electrode leads to the patient, starting with RL.
- Run the Resting ECG application.
- Press **F1** keyboard key for a new test.
- Insert patient details in the dialog and then click **OK**.
- Verify that traces are acquired and displayed on the screen.

Installing Models NR-1207-E and NR-1207-3

The PC-ECG NR-1207-E kit contains the following items:

- ♦ Acquisition box
- ♦ Patient cable
- ♦ AA size alkaline battery (optional)
- ♦ SD memory card (for NR-1207-3 model only).
- ♦ Bluetooth USB adaptor
- ♦ USB extension cable
- ♦ PC-ECG 1200 software installation package on CD or USB flash drive.
- Software license key (if optional software is included).

Document Title:	No	rav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Page 20 of 53	
No.:	54/PCECG1200	211130	21.12.2023	rage 20 01 33	

Patient Cable Connection, Memory Card Insertion, and Battery Installation

Please, refer to the **Norav NR Series Instruction for Use** for detailed information about patient cable connection, memory card and battery installation.

To install the Blue-ECG device

Install Bluetooth adapter

If there is no built-in Bluetooth, connect a Bluetooth adapter to the computer's USB port and ensure correct installation. After the driver is installed, a Bluetooth icon appears on the system tray.

Power up Blue-ECG device



Use only NiMH rechargeable batteries or alkaline batteries. Although zinc-carbon batteries and NiCd rechargeable show adequate voltage in the battery test, the output is often insufficient to carry out testing.

- Note
- a. Plug the patient cable to the round connector on the top of the Blue-ECG device.
- b. Insert the batteries according to the polarity of its terminals ("+","-").
- c. Push the button on the front of the Blue-ECG device to switch it ON.

Add the Blue-ECG to Bluetooth devices list

- Open Bluetooth settings by double-clicking the system tray icon, select Add Bluetooth or other device, then choose Bluetooth.
- b. Select the "ECGBT8-XXX" device name.
- c. Enter passkey 12345, and click Connect.
- d. Click **Done**, once paired.

Register the Blue-ECG device in the Resting ECG software application

- a. Launch Resting ECG software from the PC-ECG 1200 desktop folder.
- b. In the software, go to **Setup > Environment** and select **Bluetooth device**.
- c. Click **OK** to apply changes and exit the application.

Verify connections

- a. Reopen Resting ECG application, ensure the icon appears on the right side.
- b. Start a new test using START button or F1 key.
- c. Confirm trace acquisition on-screen, then click STOP

To install the NR-1207-E or NR-1207-3 device

Install Bluetooth adapter

To install the NR-1207-E or NR-1207-3 device, use the Blue-ECG device installation instructions above, but skip adding devices to the Bluetooth list.

To add the NR-1207-E / NR-1207-3 to Bluetooth devices list

- a. Double click on the Bluetooth icon on the system tray. Click **Add Bluetooth or other device** then select **Bluetooth**.
- b. Select the device name, which can be "NR-1207-E-xxxx", "NR-1207-3" or for some modifications it could be "NR Recorder".

Document Title:	No	rav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Dogg 21 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 21 of 53	

- c. Enter 12345 as the passkey and click Connect.
- d. After device is paired click Done.

Connecting an Exercise Device

You can connect a PC-controlled treadmill and/or ergometer to the computer via the USB, RS232, or Analog control interface.

To Connect an RS232 Controlled Treadmill/Ergometer

- Connect the Treadmill/Ergometer by the RS232 cable to the free COM port on the computer.
- Configure the Stress ECG software (in setup **Environment** tab):
 - Select the connected COM port number.
 - Select the exercise device communication protocol in the **Type** list.

To Connect an USB Controlled Treadmill/Ergometer

- Connect the Treadmill/Ergometer by the USB cable to free USB port on the computer. The computer will automatically generate a virtual COM port for this connection.
- Configure the Stress ECG software (in setup **Environment** tab):
 - Select the connected COM port number.
 - Select the exercise device communication protocol in the **Type** list.

To Connect an Analog Controlled Treadmill/Ergometer

For 1200W model with the 1200WR receiver having 3x BNC output connectors

- Connect the analog controlled Treadmill/Ergometer cables to the **Analog Out 1** and **Analog Out 2** output connectors on the 1200WR box.
- Configure the Stress ECG software (in setup Environment/Advancetab): for Treadmill
 - in **Analog Out 1** select the **Analog Control** and then choose the **Speed** option.

Adjust the control voltage range in **Settings**.

- in **Analog Out 2** select the **Analog Control** and then choose the **Grade** option. Adjust the control voltage range in **Settings**.
- for Ergometer
- in **Analog Out 1** select the **Analog Control** and then choose the **Watts** option. Adjust the control voltage range in **Settings**.

For control by the D/A convertor PCI board

- Connect the Treadmill/Ergometer by the dedicated cable to the D/A board output.
- Configure the Stress ECG software (in setup **Environment/Advance**tab):
 - in **Cards** panel select the **Analog Control** option. Adjust the control voltage range in **Settings**.

Cabling

The connection cables may be purchased from Norav Medical distributors.

ACCESSORIES INSTALLATION

Installation of the Tango M2 Automatic BP Unit

Verify Correct Cables Computer Connection

Document Title:	No	rav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Dogg 22 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 22 of 53	

Used to communicate with the stress system. This connection enables the stress system to prompt Tango M2 when it needs a BP measurement, and allows the Tango M2 BP reading to be transferred to the stress system's display and reports. Available connection options USB or RS232.

USB Cable part# C-USB-AB3 RS 232 Cable part# RS232-C-FF Computer side



Tango M2 side 9 pin female



ECG Trigger Connection

Provides the ECG signal from the stress system to the Tango M2

ECG Trigger Cable part# C-BNC



Stress ECG side



Tango M2 side



Tango M2 back side

Document Title:	No	rav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Page 23 of 53	
No.:	54/PCECG1200	211130	21.12.2023	rage 25 01 55	

Connect the Computer Connection Cable (USB or RS232)

To use the **RS232** connection:

connect the **RS232-C-FF** cable between the **RS-232** connector on the rear panel of the Tango M2 to **COM** port on the back of the stress system PC.

To use the **USB** connection:

connect the **C-USB-AB3** cable between the **USB** B-type connector on the rear panel of the Tango M2 and an **USB** port on the back of the stress system PC.

Connect the ECG Trigger Cable

From: the BNC External ECG connection on the rear panel of the Tango M2. To: the BNC connection on the 1200 USB-A adapter part of the Noray Stress ECG.

Tango M2 Setup

- When the operating screen is displayed, press the **SELECT** button once. This will bring up the **MAIN MENU** screen.
- Using the UP or DOWN arrows, highlight **MONITOR SET UP** and press the **SELECT** button.
- Using the UP or DOWN arrows, highlight **STRESS SYSTEM** and press the **SELECT** button.
- Using the UP or DOWN arrows, highlight **NORAV** and press the **SELECT** button.
- Using the UP or DOWN arrows, select **EXIT** to return to the **MAIN MENU**

screen.

• Using the UP or DOWN arrows, select **EXIT** to return to the operating screen.

Norav Stress ECG System Setup

- In the Stress ECG software, go to **Setup -> Environment.**
- Open the **Automatic BP COM Port** scroll box and choose the computer communication port to which you connected the Tango M2 device.
- Check Measure BP by automatic device option.
- Click Advance header, select R-wave Trigger/Rising option on USB frame.
- Click **OK** to close the Setup dialog.
- To check functionality, start a new stress test and when you click the **Measure BP** option under the **Test** main menu, the Tango M2 will take a measurement.

PATIENT PREPARATION

The ECG traces quality depends very much on the stability and conductivity of the electrodes during the test. Here are some basic rules to ensure good electrical contact:

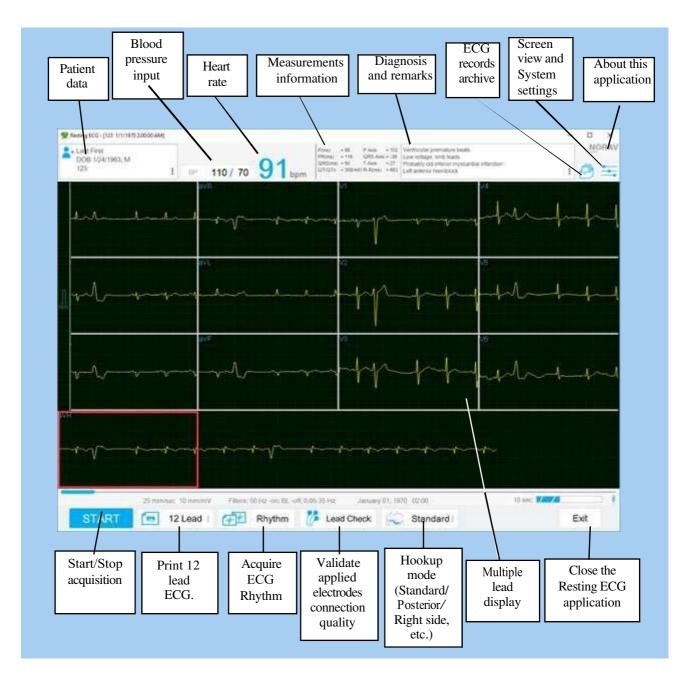
- Shave hair from the area where electrodes are to be applied.
- Abrade these areas with fine sandpaper or an abrasive pad.
- ♦ Thoroughly clean the electrodes area with alcohol.
- ♦ Let dry prior to applying the electrodes.

ECG Electrodes

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.

Document Title:	No	rav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Dogg 24 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 24 of 53	

RESTING ECG



Resting ECG Main Screen

Document Title:	No	rav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Dogg 25 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 25 of 53	

Quick Start

To Perform a New Test

1. Hook up the Patient

- a. Prepare the skin
- b. Connect electrodes

This application uses the standard 10-electrode cables with all Norav ECG modules, or optional 14-electrode cable with the 1200HR module for 15/16-lead ECG acquisition, or optional 5-electrode cable with NR-1207-E / NR-1207-3 modules for Derived 12-lead ECG acquisition.

Hook up with 10-electrode cable

The cable electrodes can have the AAMI labels or IEC labels.

The usual method is to place the leads in the standard positions.

Electr	trode Lead		Electrode Placement	
AAMI	IEC	Leau	Electrone Flacement	
RA	R	RA	right forearm or wrist	
LA	L	LA	left forearm or wrist	
LL	F	LL	left lower leg, proximal to ankle	
RL	N	RL	right lower leg, proximal to ankle	
V1	C1	V1	4-th intercostal space, right sternal edge	
V2	C2	V2	4-th intercostal space, left sternal edge	
V3	C3	V3	midway between V2 and V4	
V4	C4	V4	5-th intercostal space, mid-clavicular line	
V5	C5	V5	anterior axillary line in straight line with V4	
V6	C6	V6	mid-axillary line in straight line with V4 and V5	

With above lead placement method, the standard 12 derivations are recorded and displayed on PC screen and on print reports:

- 3 Bipolar derivations: I, II, III
- 3 Augmented derivations: aVR, aVL, aVF
- 6 Unipolar derivations: V1...V6

Posterior lead placement with 10-electrode cable

Additionally, you can place the leads on the patient in other hook up schemes, such as Posterior (V7...V9), Right Side (V3R-V6R) or Pediatric (V7, V3R, V4R).

Electrode		Lead	Electrode Placement		
AAMI	IEC	Leau	Electrode Placement		
RA	R	RA	right forearm or wrist		
LA	L	LA	left forearm or wrist		
LL	F	LL	left lower leg, proximal to ankle		
RL	N	RL	right lower leg, proximal to ankle		
V1	C1	V1	4-th intercostal space, right sternal edge		
V2	C2	V2	4-th intercostal space, left sternal edge		
V3	C3	V3	midway between V2 and V4		
V4	C4	V7	left posterior axillary line, at the same level as V6		
V5	C5	V8	under the left mid-scapular line, at the same level as V6		
V6	C6	V9	left paraspinal border, at the same level as V6		

Right Side lead placement with 10-electrode cable

Electrode L and		Lead	Electrode Placement	
AAMI	AAMI IEC			
RA	R	RA	right forearm or wrist	
LA	L	LA	left forearm or wrist	
LL	F	LL	left lower leg, proximal to ankle	
RL	N	RL	right lower leg, proximal to ankle	
V1	C1	V1	4-th intercostal space, right sternal edge	
V2	C2	V2	4-th intercostal space, left sternal edge	
V3	C3	V3R	midway between V1 and V4R, right side of chest	
V4	C4	V4R	midclavicular line in the fifth intercostal space, right side of chest	
V5	C5	V5R	anterior axillary line in straight line with V4R, right side of chest	

Document Title:	No	orav Users Guide PC-E	CG 1200	NORAV medical	1
Document	NV-	Document Rev.:	Document Date:	Page 26 of 52	ĺ
No.:	54/PCECG1200	211130	21.12.2023	Page 26 of 53	ı

V6 C6 V6R mid-axillary line in straight line with V4R and V5R, right side of chest	
TO THE MILE OF THE STATE OF THE	

Pediatric lead placement with 10-electrode cable

Electrode		Lead	Electrode Placement		
AAMI	IEC	Leau	Electroue Flacement		
RA	RA R RA right forearm or wrist				
LA	L	LA	left forearm or wrist		
LL	F	LL	left lower leg, proximal to ankle		
RL	N	RL	right lower leg, proximal to ankle		
V1	C1	V7	left posterior axillary line, at the same level as V6		
V2	C2	V3R	midway between V1 and V4R, right side of chest		
V3	C3	V4R	midclavicular line in the fifth intercostal space, right side of chest		
V4	C4	V4	5-th intercostal space, mid-clavicular line		
V5	V5 C5 V5 anterior axillary line in straight line with V4				
V6	C6	V6	mid-axillary line in straight line with V4 and V5		

Hook up with 14-electrode cable

The 14-electrode cable contains 10 standard electrodes marked by the AAMI or IEC standard labels, plus four additional electrodes marked as H, M, I and E.

Standard 15-lead lead placement with 14-electrode cable

Electrode		Lead	Electrode Placement		
AAMI	IEC	Leau			
RA	R	RA	right forearm or wrist		
LA	L	LA	left forearm or wrist		
LL	F	LL	left lower leg, proximal to ankle		
RL	N	RL	right lower leg, proximal to ankle		
V1	C1	V1	4-th intercostal space, right sternal edge		
V2	C2	V2	4-th intercostal space, left sternal edge		
V3	C3	V3	midway between V2 and V4		
V4	C4	V4	5-th intercostal space, mid-clavicular line		
V5	C5	V5	anterior axillary line in straight line with V4		
V6	C6	V6	mid-axillary line in straight line with V4 and V5		
H	H	V9	left paraspinal border, at the same level as V6		
M	M	V4R	midclavicular line in the fifth intercostal space, right side of chest		
I	I	none	not connected		
E	E	V8	under the left mid-scapular line, at the same level as V6		

Adult 16-lead lead placement with 14-electrode cable

Electrode Lead		Load	Electrode Placement		
AAMI	IEC	Leau	Electrode Flacement		
RA	R	RA	right forearm or wrist		
LA	L	LA	left forearm or wrist		
LL	F	LL	left lower leg, proximal to ankle		
RL	N	RL	right lower leg, proximal to ankle		
V1	C1	V1	4-th intercostal space, right sternal edge		
V2	C2	V2	4-th intercostal space, left sternal edge		
V3	C3	V3	midway between V2 and V4		
V4	C4	V4	5-th intercostal space, mid-clavicular line		
V5	C5	V5	anterior axillary line in straight line with V4		
V6	C6	V6			
H					
M					
I	I	V7	left posterior axillary line, at the same level as V6		
E	E	V8	under the left mid-scapular line, at the same level as V6		

Posterior 15-lead lead placement with 14-electrode cable

Electrode		Lead	Electrode Placement
AAMI	IEC	Leau	Electrode Flacement
RA	R	RA	right forearm or wrist
LA	L	LA	left forearm or wrist
LL	F	LL	left lower leg, proximal to ankle
RL	N	RL	right lower leg, proximal to ankle

Document Title:	No	rav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Dogg 27 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 27 of 53	

V1	C1	V1	4-th intercostal space, right sternal edge	
V2 C2 V2 4-th intercostal space, left sternal edge				
V3	C3	V3	midway between V2 and V4	
V4	C4 V4 5-th intercostal space, mid-clavicular line			
V5	The state of the s			
V6 C6 V6 mid-axillary line in straight line with V4 and V5				
		left paraspinal border, at the same level as V6		
M M none not connected				
I	I V7 left posterior axillary line, at the same level as V6			
E	E	V8	under the left mid-scapular line, at the same level as V6	

Pediatric 15-lead lead placement with 14-electrode cable

Electrode Lead		Load	Electrode Placement		
AAMI	IEC	Leau	Electi ode i lacement		
RA	R	RA	right forearm or wrist		
LA	L	LA	left forearm or wrist		
LL	F	LL	left lower leg, proximal to ankle		
RL	N	RL	right lower leg, proximal to ankle		
V1	C1	V1	4-th intercostal space, right sternal edge		
V2	C2	V2 4-th intercostal space, left sternal edge			
V3	C3	V3	midway between V2 and V4		
V4	C4	V4	5-th intercostal space, mid-clavicular line		
V5	C5	V5	anterior axillary line in straight line with V4		
V6	C6	V6 mid-axillary line in straight line with V4 and V5			
H					
M					
I	I	V7	left posterior axillary line, at the same level as V6		
E	E	none	not connected		

Frank XYZ lead placement with 14-electrode cable

Electrode AAMI IEC		Lead	Electrode Placement	
		Leau	Electione i lacement	
RA R RA ri			right forearm or wrist	
LA L LA left forearm or wrist				
LL F LL left lower leg, proximal to ankle				
RL	N	RL	right lower leg, proximal to ankle	
V1 C1 V1 4-th intercostal space, right sternal edge				
V2	C2	V2	4-th intercostal space, left sternal edge	
V3	V4 C4 V4 5-th intercostal space, mid-clavicular line			
V4				
V5 C5 V5 anterior axillary line in straight line with V4				
V6 C6 V6 mid-axillary line in straight line with V4 and V5				
H H back of the neck				
M	M M vertebral column		vertebral column	
I	I	I	mid-axillary to the right	
E	E	E	on the sternum	

Bipolar XYZ lead placement with 14-electrode cable

Electrode		Lead	Electrode Placement	
AAMI	AAMI IEC		Electione Flacement	
RA R RA		RA	right forearm or wrist	
LA	L	LA	left forearm or wrist	
LL	F	LL	left lower leg, proximal to ankle	
RL	N	RL	right lower leg, proximal to ankle	
V1	C1	V1	4-th intercostal space, right sternal edge	
V2	C2	V2	4-th intercostal space, left sternal edge	
V3	C3	V3	midway between V2 and V4	
V4	C4	V4	5-th intercostal space, mid-clavicular line	
V5	C5	V5	anterior axillary line in straight line with V4	
V6	C6	V6	mid-axillary line in straight line with V4 and V5	
H	H	Υ-	on the manubrium	
M	M	Z-	left paraspinal border, at the same level as V6	
Ι	I	Х-	5-th intercostal, right mid-axillary line	
E	E	X+	5-th intercostal, left mid-axillary line	

Nehb lead placement with 14-electrode cable

Electrode	
-----------	--

Document Title:	Norav Users Guide PC-ECG 1200			NORAV medical	Ì
Document		Document Rev.:	Document Date:	Page 28 of 53	
No.:	54/PCECG1200	211130	21.12.2023	1 450 20 01 33	ı

AAMI	IEC	Lead	Electrode Placement		
RA	R	RA	right forearm or wrist		
LA	L	LA	left forearm or wrist		
LL	F	LL	left lower leg, proximal to ankle		
RL	N	RL	right lower leg, proximal to ankle		
V1	C1	V1	4-th intercostal space, right sternal edge		
V2	C2	V2	4-th intercostal space, left sternal edge		
V3	C3	V3	midway between V2 and V4		
V4	C4	V4	5-th intercostal space, mid-clavicular line		
V5	C5	V5	anterior axillary line in straight line with V4		
V6	C6	V6	mid-axillary line in straight line with V4 and V5		
H	H	none	not connected		
M	M	none	not connected		
I	I	Nax	site of projection of the cardiac apex on the left axillary line		
E	E	Nst	right sternal base of the second rib		

Hook up with 5-electrode cable

Used for Derived 12-Lead ECG acquisition. The cable contains 5 electrodes marked by the AAMI or IEC labels.

Derived 12-Lead ECG lead placement with 5-electrode cable

Electrode AAMI IEC		Electrode Placement	
		Electrode Flacement	
RA	R	in the right midaxillary	
LA	L	left forearm or wrist	
LL	F	on the manubrium sterni	
RL	N	on the right lower edge of the rib cage	
V	C	at the level of the fifth of the lower sternum	



Derived from 5-electrode cable 12-Lead ECGs and their measurements are approximations to conventional 12-Lead ECGs and should not be used for diagnostic interpretations.

2. Start a new test

Run the Resting ECG application. Open the patient details panel by clicking the icon on upper tool bar or by press the **F1** keyboard key. Insert patient details then click **OK** button or press the **ENTER** keyboard key.

3. Validate the applied electrodes connection quality

Click the button to show the schematic torso picture which allows to verify the applied electrodes connection quality and the lead off status.

4. Acquire an ECG

Verify that all ECG traces are acquired and correctly displayed on the screen.

Freeze ECG by clicking the STOP button (after at least 10 seconds) or by pressing the **F2** keyboard key.

4. Create a report

To write review: open the ${\bf Remarks}$ main menu panel.

Operation with Function Keys and Hotkeys

F1	New Recording
F2	Start/Stop ECG
F3	Collect 10 second ECG
F6	Print
F11	Open Saved Study List

Document Title:	Norav Users Guide PC-ECG 1200			NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Dogg 20 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 29 of 53	

Ctrl "+" / Ctrl "-" or Ctrl and mouse wheel	ECG traces Zoom In /Zoom Out
Ctrl "0" or mouse right button double-click on ECG traces	Reset Zoom

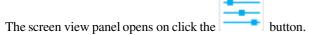
Toolbars and Panels

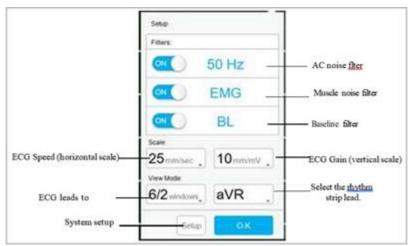
Toolbar Overview

To do this	Click this icon	Or use this short- cut key	Or select this menu	Description
Start/stop the ECG recording	START	F2		To start/stop the ECG acquisition
Patient information	*	F1		Displays the patient information.
Print the ECG page	12 land (F6		Prints the 12 lead ECG
Save the ECG Rhythm	Rhythm			Continuously stores the ECG rhythm
Enter the blood pressure	HP /			Input control for enter the BP values
Diagnosis/ Remarks	Í			To enter the ECG diagnosis and remarks
Configuration and filters	=			To adjust the screen layout, ECG filters and the system configuration
About the program	NORAV			Displays the software version, license information and Norav contact details
Lead Check	Lead Check ;			Displays the schematic torso picture to verify the applied electrodes connection quality and the lead off status.
Lead System	Posterior: Right Side: Pediatric: Standard:			Defines the electrode placement on the patient.
Data archive				Opens an existing study from local folder or from NEMS database
Exit application	Exit			Ends the ECG session, saves the data and exit the Resting ECG program

Document Title:	Norav Users Guide PC-ECG 1200			NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Dogg 20 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 30 of 53	

ECG Screen View and Filters panel





Patient Information panel

To enter the patient details, open the patient information panel by click the

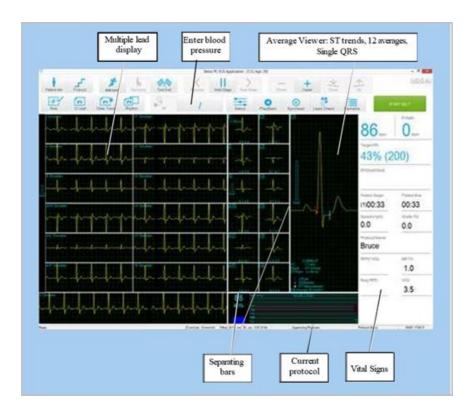




STRESS ECG

(This option is available with S1 and S2 licenses)

	Document Title:	Noray Users Guide PC-ECG 1200			NORAV medical	Ì
	Document		Document Rev.:	Document Date:	Page 31 of 53	Ì
I	No.:	54/PCECG1200	211130	21.12.2023	C	



To Lock Screen Window Borders

If you want to keep the display in its present format: Click $\mathbf{Setup} > \mathbf{View}$ tab. Check \mathbf{Lock} $\mathbf{Splitter}$.

Quick Start

To Perform a New Test

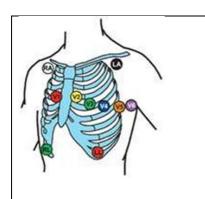
- 1. Hook up the Patient
 - a. Prepare the skin
 - b. Connect electrodes

This application uses the standard 10 contact cables. It contains four limbs (RA, LA, LL, and RL) and six chest (V1-V6) contacts. 12 derivations are recorded and displayed:

- 3 Bipolar derivations: I, II, III
- 3 Augmented derivations: aVR, aVL, aVF
- 6 Unipolar derivations: V1-V6

You can use a simpler cable with four contacts (only limbs). It produces six derivations only: three Bipolar and three Augmented. You can place the leads on the patient in various ways. The usual method is to place the leads in the standard positions on the chest (V1-V6).

Document Title:	Norav Users Guide PC-ECG 1200			NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Dogg 22 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 32 of 53	



RA – just below the right clavicle

LA – just below the left clavicle

LL – on the left lower edge of the rib cage

RL - on the right lower edge of the rib

cage **V1** – 4-th intercostal space, right

sternal edge **V2** – 4-th intercostal space, left sternal edge **V3** – midway between

V2 and V4

V4 – 5-th intercostal space, mid-clavicular line

V5 – anterior axillary line in straight line with V4

V6 - mid-axillary line in straight line with V4 and V5

- 2. Start a new test
- Run the Stress ECG application.
- Initiate a new test by clicking the **New** main menu button or by pressing the **F1** keyboard key.
- Insert patient details then click **OK** button or press the **ENTER** keyboard key.
- The Pretest phase begins.
- 3. Start the Exercise phase: click **F3** (or **Exercise** button).
- 4. Perform the examination.
- 5. To begin the Recovery phase: click on the **F5** key or the **Recovery** button.
- 6. To Stop the test: click on the **F4** key or the **Test End** button.

To Print an ECG

- Select **Print ECG** from the File menu.
- Select Current Stage\Entire Study from the Print ECG submenu.
- Select the printer from the print dialog box.
- Click **OK** to close the dialog box and start printing.

Operation with Function Keys

F1	New recording			
F2	Run/stop the test in the Pretest phase			
F3	Begin the Exercise phase of the test			
F4	Stop the test			
F5	Begin Recovery phase			
F6	Set/print Event			
F7	Hold stage			
F8	Next stage			
F9 Review				
F10	Previous stage			

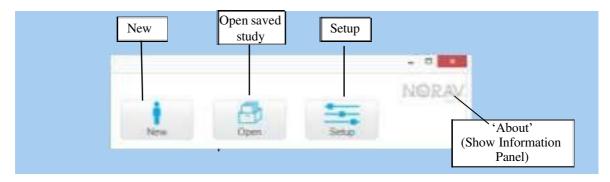
Document Title:	No	rav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Dogg 22 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 33 of 53	

F11	Open saved study
F12 Stop the treadmill in emergency	

Toolbar Overview

Main Toolbar

This toolbar is displayed during the start-up. Use it to open an existing test or to begin a new one.

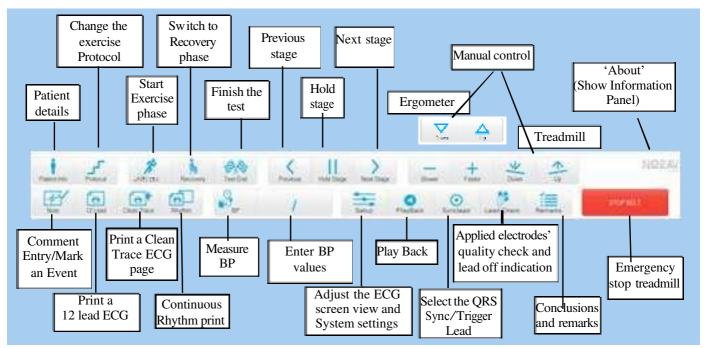


To do this	Click this icon	Or press a keyboard key	Or select this menu	Description
Start a new study	New	F1	File > New	Creates a new study
Open an existing study	Open	F11	File > Open	Opens an existing study
Setup a Printer			File > Print Setup	Set the active printer and adjust the printer settings.
Set preferences	Setup	Ctrl+T	View > Setup	Displays the setup dialog box
To display information	NORAV		Help > About Stress	Displays program information, version number, and copyright

Document Title:	No.	rav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Page 34 of 53	
No.:	54/PCECG1200	211130	21.12.2023	rage 34 01 33	

Stress Test Commands

This toolbar is displayed at the start of a new test.

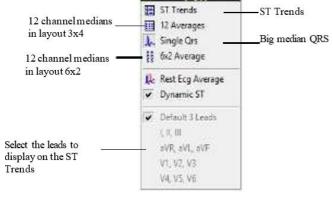


To do this	Click this icon	Or use this short- cut key	Or select this menu	Description
Start/stop the ECG recording		F2		To cancel or restart the ECG recording during the Pretest phase.
Patient information	Patient into			Displays the patient information.
Change the exercise Protocol	Protocol			To select the exercise protocol and to define the target HR and alarms.
Start the Exercise phase	Pronting	F3		Starts the Exercise phase
Start the Recovery phase	Recovery	F5		Starts the Recovery phase
Stop test/ Recovery phase		F4		Ends the stress test or recovery phase
Add Event		F6		Sets event and prints according to options
Print the ECG page				Prints ECG screen according to options
Print a Clean Trace page	Clean Trace			Prints ECG screen with the Clean Trace median
Print the ECG Rhythm	Rhylim			Continuously prints ECG traces on Z-folded paper. (P1 software license is required & thermal printer required).
Measure the blood pressure	S.,.			Saves the BP values entered on screen, or activates the blood pressure device

Document Title:	No	rav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Page 35 of 53	
No.:	54/PCECG1200	211130	21.12.2023	1 agc 33 01 33	

Freeze the current stage	Hold Stage	F7	Freezes the current stage in the protocol. Click again to release the stage and continue with the protocol.
Return to the protocol stage	Require	F7	Returns to the protocol automation.
Back to the previous stage	Previous	F10	Back to the previous stage in protocol.
Advance to the next stage	Next Stage	F8	Advances to the next stage in the protocol.
Slower speed	Slower		Decreases the treadmill belt speed. Sets the Manual workload mode.
Faster speed	+ Faster		Increases the treadmill belt speed. Sets the Manual workload mode.
Inclination down	Down		Decreases the treadmill inclination. Sets the Manual workload mode.
Inclination up	↑ Up		Move the treadmill inclination up. Sets the Manual workload mode.
Power down			Decreases the workload of the ergometer. Sets the Manual workload mode.
Power up			Increases the workload of the ergometer. Sets the Manual workload mode.
Stop the belt		F12	Emergency stop of the treadmill
Start the belt	100	F12	Starts the treadmill belt.
Configuration	Salap	Ctrl+T	To adjust the screen layout and the system configuration.
Play back the ECG traces	Playthack	Space bar key	Display and scroll back in a separate window the ECG traces recorded since the current test start.
Change the QRS Sync Lead	Syndroid		Changing the ECG lead for the BNC/trigger output.
Applied electrode quality check	Lead Check	Ctrl+ Space bar key	Display the schematic torso picture to verify the applied electrodes connection quality and the lead off status.
Remarks	Remarks	Ctrl+R	To enter the test remarks and comments.

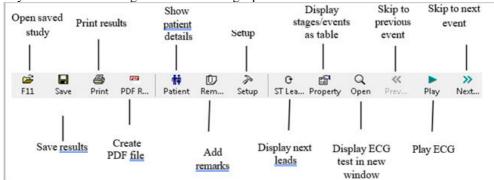
Average Viewer SettingsThe right mouse button menu is displaying various views available for the average viewer panel.



Document Title:	No	orav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Daga 26 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 36 of 53	

Post Processing Options Toolbar

When the test is complete you can review it using the Post Processing Options Toolbar.



To do this	Button	Shortcut	Menu option
View 12 leads ST trends results			View > 12 Leads ST
View 3 leads ST trends results			View > 3 Leads ST
View next ST trends Triplet	e		View > Next ST Leads
View numerical results		Ctrl+V	View > Properties
Undo the last action	3	Ctrl+Z	
View ECG 10 sec data	Q	Enter	View > Open ECG Data (requires I1 or I2 license).
Move marker to previous event	«	Ctrl+ ←	View > Event > Previous Event
Move marker left 10 sec	<	+	View > Event > Left
Play back results			View > Play ECG Data
Move marker right 10 sec	>	→	View > Event > Right
Move marker to next event	>>	Ctrl+→	View > Event > Next Event
Add (create) a new event	+		View > Add New Event
Delete the current event	_		View > Delete Current Event
Set preferences	To	Ctrl+T	View > Setup
Print the study		File/Print ECG	This enables you to print the entire study or a single stage
Position the ST marker		View /Recalculat e ST	This enables you to position the ST marker for the entire study

Perform the Stress ECG examination

Launch the Stress ECG software application. The initial screen is displayed.

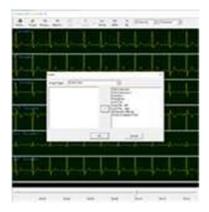
To Start a New Test

Document Title:	No	NORAV medical			
Document	NV-	Document Rev.:	Document Date:	Dogg 27 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 37 of 53	

- Click on New main menu button or press the **F1** keyboard key.
- The Stress working screen and patient data entry screen are displayed.
- Enter patient data and click **OK**. After about 15 sec the average QRS is displayed.
- Use the Lead Check button to verify the applied electrodes connection quality.
- If necessary, click on icon to change the exercise protocol, swap between the treadmill and ergometer or adjust the target HR and other alarms.
- Enter blood pressure.
- You can print a baseline ECG page using the icon.
- To start the exercise session, click on the icon (F3). The exercise time is displayed in the vital signs panel on the right side.

PlayBack display

During a Stress test in real time a period of any 10 second period of the recorded ECG can be viewed in a separate window. This option is enabled 10 seconds after the beginning of the stress test (available only with the **S2** software key option).



Recovery Phase

When the Exercise phase is completed the Recovery phase begins automatically. Press the any time during the Exercise phase. The recovery phase elapsed time is counted as well as the total elapsed time.

Wait for the recovery phase to finish according to the protocol or stop it using the are finalized. Data is no longer acquired for this test.



icon (F4). Both the TEST and RECOVERY times

There are two options for completing a stress test.

- Display the post-processing data screen (Review Screen) automatically.
- Remain in ECG display.

To Display the Review Screen Automatically/Manually

In Setup, click the **Real-Time** tab and check **Switch to Review Automatically**.

Document Title:	No	NORAV medical			
Document	NV-	Document Rev.:	Document Date:	Dogg 29 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 38 of 53	

At the end of the test protocol, or after clicking icon (**F4**), the display switches automatically to the Review Screen, and the post-processing information is displayed. If **Switch to Review Automatically** is not enabled, the signal continues to run.

• To open the Review Screen press **F9**.

Viewing Results

Viewing results are available in Review Screen after finishing the examination.

The Review Screen is displayed with the post processing data. It provides the following options:

- ♦ Validate and edit the examination results such as HR, ST, BP, SpO2 etc.
- ♦ Write conclusions.
- Display, save and print ECG traces.
- ♦ Print reports.
- Perform ECG Measurements (optionally).
- ♦ E-mail the examination results.
- ♦ Generate reports in PDF format (optionally).
- ♦ ST Reanalysis.

Configured Summary Report

User formats narrative text and selects data fields to create report template. The system automatically merges text and data according to the template selected.

To Print the Configured Summary Report

- Click **the Print** button in the main menu tab to open the final reports selector panel.
- Mark the Configured Summary Report check box.
- Click **Edit Summary** to preview the report.
- The report will be opened in the **Report Editor** window.
- If necessary, select another template from the Templates list.
- Edit the report text.
- Click **OK** button in the Report Editor top to save the changes.
- Finally, click **the Print Reports** button to print the selected reports.

To Create or Modify a Template for Configured Summary Report

- Open Setup / Printouts tab.
- Click **the Change** button near the **Configured Summary** parameter.
- Select the needed template in the list then click **Edit**.
- Edit the report template text in the Template Editor window.
- Use the **Insert Report Item** menu to enter values like patient name, DOB, protocol etc.
- Preview the example report on the right-side panel.
- Save the template changes and then close the Template Editor window.
- Select the needed template in the list then click **Set Active** to mark it as default.

Document
Title:

Norav Users Guide PC-ECG 1200

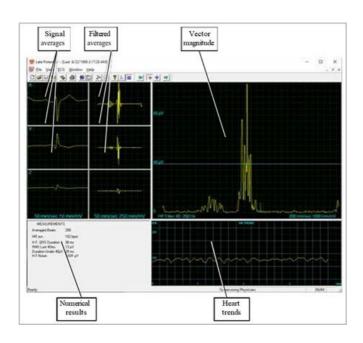
Document NVNo.: 54/PCECG1200

Document Rev.:
21.12.2023

Page 39 of 53

LATE POTENTIAL SIGNAL AVERAGING

(This option is available with the L1 license)



Quick Start

To Start a New Test

- Click **F1** (or the **New** button on the tool bar).
- Insert patient details in the dialog box.
- Click **OK**.
- Click **F3** or **F4** to start the LP averaging test.
- Enter the interval name and/or remarks as appropriate in the dialog box and click **OK**.
- Click **F3** or **F4** (or **Start/Stop Averaging** button) to stop the LP averaging test (or wait until it terminates).

To Print

- Click **F6** or select **Print item** from the File menu.
- Select the printer from the Print dialog box.
- Click **OK** to close the dialog box and print the display (the LP averaging report or the ECG test)

Leads

Recording is performed for leads X, Y, and Z (orthogonal) using the regular 12 lead cable.

12 Lead	Orthogonal Lead (position)
---------	----------------------------

Document Title:	No.	Norav Users Guide PC-ECG 1200				
Document	NV-	Document Rev.:	Document Date:	Dogg 40 of 52	i	
No.:	54/PCECG1200	211130	21.12.2023	Page 40 of 53	ì	

V2	X+ left side of the chest
V1	X- right side of the chest
V4	Y+ low er side of the chest
V3	Y- upper side of the chest
V6	Z+ middle of the chest
V5	Z- middle of the back
RA,LA,LL,RL	Same position as in 12 leads

Toolbar and Menus

To do this	Click this icon	Or use this short-cut key	Or select this menu	Description
Start a new study	۵	F1	File > New	Starts a new recording. The patient's demographic data can be entered prior to ECG recording. The three channels are displayed on the screen for quality assurance. If the results are unsatisfactory, check skin preparation and disposable electrode contacts. Then click Start/Stop Averaging.
Open an existing study	A	F11	File > Open	Opens an existing study
Save a recording		Ctrl+S	File > Save	Saves recording to disk.
Send data via email	*		File >Send	Sends recording data via email if present on the computer.
Print results		F6	File > Print	Prints the active study
Import demographic data from HIS to PC-ECG			File > GDT/BDT Format	This file always contains the last patient data.
Export the GDT/BDT file from PC-ECG to HIS			File > GDT/BDT Format	This file always contains the last patient data.
Set/change patient data	韓		View > Patient Data	Adds this data to the recording. Use the Previous option if the same patient undergoes a second study.
Add/view remarks	Û		View > Remarks	Allows you to type free text during or after the ECG recording.

Document Title:	No	NORAV medical			
Document		Document Rev.:	Document Date:	Page 41 of 53	
No.:	54/PCECG1200	211130	21.12.2023	1 age 41 01 33	

Set preferences	Po	Ctrl+T	View > Setup	Displays the setup dialog box and allows the user to tailor operation preferences.
To display information	9		Help > About	Displays software version number. Also displays memory size and disk free space.
Start/Stop Averaging	\$	F3/F4	ECG > Start/Stop Averaging	Allows the user to start the averaging period. The averaging period default is 200 beats. It can be changed in OPTIONS, ECG RECORDING, and TARGET NUMBER

To do this	Click this icon	Or use this short-cut key	Or select this menu	Description
Display/Hide the grid	#		View > Grid	Optional display of 5 mm raster. Print outs are always with 1 mm raster.
Start testing.	8	F2	ECG > Start/Stop Monitoring	Starts testing.
Stop testing	SOP	F2	ECG > Start/Stop Monitoring	Stops testing.
Activate Onset Marker	+	Ctrl+ ←	ECG Onset marker	Allows the user to move the Onset Marker.
Activate Offset Marker	#	Ctrl+→	ECG Offset marker	Allows the user to move the Offset Marker.
Move the On and Off markers	/			Allows the user to move the ON/OFF markers.

Interpreting Results
When the signal-averaging phase is complete, the result screen is displayed:

Numerical Results

The results are calculated automatically. You can overrule the automatic positioning of the ONSET/OFFSET markers with the direction keys.

Averaged Beats	Displays the number of averaged normal beats captured during the study.	
HR Average in beat/min		
High Frequency QRS Duration in Milliseconds from Onset to Offset	Displays the width of the filtered QRS containing only high frequencies. A higher number indicates higher patient risk.	
RMS LASTS 40 milli-seconds in Microvolts	Displays the total activity for the last (40ms) portion of the QRS. A lower number indicates higher patient risk.	
DURATION UNDER 40 Microvolts in Milliseconds	Shows the period in ms from offset of the QRS till the first point of 40uV activity. A higher number indicates higher patient risk.	
H.F. Noise: in Microvolts	Quality assurance. A lower number corresponds to higher result accuracy. The maximum number should not exceed 1 μV .	

"MONITORING" ECG

Document Title:	N _O	NORAV medical			
Document	NV-	Document Rev.:	Document Date:	Dogg 42 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 42 of 53	

(This option is available with the M1 license)

This option enables long-term recording and storage to disk. The user decides which leads and at which sample rate to show on screen and save to disk. During the study, you can print in real time on a thermal printer.

Throughout this document, "Monitoring" is used as a part of the names for certain applications and devices and does not imply monitoring features.

Quick Start

To Start a New Test

- Click **F1** (or the **New** button on the tool bar).
- Insert patient details in the dialog box.
- Click OK.
- Click **F2** (or **Start/Stop** button) to stop data collection or wait until end time.

To Print

- Click **F6** or select **Print item** from the File menu.
- Select the printer from the Print dialog box.
- Click **OK** to close the dialog box and print the display.

Print Study (selected time range and leads)

- Click **Print Study** on the toolbar or select **Print Study Item** from the **File** menu.
- Define the time range and select the leads to print from the dialog box.
- Click **OK** to confirm and close the dialog box.
- Select the printer in the Print dialog box.
- Click OK.

Toolbar and Menus

To do this	Click this icon	Or use this short-cut key	Or select this menu	Description
Start a new study	□ F1	F1	File > New Test	Starts a new session. Patient data can be entered prior to ECG recording. The recording time is set in SETUP for ECG RECORDING. The user can stop recording by clicking the GO/STOP icon.
Open an existing study	1	F11	File > Open	Shows recordings saved on disk.
Save a recording		Ctrl+S	File > Save	Saves recording to disk.

Document Title:	Noray Users Guide PC-ECG 1200			NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Dogg 42 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 43 of 53	

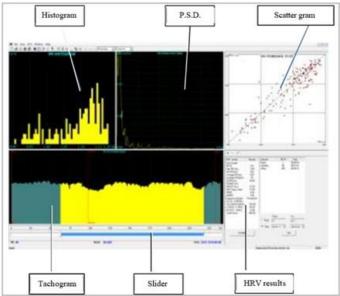
Print results		F6	File > Print	Offline printing. Determine the time range to be printed.
Export to Rest			File > Export to Rest	A 10 sec segment containing original leads I, II, V1V6 and calculated leads III, aVR, aVL, aVF is transferred into Rest format (up to 12 leads 10 sec). Calculated leads are performed only if I and II are acquired.
Export to MATLAB			File > Export to MATLAB	A 10 sec segment containing acquired leads is transferred into MATLAB format.
Import from ISHNE			File > Import from ISHNE	Long-term high-resolution ECG recorded on Holter can be transferred into a study
Plot in real time	<u>a</u>			Real time printing on a thermal printer. Can print continuously while up to 8 leads connected.
Set/change patient data	曹華		View > Patient data	Displays patient demographic information.
Add/view remarks	Û		View > Remarks	Allows the user to enter free text during or after the ECG recording.
Set preferences	To			Allows the user to tailor operation preferences.
To display information	ę		Help > About	Software version number. The HASP ID number is the ID of existing software keys. This ID number is used for adding software options.
Display/Hide the grid	#		View > Grid	Optional display of 5mm raster.
Start ECG Recording.	0	F2	ECG > Start/Stop	Starts ECG recording.
Stop ECG Recording	8	F2	ECG > Start/Stop	Stops ECG recording.
Display 3x4 Leads	5 5 5 5 5 5 5 5 5	Ctrl+1	View > Leads format > Window s	Classical format. Displays 12 lead ECG of 2.5 sec ECG + 10 sec trace. *
Display the next leads	0 -	Ctrl+0	View > Leads format > Next leads	Allows the user to scroll through all leads in the 3x1 format display

HEART RATE VARIABILITY (HRV)

(This option is available with the H1 license)

Document Title:	No.	rav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Doga 44 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 44 of 53	

Time and frequency domain analysis is designed for short studies in which one or more time segments are measured, as in a Tilt study. Measured/reported parameters are according to NASPE/ESC Guidelines.



Key:			
Histogram The histogram relates to the active part (yellow) of the tachogram			
P.S.D.	The power spectrum distribution		
Tachogram The tachogram trend shows all intervals. Each beginning of an interval is chewith a red line followed by the interval's name. To activate an interval, click activate several neighboring segments, press SHIFT and move the slider.			
Scattergram	Poincare plot of the current R-R interval plotted against the preceding R-R interval.		
Slider	Use the slider at the bottom to: Define new intervals Change interval duration, and Activate several intervals		
HRV results	The HRV results pane displays the results in numerical format.		

Quick Start

To Start a New Test

- Click **F1** (or the **New** button on the tool bar).
- Insert patient details in the dialog box.
- Click **OK**.
- Click **F3** or **F4** to start the HRV test.
- Enter interval name and/or remarks as appropriate in the dialog box and click **OK.**
- Click **F3** or **F4** (or **Start/Stop HRV** button) to stop HRV test (or wait until it ends).

To Print an HRV Report

- Click **Print** on the toolbar or select **Print** from the file menu.
- Select the printer from the print dialog box.

Document Title:	No.	NORAV medical			
Document	NV-	Document Rev.:	Document Date:	Page 45 of 53	
No.:	54/PCECG1200	211130	21.12.2023	rage 45 01 55	

• Click OK.

To Print an ECG

- Click the **Print ECG** button on the toolbar or select **Print ECG** from the file menu.
- Select the beats and leads to print from the dialog box and click **OK**.
- Select the printer from the print dialog box.
- Click **OK**.

Starting a Study

- Click New.
- Enter patient data in the Patient Data field.
- The ECG leads are shown on the screen for quality check.
- If you are satisfied with the quality check, click the **R-R** icon. The display comprises three sections:
 - ♦ The ECG leads are displayed on the upper part of the screen.
 - ♦ The tachogram trend display is built up in the middle strip.
 - ♦ A slider shows the study status and time at the bottom.
- During the study, define a new time segment (interval) by clicking the flag icon (interval). Name each interval during the study to retain it as a valid interval.
- When all predefined beats are completed, or if terminated by clicking the **R-R** icon, the HRV screen is displayed.

To Add or Subtract an Interval

- Select the interval with the slider or using the FROM-TO controls at the right-side panel.
- Click + or at the top of the HRV results pane.

To Edit Interval Names

Use the pencil icon.

To split the whole test into equally timed intervals

- <u>Online</u>: Activate the **Auto Interval** check box in **ECG Recording** setup tab. Selecting this option will create equal length time intervals during the ECG recording.
- <u>Offline</u>: Select the **Define Time Intervals** command under the **View** main menu tab. This option will create equal length time intervals on a stored recording.

Results Display

The AVERAGE HEART RATE is displayed on the lower left side.

All results are for the chosen segment (check the yellow selection or the From-To bits number). Other results are shown in the right-hand side:

	RR no.	Number of beats in the active interval

Document Title:	Noray Users Guide PC-ECG 1200			NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Dogg 46 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 46 of 53	

	max RR	Longest R-R period
	min RR	Shorter R-R period
	Average RR	Average of interval in active interval
Time	SDNN	Standard deviation of all R-R periods in interval
Domain	SDANN	Standard deviation of the averages of R-R periods in all 5 min segments of the active interval
	RMSSD	The square root of the mean of the sum of the squares of differences between adjacent NN intervals
	HRV triangular Index	Total number of all R-R intervals divided by the height of the histogram of all R-R intervals measured on a discrete scale
	ULF	Power of the ultralow frequency range
Frequency	VLF	Power of the very low frequency range
Domain	LF	Power of the low frequency range
	HF	Power of the high frequency range

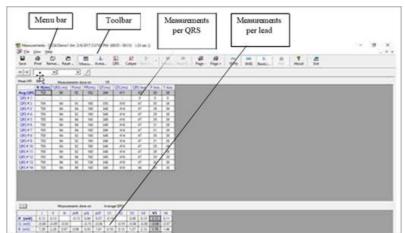
HRV Interval Measurement

A QRS detector measures intervals between two valid beats, calculating a sliding N-N average for comparison. When a significant change occurs, the current beat is either a premature beat (as in PVC) or a prolonged one, which may indicate either a compensatory pause following a PVC or a missing beat. Premature intervals followed by prolonged intervals (compensatory pauses) within twice the N-N interval are averaged to ensure time axis consistency amidst PVCs. If a prolonged interval follows a normal interval at twice the N-N interval, it suggests a missing beat, which is then computed as present. Such missing beats are rare during rest conditions as the software efficiently detects QRS in these scenarios.

MEASUREMENTS/INTERPRETATION (MEANS)

(This option is available with the I1, I2 or I3 license)

Measurements is not an autonomous application. The **Measurements** application is used for calculations of QRS and interpretation of the ECG signal. The user can manually change the QRS identification parameters. 10 seconds of data are calculated.



Quick Start

To Start Measurements

Click the measurements area in the **Resting ECG**, or ruler icon in **Stress ECG** and "**Monitoring**" **ECG** applications or click **View** > **Measurements**.

Document Title:	No	NORAV medical			
Document	NV-	Document Rev.:	Document Date:	Dogg 47 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 47 of 53	

The application has four view formats:

- Measurements Table (default display)
- ECG Averages
- QRS Signal
- Caliper

To Print Reports

- Click the printer icon or select **File > Print Reports**.
- Select the reports to print and click **OK**.

Performing Changes in Calculations

To Move the QRS Marker

(Averages and QRS views only)

- Click and drag the marker to the required position (between the previous and next markers).
- The calculations are modified accordingly.

To Add or Remove a Wave Marker

- Click the Add/Remove ECG Wave Markers icon on the toolbar.
- Check or clear wave markers in the dialog box displayed.
- Click **OK** to save the selection, close the dialog box, and display the change.

To Move the Wave Marker

(Caliper view only)

- Select a wave from the wave list on the left-hand side of the viewer (or from the Wave Type combo box).
- Select the marker from the Marker Name combo box in the toolbar or by clicking the marker.
- Use the Left/Top/Right/Bottom arrows on the toolbar or drag & drop the marker to the required position.

The calculations are modified accordingly.

Features

View all calculated parameters on every QRS, on every channel and average calculations in tabular format. The upper table displays measurements for a channel. The lower table displays measurements values for a QRS.

To View the Measurements on a QRS

Select a QRS from the upper table and view the results on the lower table.

To View the Measurements on a Channel

Select a channel from the lower table and view the values on the upper table.

To View the Measurements on All Channels for QT

Click ">" (between the two tables) to view measurements for **All Leads for QT** on the lower table.

Document Title:	No	NORAV medical			
Document	NV-	Document Rev.:	Document Date:	Dogg 49 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 48 of 53	

Tabular Screen

The Tabular screen displays calculations of the QRS parameters in all the leads in a tabular format. Original calculations or changes performed in the other screens (Averages, QRS, or Caliper) are displayed in a tabular format and can be printed out.

Averages Display

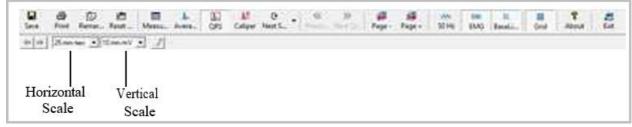


The Averages screen displays the average QRS in each of the leads and the average ECG of the Strip lead. Each QRS identified is marked with a red marker in the strip lead (The marker marks the R wave of every QRS). The QRS markers can be moved to the left and right (between the previous and the next marker). Changes in marker positions are recalculated and displayed in the tabular screen and the QRS screen.

QRS Display

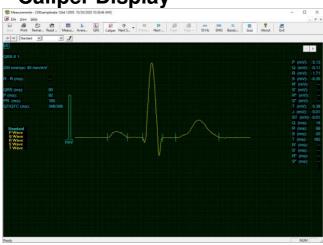
The QRS screen displays the QRS in each of the leads and a strip lead of a default lead (defined in the setup of the application from which Measurements was accessed). The QRS displayed in each of the leads is marked by a red rectangle in the strip lead. To view a different QRS in all the leads, drag and drop the square by to a different QRS. The QRS markers can be moved to the left and right (between the previous and the next marker). Changes in marker positions are recalculated and displayed in the tabular screen and the Averages screen.

Toolbar of Averages/QRS Displays

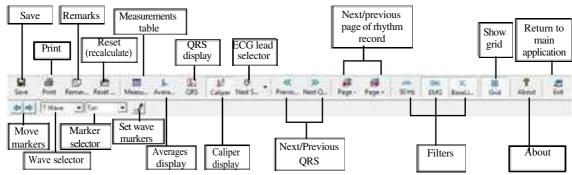


Document Title:	No	orav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Dogg 40 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 49 of 53	

Caliper Display



Toolbar of Caliper Display



The Caliper screen is opened via the menu, the toolbar, or by double clicking a lead in the QRS or Averages screens. It displays one QRS with its values. The user can edit locations of wave markers, display different QRS in the same lead, or navigate through leads and display QRS in different leads. Changes in wave marker positions are recalculated and displayed in the tabular screen.

Toolbar and Menus

To do this	Click this icon	Or use this shortcut	Or select this menu	Description
Save Measurements		Ctrl+S	File > Save	Saves measurements to test file on disk.
Print ECG		F6	File > Print ECG	Offline printing.
Add/View Remarks	Û	Alt+V+R	View > Remarks	To enter free text during or after the ECG recording.
Reset Measurements		Alt+F+M	File > Reset Measurements	Reset measurements to those calculated by the application.
To Open Measurements in Table Format			View > View Format > Measurements table	Displays the measurements in a table format.

Document Title:	No	NORAV medical		
Document	NV-	Document Rev.:	Document Date:	Page 50 of 52
No.:	54/PCECG1200	211130	21.12.2023	Page 50 of 53

To Display QRS Averages	Th		View > View Format > Averages	Displays the QRS averages on screen.
To Display QRSs in All the Channels			View > View Format > QRS	Displays the QRSs in all the channels on screen.
Display Caliper	W		View > View Format > Caliper	Displays the Caliper.
Display the Next Leads	C	Ctrl+0	View > View Format > Next strip	To scroll through all leads in the 3x1 display.
Display/Hide the Grid	#		View > Grid	Optional display of 5 mm raster.
To Display Information	ଡ଼		Help > About	Displays software version number. The HASP ID number is the ID of existing software keys. This ID number is used for adding software options.
Previous QRS Next QRS	«		View > View Format > Previous QRS/ Next QRS	Moves to previous QRS or next QRS on the same channel.
Page - Page +	44 44		View > View Format > Previous 10 sec ECG / Next 10 sec ECG	Moves to previous / next 10 sec ECG page of rhythm recording.
Set 50/60 Hz Filter	// /		ECG > Filters > 50/60 Hz	ON/OFF for line interference filter. Set OPTIONS for 50 or 60 Hz prior to operation.

To do this	Click this icon	Or use this shortcut	Or select this menu	Description
Set EMG Filter	EMG		ECG > Filters > EMG	ON/OFF for muscle noise filter.
Set Base Line Filter	BL		ECG > Filters > Baseline	ON/OFF for baseline filter on ECG data.
Move Marker to Right/Bottom	1 0			Enable in Caliper screen when a wave type and marker name are selected. Click to move the marker right or down. Disabled when no wave marker is selected, or the Caliper screen is not displayed.
Horizontal Resolution	Zivek÷ ▼			(Averages and QRS screens) To choose between horizontal displays of 12.5, 25, 50, and 100 mm/sec.
Select QRS Wave Type	F wave			In Caliper, lets you select the QRS wave type from the list to view its markers. After selecting the wavetype, select a marker name to move it.

Document Title:	No	NORAV medical			
Document	NV-	Document Rev.:	Document Date:	Dogg 51 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 51 of 53	

Vertical Resolution	Til nov-inc.		(Averages and QRS screens) To choose between vertical displays of 5, 10, 20, and 40 mm/mV.
Select Name of QRS Marker	Pul		In Caliper, lets you select the name of a marker to edit it (move it up/down/left/right).
Add/Remove ECG Wave Marker	0	File > Add/Remove ECG Wave Marker	(Caliper screen only) Opens a dialog box and lets you check/clear the wave markers to be displayed and calculated.
Print Reports		File > Print Reports	To choose the report to be printed from the submenu: Single QRS/QT Report, Multiple QRS Report, or All Reports.

TECHNICAL SPECIFICATIONS

	1200M	1200S	1200HR	1200W	Blue-ECG	NR-1207-E, NR-1207-3
Size [mm]	128 x 7	75 x 27	170 x 90 x 30	140 x 95 x 50	125 x 65 x 22	92 x 75 x 23
Weight [gram]	20	200 5V±5%		350	100	103
Power		5V±5%				
Current	100m	100mA ^{± 10%} Standard 10 lead AHA/IEC cable n/a				
Patient leads	Standard 10 lead			Detachable 10 wires conform to AAMI Standard 10 lead		cable AHA/IEC
Lead OFF detection	n,	n/a		Detached Lead or Offset	>0.5 V	
Pacemaker Pulse detection	n	n/a		From 0.1 to 2 ms at 2 to 7	00 mV	
Sampling rate of digital pacemaker detection	n	'a		00 samples/sec	r	/a
Sensitivity (mm/mV)			5,	10, 20, 40		
Horizontal scale(mm/sec)	12.5, 25, 50, 100		5, 12.5, 25, 50,	, 100	12.5, 25	, 50, 100
ECG Max. sample rate (samples/sec)	mple rate		2000 (all leads) 4000 x 4 ch	500 (12 lead in 24-bit mode) 1000 (12 lead in 12-bit mode) 1000 x 4 ch or XYZ, 2000 x 2 ch, 4000 x 1 ch	1000	
Resolution A/D	12 bits (2.44 µV/LSB)	12 bits (4.88 µV/LSB)	16 bits (0.3 μV/LSB)	24 bits (0.286 μV/LSB)/ 12 bits (2.44 μV/LSB)		bits V/LSB)
Defibrillation protection			Yes, protected against 36	0 J discharge		Yes, with Banana type ECG cable
Patient leakage current				<10 μA		
Simultaneously 12L				Yes		
CMRR				> 90 dB		
Input impedance				10 MOhm	1	
Signal dynamic range	10mV		20mV	± 2.4 V		mV
DC max. input		± 300mV		± 2.4 V	± 300mV	± 800mV
Frequency range (- 3db)	0.05 –	150 Hz	0.05 - 300 Hz	0.05 – 260 Hz	0.05 – 150 Hz	0.05 – 260 Hz
Low pass filter (software)			20, 3:	5, 40, 100 Hz		
Base line filter (software)	Yes					
Line noise filter (software)				50/60Hz		
Communication interface		USB		Digital RF, Bluetooth 2.1+EDR, Cla up to 10 m in open space up to 100 m in open spa		
Radio frequency range					2483.5 MHz	
RF output power				0.4 mW, conform to FCC		mW, n to FCC

Document Title:	No	CG 1200	NORAV medical		
Document	NV-	Document Rev.:	Document Date:	Dogg 52 of 52	
No.:	54/PCECG1200	211130	21.12.2023	Page 52 of 53	

Battery		2 x AA alkaline or NiMH	rechargeable	1x AA alkaline or NiMH rechargeable
Battery Operation Time		Up to 40 hours with alkaline batteries	Up to 12 hours	Up to 7 hours
Transport & Storage temperature	-20%	C to +60°C		
Operating temperature	10°C to +45°C			
Relative Humidity	10) to 95%		
Safety standard	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-25		IEC 60601-1-2	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-2-47
Certification	C	E, FDA		

TROUBLESHOOTING

<u>Condition</u>	<u>Causes</u>	<u>Action</u>
Unexpected Shutdown of	If the application terminates unexpectedly before the ECG test is completed and saved, it may be possible to recover	Stress ECG application stores native ECG data in the temporary file. You can convert this data into "Monitoring" ECG file format:
the Stress Application	1 1 1	Start the Stress ECG application.
		 Click Recovery File to Monitoring Format in the File main menu. The Choose files for conversion dialog box is displayed.
		Select the Windows\Temp folder.
		Select strXX.tmp last created temporary file and click Open.
		Select the "Monitoring" ECG files folder.
		 Insert "Monitoring" ECG file name according to patient ID or last name and click Save.
		Close the Stress ECG application.
		 Open the "Monitoring" ECG files folder and double click on the last stored file.
		The "Monitoring" ECG application opens.
		Click the Patient main menu button and insert patient data.
		 Save the updated "Monitoring" ECG file. You can now inspect and print ECG strip from the "Monitoring" ECG application.
Working in AutoSave Mode Without Saving		If you perform modifications while in AutoSave mode, but do not wish to save the modifications, do the following:
Modifications		Click Setup.
		 Uncheck Auto Save option and click OK.
		• Close the application (or the file) with the X
		button. A dialog box is displayed requesting acknowledgement for the save.
		• Click No.
		Reopen the application and the file.
		Check that modifications were not saved.
		It is now safe to re-enable the Auto Save mode (if required).
A Thick Straight	A thick straight line appears on	When using USB connection, check that the
Line is Displayed for All Leads	screen for all leads when the connection to the acquisition box fails.	LED on the ECG device is illuminated. If the LED is not illuminated, check connections to the USB port and to the ECG device. If the LED on the USB adapter is illuminated or if connected through RS232, check the connection to the acquisition box and make sure the box is switched on.

Document Title:	No	rav Users Guide PC-E	CG 1200	NORAV medical	
Document	NV-	Document Rev.:	Document Date:	Page 53 of 53	
No.:	54/PCECG1200	211130	21.12.2023	rage 33 01 33	

Noisy ECG Signal on Leads	A noisy ECG signal on one or more of the leads may be caused due to poor connection of the appropriate electrodes or leads on the patient.	Check the connection of the appropriate leads on the patient Make sure the electrodes are applied OK on the patient.
Missing data after a thick line	On the screen and in printouts of the ECG, appears for a few seconds a thick strait line and after that there is missing data for a period. The ECG traces resume after this random period. This problem may be caused due sleep mode or hibernation mode the PC entered while the ECG test was running.	Any settings related to the power management should be disabled: no standby, no stop HD, no hibernation on the laptop during the Stress test: Right click on the desktop. Select PROPERTIES from the pop-up menu. Select the SCREENSAVER tab. Press on the POWER button in the Monitor Power frame. Select Power Schemes as either PRESENTATION or HOME\OFFICE DESK. Set NEVER to "Turn off Hard Disk", "System Standby" and "System Hibernates". Press OK to apply this configuration.
"Lead-off" is. displayed on the screen or some leads prints as a bold lines	Electrode contact is poor. A lead may be loose. A lead is disconnected from the patient. Broken leadwire or patient cable,	Reattach the electrode. Replace the electrode. Verify that the patients' skin is properly prepared. Verify that shelf life of electrodes is not expired
Muscle tremor interference superimposed on waveforms.	 Patient is uncomfortable. Patient is cold and shivering. Exam bed is too small or narrow. Electrode straps are tight. 	 Help patient get comfortable. Check all electrode contacts. Turn the EMG filter on.
AC interference superimposed on waveforms.	Electrodes problem. Technician touching an electrode Patient touching any metal parts of an exam table or bed. Broken ECG cable, or power cord. Electrical devices in the immediate area, lighting, concealed wiring in walls or floors. Improperly grounded electrical outlet. Incorrect AC filter frequency setting or AC filter is turned off.	Verify that the patient is not touching any metal parts of the bed or environment. Verify that the AC power cable is not intertwined with the patient lead cable. Turn the AC filter on. Verify that the proper AC filter setting is selected (50Hz or 60Hz, depending on your region). If interference persists, the noise may be caused by other equipment in the room or by poorly grounded power lines. Try moving to another room.