NORAV medical

ECG Excellence

NEMS-Q Users Guide

CE

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! **Caution**	US Federal Law restricts this device to sale by, or on the order of, a physician

For software version: 2.7.0

Document Number: NV-54/NEMS-Q

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Standards Compliance

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

The 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*.

The PC-ECG conforms to MDD 93/42 EEC Annex II, EC11 and EN 60601-1-2.

The PC-ECG 1200 is tested and certified for the following standards:

EN60601/1:	International
EN60601/2/27:	International

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, lead wires, patient cables, and batteries. This warranty does not apply to any product that Norav determines that it has been modified or damaged by the customer.

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

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

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

Table of Contents

CHAPTER 1: INTRODUCTION

Manual Organization

This manual explains in detail how to install and use the NEMS-Q.

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 running quickly.

.The software must be installed before the hardware.

See NEMS-Q CLIENT Software Installation

Document Conventions

Notes and Cautions

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

WARNING

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

Caution

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

Note

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

Abbreviations and Acronyms

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

Equipment Symbols

Symbol	Description
	Type BF equipment
	Type CF equipment
	Class II equipment
	Complies with the Medical Device Directive of the European Union

CHAPTER 2: OVERVIEW

Package Contents

The NEMS-Q package contains the following elements:

- Software installation media (CD/DVD) including:
  - ◊ NEMS-Q software installation package
  - ◊ Operating Manual
  - ◊ Readme.txt
- Software key

Software

The NEMS-Q is main software application.

Compatible Devices and Applications

- PC-ECG 1200
- NECG cardiograph
- NM-700 Telemetry
- Holter NH-301
- NBP One ABPM
- NBP-24NG ABPM
- Oscar ABPM
- NSPIRO spirometry

Indications for Use of the NEMS-Q

NEMS-Q Intended Use

ECG is intended to disclose either normal condition or patterns of arrhythmia, myocardial ischemia, rate abnormalities, or features of prognostic value in the following cases:

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

QT Analysis is useful in the assessment of long QT syndrome (LQTS). In some instances, LQTS can be corrected by pharmacological therapy. QT analysis is also used to measure QT dispersion, the difference between maximal and minimal QT values. QT dispersion is a measure of the inhomogeneity of ventricular repolarization.

The PC-ECG 1200 has been tested to measure Heart Rate Variability to within 1 millisecond tolerance. The clinical significance of Heart Rate Variability measures should be determined by a physician.

The PC-ECG 1200 has been tested to measure Late Potential to a tolerance of within 1 millisecond, and 1 microvolt. The clinical significance of Late Potential measures should be determined by a physician.

Stress Testing Intended Use

Angina pectoris (chest pain) is a clinical syndrome resulting from myocardial ischemia, indicative of reduced blood supply to the cardiac muscle. The electrocardiogram may establish the diagnosis of ischemic heart disease if characteristic changes are present. 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 monitored via ECG during patient exercise. Patients exercise by bicycle, treadmill, or other means, while the ECG is monitored continuously. Exercise loads are determined by predefined protocols. The ECG signals are recorded for the resting, exercise, and recovery phase portions of the exercise protocol. The changes in ECG waveforms are compared to the resting ECG records. Most of the commercial stress test systems control the bicycle or treadmill automatically according to the requirements of the chosen protocol, although this is not essential.

ST segment monitoring is intended as an aid in the evaluation of myocardial ischemia in patients with known 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.

CHAPTER 3: NEMS-Q CLIENT SOFTWARE INSTALLATION

System Requirements and Prerequisites

PC Minimum Configuration

Operating System	Additions	RAM Memory (GB)	HDD Free Space (GB)	Number of Free USB or LAN ports
MS Windows 7 or later MS Windows	.NET Framework v4.5	2	2	1

Table 1: Minimum Computer Configuration

Installing or Updating the NEMS-Q Client Software

The software package works under Windows Win 7/8/10 operating systems.

1. Insert the CD in the drive. The installation program starts automatically.
2. Follow the instructions on-screen.

After you have completed installation, an icon NEMS is added to the desktop.

Icon	Explanation
	Norav ECG Management System

Table 2: Program Icon

CHAPTER 4: GETTING STARTED

The NEMS-Q is an optional package requiring the appropriate license. The NEMS-Q license is on a "D3" marked local HASP dongle or on a network located NetHASP key.

The system is dedicated to keep and manage ECG studies in a list organized according to patient name or ID.

In a network, users can share the database (save it in the server). Data acquisition for all applications can be initiated either in the application itself or from the database main screen.

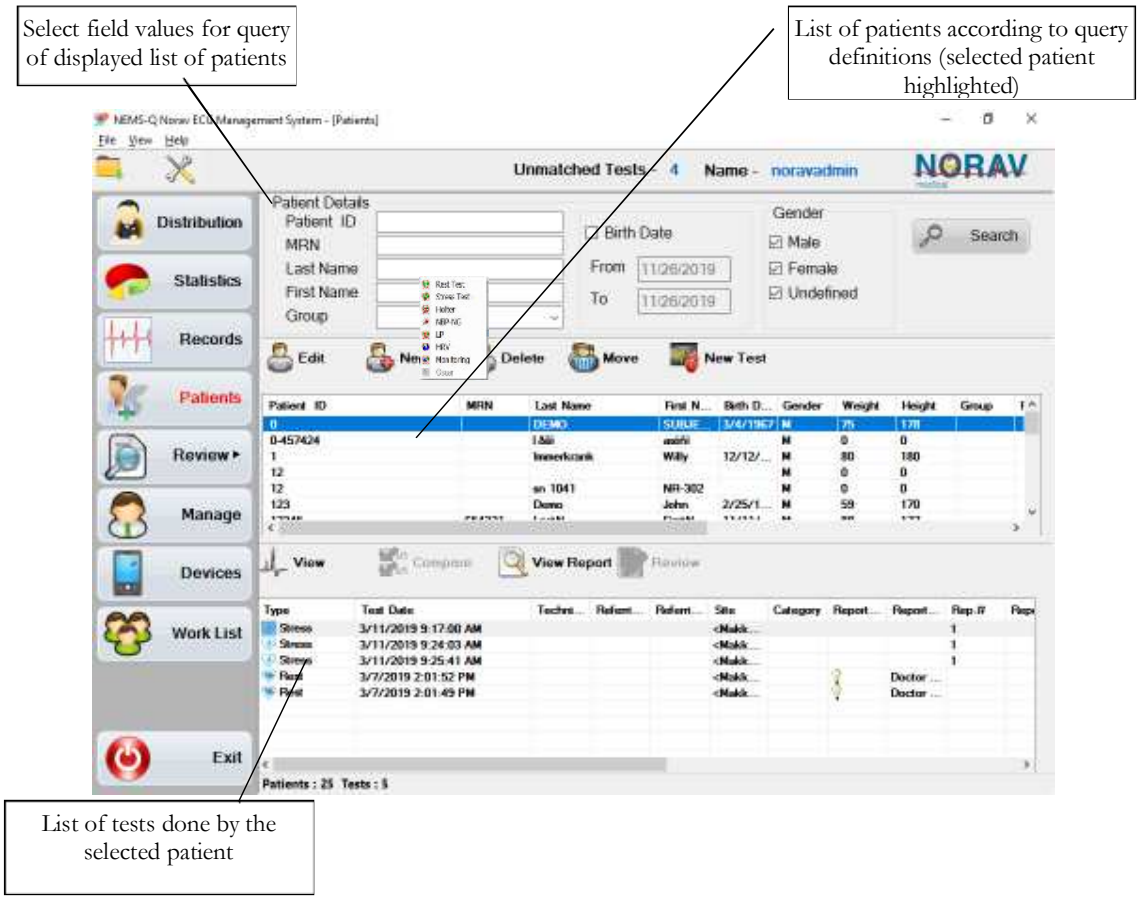


Figure 1: NEMS-Q Main Screen

Logon NEMS-Q system

When you start the NEMS-Q Client, you are prompted to provide logon information.

This is the user name and the password you received from your system administrator.

- Enter your user name.
- Enter your password.

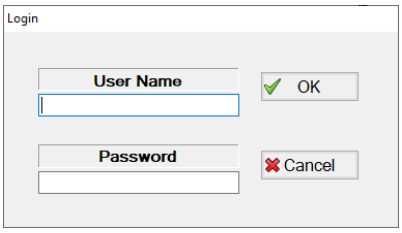


Figure 2: Connect Database

NEMS-Q Setup

Click Setup on the Toolbar to access the following parameters:

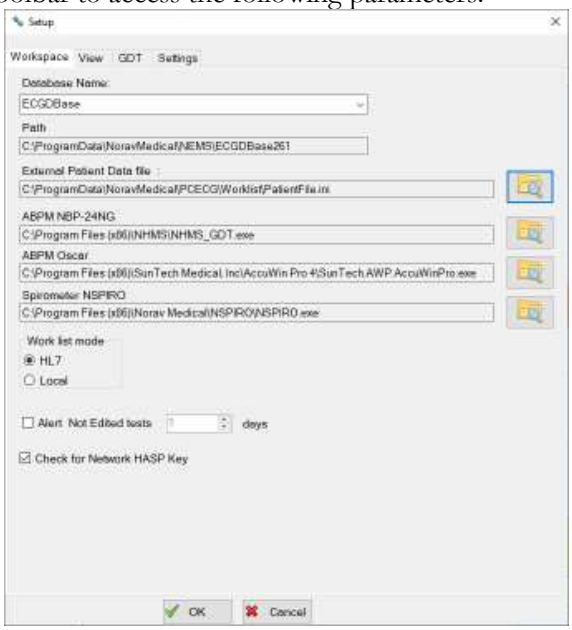


Figure 3: NEMS-Q setup. "Workspace" tab

"Workspace" tab	Description
Name	The NEMS-Q database name.
Path	Default data directory.
External Patient Data file	Location of the external patient data file for PatientFile.INI file.
ABPM NBP-24NG	Location of the main executable of NHMS blood pressure monitor program.
ABPM Oscar BP	Location of the main executable of AWP blood pressure monitor program.
Spirometer NSPIRO	Location of the main executable of NSPIRO spirometer program.
Work list mode	Selects a Worklist preparation mode: via HL7 orders or by reading the PatientFile.ini

Table 3: NEMS-Q Setup. "Workspace" tab options

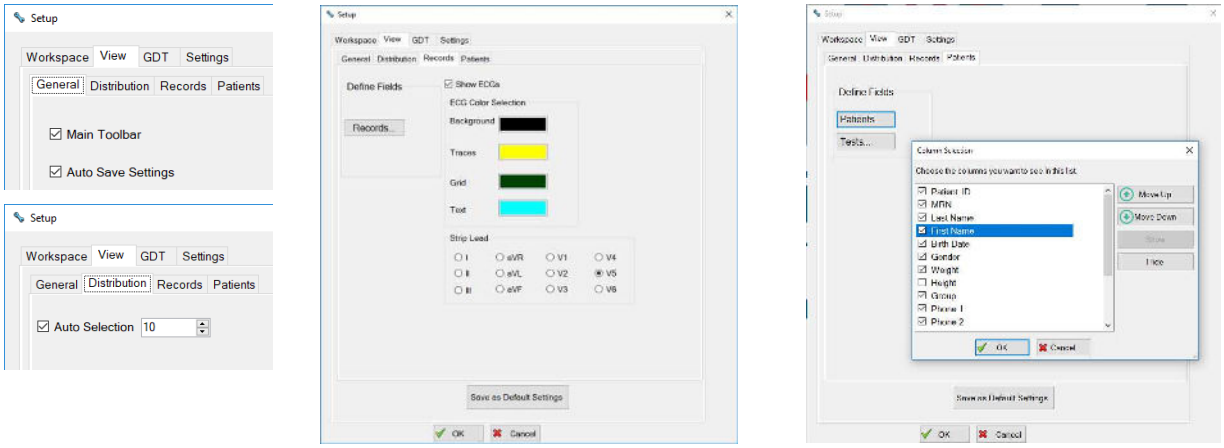


Figure 4: NEMS-Q setup. "View" tab

"View" tab	Description
Main Toolbar	Show the main toolbar buttons.
Auto Save Settings	Remember the user adjusted screen layout on exit the program.
Auto Selection	Number of recordings selected automatically on Distribution panel.
Show ECGs	Preview waveforms of Resting ECG examinations.
ECG Color Selection	Set color scheme of ECG waveforms preview panel.
Strip Lead	Set default strip lead on ECG waveforms preview panel.
Define Fields	Select and arrange data columns to display on Patients and Records panel tables
Set as Default Settings	Assign the current setup and screen layout as default settings for all users

Table 4: NEMS-Q Setup. "View" tab options

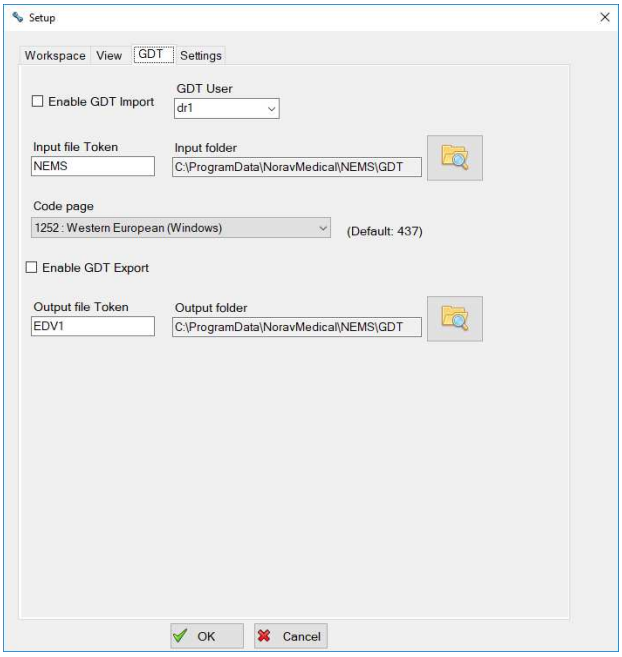


Figure 5: NEMS-Q setup. "GDT" tab

"GDT" tab	Description
Enable GDT Import	Activate to receive GDT commands from EMR.
GDT User	Select the NEMS-Q username to associate it with procedures started via GDT.
Input file Token	First four characters expected in filename of GDT inbound files generated by EMR.
Input Folder	Inbound folder to accept GDT inbound files received from EMR.
Code page	Select the character set for GDT data fields
Enable GDT Export	Activate to send GDT reports from NEMS-Q to EMR (for NBP-24NG reports only).
Output file Token	First four characters in filename of GDT report files generated by NEMS-Q.
Output Folder	Output folder for place the GDT report files generated by NEMS-Q.

Table 5: NEMS-Q Setup. "GDT" tab options

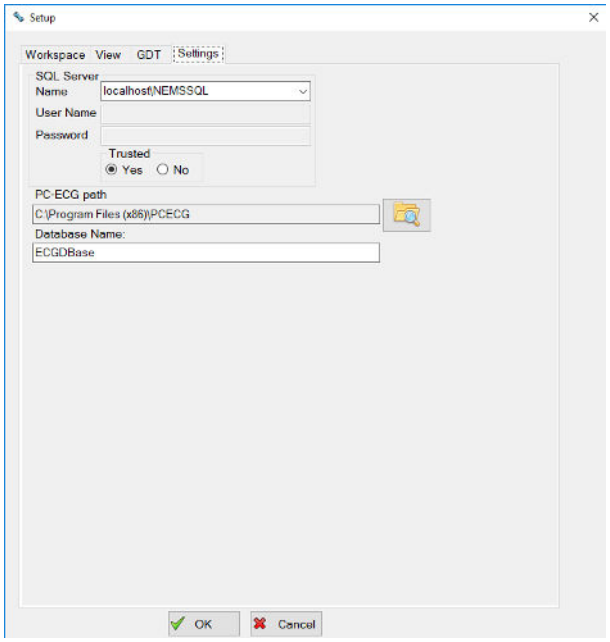
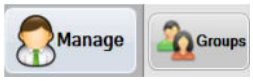
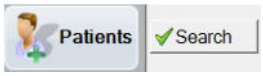
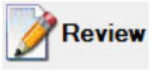


Figure 6: NEMS-Q setup. "Settings" tab

"Settings" tab	Description
SQL Server Name	The instance name of the SQL server where the NEMS-Q database is installed
User Name	User name to logon the NEMS-Q SQL server
Password	User password to logon the NEMS-Q SQL server
Trusted	Select the trusted or mixed authentication mode of NEMS-Q SQL server user logon
PC-ECG path	PC-ECG Stress ECG and Resting ECG applications executable files path
Database Name	The name of SQL database where the NEMS-Q data tables are located

Table 6: NEMS-Q Setup. "Settings" tab options

Toolbar and Menus

To do this	Click this icon	Select this menu	Description
Import tests to database		File > Import	Adds studies recorded and saved outside the database. To select all patient data files within a directory, press CTRL + A and verify that all files are checked.
Define Workspace Preferences		File > Setup	Defines the location of default workspace, patient identification, and a special file called External File. This file (Windows.INI format) allows the user to prepare a list of patients that can be read by PC-ECG 1200 applications.
View Application Information		Help > About	Displays version number; licenses; Norav contact info; memory size and free disk space; HASP ID number (is used for identification of the software key for adding software options).
Edit Groups		Manage panel > Groups	Defines different patient groups, such as Private, HMO, Military, etc.
Find a Patient		Patients panel > Search button	Allows the user to find a patient by entering a string in any or all of ID, Last Name, and First Name fields.
Open Patient Detail		Patients panel > Edit	Allows the Administrator users to check or change patient information before performing a study on a patient.
Add New Patient to Database		Patients panel > New	Inserts a new patient. You are prompted to enter partial or complete patient details. Enter ID, Last, and First Name at least. If patient details match an existing one you cannot add this patient to the list. The existing patient matching the details will be checked to allow the user to add a study.
Delete a Patient		Patients panel > Delete	Deletes an entry. If the entry is not empty of studies, you will be asked to confirm deletion.
Perform a New Test		On Patients or Worklist tab > New test	Starts the PC-ECG application to new recording or prepare the Holter recorder for new patient.
Move Patient		Patients panel > Move	Move patient to another Group.
Open a Test for review			Allows the user to view and edit study results.

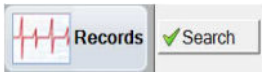
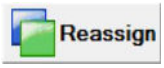
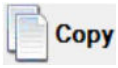
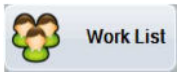
To do this	Click this icon	Select this menu	Description
Compare Rest tests			On a Patient's records panel. Select several Resting ECG tests from the records list then click **Compare**.
Search for a Test		Records panel > Search button	Allows the user to find a test by entering test type or time period of the test
Reassign		Records > Reassign	Allows the Administrator users to assign the stored recording to another patient.
Copy a Test		Records > Copy	Makes a backup copy of selected tests.
Move a Test		Records > Move	Moves a study and deletes it from the database. The default option is to leave the study's properties in the database: upon completion of the operation. The study remains in the list with an X sign. You can choose to remove the entire study instead.
Delete a Test		Records > Delete Test	Deletes a study from the database. The default option is to leave the study's property in the database: upon completion of the operation, the study remains in the list with an X sign. You can choose to delete the entire study instead.
Print Test Report		Records > Print	Print report of selected Resting ECG or Stress ECG study record.
Generate PDF Report		Records > Export	Create PDF report file of Resting ECG or Stress ECG study.
View Test Properties		Record > Properties	Displays study properties.
Download ECG recordings from the recorder		Devices > Scan recorder	Get the data file from ECG or ABPM recorder.
Scheduled tests			View examination orders list, search by date, start the scheduled ECG test.

Table 7: NEMS-Q Toolbar and Menus

CHAPTER 5: OPERATION

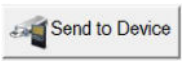
Working with the NH301 Holter Analysis System

Following operations are specific for operating the NEMS-Q together with the NH301 Holter systems:

- Prepare the holter recorder for the new patient.
- Download the ECG recording from the holter recorder.
- Open the ECG recording to analyze it in the NH301 software interface. (the NH301 Holter software license is required).

To prepare the holter recorder for a new examination

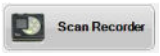
1. Check that the holter recorder is connected to the computer, or the Flash Card of the recorder is connected to the computer via the Card Reader device.
2. Select the holter order in Worklist or select patient on Patient panel, click 

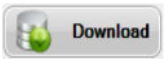
button. Starting in Patient panel - then select "**Holter**" test type. Patient details panel will appear.
3. Validate the patient information on screen then click the 

button.
4. Disconnect the holter recorder or the Flash Card from the computer.

To download the ECG recording from the holter recorder

1. Check that the holter recorder is connected to the computer, or the Flash Card of the recorder is connected to the computer via the Card Reader device.
2. Select the 

in the left side panel then click the 

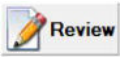
button.
3. Validate/Edit the patient information then click the 

button.
4. After the "**Download Complete**" message appears disconnect the holter recorder from the computer.

To open the holter ECG recording for analysis

(the NH301 Holter software and license are required)

1. Select the holter recording in the 

list then click the 

button in the records list tool bar. Selected recording will be opened within the NH301 program interface.

Working with the PC-ECG 1200 System

(the PC ECG software is required)

Following operations are specific for operating the NEMS-Q together with the Norav PC ECG system:

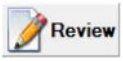
- Launch a new ECG examination with the patient name selected in a list. (the appropriate PC ECG software license is required).
- Open the ECG recording to analyze it in the PC ECG software interface.

To begin new ECG examination

1. Select the examination order in Worklist or patient name in Patient panel, click 

button. Starting in a Worklist – an appropriate examination interface will start automatically. Starting on Patient panel - then select an appropriate test type in a drop down menu list.
2. When the PC ECG application screen appears validate the patient information then click the OK button to start the examination.
3. After finish the ECG recording procedure exit the PC ECG application. The ECG recording will be automatically imported in the database and appears in the patient's recordings list.

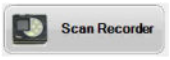
To open the ECG recording for review

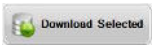
Select the ECG recording in the recordings list then click the 

button in the tool bar. The ECG recording will be opened within the PC-ECG program interface.

Downloading "ECG+" recordings from a NR-1207-3

1. Connect the NR-1207-3 recorder containing the data acquired in the ECG+ mode to the computer with a USB cable or inserting the recorders' SD card into the card reader.
2. Select 

on the left side panel then click the 

button. The system will show the list of ECG records collected in the recorders' memory card.
3. Validate/edit one-by-one the records in the download list. After editing the patient data click the  button to apply the changes in the download list.
4. Select the records to download by mark the ☑ check box and click the 

button.
5. Wait until the procedure ends. The successfully downloaded records will be marked  ; any unsuccessful downloads will be indicated  in the list.
6. Disconnect the recorder or the SD card from the computer.
7. Open the 

tab and validate that all new Resting ECG records appear in the list.

Working with the NBP One ABPM recorder

Following operations are specific for operating the NEMS-Q with the NBP One ABPM recorder:

- Prepare the NBP One recorder for the new patient.
- Download the ABPM recording from the NBP One recorder.
- Open the ABPM recording to review and print report.

To prepare the NBP One recorder for a new ABPM examination

1. Check that the NBP One recorder is connected to the computer USB port.
2. Select the ABPM order in Worklist, or select patient on Patient panel then click 

button and select the "**NBP One**" test type. Patient details panel will appear.

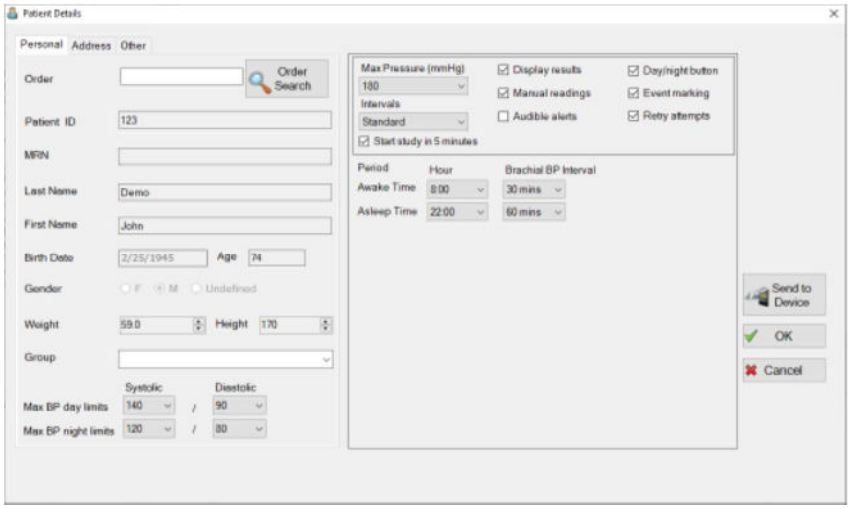
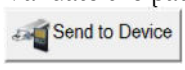


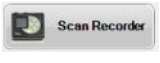
Figure 7: Prepare the NBP One recorder for new study

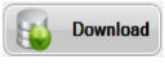
3. Validate the patient information, configure the ABPM protocol settings and then click the 

button.
4. Disconnect the NBP One recorder from the computer.

To download the ABPM study from the NBP One recorder

1. Check that the NBP One recorder is connected to the computer USB port.
2. Select the 

in the left side panel then click the 

button.
3. Validate/Edit the patient information then click the 

button.
4. After the "**Download Complete**" message appears disconnect the NBP One recorder from the computer.

To review the NBP One ABPM study

1. Select the NBP One recording in the Records list then click the Review button in the records list tool bar. ABPM Review screen will appear.

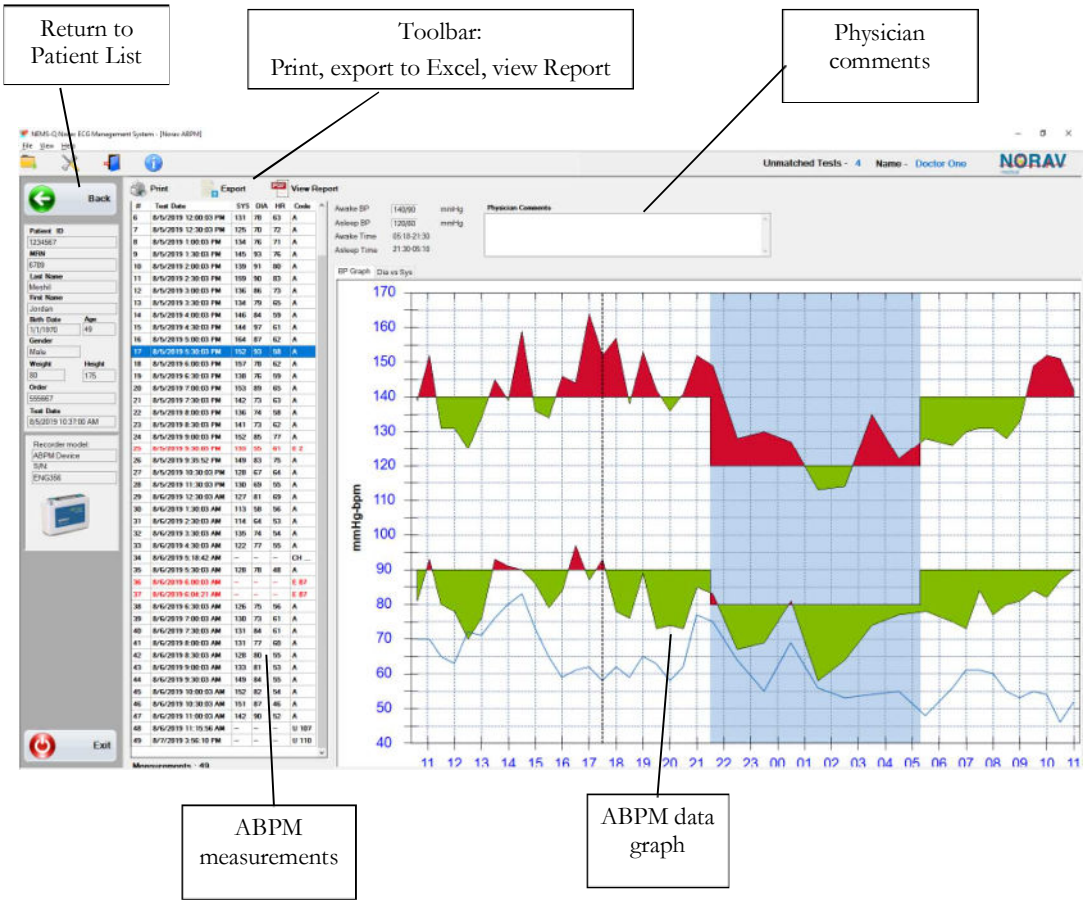


Figure 8: ABPM Review screen

2. Review the BP measurements, write physician comments.
3. To generate the report preview click the View Report button above the BP measurements list.
4. To print the report, click the Print button.
5. Optionally, click the Export button to export the BP measurements table to Excel file.
6. Finally, click the Back button to return to the Patient List main screen.

APPENDIX A: INTERFACING WITH INFORMATION SYSTEMS

There are several ways to exchange information between NEMS-Q and Hospital Information System (HIS). These are described below.

Demographic Data

Information System Prepares Patient Demographic Data for NEMS:

This uses a text file called **PatientFile.ini**. The file location is defined in NEMS-Q setup. File consists of patient data segments. Maximal length is up to 999 patients.

Field Name	Type	Max. Length	Format	Comments
[PatientDataXXX**]**	Header	Fixed	**[PatientData001]** to **[PatientData999]**	Segment counter
ID	Alphanumeric	30	*Cannot contain* **\ / ? * " <> | _** *symbols*	ID number (MRN)
LastName	Alphanumeric	30	*Cannot contain* **\ / ? * " <> | _** *symbols*	
FirstName	Alphanumeric	30	*Cannot contain* **\ / ? * " <> | _** *symbols*	
BirthDay	Number	2	**01..31** or **1..31**	
BirthMonth	Number	2	**01..12** or **1..12**	
BirthYear	Number	4	**YYYY**	
Sex	Number	1	**0**-*Female*, **1**-*Male*, **2**-*Udefined*	
Weight	Number	3	**0..500** (integer)	Kilograms
Height	Number	3	**0..300** (integer)	Centimeters
Address	String	256	Any text	
Phone1	String	15	Any text	
Phone2	String	15	Any text	
Fax	String	15	Any text	
E-Mail	String	30	Any text	
Medications	String	256	Any text	
Other	String	256	Any text	Any textual data
TechName	String	30	*Cannot contain* **\ / ? * " <> | _** *symbols*	Performing person
PhysName	String	30	*Cannot contain* **\ / ? * " <> | _** *symbols*	Attending doctor
IDR	Alphanumeric	30	*Cannot contain* **\ / ? * " <> | _** *symbols*	Accession number
Case_Id	Alphanumeric	30	*Cannot contain* **\ / ? * " <> | _** *symbols*	Visit number
Employee_Resp	String	30	Any text	
Type	String	30	**EKG**, **STRESS**, **HOLTER, ABPM, SPIRO**	Examination type
ScheduledDate	Number	12	**YYYYMMDDHHMM**	Scheduled date
Status	Number	1	**0**-scheduled, **1**-*in process*, **2**-*completed*	Examination status
Location	String	30	Any text	Examination office
ReferPhys	String	30	Any text	Reference physician
AlternateID	String	30	*Cannot contain* **\ / ? * " <> | _** *symbols*	Alternate ID number

Table 8: PatienfFile.ini format

At least one of the keys **ID**, **LastName,** or **FirstName** must be completed. If all these keys are empty, the section of this patient will be ignored.

Example:

[PatientData001]
ID=1234567890
LastName=Smith
FirstName=Worker
BirthDay=11
BirthMonth=6
BirthYear=1959
Sex=1
Weight=59
Height=170
Address=523 Main St. Tacoma Mexico
Phone1=702-8765643
Phone2=702-8743031
Fax=702-8743032
E-Mail=nkir@sympo.ca
Medications=none
Other=none

[PatientData003]
ID=123456789
LastName=Smith
FirstName=Worker3

HL7 Orders and Reports

The HL7 interface enables NEMS-Q system to receive examination orders from HIS and return observation results back to HIS. This exchange of data can be via a TCP/IP socket or using a Shared Folder method.

Interface via TCP/IP

The **HL7 Integration Engine** optional software module is required.

Shared Folder Method

Communication is through two shared folders: the "***Inbound***" folder (where HIS is sending the ORM^O01 format HL7 files) and "***Oubound***" folder (where NEMS-Q is returning the observation results as ORM^R01 format HL7 files).

GDT Interface

The GDT interface enables NEMS-Q system to communicate with EMR programs. The patient is always selected in the EMR program. NEMS-Q should be called after the patient's electronic recording file in the EMR program is selected. Patient data management is done in the EMR program, whereas the medical signals (ECG, ABPM, spirometry data, etc.) are handled in the NEMS-Q. New procedures are created via NEMS-Q. Existing procedures can be edited via NEMS-Q. Upon new procedure is completed or after review of the existing procedure the EMR program adopts the most important data of all new and edited procedures.

Calling the NEMS-Q from EMR via GDT

Adjust the EMR configuration to call the NEMS-Q Client with "**/GDT**" command line switch.

Example: ***C:\Program Files (x86)\Norav Medical\NEMS\EMSApplication.exe /GDT***

Functionality:

1. EMR prepares a GDT command file and then places it to the GDT Inbound folder.
2. Launch the NEMS-Q Client application with "/GDT" command line switch.
3. NEMS-Q starts and performs the procedure defined in the GDT command file.
4. After the procedure is completed the GDT report is generated in the GDT Outbound folder.
5. Exit the NEMS-Q Client application (which can be done automatically or by operator).

To open a patient data in NEMS-Q interface via GDT

1. Initiate EMR program, select a patient.
2. Perform OPEN PATIENT HISTORY whatever command in the EMR program interface.
3. NEMS-Q starts with patient record selected or automatically creates a new patient record.
4. Then do new procedure or review existing recordings in appropriate software application.
5. Upon the action is completed the software application sends results to the EMR.
6. The EMR program automatically adopts the updated data.

To perform a new test via GDT

1. Initiate EMR program, select patient
2. Start the desired procedure in the EMR interface that initiates a NEMS-Q application.
3. The NEMS-Q displays the initiated procedure details to be validated by operator. Operator must confirm the selected procedure either can select another procedure type for the patient.
4. Upon procedure type is confirmed NEMS-Q starts the appropriate software application.
5. Perform the procedure (acquire ECG, do a spirometry test, prepare ABPM recorder etc.)
6. Upon the procedure is completed the software application sends results to the EMR.
7. The EMR program automatically adopts the new results.

To display an existing procedure via GDT

1. Initiate EMR program, select a patient then select the existing procedure in the list.
2. Perform REVIEW or OPEN whatever command in the EMR interface.
3. That will activate the NEMS-Q which displays the study details to be validated by operator.
4. Operator opens the selected study record, review and then saves the study record.
5. Upon review is completed the software application sends results to the EMR.
6. EMR program automatically adopts the updated review report.

APPENDIX B: TROUBLESHOOTING

Failure to Connect Database

Problem

On attempting to perform an action, an error message appears on screen to indicate there is a failure in connecting database.

Solution

Consult your system administrator if you are working on the network then check network connection if so.

File not found when selecting a recording in NEMS

Problem

When selecting a file on the NEMS interface, appears an indication that the file is not found.

Solution

Check network connections.