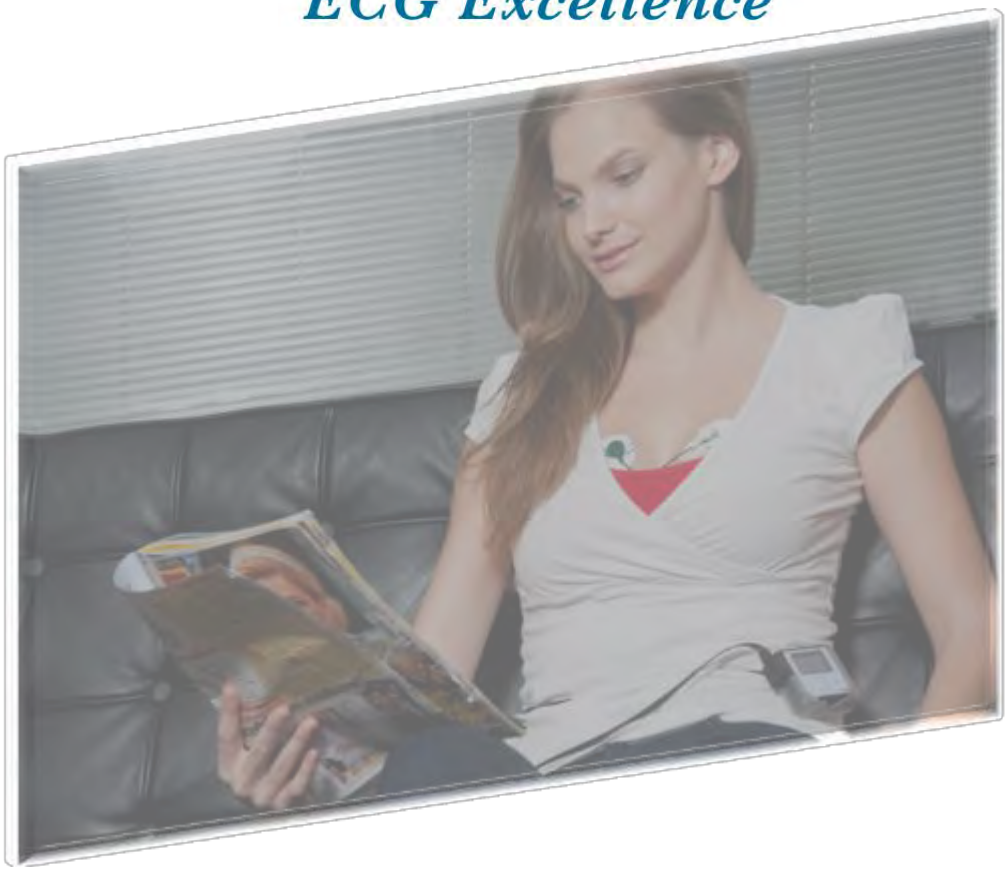
NORAV medical

ECG Excellence



Operating Manual for the Norav Holter Analysis Software NH-301

Part No.: NV-54/NH-301

Norav NH-301 Operating Manual
The greatest care has been taken in compiling the text and diagrams for this manual. However, the possibility of errors cannot be ruled out. The publisher, authors and translator accept no legal responsibilities or any other kind of liability for incorrect data and their consequences.

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The Norav Medical Holter Analysis NH-301 meets the essential requirements of the European Council Directive 93/42/EEC Annex 2

The software complies with the Requirements "IEC 60601-2-47 Medical electrical equipment – Part 2-47" (Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems.

This application also complies with FDA and Health Canada requirements for medical devices.
The FDA 510(k) number: K111487

1. General Safety Instructions

Failing to follow the operation instructions in this manual may result in improper analysis of the data. The manufacturer accepts no liability for damages resulting from improper use.

- The Operating Manual is part of the Norav Holter Analysis NH-301 and should therefore always be stored in close vicinity of the instrument.

- The Norav Holter Analysis NH-301 is designed for use under clinical supervision. It should be operated, and the results interpreted, by persons trained in professional healthcare. It is not designed for use in critical-care applications. Institutions using Norav Holter Analysis should ensure that it is used only in the testing of suitable patients and only by suitably qualified individuals.

- This software must be used by trained personnel only. Patients must not come into possession of the software or a computer installed with this software.

- This software has been designed and evaluated using state-of-the-art design methods. However, errors cannot be ruled out. Before prescribing therapeutic measures based on the results from this software or software modules, the results should first be checked by an expert and confirmed using other diagnostic procedures.

- Non approved third party software applications might cause conflict with Norav Holter Analysis. Where it is not absolutely beyond doubt from the documents supplied with the third party software that such conflicts are excluded, the user must exclude such conflicts by consulting the manufacturers concerned or a relevant expert.

- Patient safety, maintenance of equipment functionality and optimum interference immunity can only be assured when used with accessories and consumables recommended by Norav Medical.

- Any time before the equipment is used the user must verify its **functionality and proper condition**.

- **Magnetic and electrical fields** can have an influence on the function of instruments. Ensure that all non Norav Medical equipment which is operated nearby complies with the EMC requirements (regulations for Electro Magnetic Compatibility). X-Ray, Tomographs, etc. can cause interference to other equipment, as a result of their authorized higher emission of electromagnetic interference.

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.

IMPORTANT MESSAGE:

As in all Holter systems, noise and artifact may produce false positive ECG events. Therefore, patient data MUST be reviewed and edited by a qualified technician or a physician. Norav Medical and its staff cannot be held liable for patient data edited by a nonqualified person nor for data edited by a qualified person.

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 Medical or the Norav Medical authorized representative to the original purchaser.
Excluded from this warranty are expendable supply items including, but not limited to, electrodes, lead wires, patient cables, and batteries. This warranty does not apply to any product that Norav Medical determines that it has been modified or damaged by the customer.
Except for the express warranties stated above, Norav Medical disclaims all warranties including implied warranties of merchantability and fitness. The stated express warranties are in lieu of all obligations or liabilities on the part of Norav Medical for damages, including but not limited to, special, indirect, or consequential, arising out of or in connection with the use or performance of Norav Medical products.
Any action for breach of warranty shall be commenced within one (1) year of said breach or be forever barred. Any repairs made to the product that are not covered by the warranty shall be billed to the customer.
For service or technical support contact your local Norav Medical authorized representative or Norav Medical as follows:

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2. Introduction

About this operating manual

This operating manual explains in detail how to use the Norav Holter Analysis NH-301 and will guide you through the various features of the software and their relevant controls.

Important notes, warnings or cautions are highlighted in this manual by the following symbols. Please pay particular attention at those specific messages.

Notes provide pertinent information to obtain the optimum performance from the Norav Medical NH-301 Holter analysis software or signify an important step or a procedure which requires special attention.

Cautions explain procedures which are necessary to protect equipment against potential risk of damage or loss of data. Please pay particular attention to any caution highlighted in the operating manual.

Warnings point out to possible hazards involving potential damage or injury to persons.

Indications for using Norav Medical NH-301 Holter analysis

The Norav Medical NH-301 Holter analysis system is intended for patients requiring ambulatory (Holter) monitoring from 1 to 336 hours. Such monitoring is most frequently used for the following indications:

- Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
- Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.
- Evaluation of patients for ST segment changes.
- Evaluation of a patient's response after resuming occupational or recreational activities, e.g., after M.I. or cardiac surgery.
- Clinical and epidemiological research studies.

The Norav Medical NH-301 Holter analysis system is containing Heart Rate Variability (HRV).
The clinical significance of Heart Rate Variability measures should be determined by a physician.

Evaluation of patients with pacemaker

The Norav Medical NH-301 Holter analysis system operates with a compatible ECG recorder to record and analyze pacemaker activities – see *Supported Holter Recorders* on page 8

Contraindications and adverse effects

There are no known contraindications or adverse effects for using Holter monitoring equipment.

Sample Rates and Specification

The Norav Medical NH-301 Holter analysis system reads and analyses data recorded with sample rates of 128, 250, 500 and 1000 samples per seconds (s/s) and recording durations from 1 hour to up to 336 hours.

Patient data and ECG raw data are stored under Patient ID, Last Name and First Name for review, editing or re-analysis. It provides comprehensive arrhythmia detection based on the data of the high level accurate beat analysis. In addition it provides Pacemaker analysis, ST-analysis, HRV analysis, QT-analysis and Sleep Apnea report. The following standard events types are detected/reported:

Arrhythmia type
Pause
Bradycardia
Tachycardia
Ventricular Premature Beats
Ventricular Couplet
Ventricular Triplet
Ventricular Tachycardia
Bigeminy
Trigeminy
Supra Ventricular Ectopic SVE
Supra Ventricular Ectopic Pair
Supra Ventricular Ectopic Run
ST Elevation/Depression
Maximum RR Interval
Minimum RR Interval
Maximum Heart Rate
Minimum Heart Rate
Atrial Fibrillation

Pacemaker Analysis
Total Paced Beats
Atrial Paced Beats
Ventricular Paced Beats
AV Paced Beats
Failure to Capture
Failure to Sense
Inhibition

Respiration
Sleep Apnea

Supported Holter Recorders

The Norav Medical NH-301 Holter analysis system is compatible with the following Holter recording units:

Norav **NR-302/NR-314/NR-1207/NR-1207-3** Holter Recorders
Norav **DL800** Holter Recorder
Norav **DL900** Holter Recorder
Norav **DL1200** Holter Recorder

3. Software installation

This chapter summarizes the necessary steps to install and setup the Norav Medical NH-301 software. Further you find here some useful hints for cleaning devices and maintenance of software and data.

Before you start the installation please read the following instructions carefully in order to avoid any data losses or permanent damage of the computer or its peripherals.

Minimum specification for the computer system

The hardware for the Norav Medical NH-301 should have the following minimum specification. If you plan to use hardware of a lower specification please bear in mind that this can affect the function of the software and as a result it may run slower or in worst case get instable. The software can be run on a Notebook computer as long as it has the minimum specification.

Minimum hardware specification:

- Computer CPU: **Intel Dual Core 2.8 GHz or stronger (recommended Intel i5)**
- RAM memory: **4 GB or more (recommended 8 GB)**
- Free hard disk capacity: **20 GB (recommended 1TB)**
- Operating System: **Windows®8/10 64bit**
- Graphic resolution: **1280 x 768 or higher (recommended 1600 x 900)**
- USB Ports: **1) For the software protection key,**
  2) For data downloads when using Norav Medical NR-302, NR-314, NR-1207, NR-1207-3, DL800, DL900 or DL1200 recorders
- Bluetooth **Bluetooth 2.0 compatible connection for patient data wirelessly sending to Norav Medical NR-314, NR-1207 or NR-1207-3 recorders**
- Other drives: **DVD / DVD+RW writer for archiving,**
  Compact Flash Card reader when using Norav Medical NR-302, NR-314, NR-1207, NR-1207-3, DL800 or DL1200 recorders
- Network capability: **TCP/IP compatible network hardware**
- Monitor type & size: **TFT Monitor 19” or larger screen recommended**

To print out the reports generated, we recommend using a Windows® compatible Color InkJet printer or even better, a compatible Color Laser printer.

How to install the software

The installation of the Norav Medical NH-301 software is very easy and runs almost automatically without any interaction.

- First close any running application in order to avoid any disturbances during the installation and setup process.
- Then insert the software CD in the CD/DVD drive of your computer. The installation process should start automatically. If not, the Autoplay Function for your CD/DVD drive has been switched off.
  In this case open the Windows Explorer and start the program “Setup.exe” on the CD with a mouse’ double click.
- Follow the instructions on screen and if asked to do so, reboot your computer system to finish the installation.

Data structure after the standard installation

The default path for the software application is “**C:\Program Files\Norav Medical**”.

The settings for the software application such as layout, setup, physician name etc. are stored in **“C:\ProgramData\NoravMedical\NH301”**.

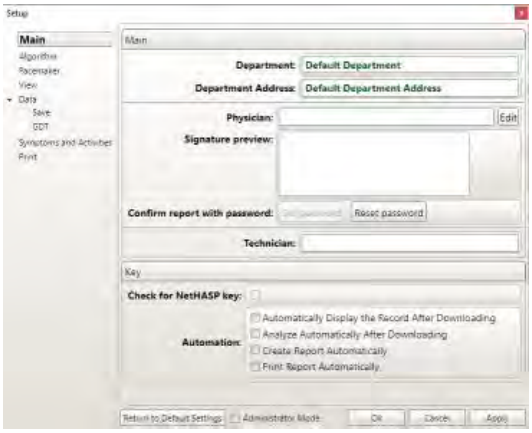
“C\ProgramData\NoravMedical\NH301\Data” is the default path for downloaded raw data and analysis results. All ECG raw data (*.res) and all analysis results (*.hl4) are stored here.

Software Setup after Installation

When the installation has completed you may customize the software and adapt it to your personal needs.
Run the Norav Medical NH-301 software by double clicking on its icon on your Desktop.
In the opening screen select **Setup** option from the **File** menu.

With the **Setup** menu item you open another Dialogue as shown below. With the buttons on the left you may select the relevant settings to check and/or change.

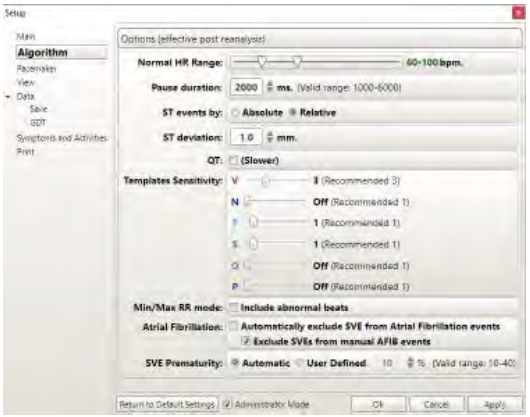
The first setting "**Main**" covers the report header, the software license key location and the workflow automation options.



You can enter up to four lines of text with address details of your hospital, clinic or business and the names of the physicians and technicians.
As the labels of the text boxes are not printed in the report you can use the text lines for any text that you want to get printed in the header of your reports.
Click on *Set password* to protect the report setup.
After setting a password you may also load an image of your signature. Use the *Edit* button to change the physicians' name and to add the image file which will appear as the signature in the bottom right corner of your main page of the printed reports.
Enable the *Check for NetHASP* key option to activate the software license search in the local network.

The workflow process may be automated to perform it in sequence. To activate the automation enable the desired options in the *Automation* panel.

The next setting "**Algorithm**" allows to setup some basic parameters for the analysis.



With *Normal HR Range* you may set the minimum and maximum heart rate. Significant deviations from this range are considered to be Tachycardia or Bradycardia.
With *Pause duration* you may set the minimum length for a pause to be detected.
With *ST events by* you may choose Absolute (ESC) or Relative (AHA) ST measurement.
With *ST deviation* you may set the minimum deviation for the ST event detection.
To include *QT analysis* - tick *QT*.

When the QT option is activated, the QT analysis is done automatically together with the analysis. Please bear in mind that this additional analysis process includes time intensive mathematics hence the analysis will run a few seconds longer.

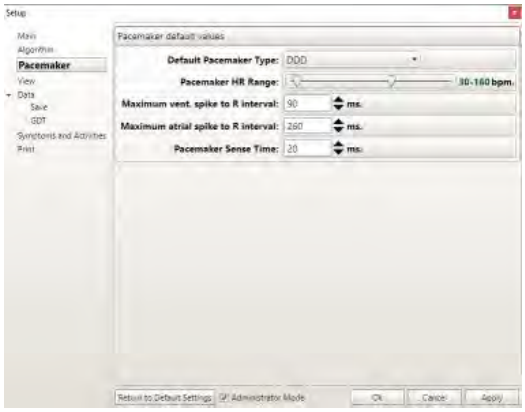
Template Sensitivity – set the sensitivity for each type between 1 and 10, or set it "Off" to disable templates for beats of a specific type. (Analysis is faster when templates are disabled).

Min/Max RR mode – to include abnormal beats tick the checkbox. Otherwise, remove the tick from the checkbox (Default: abnormal beats are not included).

Atrial Fibrillation - SVE beats can be relabeled as Normal within the automatically detected or manually marked AFIB events. To enable this option mark the appropriate check box.

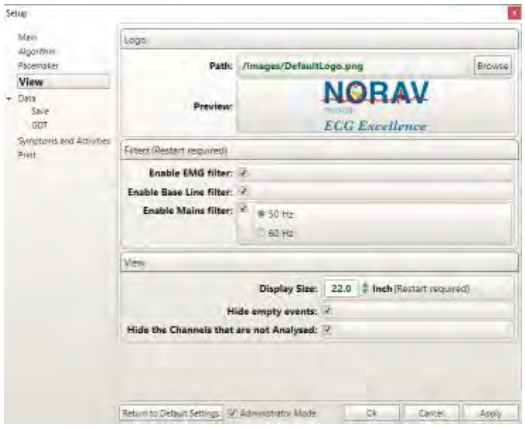
SVE Prematurity – RR interval prematurity percentage threshold for SVE beats detection (Default: *Automatic*).

The "**Pacemaker**" setting allows configuring the default parameters for the pacemaker analysis, such as pacemaker type, pacemaker-initiated heart rate range, maximal intervals between the pacemaker and the initiated QRS beats.



If the pacemaker detection has been switched on in the recorder then these parameters will appear on the Download page as well on the Analysis start page, where the parameters can be adjusted in accordance with the actual configuration of the implanted pacemaker of the patient.

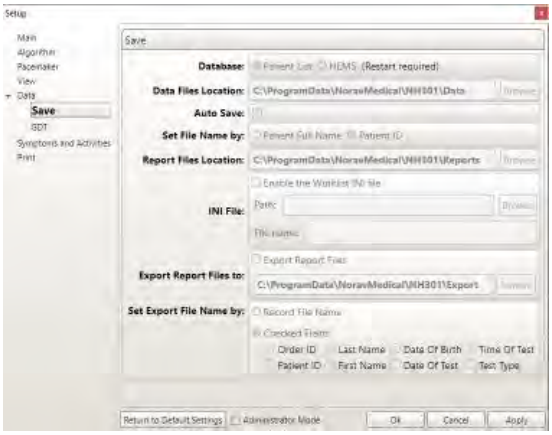
In the "**View**" setting you may load an image with the logo of your hospital / clinic or any other pictogram. Use the button *Browse* to select the image file which will appear in the top right corner of your printed reports.



You may switch on or off some filters for the display. The *EMG filter* reduces high frequency noise such as muscle artifacts. The *Base Line filter* reduces slow wave artifacts which may appear when the Patient made heavy movements.
The *Mains filter* reduces noise which is introduced by power supplies or machines which emit electric energy. When activating the *Mains filter* you must select also the local frequency of the mains power supply (50Hz or 60Hz).
For setting the view of *Display Size* adjust the required value in Inches by using the arrows.
To not display event types with zero occurrences, tick the *Hide empty events* checkbox. Otherwise remove the tick from the checkbox.

Hide the Channels that are not Analyzed – enable this option to not display on screen and exclude from printouts the ECG channels not included in the automatic analysis. This option helps by hiding a very noisy ECG channel.

The setting "**Save**" is to setup the default path where the analysis results will be stored. When working in the "Patient List" mode use the *Browse* button to select the path for the data files location. When the *NEMS* option is selected the data files path is handled by the NEMS.



When the option *Auto save* is activated, any changes to the analysis results such as beat editing or event editing are saved automatically upon closing the patient recording.

With Set *File Name by:* You may select to store the data as the Patients' full name or only as the Patients' ID.

Report files location - to set the location to store the report files to.

The data store options are read-only in the User Mode setup. To activate the *Administrator Mode setup* – mark the check box at the bottom of the setup panel.
The administrator's password is "*norav*".

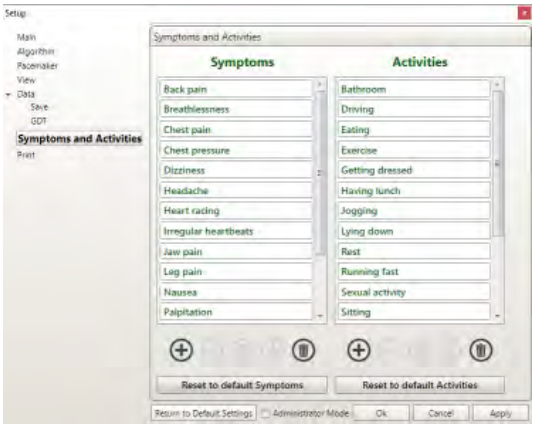
Enable the Worklist INI file - enables reading the patient names from a pre-defined list (a Worklist) during the Prepare Recorder procedure. Fill in setup the INI file folder path and the filename.

Export Report Files – enables saving PDF reports to an external folder. PDF report filenames can be generated according to the ECG recoding filenames or a combination of the patient and record data. Mark the appropriate check boxes to include the necessary data in the PDF report filename.

The setting "**GDT**" allows to setup a communication with and EHR system via the GDT protocol interface. The GDT communication works in the "Patient List" database mode only. It does not work in the "NEMS" database mode.

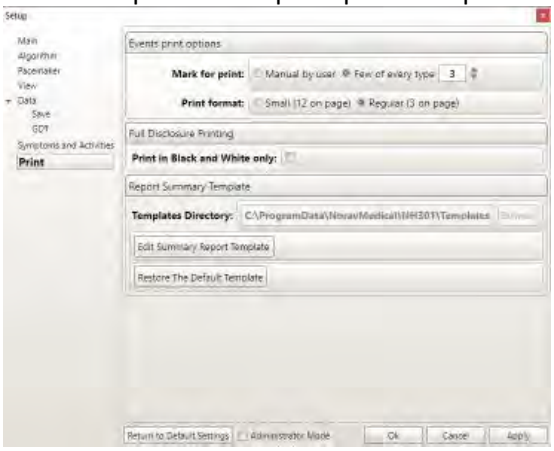
The GDT panel is active in the *Administrator Mode* setup.

The "**Symptoms and Activities**" panel contains predefined lists of symptoms and activities to be used with the Patient Diary feature. The user can edit the items, add new item or remove an existing item.



Clicking on *Reset to default…* button will restore the appropriate list to its original state.

The “**Print**” panel sets up the printed reports content and layout. With *Mark for print* you may choose whether to select “manually” all example strips for your report or whether the software should “automatically” mark some example strips for the report. If you choose “Few of every type” then you will have to select how many ECG strips of each event type should be printed.



With *Print format* you may select whether you want to have 12 ECGs on one page (small strips) or only 3 ECG strips (large).

Print in Black and White only – enable this check box to print reports in black and white mode.

Report Summary Template is a tool for preparing and editing the templates of user customized reports. Templates are separate files stored in the *Template Directory* path.

Clicking on the *Edit Summary Report Template* button will launch the Template Editor tool. The user can load and edit the existing template or create a new template.

Clicking on the *Restore the Default Template* button resets the Default Template file to the initial state in case user made changes in this template. Effects only the Default Template file. All other templates created by the user will remain unchanged.

When you return to the *Setup* dialogue from any of the other display tabs after applying changes to the settings, it will affect the existing results. In order to ensure that your changes become active you must reanalyze the whole recording.

Storage, cleaning and disposal of CD and software protection key

Conditions for Operation-, storage- and transportation

Operating temperature	**+5°C to +35°C**
Storage- and transportation temperature	**-20°C to +50°C**
Operating atmospheric pressure	**68kPa to 106kPa (680mB to 1060mB)**
Atmospheric pressure for storage and transportation	**68kPa to 106kPa (680mB to 1060mB)**
Operating humidity	**0% to 75% RH, non-condensing**
Humidity for storage and transportation	**10% to 90% RH, non-condensing**

During storage avoid exposure to extreme temperatures, humidity, dust or vibrations. Do not expose the CD or the software protection key to direct sunlight or any other UVA/UVB radiation.

Cleaning of CDs or software protection key

Cleaning of CDs should be done with a CD cleaning kit, may also be done with a normal clean cotton cloth.
Do not clean the CD or the software protection key with a solvent or with cleaning agents.

Disposal of CDs and software protection key

CDs and software protection key

- Dispose the software protection key as prescribed by your local regulations
- Before disposing CDs you should **ensure that no confidential data remain on the CD**
- It is best choice to destroy the CD using a shredder and then dispose of the plastic material as prescribed by your local regulations

4. Holter Recording

This is a short general description how to prepare and perform a Holter recording. For details about the setup and operation of the recorder please refer to the relevant operating manual.

Follow the appropriate steps listed below. The steps sequence can vary per Holter recorder model and the type of connection to the NH-301 systems' computer.

- Hook up patient
- Connect the recorder or the recorders' memory card to the NH-301 systems' computer
- Enter the patient data
- Set the recording duration limit and other parameters
- Check the ECG lead quality
- Upload the patient data and the recording parameters to the recorders' memory
- Initiate the recorder
- Verify/change the data in the recorder
- Start recording

Step #1: Patient preparation

The signal quality of a Holter recording is dependent on the quality of the electrodes used and on the skin preparation. Always ensure that the electrodes which you are planning to use have not exceeded their shelf life. Insufficient skin preparation, bad electrodes or wrong electrode positions may cause artifacts and therefore, a great deal of extra work for the person who has to analyze and review the recorded data!

Skin preparation

Some basic rules which should help to ensure good electrode placement and good recording results:

1. Find the correct electrode locations according to the drawings on the next pages or as described in the recorders operating manual.
2. If necessary shave the area of the electrode positions.
3. Scrub each electrode site in order to remove the dead skin, as well as the skin oil and dirt. For proper cleaning you may use an abrasive skin cleaner paste which consists of soap and pumice.
4. Clean the scrubbed site with physician approved alcohol.

Don't use electrode spray which is used for exercise tests to clean the skin.
Such fluids are not suitable for disposable electrodes.

Electrode placement

1. Only use high quality disposable electrodes with solid gel which are designed to be used for Holter recordings.

2. First connect the recorder input leads snap on contacts with the electrode press on studs. When you first place the electrode on the Patient's chest the electrode gel may be squeezed out which can lead to poor electrode impedance.

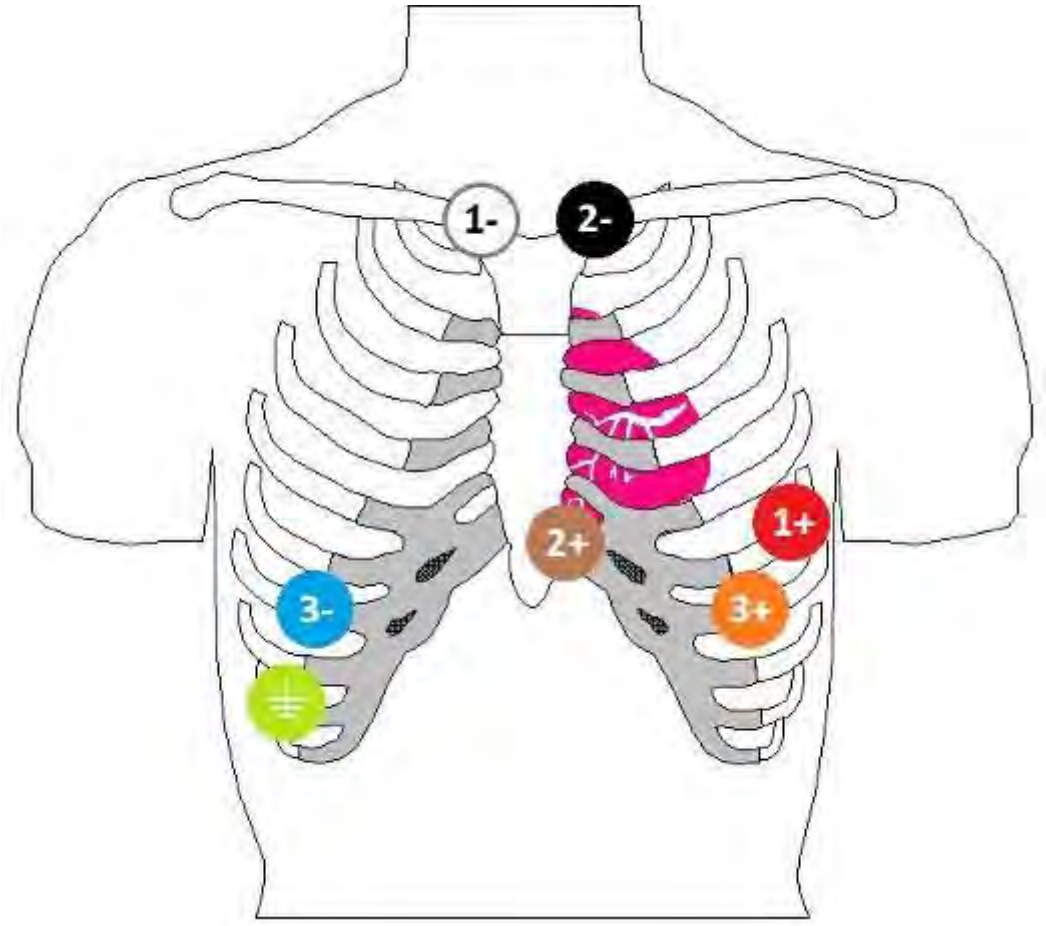
3. Place the electrodes on the desired, properly cleaned locations.

4. Always apply a circular stress relief loop on each electrode lead about 1.5 inches away from the electrode site. This is to ensure that body movements do not cause electrode artifacts.

There are different lead number versions of input cables available for the Norav Medical Holter recorders. The Norav Medical NH-301 Holter application automatically detects the number of channels recorded.

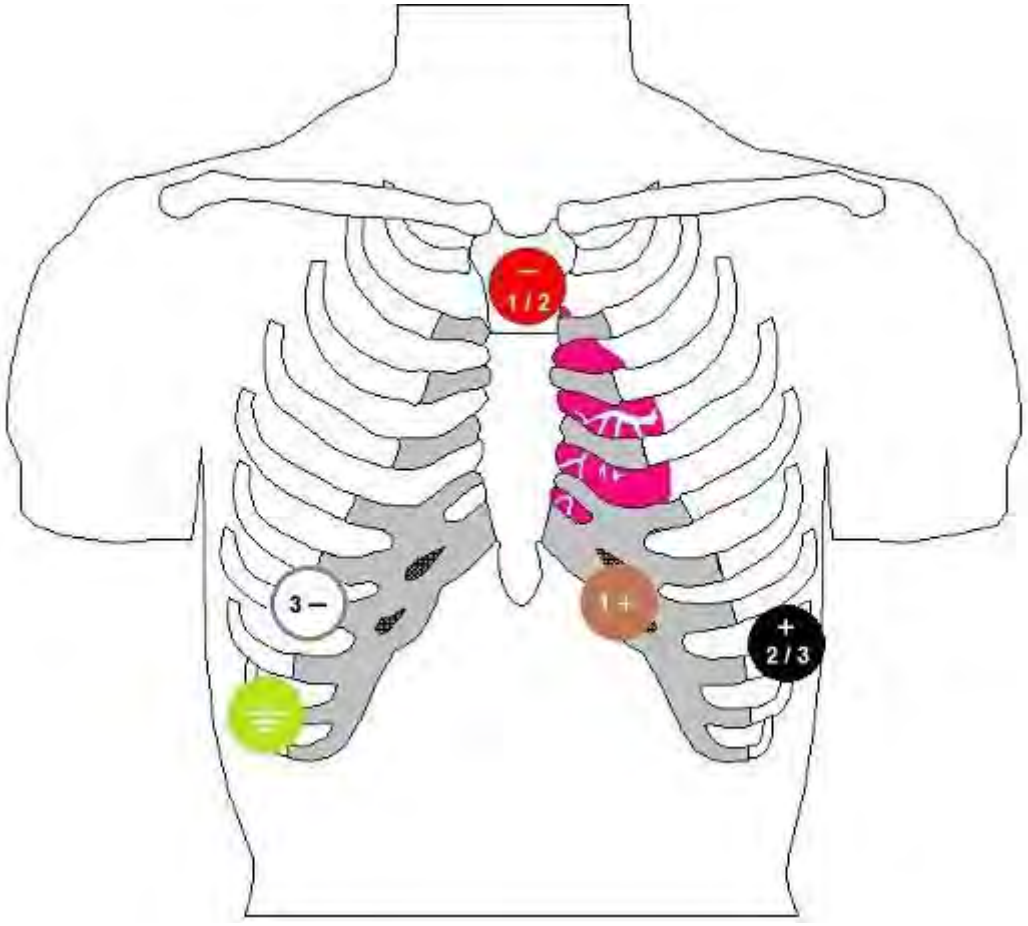
Recommended electrode placement for 3 channels with 7 leads input cable

Channel	Colour	Placement
Ch 1 –	White	Right border of manubrium of the sternum.
Ch 1 +	Red	Left anterior axillary line on the 6th costal arch.
Ch 2 –	Black	Left border of manubrium of the sternum.
Ch 2 +	Brown	Approximately 1 inch left of the xiphoid process.
Ch 3 –	Blue	Right mid clavicular line on the 7th costal arch.
Ch 3 +	Orange	Left mid clavicular line on the 7th costal arch.
Gnd	Green	Lower right costal arch.



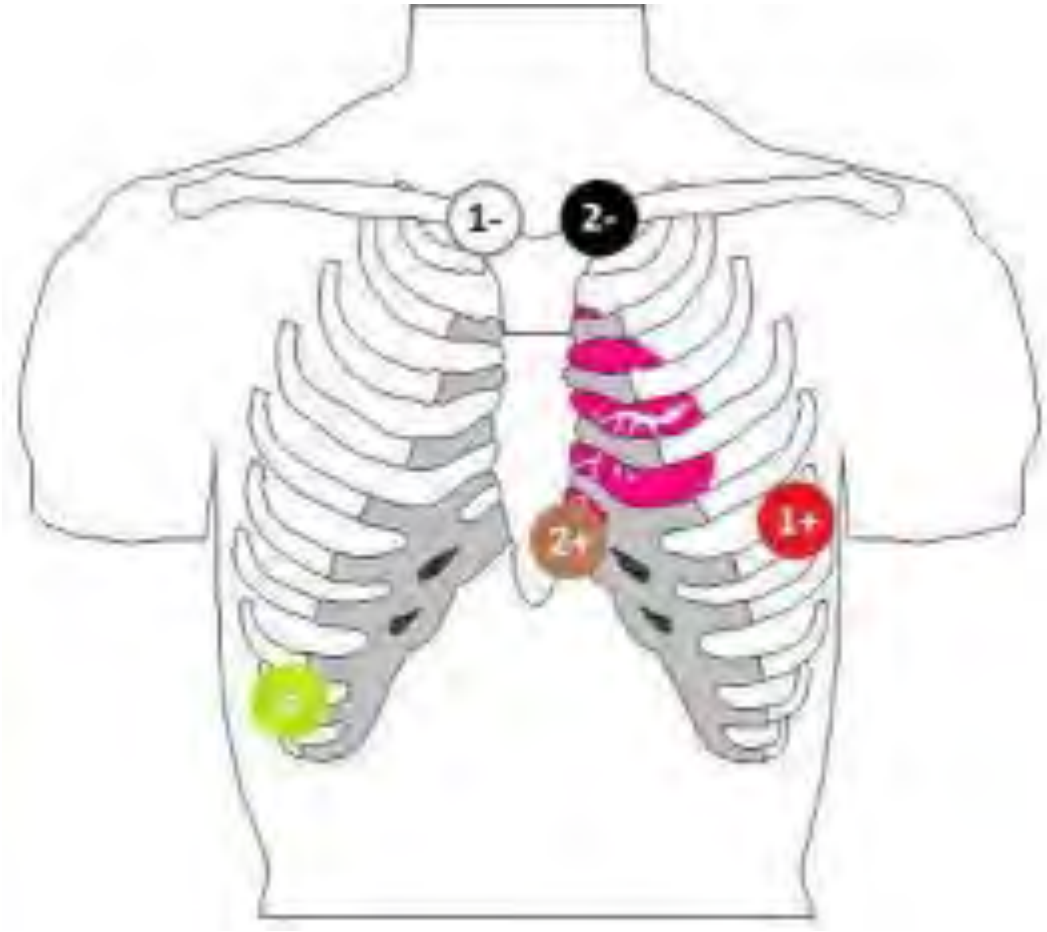
Recommended electrode placement for 3 channels with 5 leads input cable

Channel	Colour	Placement
Ch 1 – Ch 2 –	Red	Center of manubrium of the sternum.
Ch 1 +	Brown	Approximately 2 inch left of the xiphoid process.
Ch 2 + Ch 3 +	Black	Left anterior axillary line on the 8th costal arch.
Ch 3 –	White	Right mid clavicular line on the 7th costal arch.
Gnd	Green	Lower right costal arch.



Recommended electrode placement for 2 channels with 5 leads input cable

Channel	Colour	Placement
Ch 1 –	White	Right border of manubrium of the sternum.
Ch 1 +	Red	Left anterior axillary line on the 6th costal arch.
Ch 2 –	Black	Left border of manubrium of the sternum.
Ch 2 +	Brown	Approximately 1 inch left of the xiphoid process.
Gnd	Green	Lower right costal arch.

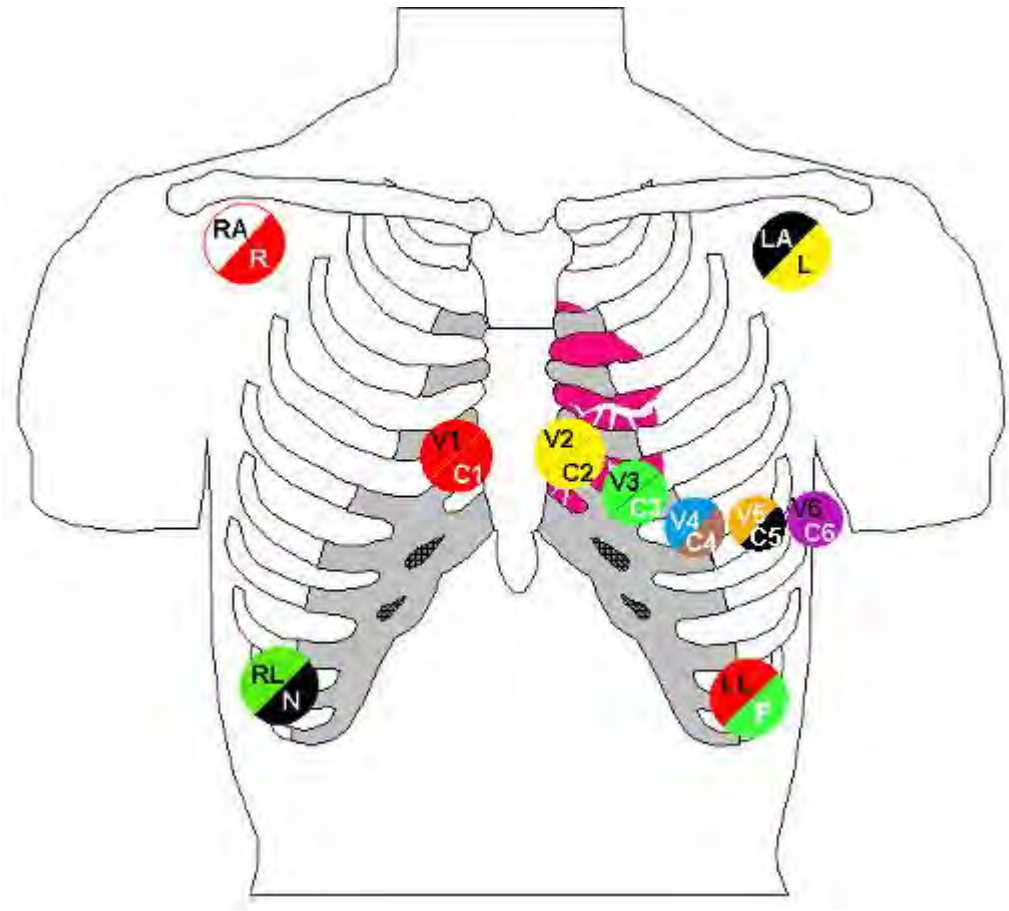


Recommended electrode placement for 3 channels with 3 leads input cable

Channel	Colour	Placement
Ch 1 – **Ch 2 –**	**White**	**Right mid-clavicular.**
Ch 1 + **Ch 3 +**	**Red**	**Left anterior axillary line on the 6th costal arch.**
Ch 2 + **Ch 3 -**	**Black**	**Left mid-clavicular.**

#	AHA Color	AHA Lead	IEC Color	IEC Lead	Placement
1	Red	V1	Red	C1	Fourth intercostal space at the right border of the sternum
2	Yellow	V2	Yellow	C2	Fourth intercostal space at the left border of the sternum
3	Green	V3	Green	C3	Midway between location V2 and V4
4	Blue	V4	Brown	C4	At the midclavicular line in the fifth intercostal space
5	Orange	V5	Black	C5	At the anterior axillary line on the same horizontal level as V4
6	Violet	V6	Violet	C6	At the midaxillary line on the same horizontal level as V4 and V5
7	Black	LA	Yellow	L	Left shoulder
8	Red	LL	Green	F	Lower edge of the rib cage, or at the level of the umbilicus at the midclavicular line
9	Green	RL	Black	N	Lower edge of the rib cage, or at the level of the umbilicus at the midclavicular line
10	White	RA	Red	R	Right shoulder

Recommended electrode placement for 12-ECG channels with 10 leads input cable



Step #2: Recorder Preparation

The Holter recorder should be inspected regularly for signs of damage (especially the input leads!) in order to avoid trouble during the hook up to the Patient.

Before starting a new recording check that the recorder memory does not contain a previous recording. If a recording exists first download it and then clean the recorder memory.

Insert a new battery(s) according to the recorders' specifications.

Connect the recorder to the NH-301 systems' computer:

Option #1: connection via USB

Applicable to NR-302, NR-314, NR-1207 and DL900 recorders

- Validate that a battery is not inserted in the recorder.
- Check that a Flash Card is in the recorder.
- Detach the ECG cable from the recorder and then attach a USB cable instead.
- Connect the recorder to a USB port on the NH-301 systems' computer.

Option #2: via Flash Card Reader

Applicable to NR-302, NR-314, NR-1207, DL800 and DL1200 recorders

- Extract the Flash Card from the recorder.
- Insert the Flash Card into the Card Reader.
- Connect the Card Reader to a USB port on the NH-301 systems' computer.

Option #3: wireless connection via Bluetooth

Applicable to NR-314 and NR-1207 Bluetooth-enabled recorders only

- Hook up patient
- Validate that a Flash Card is inserted in the recorder.
- Attach the ECG cable to the recorder.
- Insert a battery into the recorder.
- Turn the recorder ON.

Step #3: Enter Patient Details

For "Patient List" mode. To prepare the recorder in "NEMS" mode refer to the NEMS user manual.

Click the *Prepare recorder* button on the Patient List panel tool bar

Enter Patient details or select a patient from the Work List and click the Next button.

NOTE

The Work List panel is visible only if the *Enable the Worklist INI file* option is marked in the setup.

Select the recorder from the available recorders list and click the Next button.

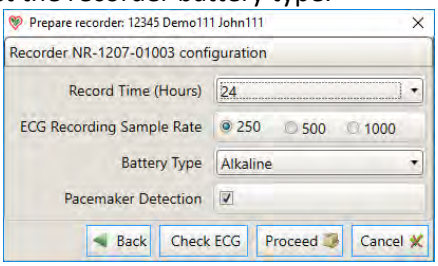
For DL800/DL900/DL1200 model recorders: The preparation procedure is completed. The patient data is uploaded to the recorders' memory card.
Skip to Step #6.

For NR-302/NR-314/NR-1207 recorders: Continue to Step #4 to adjust the recording settings.

Step #4: Adjust Recording Settings

Applicable to NR-302/314/1207 models only

Adjust the recording settings: the recording duration limit, ECG sampling rate, enable/disable the pacemaker pulse detector, select the recorder battery type.



For Bluetooth connected NR-314/1207 recorders: click the *Check ECG* button to start the ECG Lead Quality Check procedure (Step #5).

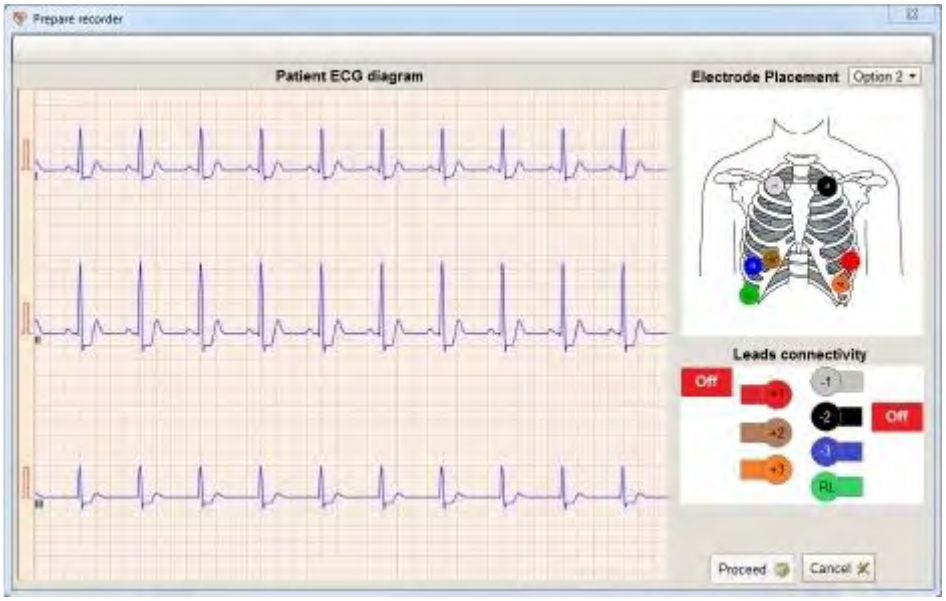
For USB connected NR-302/314/1207 recorders: click the *Proceed* button. The preparation procedure is completed. The patient data is uploaded to the recorders' memory card.
Skip to Step #6.

Step #5: ECG Lead Quality Check

Applicable to NR-314/1207 models connected via Bluetooth only

There are ECG traces running for each channel and a torso image with recommended electrode placements. The electrodes status is displayed beneath the image of the torso. If an electrode is loose, a Lead OFF red label will begin flashing near the respective electrode.

The ECG shown on the preview screen is used for lead quality check only.
Do not use these ECG waveforms for diagnostic purposes.



Once the lead quality is validated, click on the *Proceed* button. The preparation procedure is completed. The patient data is uploaded to the recorders' memory card.
Go to Step #6.

Step #6: Initiate Recorder

For recorders prepared via USB

Applicable to NR-302, NR-314, NR-1207 and DL900 recorders

- Disconnect the recorder from the USB port of the computer.
- Detach the USB cable from the recorder.
- Connect the ECG cable of the prepared patient.
- Insert a new battery in the recorder, switch the recorder to ON.
- Validate that the recorder's screen turns on.

For recorders prepared via a Flash Card Reader

Applicable to NR-302, NR-314, NR-1207, DL800 and DL1200 recorders

- Extract a Flash Card from the card reader.
- Insert the Flash Card to the recorder of prepared patient.
- Insert a new battery in the recorder, switch the recorder ON.
- Validate that the recorder's screen turns on.

For recorders prepared via Bluetooth

Applicable to NR-314 and NR-1207 Bluetooth-enabled recorders only

- Validate that the recorder's screen turns on.

Step #7: Verify the Data in Recorder

For details about the setup and operation of the recorder refer to the recorder's operating manual

Verify (and if necessary change) the information uploaded to the recorder: patient data, recording duration limit, internal clock, pacemaker detection and other parameters.

Validate the lead connections and the quality of the ECG traces displayed on the recorders' screen.

Step #8: Start Recording

Refer to the instructions of the relevant recorders operating manual to start the recording.

5. Download and Analysis of a Holter Recording

If you are using the Norav Medical NH-301 Holter software for the first time after installing please ensure that the software has been setup correctly and that all preferences have been checked. Refer to chapter Installation.

General information

Before a Holter recording can be analyzed the recorded data has to be uploaded from the Flash Card or directly from the recorder (if applicable).
Once the data has been uploaded, the Flash Card can be used for the next recording. The Norav Medical NH-301 Holter software reads and analyzes the data and provides comprehensive facilities to review and edit the recorded data and finally to create a report with your findings.
The analysis process is split into two main parts which are *Beat Analysis* and *Arrhythmia Analysis*.
The *Beat Analysis* locates heart beats and classifies them according to estimated pacing source (N, S, V, F, P). Then the beat analysis builds templates (morphology families) for each annotation type (unless templates were disabled for this type).

If the analysis process is unsure what the pacing source of the beat was, it classifies it as Questionable (Q).

The *Arrhythmia Analysis* automatically follows the *Beat Analysis* and performs several calculations. The analysis detects and\or displays events of the following types of arrhythmia:

Arrhythmia type	Arrhythmia type
• Pauses	• Supra Ventricular Ectopic beats (SVES)
• Bradycardia	• Supra Ventricular Ectopic Pair
• Tachycardia	• Supra Ventricular Ectopic Run (PSVT)
• Ventricular Ectopic Beats (VES or VPB)	• Paced Beats
• Couplet (ventricular)	• ST Events
• Triplet (ventricular)	• Maximum and Minimum Heart Rate
• Ventricular Tachycardia	• Maximum and Minimum RR interval
• Bigeminy (ventricular)	• Patient Events
• Trigeminy (ventricular)	• User defined Events
• Atrial Fibrillation	

Whenever a user edits a beat's interpretation (changes beat types, deletes or adds new beats) the arrhythmia analysis is repeated, and the events are adjusted accordingly. This is unlike beat analysis which is performed only once.

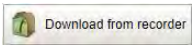
Download the ECG data

For "Patient List" database mode downloading. To download the ECG data in "NEMS" database mode refer to the NEMS operating manual.

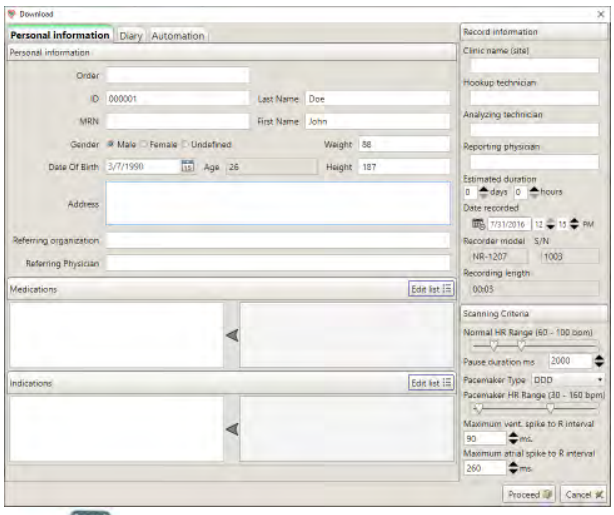
Whenever a patient returns to your office and the recorder has not yet switched off automatically, follow the procedure in the operating manual of the recorder in order to terminate the recording. This process is very important, otherwise the recorder will continue recording and collect artifacts! Depending on the recorder type download the data as follows:

- ***Option #1:*** applicable to NR-302, NR-314, NR-1207, DL800 and DL1200 recorders
  - remove the Flash Card and insert it into the card reader.
- ***Option #2:*** applicable to NR-302, NR-314, NR-1207 and DL900 recorders
  - connect the recorder with the USB cable which came together with the unit.

Start the Norav Medical NH-301 Holter application. The "Patient List" screen allows you either to open an existing recording on the hard drive of your computer or to download a recording from a Flash Card or via USB.

To download the recording from a Flash Card or via USB from the recorder: click 

button on the Patient List tool bar.
As soon as the recording is recognized, the application allows enter the Patient details:



- validate and edit the patient data,

- define the estimated duration for reporting: 24 hours, 48 hours etc.

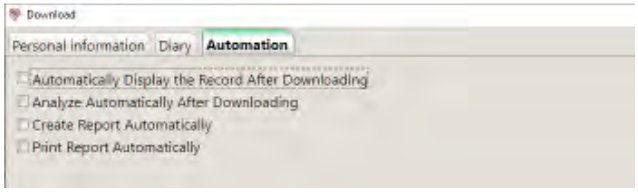
- enter indications, medications,

- adjust scanning criteria: Tachycardia, Bradycardia and Pause thresholds.

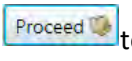
- adjust the pacemaker settings

In order for the software to correctly analyze the operation of the pacemaker, the parameters of the pacemaker must be set in accordance with the actual configuration of the implanted pacemaker of the patient.

– in the Diary tab: enter the Patient Diary items.



– in the Automation tab: select further steps to be performed automatically after the download.

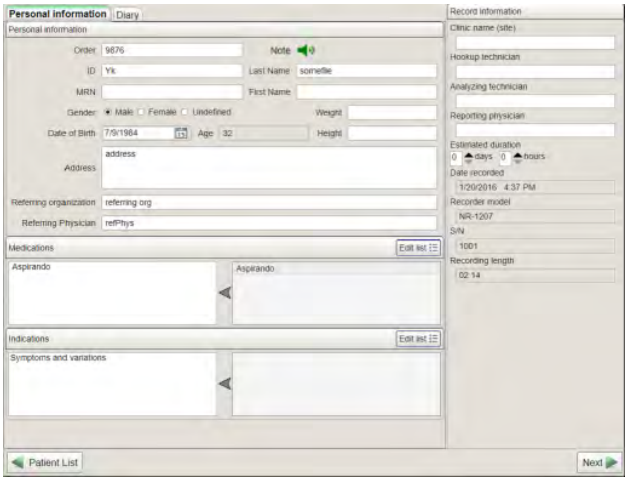
Finally, click 

to begin the download.

To open a recording - select the record in the list and press the 

button.

As soon as the recording is opened, the application allows you to view and edit the Patient details.



Click the 

icon to listen the audible note optionally registered in recorder during the patient hookup (*for NR-314 and NR-1207 only*).

Enter indications and medications or select the relevant entry in the right side list and then copy the text by click on the  arrow button. To add or remove indications or medications internal list, click the 

button.

Click the *Diary* tab to preview and edit the Patient Diary items.

Click the  icon to listen the patient diary audible item optionally noted by patient in the recorder during the study.
(*for NR-314 and NR-1207 only*)

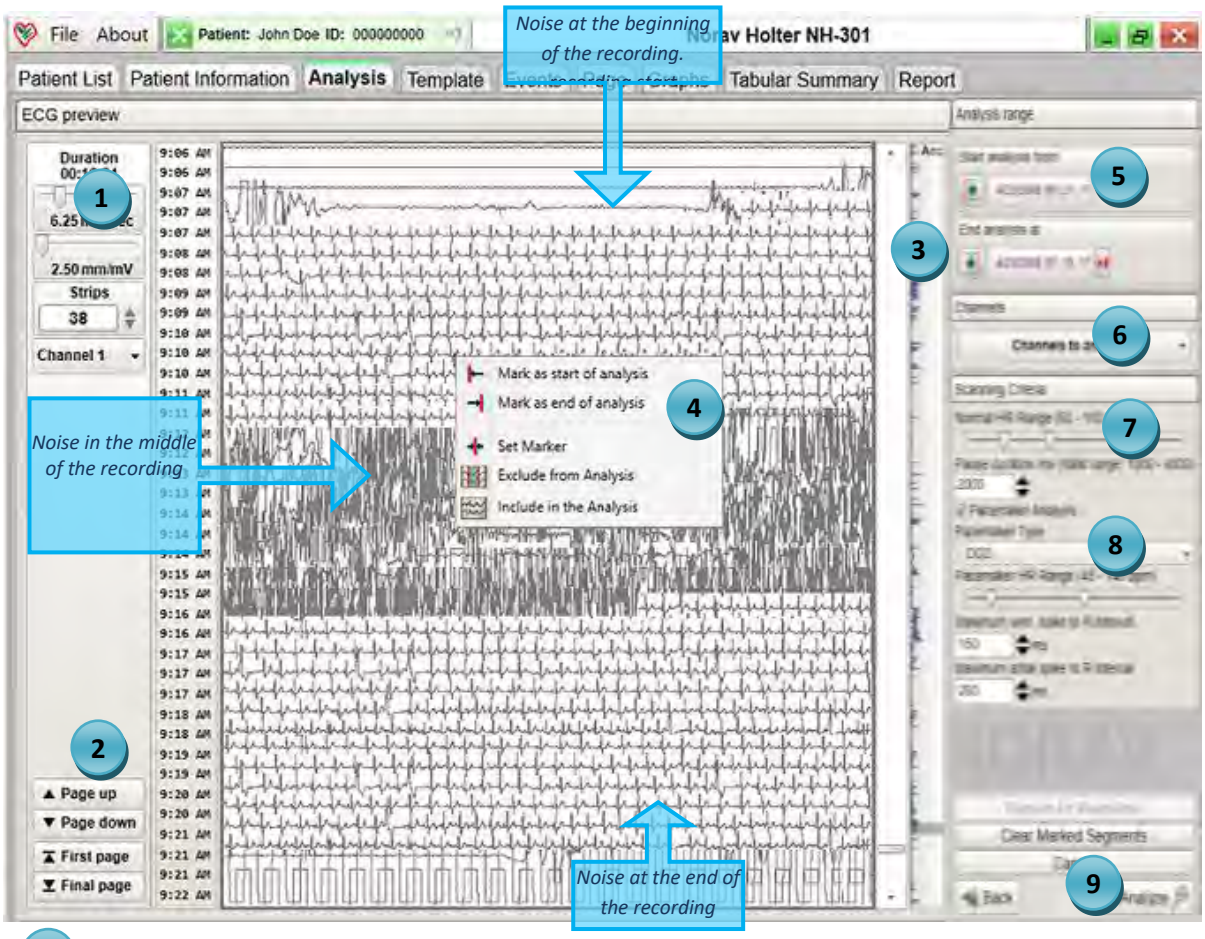
Click the 

button to go to the ECG Overview screen for the analysis.

Click 

to return to the patient List to select a different patient.

Analyzing the ECG data



1 *ECG screen adjustment*: use these controls to adjust the speed and amplitude of the ECG display. Furthermore you may select which channel should be displayed and how many lines or strips should be drawn per page.

2 *Navigation*: if you wish to get a quick overview over the recording use the controls to navigate single pages forwards/backwards or even to skip to the last/first page.

3 *Activity Monitor*: the trend of patient physical activity registered by the accelerometer sensor (*for NR-314 and NR-1207 models only*).

Excluding noisy segments

4 Use the right mouse button context menu to mark the Start and End points of the analysis interval and to exclude the noisy regions in the middle of the recording.

To exclude the noisy region in the middle of the recording – highlight the region by right clicking the mouse and dragging over it & then select the *Exclude from Analysis* command in the context menu.
To exclude a large region from the analysis – place the marker on the regions' start point by clicking on the *Set Marker* command then navigate to the end of the large noisy region and click on the *Exclude from Analysis* command.

To reinsert the excluded region into the analysis – highlight the region then click on the *Include in the Analysis* context menu command.

To remove all the marked segments – click the *Clear Marked Segments* button.

5 *To set the analysis Start or End point* – click the  or  button at the right side panel then click on the ECG point accordingly, or set the Start/End point using the right mouse button context menu.

To cancel the Start or End mark - press on the  or on the  button respectively.

6 *To select which ECG channels to include in the analysis* – click on the *Channels to analyze* button and then mark the desired channels in the drop box list.

Adjusting the scanning criteria

7 *To adjust the scanning criteria* – use the Normal HR Range control to define the Bradycardia and Tachycardia thresholds; use the Pause Duration input box to enter the pause threshold.

Pacemaker analysis settings

8 *To activate or deactivate the pacemaker analysis* – if the pacemaker detection has been switched on in the recorder then this option here appears. Use the *Pacemaker HR Range* control to define the range of heart rate initiated by pacemaker; use the *Maximal atrial spike to R interval* input to define the time limit between atrial spike and the subsequent R-wave; use the *Maximal vent. spike to R interval* input to define the time limit between ventricular spike and the subsequent R-wave.

In order for the software to correctly analyze the operation of the pacemaker, the parameters of the pacemaker must be set in accordance with the actual configuration of the implanted pacemaker of the patient.

Performing the analysis

9 *To start the analysis* process – click on the 

button.
The software will now analyze the ECG data and sort the beats according to their shape and timing in different morphology families / Templates.
The analysis process may take a while. When the analysis has finished the Templates view will appear on screen.

To reanalyze an analyzed recording –click on the *Prepare for Reanalysis* button, then mark segments and launch the analysis.

6. Review and edit an ECG recording

This screen layout allows you to check quickly the results of the beat analysis. If necessary you may edit a single beat annotation or even a complete template annotation. First the various editing tools in the upper pane of the screen are explained and the lower pane is explained subsequently.

1 Here you may see the different beat morphologies found during the beat analysis. Each box is a template that contains beats of similar morphology. Use the left or right arrow buttons or the scroll wheel to go through the beats. If you keep the mouse button pressed on an arrow, the display automatically scans very fast through all beats in the template.

2 Using these icon buttons you may quickly reclassify the selected template or a group of templates. You may also use the drop down menu at the top of each template box. Alternatively it's possible to change or delete a template with the keyboard.

Available corrections are:

Action	Command	Keyboard key
Classify the template as **Normal**	N	Shift + N
Classify the template as **R on T**	R	Shift + R
Classify the template as **Fusion**	F	Shift + F
Classify the template as **VPB**	V	Shift + V
Classify the template as **SVE**	S	Shift + S
Classify template beats as **Questionable**	Q	Shift + Q
Classify template beats as **Paced**	P	Shift + P
Delete the template	*Delete template*	Shift + Delete

3 With these icon buttons you may easily control which templates are visible and which are hidden. You may select first the '**Q**uestionable' beats and edit them. Then proceed with the '**V**entricular' templates and so forth. With the icon button '**All**' you can quickly select or deselect all templates with a single click.
Groups of templates can also be selected when you keep the **CTRL** button pressed while clicking the left mouse button on each template you want to select. To select consecutive templates select the first template in the series and then keep the **SHIFT** key pressed. Now click the last template in the series and all of the templates in between are selected.

4 With the two sliders you may select the appropriate paper speed and amplitude for the display of the template boxes.

5 To control the speed of scanning on screen, select the preferred speed of scanning from the drop-down menu.

6 For printing out the ECG with or without remarks, press on the button and select your preference from the pop-up menu.

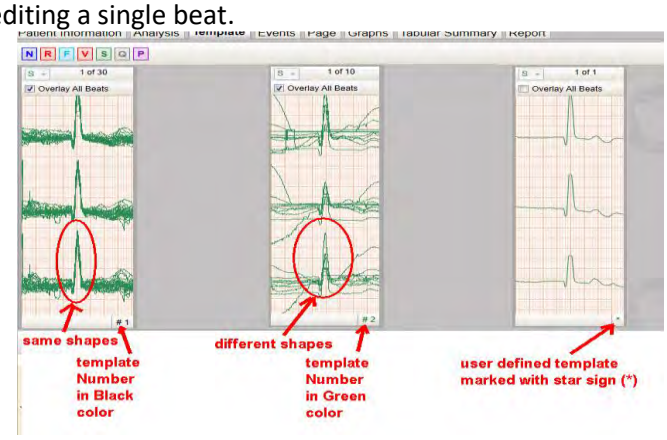
NOTE

To go through large numbers of beats in order to ensure that all beats have been annotated correctly and have been sorted to the right beat families is very time consuming.
The Norav Medical NH-301 Holter software provides you not only with an extremely accurate analysis algorithm but also with outstanding editing features which are described below in detail.

General features

The Norav Medical NH-301 software distinguishes between templates which contain beats of the same morphology and editing templates which contain dissimilar beats or templates which have been generated manually by editing single beats within templates.
The templates have a number in their right bottom corner which reflects the template number as it was generated during analysis and later on during editing.

- If the number is shown in black color, it is a template which was automatically generated and contains clean beats of the same morphology.
- If the number is green, the relevant template is a mixture of beats with different morphologies.
- If only an asterisk is in the bottom right corner then this template has been generated manually by editing a single beat.



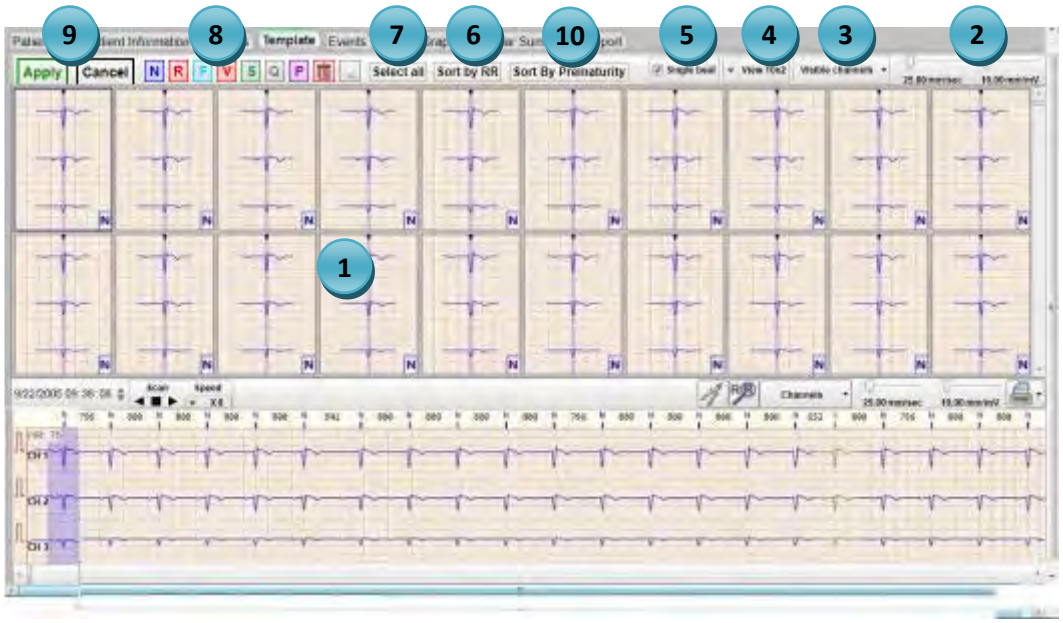
You may quickly scroll through all beats forwards and backwards within a template if you use the scroll wheel of your mouse.

After changing a beats' annotation type (single beat), you may copy this annotation to another beat by simply right clicking on the beat. When you click the right mouse a second time, the previous operation will be cancelled and the beat will return to its original annotation.

Using the combination of **CTRL** or **SHIFT** key with the mouse you may select more templates. Select a template which you wish to change and then hold down the **CTRL** key on your keyboard then click the left mouse button on every template which you wish to select. Now you may for example quickly change the annotation for all selected templates. If you wish to select many templates in series then click the first template. Now hold down the **SHIFT** key on your keyboard and click on the last template in the series. All templates between the first and the last are now selected and ready for a common operation.

Edit Template feature

This feature permits you to view every single beat within a template at a glance for the most thorough inspection possible.
In the relevant template box simply click the right mouse button and choose the option *Edit Template* from the context menu.
The screen layout changes automatically to the one shown here:



1. In this area you can view every single beat of the template which makes it easier to find beats which could be noise or labeled incorrectly due to noise or artifacts.

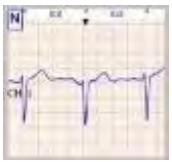
2. Use the slider controls to adjust paper speed and/or amplitude of the single displayed beats.

3. With this drop down control you may select which channel(s) should be displayed.

4. Use this control to set how many beats are shown per row and how many rows should be shown in the window.

5. To view the beat/s previous to the beat of interest unclick Single Beat. This is especially useful in determining prematurity such as VPBs and SVEs. This is easier if you set the above

described display control to view only a few beats per row. If don't wish to view the next and previous beats, tick Single Beat and only the beat of interest is shown in the center of each box.
For the assessment of prematurity you may have to unclick Single Beat to show the adjacent beats again.


Adjacent visible


focus only on beat

6 10 With these options you may view the beats sorted: by their RR interval duration or by beat prematurity.

7 If you wish to rename all beats in the template then you may use the option '**Select All**' to select all beats with one click.

8 With these buttons you may rename the selected beat(s). Alternatively it's possible to change or delete a beat via the keyboard keys. To select more than one beat use the above described method with CTRL key or SHIFT key together with the mouse. The available annotations are:

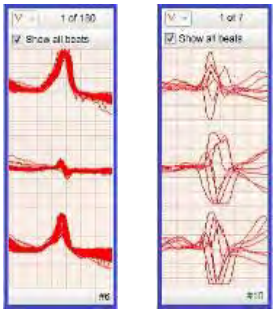
Action	Command button	Keyboard key
Classify beat as **Normal**	N	N
Classify beat as **R on T**	R	R
Classify beat as **Fusion**	F	F
Classify beat as **VPB**	V	V
Classify beat as **SVE**	S	S
Classify beat as **Questionable**	Q	Q
Classify beat as **Paced**	P	P
Delete beat		Delete

9 When you have finished editing click the **Apply** button in order to save your changes. If you wish to terminate without saving any changes just click the **Cancel** button.

Overlay All Beats feature

The function ‘Overlay All Beats’ can be activated on top of each template box. All beats in the template are then superimposed as shown in the examples below.

Depending on the number of beats in a template it can take a few seconds to superimpose all beats. Once superimposed, you can view whether the beats match to the same pattern as can be seen in the left template box.

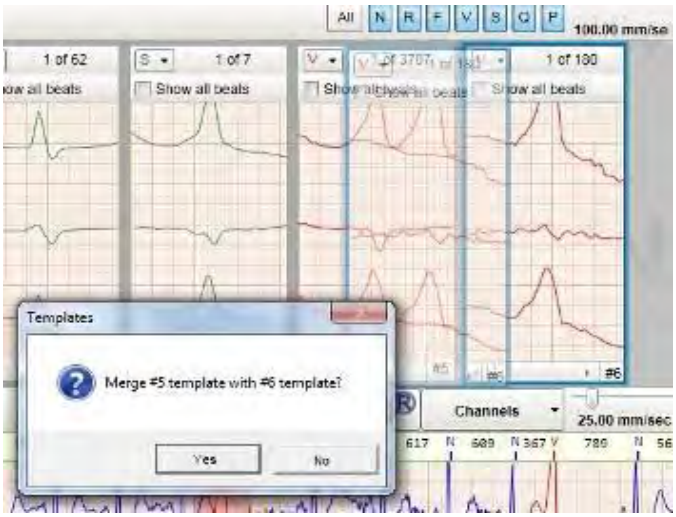


This template box example displays many beats with different shapes which are together in this one template example box. This can happen if, for example beats are manually renamed or if templates have been merged together.

It is recommended that the paper speed of the templates view be set to 100mm/sec. This will enlarge the template view and beat patterns can be inspected more easily.
You may quickly check all templates in Overlay All Beats mode. Just open in the template view the context menu with right mouse click and choose the option “*Select all*”. Then open the context menu again and choose the option “Overlay All Beats”. All templates are switched to the Overlay All Beats mode.

Merge Templates feature

If you have a recording with many templates it may be useful to merge together templates which have almost identical morphology. To merge templates simply click on one of the two templates and ‘drag’ the box with the mouse button pressed over the second template box.



While the mouse button is pressed and the template box moved, it is transparent so that you can double check whether the beat shapes will fit together.

As soon as you release the mouse button to ‘drop’ the template a message box appears as shown here.

Click **Yes** if you wish to merge these templates or **No** if not.

NOTE

The feature *Merge Templates* does not influence the result of the beat analysis either the result of the arrhythmia analysis. It is just to reduce the number of templates if you don’t want to view too many templates.
The Norav Medical NH-301 software can deal with many, many templates and so there is no need to reduce the number but if you prefer to present the report with fewer templates, the *Merge Templates* feature is your first choice.

Mark Reviewed Template feature

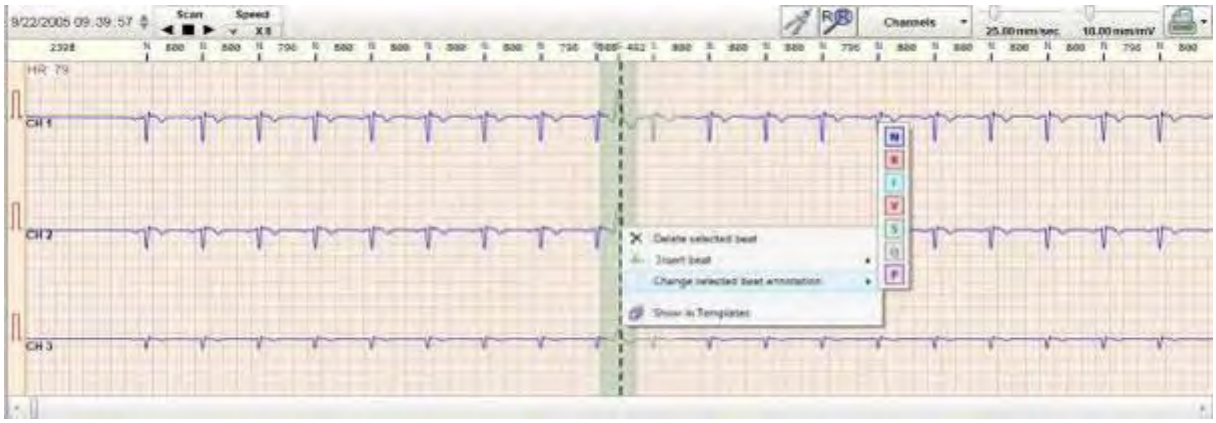
The reviewed templates can be marked to help you distinguish between them and the templates not yet reviewed.

To place a  mark on a reviewed template select a template or a group of templates then press the spacebar or click on the "Add Reviewed Mark" button.

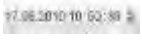
ECG Detailed Strip View

This lower pane of the screen layout will display an ECG Detailed strip of the currently selected beat and the surrounding ECG. The strip contains normally about 12 to 16 seconds of ECG depending on the computer monitor and the settings for paper speed.

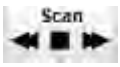
The underlying grid is scaled exactly to millimeters, no matter which computer is used or what size your monitor is!
The Norav Medical NH-301 Holter software automatically adjusts all windows according to the computer graphics and the connected monitor. That means you may use any ruler or even an ECG ruler such as the NORAV Medical ECG ruler and measure size, amplitude, cycles, frequency, RR intervals – whatever you would like to measure.



In the toolbar on top of this detailed ECG view you will notice some icons for additional functions which are:

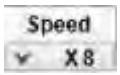


Enter a certain time to view instantly this point in the ECG
Additionally you may use this control to scan through the ECG at different step sizes: Click on the hours and then click the up or down button on the right in order to jump from hour to hour; click on the minutes and use the up or down button to jump in steps of one minute; finally click on the seconds in order to scan through smoothly second by second.
All the above functions work as well with the mouse wheel instead of the up or down buttons.



Use the double arrow buttons to start the automatic scan forward or

backward. With the block button in the center you may stop the scan.



Press to open a pop-up menu to select the preferred scanning speed.

Toggle on/off the calipers for measurement

Toggle on/off the RR interval numbers

Select the channels to be displayed

Change the paper speed and signal amplitude

Press for print out. A pop-up menu is opened to select with or without Remarks.

When you point with the mouse pointer at an ECG strip and drag the mouse while you hold down the left mouse key, you may drag the ECG strip to either side in order to view the very next beats to the ones shown in the strip.

To change or delete a beat in the Strip View

Simply point with the mouse to the relevant beat and then right click the mouse button in order to open the context menu as shown below. Alternatively it's possible to reclassify or delete a beat by using keyboard keys.

Action	Mouse command	Keyboard key
Classify the beat as **Normal**	N	N
Classify the beat as **R on T**	R	R
Classify the beat as **Fusion**	F	F
Classify the beat as **VPB**	V	V
Classify the beat as **SVE**	S	S
Classify the beat as **Questionable**	Q	Q
Classify the beat as **Paced**	P	P
Delete the beat	X	Delete

To Insert a Beat in the Strip View

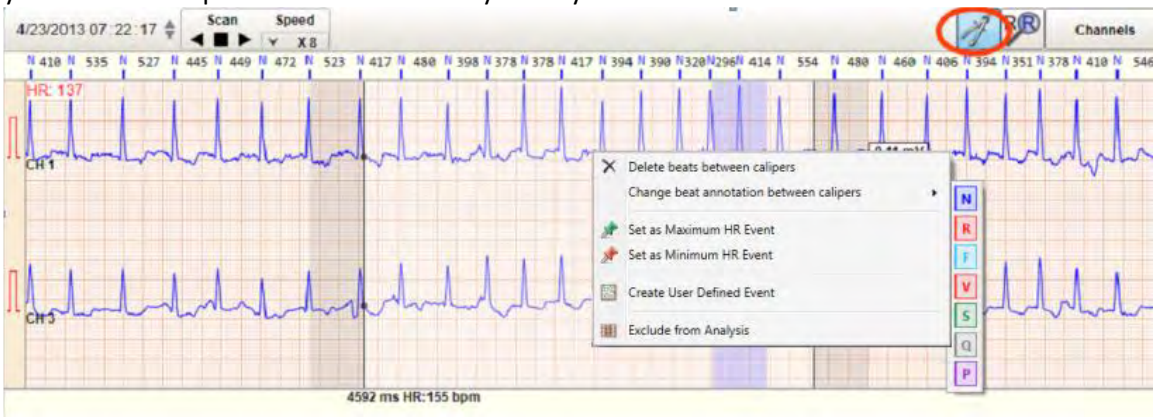
Select the Insert Beat command in the drop down menu which allows you to select the beat type.

"Show in Templates"

This command highlights the template that includes the beat. It's displayed in the upper view of the screen.

Measuring ECG

To measure the RR interval or the amplitude at the cursor position, use the Caliper function. When you click the Caliper icon in the tool bar you may notice two cursor lines as shown below.



Each cursor may be moved separately. Just move the mouse pointer to the cursor line and the mouse pointer changes to a double arrow icon. Now click and keep the left mouse button pressed while dragging the mouse to the new position and then release the mouse button.

To keep the caliper distance and move to a different spot to check if the interval is the same, just move the mouse pointer to the area between the two cursors(the mouse pointer changes to a hand) and drag the caliper to the desired location.

For each channel in the strip a little window at the right of the cursors shows the measured amplitude difference between both cursors.
Below the two cursors you see the distance in milliseconds and the relevant heart rate.

To edit the annotations in the caliper

Drag to the desired interval & hold shift while clicking on right mouse button. A pop-up menu appears with following options:

- '*Delete beats between calipers*' – the selected beats marks will be removed and then the not counted in the analysis.

NOTE

Beat deletion might generate Pause events. To mark noisy segment use the '*Exclude from Analysis*' command instead of '*Delete beats…*'

- '*Change beat annotation between calipers*' – use this command to manually reclassify all beats in the selected interval.

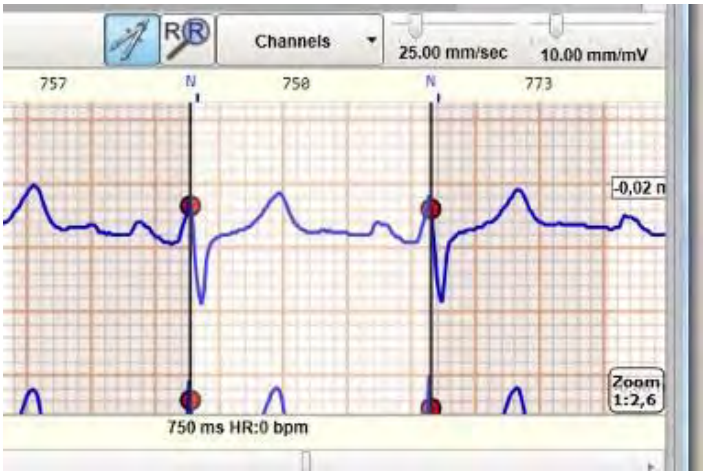
- Commands '*Maximum Heart Rate*' / '*Minimum Heart Rate*' allows assigning the selected interval as the maximal or minimal HR.

- '*Create a User Defined Event*' - use this command to create a new User Event.

- '*Exclude from Analysis*' – use this option to mark a noisy segment. The segment will not be included in the HR and RR calculations. Unlike beat deletion, it does not produce a lower HR or generate wider RR intervals.

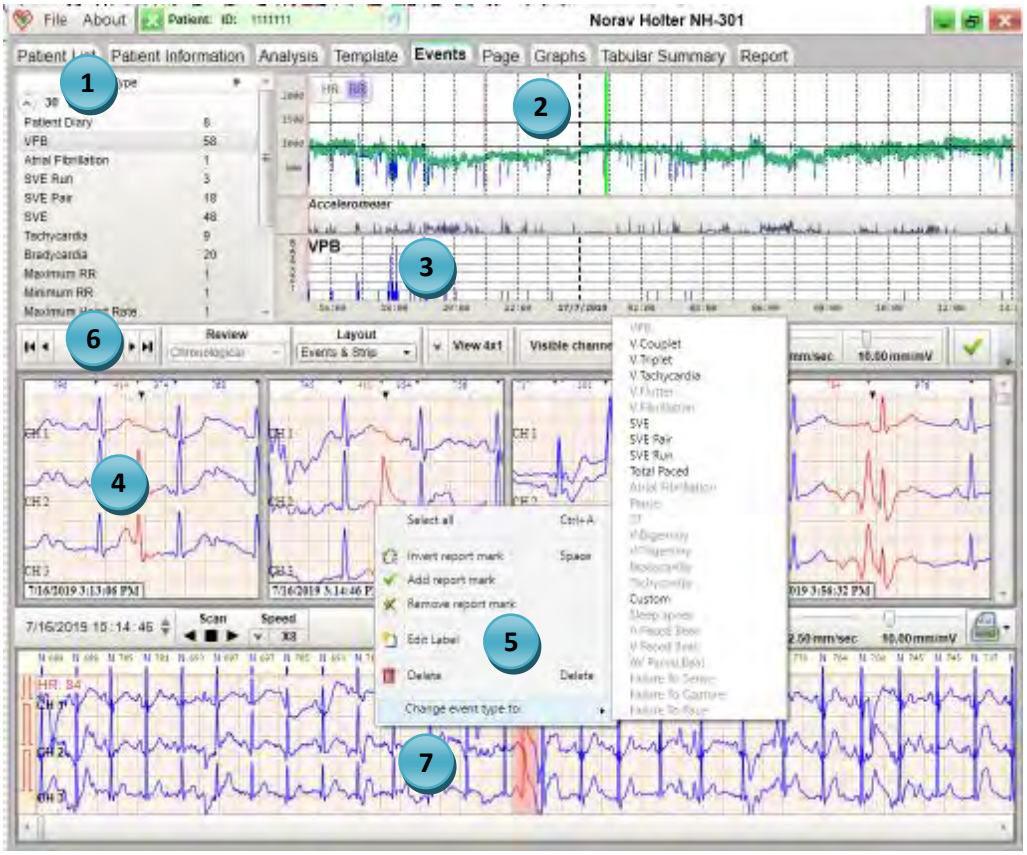
Zoom in/out

If you wish to view more details of the signal you may zoom in the ECG display, simply press the **Ctrl** key on your keyboard while using the mouse wheel. Turning forward will zoom in and turning backward will zoom out. In order to quickly return to the original size, just click the small **Zoom** icon on the right bottom corner.



Event view (arrhythmia overview)

The ‘Events’ tab enables you to assess the arrhythmias which have been detected by the analysis software. You may quickly go through the example strips, look at overall trend views and use several editing functions which are explained below.



1 ***Event List***

This list displays the different arrhythmia types which were found in the recording. With the arrow buttons on the left you can expand or minimize the list. Furthermore, you may select to display all strips in the middle pane which have been selected for printing or even ALL example strips together.

2 ***HR/RR Trends***

On the upper edge of the trend display you will notice these buttons: 

The buttons allow you to set the trend display to show either the Heart Rate (**HR**) or the RR intervals (**RR**).

If you wish to view instantly the ECG strip with the fastest heart rate, just select “*Maximum Heart Rate*” from the Event list. The 

toolbar will appear. (The “Pin” Icon is green).

To view the ECG strip with the lowest heart rate, select “*Minimum Heart Rate*” from the Event list. The 

toolbar will appear. (The “Pin” Icon is red).

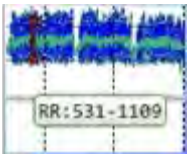
If you wish to view instantly the ECG strip with the longest RR interval select “*Maximum RR*” from the Event list. The 

toolbar will appear. (The “Pin” Icon is green).

Select “*Minimum RR*” from the Event list to view the ECG strip with the shortest RR interval. The 

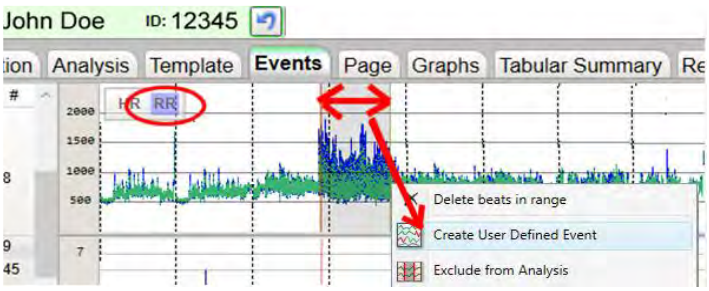
toolbar will appear. (The “Pin” Icon is red).

The left and right pointing arrow buttons allow you to scroll the ECG strip to the next slower or faster heart rate or the next longer or shorter RR interval respectively.
If you don't agree with the example strips for maximum or minimum you may select a different strip manually by using the mouse to move the marker and press on the "Pin" button on the toolbar.



When you point with the mouse to a certain point within the trend a little text box appears as shown here. It exactly displays the values of either the heart rate or the RR interval duration.

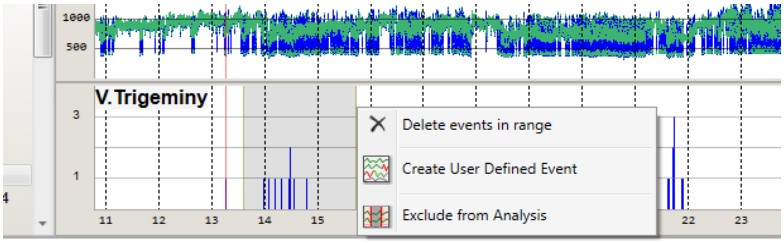
Some actions are allowed directly on the trend when it is in RR mode. You may define an Event, exclude a noisy segment, or delete group of beats.



To select the region on the trend right click and drag the mouse, then choose the necessary action in the command menu.

3 *Histogram*

Under the trend view you will found the histogram panel with the number of occurrences of the selected arrhythmia type. The histogram is editable same way like it is on the RR trend above.

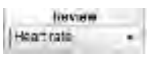


You may select the interval by right clicking and dragging the mouse, then define an Event, or exclude a noisy segment, or delete events in the selected range.

4 *Events Overview Panel*

On top of the middle pane you will notice a tool bar with several buttons which allow you to set up the display of example strips and the lower pane. The functions of the buttons are explained below.

Page through the example strips of the currently selected strip example. With the two outside buttons you may call up quickly the first or last strip.



Use this drop down menu to select the order the example strips will be sorted in the middle pane either by : Heart rate; Chronological; Duration

This setting allows you to select the display layout of both the middle and lower panes. You may show Events in the middle pane and a full disclosure or detailed strip view in the lower pane (as shown here) or any other combination.

With this function you may adjust the amount of arrhythmia strips shown. You may select the number of columns and lines with a simple selection tool as shown here.

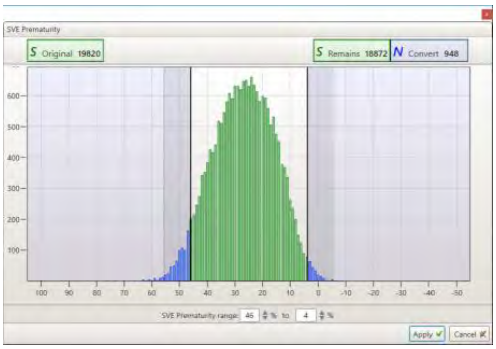
Select here which channels should be displayed in the strips within the middle pane.

These buttons allow you to adjust the strip display to show the arrhythmias' start or end, or the most severe point (point of interest) of the arrhythmia.

Using the sliders you may adjust the paper speed and amplitude of the strip display of the middle pane.

With these two buttons you may select or deselect a strip for being included or excluded from the final report.

Press this button to manually refine the beat prematurity range of the SVE events. Adjust the left and right markers position on the histogram and then click Apply. SVE beats whose prematurity lays outside of the selected range will be converted to Normal.

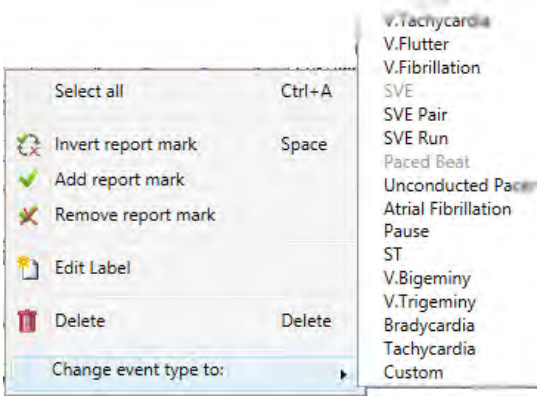


Press this button to delete the selected event.

Your last settings are stored automatically per arrhythmia type. The next time you open the Event view it will present the results to you as you set it up the last time.

Click the right mouse button on the event strip in order to open a context menu.

With a click on **Select all** you may select all strip windows in order to apply changes to all strips such as "include in report".



The next three options allow selecting or unselecting a strip to be included in the report. With the **Invert report mark** you simply unmark a marked strip or mark an unmarked strip. *Alternatively, the report mark can be toggled by using the Spacebar.*

Change event type to: allows reclassifying selected events as a different event type, for instance you can change an ***SVE Run*** event to ***Atrial Fibrillation*** or convert a ***Triplet*** to a ***Couplet*** etc.

The option **Edit Label** allows you to add an extra comment to the selected strip. Just type the comment in the text box which appears and then click the **OK** button.
With **Delete** you may delete the selected events. P*ressing on the Delete key will also delete*.

You may use the Ctrl, Shift and cursor keys on the keyboard to select and navigate between certain event strips or even select a complete series of events.

6 The green line on top of each event strip represents the duration of the event and shows the RR interval values.

7 ***ECG Preview Panel***

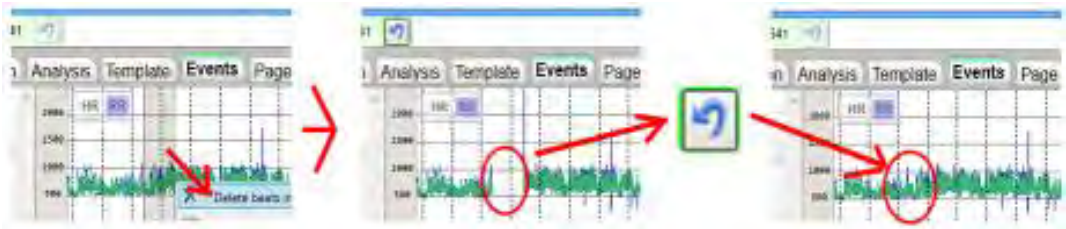
The lower panel can display either a "strip" or a "page" (full disclosure).
Here you may preview and scan the ECG traces, create a user defined event, reclassify or delete beats, exclude noisy segments, and print out the ECG examples.

Undo changes

You can undo recent edits, additions and deletions of beats, events and templates.

To cancel the last change click the "Undo" button on the main toolbar or press 'Ctrl-Z'. The process can be repeated to undo preceding commands.

Example:



A B C

- In 'A' a region is selected for beat deletion.
- In 'B' the beats are deleted from the region. The user decides this is a mistake.
- In 'C' the beats are restored thanks to Undo.

You can undo recent edits, additions and deletions of beats, events and templates.

To cancel the last change click .

Page view

The screen layout ‘Page’ displays the entire ECG data as Full Disclosure and allows you to scroll page forward and backward from the beginning to end of the study in order to review the complete recording.

1 *ECG Size and Scale*

Use the mouse to drag and drop the slider of this control to set the paper speed. You may also click at either side of the slider to switch to the next available speed. Speed settings are: **1.56**; **3.12**; **6.25**; **12.5 or 25mm/sec**.

Same as the paper speed control you may use this control to set the amplitude of the display. Available settings are: **5**; **10**; **20**; **40 or 80mm/mV**.

Use this control to select the channel which you wish to display.

Here you may choose the number of ECG strips which are displayed. You may either enter a number between **1** and **100** or simply use the two arrow buttons on the right to increase or decrease the number.

With the option displaying events you may highlight the events which have been discovered by the automatic analysis.

2 *Page Navigation*

This control block allows you to scroll **Page up** or **Page down** in order to view the next or previous page of ECG. If you wish to quickly view the end or the beginning of the recording use the two controls **First page** or **Final page** in order to switch to the commence or end of the ECG recording.

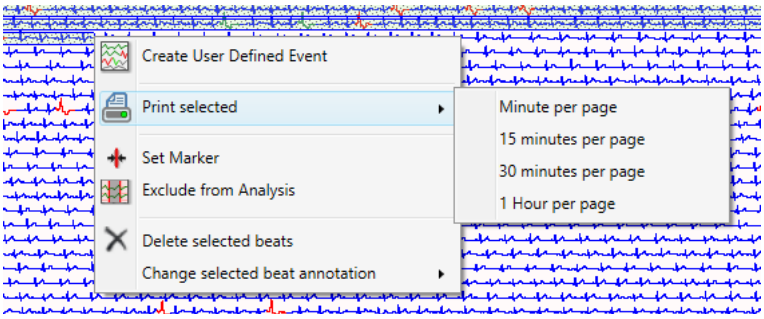
3 *ECG Detailed Strip*

At the bottom of the screen layout you will notice the ECG Detailed strip view.

4 *Full Disclosure Page*

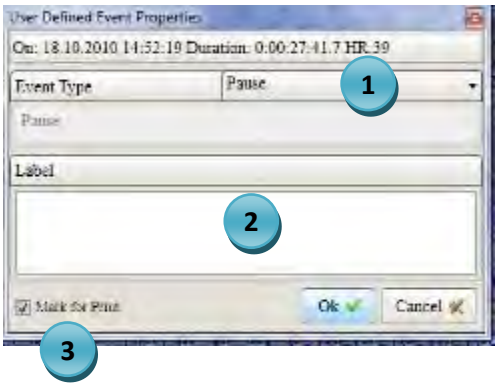
The full disclosure ECG display area allows viewing large sections of one selectable ECG channel. The green circle in the middle of the page represents the current cursor position in the bottom ECG Detailed Strip view.

Here on the Page panel you may use the mouse to highlight an ECG interval for create Event, delete beats, exclude the noisy interval, or immediately print the ECG examples.

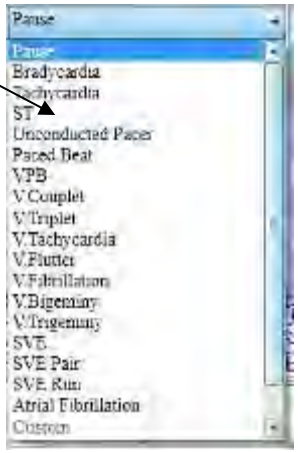


To print the highlighted section, simply select the format for printing: 15 min, 30 min or 60 min per page.

In order to create an event, select the option **Create User Defined event** which opens the following dialogue:



1 Select one of the event types from the drop down menu:



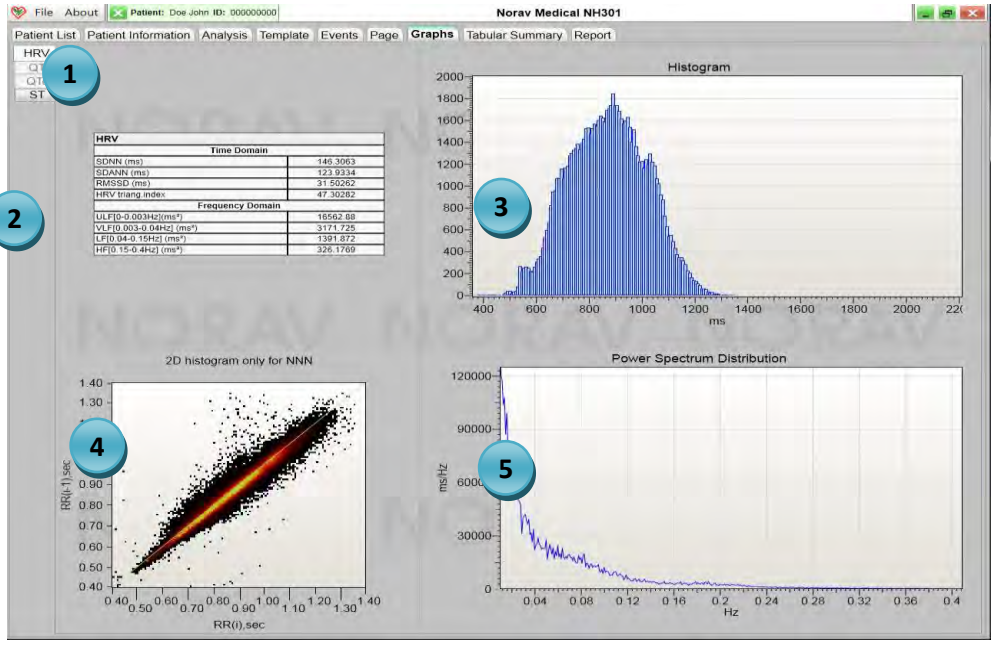
2 If you wish you may add an extra label to the ECG strip which will then appear on screen and will be printed.

3 Use this option to mark the event to be included in your final report.

Finally click the button '**OK**' to save your changes and close the dialogue. If you don't want to include the ECG strip click the '**Cancel**' button.

Graphics view – HRV, QT-QTc and ST

The Graphics view allows you to check the results of HRV/QT-QTc analysis and preview ST trends. HRV/QT-QTc graphs display all the results of the time domain analysis as well as the frequency domain spectrum.



HRV	
Time Domain	
SDNN (ms)	146.3063
SDANN (ms)	123.9334
RMSSD (ms)	31.50262
HRV triang.index	47.30282
Frequency Domain	
ULF[0-0.003Hz](ms²)	16562.88
VLF[0.003-0.04Hz] (ms²)	3171.725
LF[0.04-0.15Hz] (ms²)	1391.872
HF[0.15-0.4Hz] (ms²)	326.1769

1 The buttons on the left hand side permit you to select the page with HRV or QT analysis or display the ST trends.

NOTE

In order to get QT-QTc analysis results, the option QT Analysis in the Setup menu must be activated before the analysis is done. To activate the option retrospectively will cause a complete re-analysis which means that you may lose all editing you have done so far.

HRV/QT-QTc Analysis

2 The table lists the most common values of the HRV/QT-QTc time & frequency domain analysis, such as SDNN, SDANN, RMSSD and so forth.

NOTE

QTc intervals are calculated according to Bazett formula: $$QTc\ (Bazett) = \frac{QT}{\sqrt{RR}}$$

3 The Intervals Histogram displays the numbers of RR (or QT) Intervals with equal interval durations. The shape of the graph gives you the information about the variability at a glance.

4 The Lorenz plot or Scatter gram is based on the RR (or QT) Intervals of consecutive N annotated beats (no **S** or **V** proceeding or following the actual beat!). The X-axis represents the Interval (n) and the Y-axis represents the Interval (n+1). Again this graph gives a quick impression about the variability. The smaller the diagonal line appears the lower is the variability. Single dots outside the condensed cloud represent extreme short or long intervals such as SVTs or Pauses.

5 The Power Spectrum finally displays the result of the frequency domain analysis.

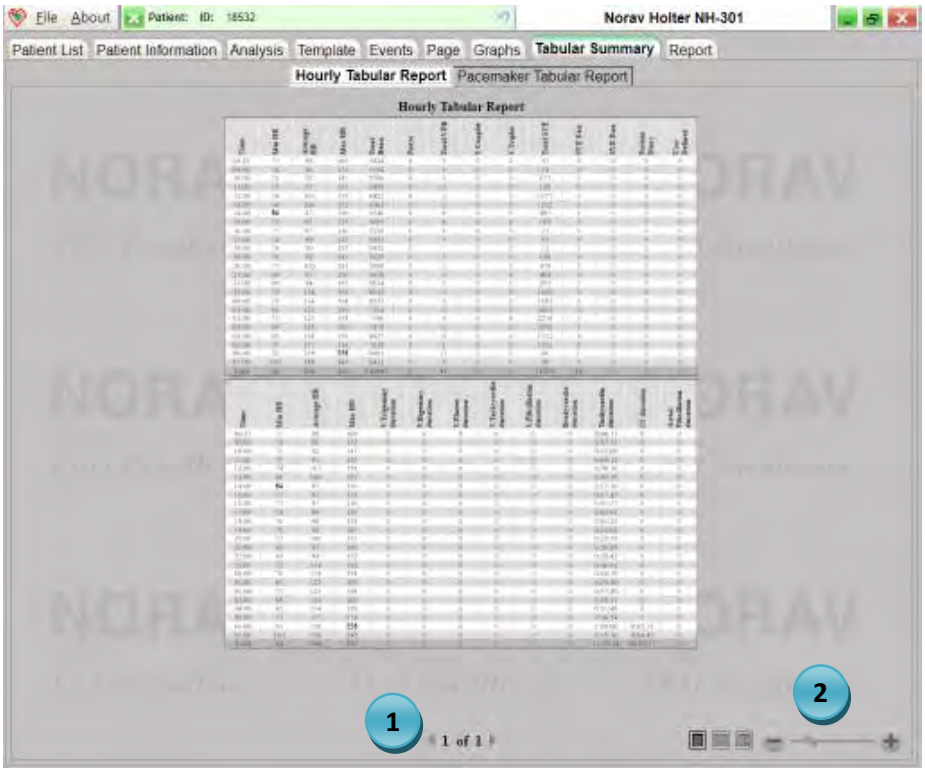
ST Trends

This page represents the ST calculations per each ECG channel. The top trend on the page represents the HR or RR intervals.

The lower panel can display ECG strip view where you may preview and scan the ECG traces, create a user defined event, reclassify or delete beats, exclude noisy segments, and print out the ECG examples.

Tabular Summary

The Tabular Summary displays *Hourly Tabular Report* table with all arrhythmias which were detected by the software during the analysis. This table is useful to predict whether certain arrhythmias appeared only under certain circumstances.

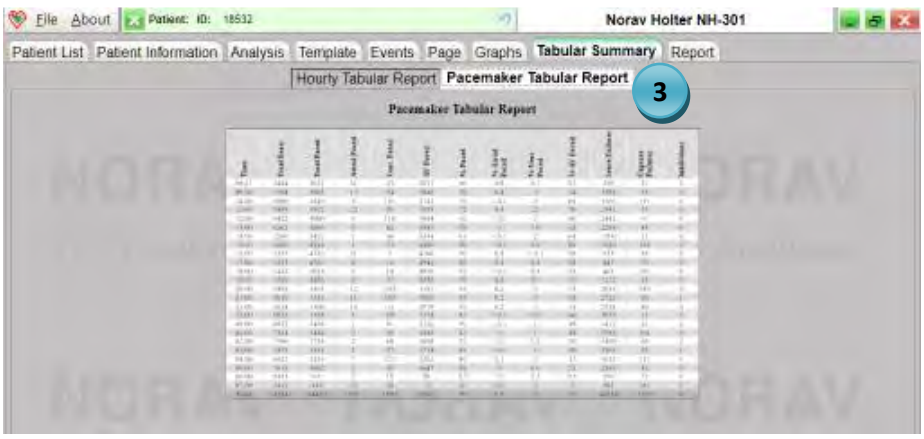


1 If the recording was more than one day long, and the table exceeds the page, it is possible to scroll forward or backward through the pages.

2 Using the buttons you may change on how to view a long table. The left button activates page wise view (paging with the arrow buttons – see above). The middle button splits the table in two parts and displays side by side. The right button activates a slide bar on the right edge of the window which allows you to scroll the table up or down.
With the two buttons to the left (-) and right (+) of the small slide bar you may zoom in or zoom out the table view.

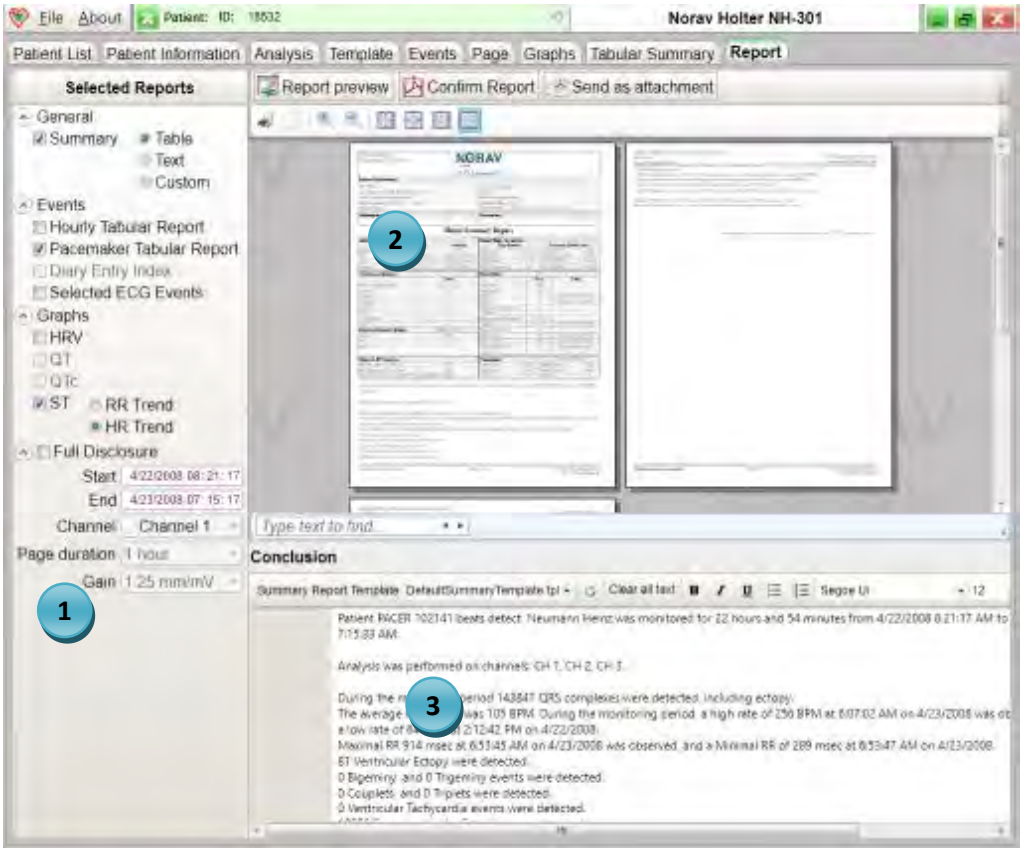
Pacemaker Analysis

3 If pacemaker detection was enabled in the recorder the *Pacemaker Tabular Report* table represents the pacemaker analysis hourly statistics.



Reports

You may customize your report with the address details and logo of your hospital or clinic. Please refer to the '*Software Setup after Installation*' chapter.



1 This list of report sections allows you to include or exclude report sections from the final printed report. To include a section just tick the relevant tick box. Any excluded section can always be included again and vice versa.

2 ***Report preview screen.***

To preview a report, click on the **Report preview** button above the screen. It may take a few seconds while the software generates a comprehensive report. Click on **Confirm Report** to finalize and save the report as a PDF file.

To send the report by email: click on **Send as attachment** button (an email client software is required).

To print the report: click on the printer icon  on the preview screen tool bar.

3 ***Edit Summary***

The text box below the report preview window enables writing conclusions. The text can be entered via a keyboard or generated from one of the configured Report Templates.

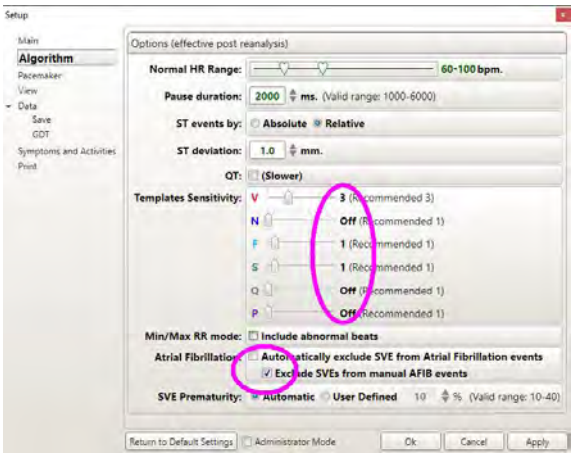
To use the configured report template: select a report template from the list on the Conclusions panel tool bar.

7. Recommended Workflow Options

The previous chapters explained what the analysis does and how you may adapt the analysis to your needs. Further you got an overview over the various possibilities to edit analysis results and finally how to get a printed report with your personal findings included.

Standard Workflow

- Setup configuration:
  - Templates sensitivity:
    Off - for N, Q and P type annotations,
    3 - for V type annotations,
    1 - for F and S type annotations.
  - "Automatically exclude SVE from Atrial Fibrillation events" - **disabled**
  - "Exclude SVEs from manual AFIB events" - **enabled**



- Open the record:
  - in **"Patient List" database mode** run the "Norav Holter Analysis" application. After the program opens double click the selected patient test on '**Patient List**' panel.
  - in **"NEMS" database mode** run "NEMS" application, open Holter recording for Review. *(see NEMS User Guide operating manual for instructions).*
- When patient data panel appears click the '**Next**' button here or just go to '**Analysis**' main menu tab.
- On the '**Analysis'** display click the '**Analyze**' button (nothing needs to be done on this display).
- Upon completion of the analysis go to the '**Events**' display:
  - Select '**Maximum RR**' in the event type list (or use any other means to make sure that the RR-trend and the ECG strip are shown).
  - Using the RR-trend and the ECG strip select regions which should be excluded from analysis.
  - If there are events of the type '**Atrial Fibrillation**' then:
    - Select '**Atrial Fibrillation**' in the event type list.
    - Review Atrial Fibrillation events and delete those events which are not true Atrial Fibrillation (AFib).
    - If there are any AFib events remaining, then select them all (using right mouse click on the Event strips and selecting '**Select all**') and press '**S->N**' button.
  - Create any additional AFib events if required.
- Go to the '**Template**' display.
- Use the slider on the top right to set the paper speed for the template boxes **100mm/sec** as this will show more details of the beat morphologies.

- Now click the right mouse button on the first template and select from the context menu the option '**Select all**'. Click the right mouse button again and select from the context menu the option '**Overlay All Beats**'.
- Now you should see all beats overlaid in their relevant template boxes and you can now quickly distinguish which templates can be handled as a whole and which need individual editing.
- Check the annotations of the templates which can be handled as a whole and correct the annotation if necessary. Always start with "V", then "F" and finish with "S".
- The templates with number in green on bottom right which need extra editing contain various morphologies. You can page through the relevant template and edit every single beat.
  You can also click the right mouse button on the relevant template and select from the context menu the option '**Edit Template**'. Using the Windows® conventions (CTRL + mouse or SHIFT + mouse) you can now select beats which should be removed as artifacts. Proceed with the next beats. Make sure to click the button '**Apply**' at the end to ensure your changes will be saved.
- When you edit a template in "S" always use the option '**Sort by RR**' and then select the option '**View Multiple Beats**' from the context menu. This allows you to identify very easily beats which are premature.
- Go to the Events display. Quickly check the example ECG strips for the various arrhythmia types. If you want to select an ECG strip for printing, press the spacebar when the strip is highlighted.
- Go to the Report display. Check that all report sections you want to include are ticked. Click the button '**Report Preview**' and wait a few seconds until the final report is generated.
- If you prefer, enter your personal findings in the text box below the report view.
- Click '**Confirm Report**' to finalize your review and build the PDF report. If Signature stamp option is enabled, you will be prompted for inserting the password.
- Print out the report or/and click '**Send'** button to send the copy of PDF report via e-mail.
- Close the study.

Perfectionist Workflow

This workflow is designed for a user who desires to review every single decision made by the analysis system.

- Setup configuration:
  - Templates sensitivity:
    3 - for V type annotations ,
    1 - for all other annotation types.
  - "Automatically exclude SVE from Atrial Fibrillation events" - **disabled**
  - "Exclude SVEs from manual AFIB events" – **enabled**.

- Open the record:

- **in "Patient List" database mode** run the "Norav Holter Analysis" application. After the program opens double click the selected patient test on '**Patient List**' panel.
- **in "NEMS" database mode** run "NEMS" application, open Holter recording for Review.
  (see NEMS User Guide operating manual for instructions).

- When patient data panel appears click the '**Next**' button here or just go to '**Analysis**' main menu tab.
- On the '**Analysis'** display:
  - Click the '**Final page'** button
  - If there are no ECG visible on the page (only noise), then click the '**Page up'** button repeatedly till ECG is found, while after each couple of times the '**Page up'** button is clicked switch the channel to check if any of the other channels have ECG.

    - Once a point where at least one of the channels has ECG is found, mark it as the point for the end of analysis.
    - Click the '**Analyze**' button (nothing else needs to be done on this display).
- Upon completion of the analysis go to the '**Events**' display:
    - Select '**Maximum RR**' in the event type list (or use any other means to make sure that the RR-trend and the ECG strip are shown).
    - Using the RR-trend and the ECG strip select regions which should be excluded from analysis.
- Go to the '**Template**' display to review the decisions of the algorithm regarding the shapes of the heart beats but not the decisions about their prematurity. I.e. review if the heart beats annotated as N and S really have a normal shape and if the heart beats annotated as V and F really have an abnormal shape. At this stage, there is no need to review if the heart beats annotated as S are really premature; it will be done later (after AFib events are reviewed).
- Use the slider on the top right to set the paper speed for the template boxes **100mm/sec** as this will show more details of the beat morphologies.
- Now click the right mouse button on the first template and select from the context menu the option '**Select all**'. Click the right mouse button again and select from the context menu the option '**Overlay All Beats**'.
- Now you should see all beats overlaid in their relevant template boxes and you can now quickly distinguish which templates can be handled as a whole and which need individual editing.
- Check the annotations of the templates which can be handled as a whole and correct the annotation if necessary. Always start with "Q", proceed with "V", then "F" and finish with "S".
- Go to the '**Events**' display:
    - If there are events of the type '**Atrial Fibrillation**' then select '**Atrial Fibrillation**' in the event type list, otherwise select '**Maximum RR**' in the event type list (or use any other means to make sure that the RR-trend and the ECG strip are shown).
    - Review Atrial Fibrillation events and delete those events which are not true Atrial Fibrillation (AFib).
    - If there are any AFib events remaining, then select them all (using right mouse click on the Event strips and selecting '**Select all**') and press '**S->N**' button.
    - Create any additional AFib events if required.
- Go to the '**Template**' display to review the decisions of the algorithm regarding the prematurity of the heart beats.
- When you edit a template in "S" always use the option '**Sort by RR**' and then select the option '**View Multiple Beats**' from the context menu. This allows you to identify very easily beats which are premature.
- The templates with number in green on bottom right which need extra editing contain various morphologies. You can page through the relevant template and edit every single beat.
  You can also click the right mouse button on the relevant template and select from the context menu the option '**Edit Template**'. Using the Windows® conventions (CTRL + mouse or SHIFT + mouse) you can now select beats which should be removed as artifacts. Proceed with the next beats. Make sure to click the button '**Apply**' at the end to ensure your changes will be saved.
- Go to the Events display. Quickly check the example ECG strips for the various arrhythmia types. If you want to select an ECG strip for printing, press the spacebar when the strip is highlighted.
- Go to the Report display. Check that all report sections you want to include are ticked. Click the button '**Report Preview**' and wait a few seconds until the final report is generated.
- If you prefer, enter your personal findings in the text box below the report view.
- Click '**Confirm Report**' to finalize your review and build the PDF report. If Signature stamp option is enabled, you will be prompted for inserting the password.
- Print out the report or/and click '**Send'** button to send the copy of PDF report via e-mail.
- Close the study.

Clarifications and Explanations

- In the both workflows no selection of channels for analysis is done. This is because the algorithm estimates usefulness of each of the channels at a specific time and acts accordingly. In absolute majority of records this leads to an additional channel being beneficial for the analysis even if it has a low quality signal.

- In the '*Standard'* workflow in the **'Analysis'** display no region is excluded from analysis and the start and the end for analysis are not selected either. This is because it is faster and easier to exclude regions from analysis after the analysis is completed (RR-trend) and there is nothing to gain from doing so before the analysis.

- Unlike in the '*Standard'* workflow, in the '*Perfectionist'* workflow, the end point for analysis is selected. This is because the algorithm slows down as the result of the combination of both:

    - *templates being enabled for annotations of type N, Q or P*
      and
    - *many hours with none of the channels having any ECG (detached electrodes)*.

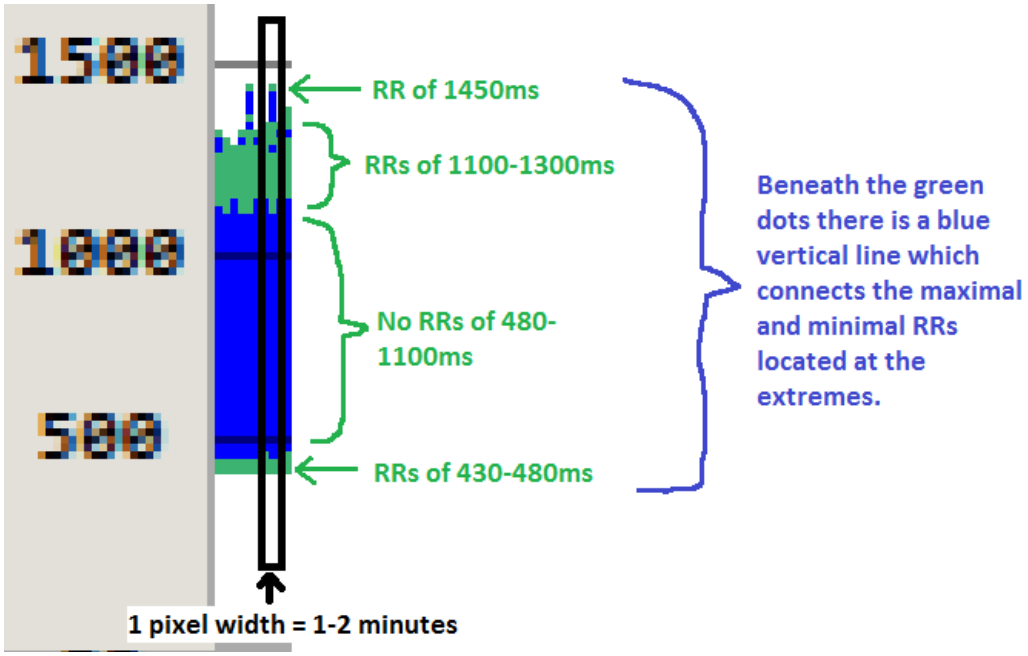
  When the both above conditions happen, the algorithm tries to find similar shapes where no such similarities can be found. Relatively short periods (up to tens of minutes) where none of the channels have ECG do not create such a problem, and if at least one of the channels has ECG, the problem doesn't exist either. Such a long period without ECG on any of the channels can exist only at the end of a record. Thus, if templates sensitivity is enabled for annotations of any of the types N, Q or P, then the end of the record should be checked and the end of the analysis should be selected.

- When SVEs are excluded from Atrial Fibrillation events (either through '**S->N**' button, or automatically when Atrial Fibrillation event is created manually) all the beats previously annotated as 'S' are placed in the same template and shape similarity information is not retained. Thus the review of the shapes of heart beats should be performed before any SVEs are excluded from Atrial Fibrillation (but after bad ECG regions were excluded from the analysis). However, the review of the prematurity of heart beats should be performed after SVEs are excluded from Atrial Fibrillation. This is why the perfectionist workflow has multiple switches between the '**Template**' and the '**Event**' displays.

APPENDIX A: RR Trend Use and Explanations

The RR trend consists of blue vertical lines with green dots on top of them. Each vertical line of pixels shows information regarding 1 to 2 minutes of the record (see the illustration below):

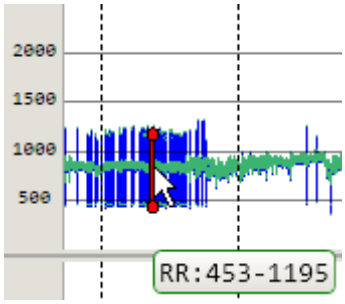
- The Blue Lines represent the connection between the maximal and minimal RRs within the 1-2 minute intervals.
- For each RR interval within those 1-2 minutes there is a green dot at the height which represents the duration of the interval. Frequently, there are various RR intervals with close values, as the result many green dots fall into the same pixel (i.e. one green pixel can represent multiple RR intervals).



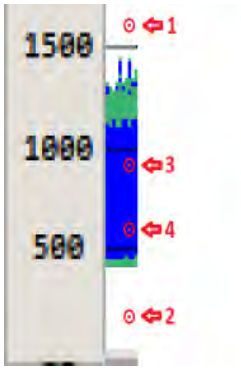
The RR trend also includes 3 additional vertical lines (refer to illustration on the next page):

- Green thick line – maximum RR event
- Red thick line – minimum RR event
- Red thin line – current ECG marker

While user moves mouse pointer over the RR trend, the mouse pointer is accompanied by a vertical red line with red circles at its ends. This line highlights the 1-2 minute period where the mouse pointer is and the circles denote the minimal and maximal RR in this period. Moreover, the actual values of minimal and maximal RRs are shown below in milliseconds, for example:



A mouse click on the RR trend moves the current ECG of the Event Tab to show a location inside the 1-2 minute period corresponding to the columnwhere the mouse was clicked. The height at which the mouse is clicked is significant as it determines the specific location inside that 1-2 minute period displayed. The shown location is the RR which is closest to the height at which the mouse was clicked. If clicked above the blue line will show the maximal while if clicked below will show the minimal RR during those 1-2 minutes. For example:



1. Shows maximal RR within those 1-2 minutes (1450ms)

2. Shows minimal RR within those 1-2 minutes (420ms)

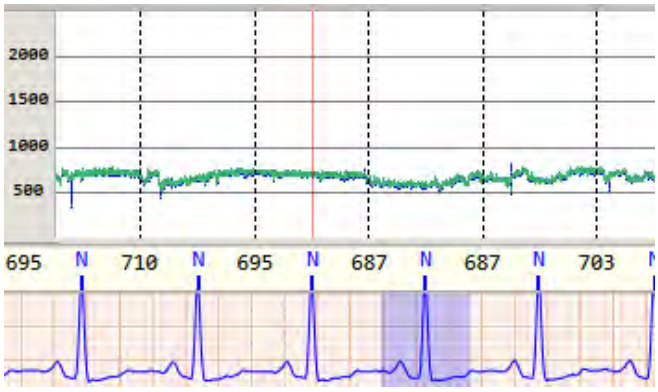
3. Shows RR of 1120ms, which is the shortest RR among RRs that are longer than 1000ms.
   Explanation:
   - The mouse was clicked in an area without RRs (a blue pixel and not a green one), so the RR which will be shown is either the longest RR below the height of mouse click (450ms) or the shortest RR above the mouse click (1120ms). As the mouse click is closer to the latter than the former, so RR of 1120ms is shown.

4. Shows RR of 450ms, which is the longest RR among RRs which are shorter than 500ms,

   Explanation:
   - The mouse was clicked in an area without RRs (a blue pixel and not a green one), so the RR which will be shown is either the longest RR below the height of mouse click (450ms) or the shortest RR above the mouse click (1120ms). As the mouse click is closer to the former than the latter, so RR of 450ms is shown.

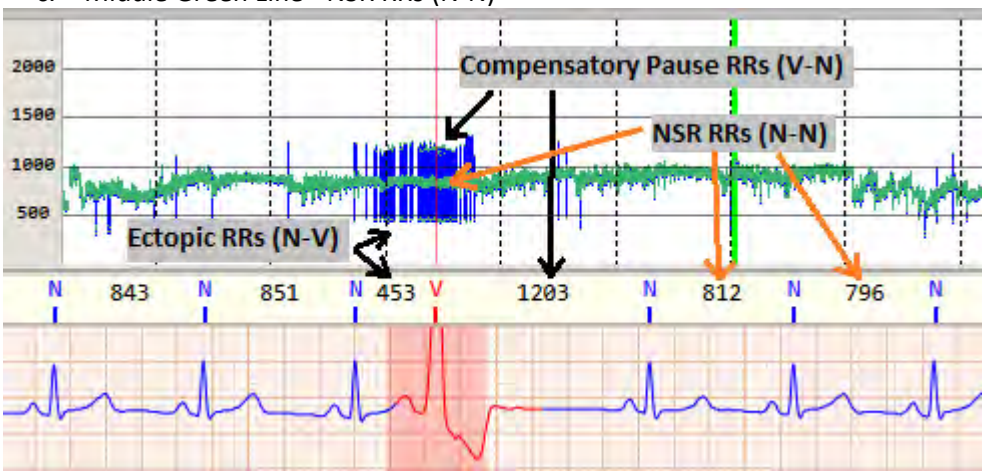
RR trend examples

Normal Sinus Rhythm:



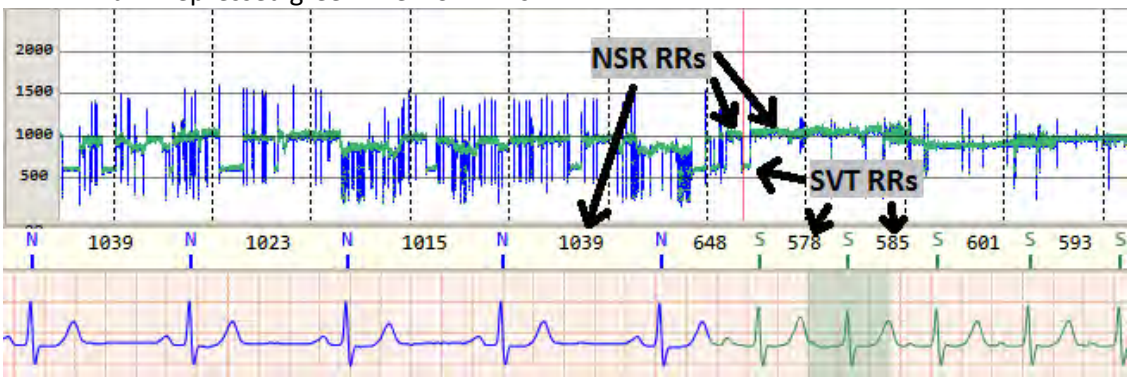
Normal Sinus Rhythm with VPBs:

a. Lower Green Line - Ectopic RRs (N-V)
b. Upper Green Line - Compensatory Pause RRs (V-N)
c. Middle Green Line - NSR RRs (N-N)



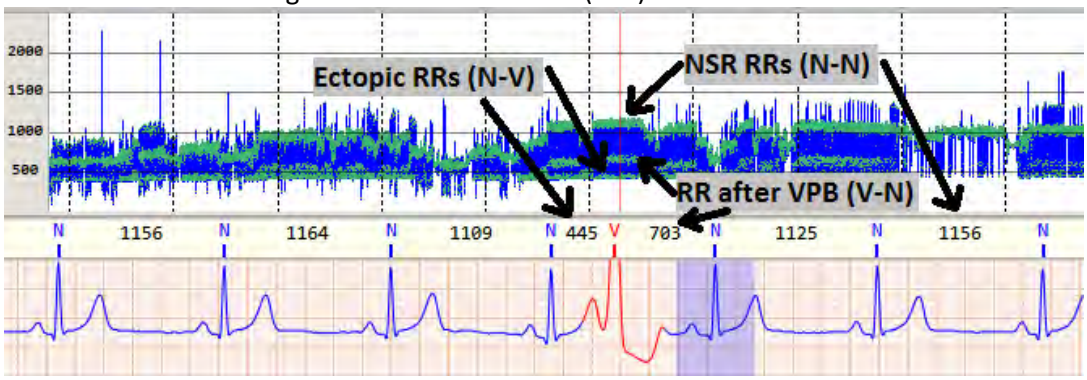
Sustained Supraventricular Tachycardia:

a. Upper green line – NSR RRs
b. Depressed green line – SVT RRs



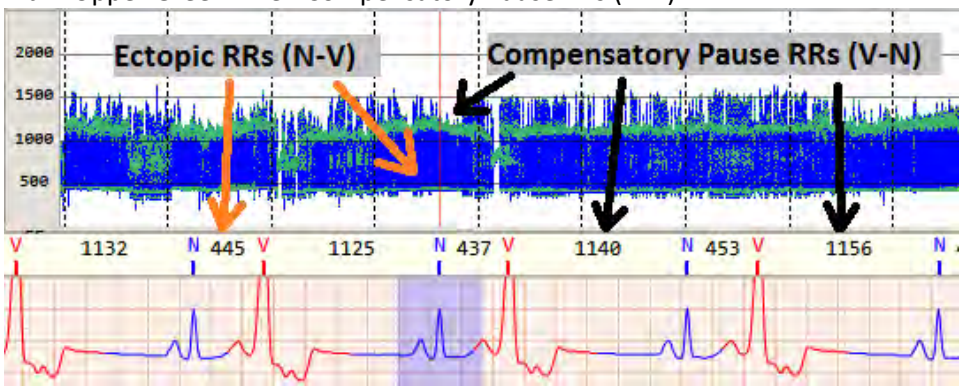
Normal Sinus Rhythm with VPBs, which have no compensatory pause:

a. Upper green line - NSR (N-N)
b. lower green line - Ectopic RRs (N-V)
c. middle green line - RR after VPB (V-N)



Ventricular Bigeminy

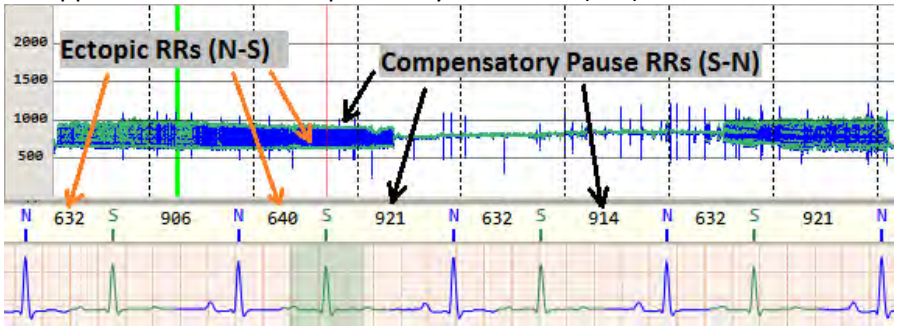
a. Lower Green Line - Ectopic RRs (N-V)
b. Upper Green Line - Compensatory Pause RRs (V-N)



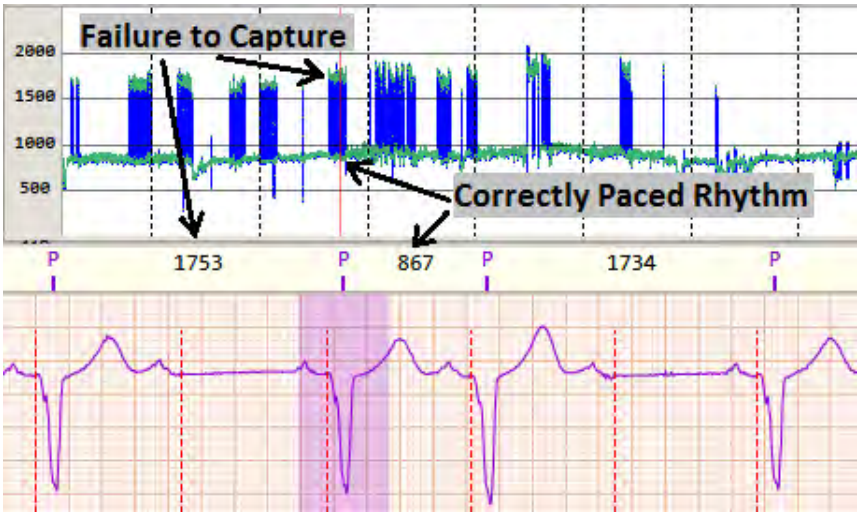
Mouse click at	*will show*
White area below Lower Green Line	Shortest Ectopic RR (N-V)
Lower part of blue area	Longest Ectopic RR (N-V)
White area above Upper Green Line	Longest Compensatory Pause (V-N)
Upper part of blue area	Shortest Compensatory Pause (V-N)

Supraventricular Bigeminy:

a. Lower Green Line - Ectopic RRs (N-S)
b. Upper Green Line - Compensatory Pause RRs (S-N)

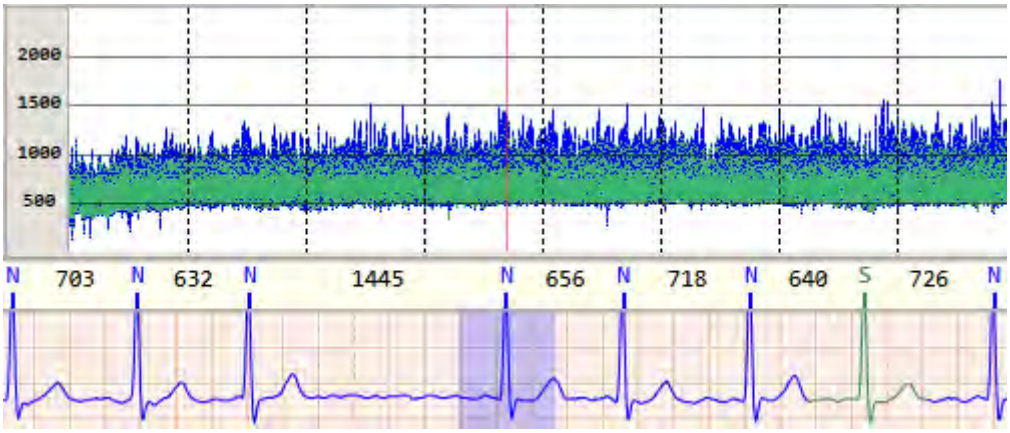


Pacemaker, Failure to Capture



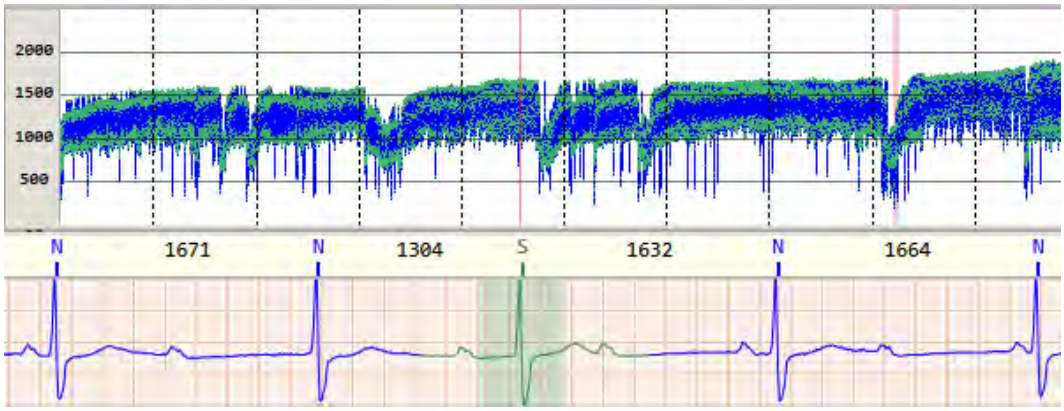
Atrial Fibrillation

Wide Green Ribbon.



Wenkebach (Mobitz I)

In the screenshot below in the immediate vicinity of the thin red line the RR-trend looks very similar to Atrial Fibrillation and other events, thus when the RR trend looks like a wide green ribbon then the strip and page should be consulted too to differentiate between the different possibilities.

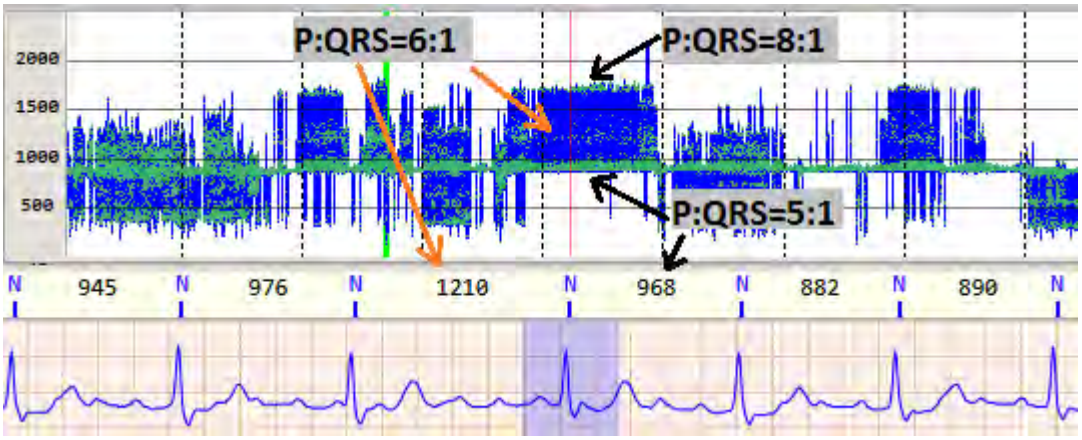


Sick Sinus Syndrome

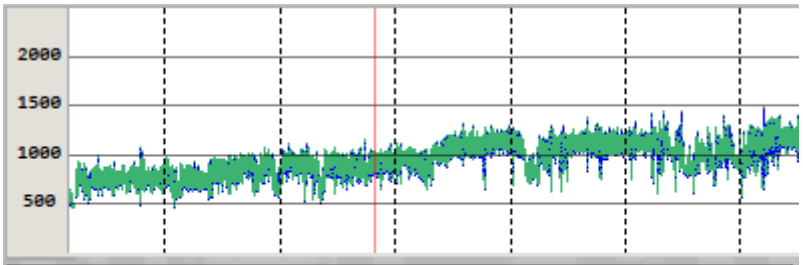
Wide Green Ribbon –The RR trend might look similar to that of Atrial Fibrillation and other events, thus when the RR trend looks like a wide green ribbon then the strip and page should be consulted too.

Atrial Flutter.

Different horizontal green lines correspond to different P:R ratios.

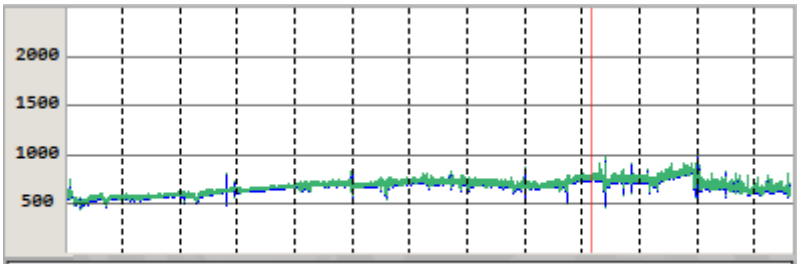


NSR with high HRV



HRV	
Time Domain	
SDNN (ms)	214.3904
SDANN (ms)	200.843
RMSSD (ms)	35.87594
HRV triang.index	56.24861
Frequency Domain	
ULF[0-0.003Hz](ms²)	41770.3
VLF[0.003-0.04Hz] (ms²)	3688.52
LF[0.04-0.15Hz] (ms²)	1846.854
HF[0.15-0.4Hz] (ms²)	481.4632

NSR with low HRV



HRV	
Time Domain	
SDNN (ms)	63.19224
SDANN (ms)	60.1311
RMSSD (ms)	7.513971
HRV triang.index	18.13672
Frequency Domain	
ULF[0-0.003Hz](ms²)	3704.025
VLF[0.003-0.04Hz] (ms²)	189.9941
LF[0.04-0.15Hz] (ms²)	70.07948
HF[0.15-0.4Hz] (ms²)	20.47246

APPENDIX B: Holter Monitor Patient Diary Form

Institution:					
Referring MD:					
Patient Name:					
Date of Birth:		**Sex:**		**MRN:**	
Recording Period:		**Hours**	**from:**		**to:**
Recorder:			**Connected by:**		

Dear patient,

While you are being monitored by a Holter monitor, it's important to keep an accurate diary of your activities and symptoms during the test. If you feel symptoms such as chest pain, shortness of breath, uneven heartbeats or dizziness, note in your diary the time of day they began and what you were doing. Your diary will be compared to the changes in your ECG recorded by the Holter monitor.

Remember that your doctor needs a complete picture of your activities. If in doubt, write it down.

Use the following diary to record all of your daily activities:

- **Time of day**- Write the time of day for every activity or symptom that you write in the diary.
- **Your symptoms**- Chest pain, back pain, dizziness, nausea, etc.- whether or not you feel they are important.
- **Your activities**- Sitting, walking, strenuous exercise, eating, sexual activity, taking medications, etc.

Date	Time	Symptoms	Activity