

Holter NH-301 INSTRUCTIONS FOR USE

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NV-200.400.028

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NH-301 Instructions for Use

For software version: 4.0.0

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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 misuse of the software product.

Important Notice

Like 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 physician. Norav Medical and its staff cannot be held liable for patient data edited by a nonqualified person or 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 or the dealer to the original purchaser.

Excluded from this warranty are expendable supply items including, but not limited to, electrodes, lead wires, patient cables, and batteries. This warranty does not apply to any product that Norav determines to have been modified or damaged by the customer.

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

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

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

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1. Introduction

Document Conventions

Warnings Cautions and Notes

Pay particular attention to specific points in a procedure when one of the following messages is displayed:



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



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



Notes provide pertinent information to help obtain optimum software performance or signify an important step or procedure requiring special attention.

Abbreviations and Acronyms

Abbreviation	Meaning	
АНА	American Heart Association	
ECG	Electrocardiogram	
EMC	Electro Magnetic Compatibility	
HRV	leart Rate Variability	
ID	Patient Identification	
IEC	International Electrotechnical Commission	
MI	Myocardial Infarction	
NH	Norav Holter	
NR	Norav Recorder	
Record	ECG test	
ST	Time from the start of the S wave to the end of the T wave	
USB	Universal Serial Bus	

Equipment Symbols

Symbol	Description
CE 2797	Complies with the Medical Device Directive of the European Union

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Safety

Caution

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 Instructions for Use are part of the NH-301 Holter analysis system and should therefore always be stored in close vicinity of the instrument.
- The NH-301 Holter analysis system 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 the NH-301 Holter analysis system should make sure it is used only for testing 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 be checked first by an expert and confirmed using other diagnostic procedures.
- Nonapproved third party software applications may cause conflict with the NH-301 Holter analysis system. 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.
- Anytime 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.

Intended Use

The NH-301 Holter analysis system is intended for patients requiring ambulatory (Holter) cardiac monitoring from 1 to 336 hours, which 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 patient groups.
- Evaluation of patients for ST segment changes.
- Evaluation of a patient's response after resuming occupational or recreational activities e.g., after MI or cardiac surgery.
- Clinical and epidemiological research studies.

The NH-301 Holter analysis system contains Heart Rate Variability (HRV).

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

Evaluation of Patients with Pacemaker

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

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Contraindications for Use and Adverse Effects

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

Sample Rates and Specification

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

Patient data and ECG raw data are stored under Patient ID, Last Name, and First Name for review, editing, or reanalysis. It provides comprehensive arrhythmia detection based on the data of the high-level accurate beat analysis. In addition, it provides Pacemaker analysis, ST-analysis, and HRV analysis.

The following standard event 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

Supported Holter Recorders

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

2. Software Installation

Recommended PC Specifications

The hardware for NH-301 should have the following or higher specifications. If you plan to use hardware of lower specifications, please bear in mind that this can affect the functioning performance of the software, so it may run slower or in worst case, become unstable.

The software can run on a laptop if it has the recommended specifications.

Component	Specification				
Operating System	Windows [®] 10/11 Pro 64 bit				
CPU	Intel [®] Core TM – recommended: i9 , minimal: i5				
RAM	Recommended: 2 x 16 GB 3200 MHz, minimal: 1 x 16 GB				
Data Storage	Secondary SSD – recommended capacity: 1 TB, minimal: 250 GB				
Graphics	Recommended: discrete video card GeForce 2600 or similar				
Display Resolution	HD+ or higher – recommended: 1920 x 1200 , minimal: 1600 x 900				
USB Ports	4 x USB A slots for:				
	Software license key				
	Memory card reader used for downloading data				
	Preparing recorders for new study				
	Local printer				
Memory Card Reader	SD card reader when using NR-series or DL900 models				
	or				
	CF card reader when using DL800 or DL1200 models				
Network Capability	TCP/IP network interface				
Printer	A4/Letter standard color printer, Laser or InkJet				

Installation

- 1. Install **MATLAB R2022b runtime** from the MathWorks website: <u>https://ssd.mathworks.com/supportfiles/downloads/R2022b/Release/3/deployment_fil</u> <u>es/i nstaller/complete/win64/MATLAB_Runtime_R2022b_Update_3_win64.zip</u>
- 2. Install **Norav Holter Bundle** (run **Norav.Installer.Holter.Bundle.exe**) from the provided link, USB drive, or another source.
- 3. Restart the computer.

Data Structure after Standard Installation

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

The settings for the software application such as layout, setup, department name etc., are stored in **C:\Program Files\Norav\Holter folder**.

C:\Norav\Holter\Data is the default path for downloaded raw data and analysis results. All ECG raw data (*.nrr) and all analysis results (*.hl5) are stored here.

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Software Setup after Installation

When installation is completed, you can customize and adapt the software to your personal needs.

- 1. To run the NH-301 software, double-click the icon on your desktop.
- 2. On the opening screen, click **File** and then click **Settings** on the drop-down list (see Figure 1).

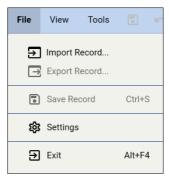


Figure 1: Selecting Setings from the File Menu

The Settings Dialog Box is displayed (see Figure 2).

🔯 Settings		×
Defaults	T Department Name Default Department	
General	T Department Address Default Department Address	-
Algorithm		
Pacemaker	6.25 mm/sec	1
Symptoms	13 Signal Page Gain	_
Activities	2.5 mm/mV	1
Medications	Ecg Strip Scale	,
Indications	Ecg Strip Gain	
Records	10 mm/mV	1
Reports	12 Templates Scale	1
	15 Templates Gain	_
	' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' '	1
	Restore Defaults OK Cancel	Apply

Figure 2: Settings Dialog Box - Defaults Tab

3. Use the tabs on the left for selecting the relevant settings to check and/or change.

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Defaults Tab

The **Defaults** tab includes the default settings in the system.

- 1. Enter the **Default Department** in the **Department Name** field.
- 2. Enter the **Default Department Address** in the **Department Address** field.
- 3. Set the **Signal Page Scale**.
- 4. Set the **Signal Page Gain**.
- 5. Set the **ECG Page Scale**.
- 6. Set the **ECG Strip Gain**.
- 7. Set the **Templates Scale**.
- 8. Set the **Templates Gain**.
- 9. To save your default settings, click **OK** or **Cancel** to abort your settings.
- 10. To restore all default settings, click Restore Defaults.

The Restore Default Settings Dialog Box is displayed.



11. Click Yes.

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General Tab

The General setting allows setting general parameters for the system (see Figure 3).

鎔 Settings				×
Defaults	Temp Folder C:\Norav\Holter\Temp			
General	Report Logo D:\Norav-logo1.png			
Algorithm				_
Pacemaker	DirectX9c			•
Symptoms	≡ MeasurementUnits Metric			•
Activities	≡Log Minimum Level Warning			•
Medications	E SecurityType			
Indications	Auto			<u> </u>
Records	<u>on</u> off			
Reports				
	Restore Defaults	ОК	Cancel	Apply

Figure 3: Settings Dialog Box - General Tab

- 1. **Temp Folder** Set the temporary folder for the NH-301 app.
- 2. **Report Logo** Set the path for the Logo on the report.
- 3. **DirectX Mode** Select mode from the drop-down list:
 - ♦ None
 - ♦ AutoDetect
 - ♦ DirectX9c
 - ♦ DirectX11
- 4. Mesurement Units Select Metric for metric units or Imperial for US units.
- 5. Log Minimum Level Select from the drop-down list:
 - ♦ Verbose
 - ♦ Debug
 - ♦ Information
 - ♦ Warning
 - ♦ Error
 - ◊ Fatal
- 6. Security Type Select from the drop-down list:
 - ♦ Auto
 - ♦ Hasp
 - ♦ SecureX
- 7. Autosave on record close to save the record when closing it, select **ON**.
- 8. To save your default settings, click **OK** or **Cancel** to abort your settings.

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Algorithm Tab

The Algorithm setting allows setting the following parameters for the analysis (see Figure 4).

🔯 Settings		Х
Defaults	미골 ST Deviation	
General	Templates Sensitivity	
Algorithm	V 3 (Recommended: 3) N 4 1 (Recommended: 1)	
Pacemaker	F + 1 (Recommended: 1) S + 1 (Recommended: 1)	
Symptoms	Q - 1 (Recommended: 1)	
Activities	P	
Medications	2000 ms	
Indications	IN Normal HR Range	
Records	(60 - 100) bpm	
Reports		
	Restore Defaults OK Cancel A	pply

Figure 4: Settings Dialog Box – Algorithm Tab

- 1. **ST Deviation** Set the minimum deviation for ST event detection.
- 2. **Templates Sensitivity** Set the sensitivity for each type as recommended or set it to **0** to disable templates for beats of a specific type (analysis is faster when templates are disabled).
- 3. Pause Duration Set the minimum length for a pause to be detected (1000 ms to 6000 ms).
- 4. **Normal HR Range** Set the minimum and maximum heart rate. Significant deviations from this range are considered as Tachycardia or Bradycardia.
- 5. To save your default settings, click **OK** or **Cancel** to abort your settings.

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Pacemaker Tab

The **Pacemaker** setting allows configuring default parameters for the pacemaker analysis, like pacemaker type, pacemaker-initiated heart rate range, and maximal intervals between the pacemaker and the initiated QRS beats (see Figure 5).

袋 Settings				×
Defaults	E Default Pacemaker Type			_
General	DDD IB Pacemaker HR Range			•
Algorithm	(50 - 120) bpm			
Pacemaker	90			▲ ▼
Symptoms	I Maximum atrial spike to R interval 260			*
Activities	Pacemaker Sense time			*
Medications	20			•
Indications				
Records				
Reports				
	Restore Defaults	ОК	Cancel	Apply

Figure 5: Setup Dialog Box – Pacemaker Tab

When pacemaker detection is ON in the recorder, these parameters appear on the Download page and on the Analysis start page, where you can set the parameters according to the actual configuration of the patient's implanted pacemaker.

To save your default settings, click **OK** or **Cancel** to abort your settings.

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Symptoms Tab

The **Symptoms** panel contains a predefined list of symptoms for use with the **Patient Diary** feature (see Figure 6).

🐼 Settings			×
Defaults	Symptoms		
General	Back pain		
Algorithm	Breathlessness Chest pain		
Pacemaker	Chest pressure		
Sumptome	Dizziness		
Symptoms	Headache		
Activities	Heart racing		
Medications	Irregular heartbeats		
	Jaw pain		
Indications	Leg pain		
Records	Nausea		
Reports	Palpitation		
	Quick heartbeats		
	Sharp chest pain		
	Respiration difficult		
	Shortness of breath		
	··· 🔻		
	Restore Defaults OK	Cancel	Apply

Figure 6: Settings Dialog Box – Symptoms Tab

The user can edit the items, add new item(s), or remove existing item(s).

To save your default settings, click \mathbf{OK} or \mathbf{Cancel} to abort your settings.

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Activities Tab

The **Activities** panel contains a predefined list of activities for use with the **Patient Diary** feature (see Figure 7).

🐼 Settings				×
Defaults	Activities			
General	Bathroom			Ŷ
	Driving			
Algorithm	Eating			
Pacemaker	Exercise			
Sumptome	Getting dressed			
Symptoms	Having lunch			
Activities	Jogging			
Medications	Lying down			
	Rest			- 1
Indications	Running fast			
Records	Sexual activity			- 1
	Sitting			
Reports	Sleeping			
	Strenuous exercise			
	Taking medications			
	Traveling			
	···· •			
	Restore Defaults	ОК	Cancel	Apply

Figure 7: Settings Dialog Box – Activities Tab

The user can edit the items, add new item(s), or remove existing item(s).

After editing, adding, or removing items, click **OK** to save your changes or **Cancel** to abort the changes.

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Medications Tab

The **Medications** panel contains a list of medications used by the patient (see Figure 8).

🐼 Settings	×	:
Defaults	Medications	
	Acamol	
General	Advil	
Algorithm	Add New	
Pacemaker		
Symptoms		
Activities		
Medications		
Indications		
Records		
Reports		
	Restore Defaults OK Cancel Apply	y

Figure 8: Settings Dialog Box – Medications Tab

The user can add new item(s) or remove existing item(s).

After adding or removing items, click **OK** to save your changes or **Cancel** to abort the changes.

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Indications Tab

The **Medications** panel contains a list of indications for the patient (see Figure 9).

🐼 Settings				×
Defaults	Indications			
	Cough			
General	Coryza			
Algorithm	Add New			
Pacemaker				
Symptoms				
Activities				
Medications				
Indications				
Records				
Reports				
	Restore Defaults	OK	Cancel	Apply

Figure 9: Settings Dialog Box – Indications Tab

The user can add new item(s) or remove existing item(s).

After adding or removing items, click **OK** to save your changes or **Cancel** to abort the changes.

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Records Tab

The **Records** panel contains the Base Data Folder path (see Figure 10).

🔯 Settings		X
Defaults	BaseDataFolder C:\Norav\Holter\Data	
General		
Algorithm		
Pacemaker		
Symptoms		
Activities		
Medications		
Indications		
Records		
Reports		
	Restore Defaults OK Cancel	Apply

Figure 10: Settings Dialog Box – Records Tab

The user can change the path.

After changing, click **OK** to save your changes or **Cancel** to abort the changes.

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Reports Tab

The **Reports** panel contains the Templates Folder path (see Figure 11).

🐯 Settings				Х
Defaults	TemplatesFolder \\@Templates			
General				_
Algorithm				
Pacemaker				
Symptoms				
Activities				
Medications				
Indications				
Records				
Reports				
	Restore Defaults	ОК	Cancel	Apply

Figure 11: Settings Dialog Box – Reports Tab

The user can change the path.

After changing, click **OK** to save your changes or **Cancel** to abort the changes.

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Storage Cleaning and Disposal of SW License Key

Operation Storage and Transportation Conditions

Operating temperature	10 °C to 45 °C
Storage and transportation temperature	-20 °C to 60 °C
Operating atmospheric pressure	$(2 h P_{0} t_{0} 10 (h P_{0} (60 m h t_{0} 10 (0 m h))))$
Atmospheric pressure for storage and transportation	68 kPa to 106 kPa (680 mb to 1060 mb)
Operating humidity	100/ DIL to 050/ DIL or or of the size
Humidity for storage and transportation	10% RH to 95% RH non-condensing

During storage, avoid exposure to extreme temperatures, humidity, dust, or vibrations.

Do not expose the software license key to direct sunlight or any other UVA/UVB radiation.

Cleaning Software License Key

- Clean the software license key using cleaning kit or a normal cleaning cotton cloth.
- Do not use solvent or cleaning agents for cleaning the software license key.

Disposal of Software License Key

Dispose the software license key as prescribed by your local regulations.

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3. Holter Recording

This Chapter includes general short description how to prepare and perform a Holter recording.

For details about the setup and operation of the recorder, refer to the relevant operating manual.

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

- 1. Hook up patient.
- 2. Connect the recorder or the recorder memory card to the NH-301 system computer.
- 3. Enter the patient data.
- 4. Set the recording duration limit and other parameters.
- 5. Upload the patient data and the recording parameters to the recorder memory card.
- 6. Initiate the recorder.
- 7. Verify/change the data in the recorder.
- 8. Start recording.

Step 1 – Prepare Patient



The signal quality of a Holter recording depends on the quality of electrodes used and skin preparation. Always ensure that the electrodes you plan to use have not exceeded their shelf life. Insufficient skin preparation, bad electrodes, or wrong electrode positioning may cause artifacts and therefore, a great deal of extra work for the person who analyzes and reviews the recorded data!

Prepare Skin

Following are basic rules that 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 recorder operating manual.
- 2. If necessary, shave the area of the electrode position.
- 3. Scrub each electrode area to remove dead skin, oil, and dirt. For proper cleaning, use an abrasive skin cleaner paste consisting soap and pumice.
- 4. Clean the scrubbed area with physician-approved alcohol.



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

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Place Electrodes

- 1. Use only high-quality disposable electrodes with solid gel, designed for use with Holter recordings.
- 2. Connect the recorder input lead 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 location (see following figure).

This ensures that body movements do not cause electrode artifacts.





Different lead number versions of ECG cables are available for the Norav Holter recorders. The NH-301 Holter analysis system automatically detects the number of channels recorded.

Table 1: Recommended Electrode Placement for 3 Channels with 7-Lead ECG Cable

Channel	Color	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 midclavicular line on the 7th costal arch
Ch 3 +	Orange	Left midclavicular line on the 7th costal arch
GND	Green	Lower right costal arch

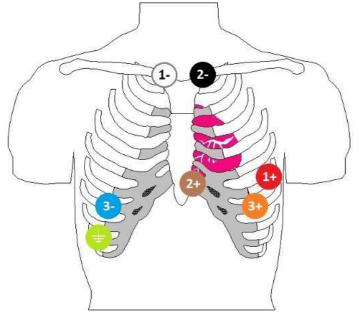


Figure 12: Recommended Electrode Placement for 3 Channels with 7-Lead ECG Cable

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Channel	Color	Placement	
Ch 1 –	White	Right midclavicular	
Ch 1 +	Red	Left anterior axillary line on the 5th costal arch	
Ch 2 –	Black	Left midclavicular	
Ch 2 +	Brown	Approximately 1 inch right of the xiphoid proces	
Ch 3 –	Blue	Center of manubrium of the sternum	
Ch 3 +	Orange	Left midclavicular line on the 5th costal arch	
GND	Green	Lower right costal arch	

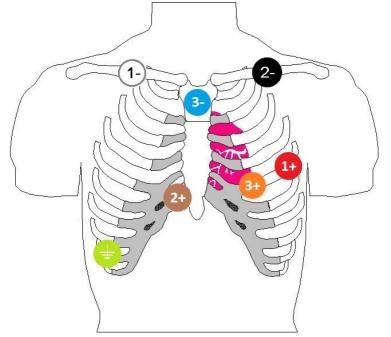


Figure 13: Alternative Electrode Placement for 3 (Channels with 7-Lead ECG Cable
--	--------------------------------

Channel	Electrode Colors	Standard 12-Lead Equivalent
Ch 1	White-Red	Modified V5
Ch 2	Black–Brown	Modified V1
Ch 3	Blue–Orange	Lead III

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Table 3: Recommended Electrode Placement for 3 Channels with 5-Lead ECG Cabl
--

Channel	Color	Placement
Ch 1 –	Red	Center of manubrium of the sternum
Ch 2 –	neu	Center of manufium of the sternum
Ch 1 +	Brown	Approximately 2 inches left of the xiphoid process
Ch 2 +	Black	Laft antonion avillary line on the 9th postal arch
Ch 3 +	DIACK	Left anterior axillary line on the 8th costal arch
Ch 3 –	White	Right midclavicular line on the 7th costal arch
GND	Green	Lower right costal arch

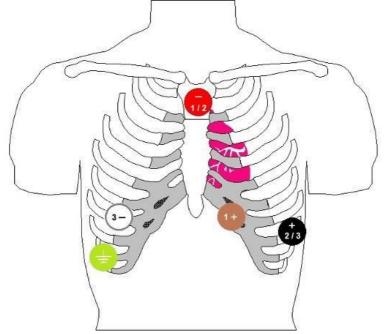


Figure 14: Recommended Electrode Placement for 3 Channels with 5-Lead ECG Cable

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Channel	Color	Placement	
Ch 1 –	Red	Center of manubrium of the sternum	
Ch 2 –	Kcu	Center of manubrum of the stemum	
Ch 1 +	Brown	Left anterior axillary line on the 5th costal arch	
Ch 2 +	Black Left midclavicular line on the 5th costal arch		
Ch 3 +	DIACK	Left midelavicular line on the 5th costal arch	
Ch 3 –	White	Right midclavicular	
GND	Green	Lower right costal arch	

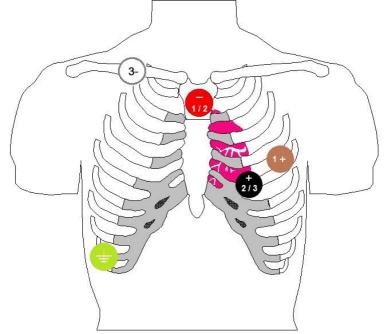


Figure 15: Alternative Electrode Placement for 3 Channels with 5-Lead ECG Cable

Channel	Electrode Colors	Standard 12-Lead Equivalent
Ch 1	Red-Brown	CM5
Ch 2	Red–Black	aFV
Ch 3	White–Black	Lead III

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Channel	Color	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	

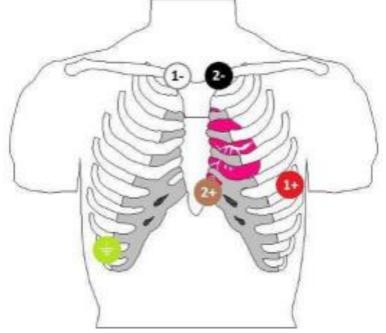


Figure 16: Recommended Electrode Placement for 2 Channels with 5-Lead ECG Cable

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Channel	Color	Placement	
Ch 1 –	White	Right midclavicular	
Ch 2 –	winte		
Ch 1 +	Red	Left anterior axillary line on the 6th costal arch	
Ch 3 +	Keu	Tert anterior axinary line on the our costar aren	
Ch 2 +	Black	Left midclavicular	
Ch 3 –	DIACK		

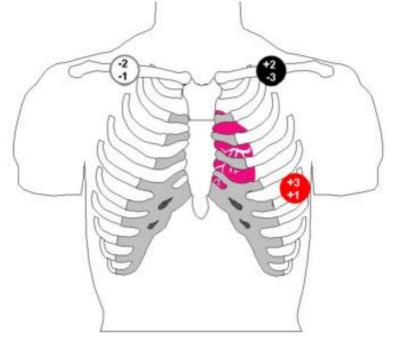


Figure 17: Alternative Electrode Placement for 3 Channels with 5-Lead ECG Cable

Channel	Electrode Colors	Standard 12-Lead Equivalent
Ch 1	White-Red	Lead II
Ch 2	Red–Black	Lead I
Ch 3	White–Black	Lead III

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Table 7: Recommended Electrode Placement for 12 ECG Channels with 10-Lead ECG Cable

#	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	С3	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	Ν	Lower edge of the rib cage, or at the level of the umbilicus at the midclavicular line
10	White	RA	Red	R	Right shoulder

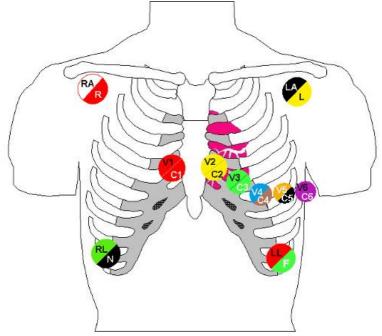


Figure 18: Recommended Electrode Placement for 12 ECG Channels with 10-Lead ECG Cable

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Step 2 – Prepare Recorder

The Holter recorder should be inspected regularly for signs of damage (especially the ECG cable leads!) to avoid problems during hook up to the patient.

- 1. Before starting a new recording, verify that the recorder memory does not contain a previous recording. If a recording exists, first download it and then clean the recorder memory.
- 2. Insert a new battery according to the recorder specifications.
- 3. Connect the recorder to the NH-301 system computer:
 - Option 1 Connection via USB Applies to NR-302, NR-314, NR-1207, NR-1207-3, and DL900 recorders
 - a. Make sure a battery is not inserted in the recorder.
 - b. Make sure that a Memory Card is in the recorder.
 - c. Detach the ECG cable from the recorder and then attach a USB cable instead.
 - d. Connect the recorder to a USB port on the NH-301 system computer.
 - Option 2 Connection of Memory Card Reader Applies to all recorders
 - a. Remove the Memory Card from the recorder.
 - b. Insert the Memory Card into the Card Reader.
 - c. Connect the Card Reader to a USB port on the NH-301 system computer.

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Step 3 – Enter Patient Information

1. Click the Prepare recorder button on the **Record List** panel toolbar (see Figure 19).

• File View Tools				١	lorav Holter 2022.1	-	ð	::	×
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🍫 Analysis	Search record Id First Name Last Name	Gender Order	Recorded T	Duration	Status T				_
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Graphs	3500 123456 John DOE	Unspecified Male	12/14/2017 12:21	00:30	Analyzed				
<u> </u>	123456 John DOE	Male	10/29/2019 10:30	71:34	Confirmed				
Tabular Summary									
🔤 Report									

Figure 19

The Patient Information window is displayed (see Figure 20).

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😋 Analysis	Patient Id	•	Order			-
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Figure 20

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2. Enter patient details or double-click a record from the **Record List** (see Figure 21).

File View Tools			N	lorav Holter 2022.1	-	ð	:: ×
Record List	🔋 Prepare recorder 🛛 👲 Download fro	om recorder 🕞 Load selected	Unload Record	Delete selected 🛛 🗹 View report 🗹 Email report			
≟ Record Info							
🍫 Analysis	Search record Id First Name Last Name	Gender T Order Recorde	d	Status T			
< Templates	25104811	Unspecified 12/13/20	016 13:11 19:32	Downloaded			
▲ Events			018 10:43 20:06	Downloaded			
🔳 Page	3500		017 16:37 00:27	Downloaded Analyzed			
🖾 Graphs	123456 John DOE		017 12:21 00:30 019 10:30 71:34	Confirmed			
🖽 Tabular Summary							
🔤 Report							

Figure 21

3. Click Next \rightarrow at the bottom right of the screen.

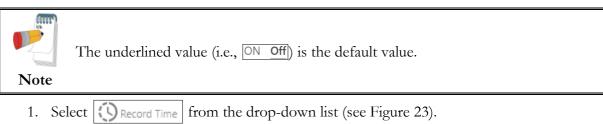
The Recorder Settings window is displayed (see Figure 22).

Step 4 – Adjust Recorder Settings

Adjust the recording settings: **Record Time, Diary Mode, ECG Recording Sample Rate, Battery Type,** and **Pacemaker Detection** (see Figure 22).

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≟ ≡ Record Info	() Record Time					
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🗮 Page	Battery Type					
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🌐 Tabular Summary	ON Off					
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Figure 22





Document No.: NV-200.400.028 Document Rev.: 02 Document Date: 02.02.2023 Page 33 of 86 2. Select Dary Mode from the drop-down list (see Figure 24). Diary is off Press "Enter" to generate diary event Select diary event from list Record voice message Figure 24 3. Select Select Seconding Sample Rate (see Figure 25). 250 500 1000 Figure 25 4. Select Battery Type (see Figure 26). Alkaline Lithium NiMh Figure 26 5. Select Pacemaker Detection $-ON Off$ 6. Click Next at the bottom right of the screen. The Select Connection window is displayed (see Figure 27). SELECT CONNECTION SELECT CONNECTION SELECT CONNECTION Mary Holter 2022.1 • 0 Norav Holter 202.1 • 0 Norav	Document Title:	N				
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Press "Enter" to generate diary event Select diary event from list Record voice message Figure 24 3. Select CG Recording Sample Rate (see Figure 25). 250 500 1000 Figure 25 4. Select Battery Type (see Figure 26). Alkaline Lithium NiMh Figure 26 5. Select Pacemaker Detection - ON Off. 6. Click Next > at the bottom right of the screen. The Select Connection window is displayed (see Figure 27). The Select Connection window is displayed (see Figure 27). SELECT CONNECTION Figure 10 SELECT CONNECTION Select Select	2. Select	Diary Mode fr	om the drop-down	list (see Figure 24).		
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250 500 1000 Figure 25 4. Select Battery Type (see Figure 26). Alkaline Lithium NiMh Figure 26 5. Select Pacemaker Detection - ON Off. 6. Click Next > at the bottom right of the screen. The Select Connection window is displayed (see Figure 27). Image: Select Connection SELECT CONNECTION Image: Select Connection			Figure	e 24		
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Figure 27

Refresh 🔿

Finish

- 7. Select USB connection for the required recorder F:\ 1.91 Gb.
- 8. Click Finish \checkmark .

< Back X Cancel

File

■ Page✓ Graphs■ Tabular■ Report

The patient data is uploaded to the recorder memory card.

9. Proceed to Step 5 – Initiate Recording on page 34.

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Step 5 – Initiate Recording

- For recorders prepared via USB
 - A. Disconnect the recorder from the USB port of the computer.
 - B. Detach the USB cable from the recorder.
 - C. Connect the ECG cable of the prepared patient.
 - D. Insert a new battery into the recorder, and turn **ON** the recorder.
 - E. Make sure the recorder screen turns **ON**.
- For recorders prepared via a Memory Card Reader
 - A. Remove the Memory Card from the card reader.
 - B. Insert the Memory Card to the recorder of prepared patient.
 - C. Insert a new battery into the recorder and turn **ON** the recorder.
 - D. Make sure the recorder screen turns **ON**.

Step 6 – Verify Data in Recorder

For details about setup and operation of the recorder, refer to the recorder operating manual.

- 1. Verify (and if necessary change) the data uploaded to the recorder: patient data, recording duration limit, internal clock, pacemaker detection, and other parameters.
- 2. Validate the lead connections and the quality of ECG traces displayed on the recorder screen.

Step 7 – Start Recording

To Start recording, see the relevant recorder operating manual.

4. Downloading and Analyzing Holter Recording



If you are using the NH-301 Holter analysis system for the first time after installation, ensure that the software has been set up correctly and all preferences have been checked (see Chapter 2 - Software Installation.

General Information

Before a Holter recording can be analyzed, the recorded data must be uploaded from the Memory Card or directly from the recorder (if applicable).

Once the data has been uploaded, the Memory Card can be used for the next recording.

The NH-301 Holter analysis system reads and analyzes the data and provides comprehensive measures to review and edit the recorded data, and finally to create a report with your findings.

The analysis process is split to two main parts: Beat Analysis and Arrhythmia Analysis.

The beat analysis locates heart beats and classifies them according to estimated pacing source (N, R, F, V, S, P).

Then, the beat analysis builds templates (morphology families) for each annotation type (unless templates were disabled for this type).

ann
Note

If the analysis process is unsure what the pacing source of the beat was, it classifies it as Questionable (\mathbb{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 editing a beat interpretation (changing beat types, deleting or adding new beats), the arrhythmia analysis is repeated and the events are adjusted accordingly.

This is unlike beat analysis that is performed only once.

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Downloading the ECG Data

Whenever a patient returns to your office and the recorder has not been turned off automatically, follow the procedure in recorder operating manual to terminate the recording. This procedure is very important, to avoid recording and collect artifacts!

This procedure applies to NR-302, NR-314, NR-1207, NR-1207-3, DL800, DL900, and DL1200 recorders.

Download the data as follows:

1. Start the NH-301 Holter analysis system.

The **Record List** screen allows either opening an existing recording on the hard drive of your computer or downloading a recording from a Memory Card or via USB (see Figure 19).

To open an existing recording on the hard drive of your computer, click File on the top toolbar (see Figure 28), then click Import Record..., and then double-click the required file. Or

To download the recording from a Memory Card or via USB from the recorder,

click **Download** from recorder on the **Record List panel toolbar** (see Figure 19).

When few recordings are recognized (few recorders can be connected to the PC), the list of the recognized recordings is displayed for the selection.

3. Select one recording.

The Patient Personal Information screen is displayed (see Figure 28).

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Figure 28: Personal Information Dialog Box

4. Validate and edit patient data.

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- 5. Define the estimated duration for reporting: 24 hours, 48 hours, etc.
- 6. Enter indications and medications.
- 7. Adjust scanning criteria: Tachycardia, Bradycardia, and Pause thresholds.
- 8. Adjust the pacemaker settings.



To enable the software to analyze the operation of the pacemaker correctly, the parameters of the pacemaker must be set according to the actual configuration of the patient's implanted pacemaker.

9. Click Proceed ✓.

the Records list is displayed (if one recording was recognized) or list of recordings for the next selection.

When the recording is loaded from the Record List (after downloading), the **Patient Information Screen** is displayed (see Figure 29).

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General	Last Name		······	
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🗢 Templates	©6/13/1945 ••••	Referring Physician	Reporting Physician	
A Events	♥ Age O ^{R Gender} 74 Male Female	طاً Address Line 1	Recorded 10/29/2019 10:30	*
📄 Page			() Estimated Duration	Recording Length
🗹 Graphs	Weight kg Height m		72 Hours	- 71:34 ∑ Serial Number
I Tabular Summary	MEDICATIONS C Edit List Add New Medication	INDICATIONS Add New Indication	✓ Edit List Recorder Model NR314	10232
🔤 Report				
				Diary >
				,

Figure 29 Patient Information Screen

10. Click Diary >.

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The **Diary Screen** is displayed (see Figure 30).

		-		· - ·				
File View Tools	s 🗊 🛌			Patient: John DOE	ID: 123456	- 6	p (;)	>
Record List	Date	↑ Symptom	Activity					
≟ ≡ Record Info	10/29/2019 10:30	Back pain	Exercise					
General	10/29/2019 10:30	Breathlessness	Driving					
Diary	10/29/2019 10:30	Dizziness	Bathroom					
🗘 Analysis	New event							
Templates								
Events								
Page Page								
🗹 Graphs								
Tabular Summary								
🔤 Report								
	< General							
				Eigung 20 Diams				

Figure 30 Diary Screen

- 11. Enter the patient diary items.
- 12. Click 🍲 Analysis .

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Analyzing the ECG Data

See Figure 31.

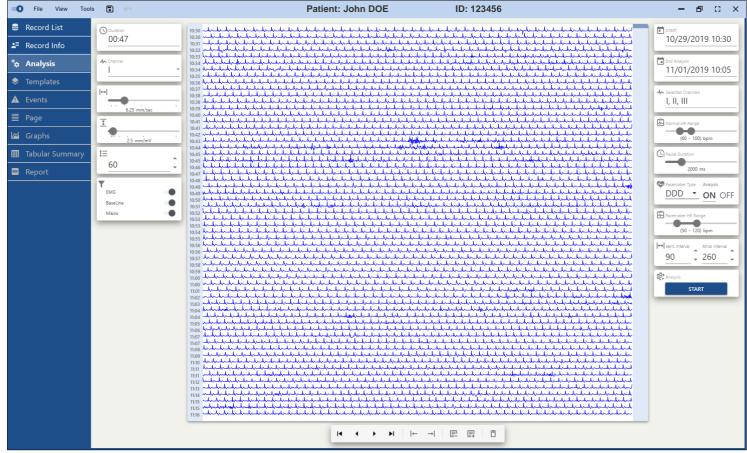


Figure 31: Analyzing ECG Data

↔	6.25 r	mm/sec		EC and filte
<u>+</u>	2.5 m	ım/mV	1	stri
I	•	•	►I	Na Use

ECG Screen Adjustment: Use these controls to adjust the speed nd amplitude of the ECG display. Furthermore, you can select ilter(s), which channel should be displayed, and how many lines or trips should be drawn per page.

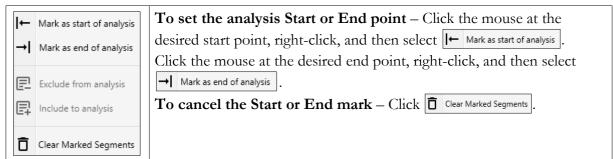
Navigation: if you wish to get a quick overview over the recording use the \triangleleft or \triangleright to navigate single pages forward/backward or use $\mid \triangleleft$ or $\triangleright \mid$ to skip to the last/first page.

Excluding Noisy Segments

 → Mark as start of analysis → Mark as end of analysis 	To mark the Start and End points of the analysis interval and exclude the noisy regions in the middle of the recording – Right-click (see below).
← Mark as start of analysis	To exclude the noisy region in the middle of the recording –
→ Mark as end of analysis	Highlight the region by right-clicking at the start point and dragging until the end point, and then select Exclude from analysis from the context menu.
Exclude from analysis	To reinsert the excluded region into the analysis – Highlight the
Include to analysis	region and then click 📮 Include to analysis from the context menu.
Clear Marked Segments	To remove all the marked segments – Click Clear Marked Segments .

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Setting Analysis Start or End Point



Selecting ECG Channels to Include in Analysis

-∕⊷ Selected Channels	To select the ECG channels for inclusion in analysis, -	Click the
<u> </u>	A Sector Otheres and then select the required channels from the	
	drop-down list.	

Adjusting the Scanning Criteria

(60 - 100) bpm	Use the Normal HR Range buttons for defining the Bradycardia and Tachycardia thresholds.
Pause Duration	Use the Pause Duration button to enter the pause threshold.

Pacemaker Analysis Settings

When the pacemaker detection has been turned ON in the recorder, this option appears.

Pacemaker Type Analysis DDD Analysis ON OFF NONE VVI AV DDD	Select the Pacemaker Type from the drop-down list. Set Pacemaker Analysis to ON .
(50 - 120) bpm	To define the heart rate range (Bradycardia and Tachycardia thresholds) initiated by pacemaker, use the Pacemaker HR Range buttons.
Vent. interval Atrial interval 90 260	To define the time limit between ventricular spike and the subsequent R-wave, use the Vent. Interval input. To define the time limit between atrial spike and the subsequent R-wave, use the Maximum atrial spike to R interval input.



To enable the software to analyze correctly the operation of the pacemaker, the parameters of the pacemaker must be set according to the actual configuration of the patient's implanted pacemaker.

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Performing Analysis

1. To start the analysis process, click the

START

button.

♦ The software analyzes the ECG data and sorts the beats according to their shape and timing in different morphology families/templates.

START

- ♦ The analysis process may take a while. When the analysis is finished, the **Templates** view appears on screen.
- 2. To reanalyze an analyzed recording, click the Prepare button, mark segments, and then

click the

button to begin the analysis.

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5. Reviewing and Editing ECG Recording

The Templates screen allows inspecting quickly the results of the beat analysis (see Figure 32).

If necessary, you can 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 (see Section ECG Detailed Strip View on page 49).

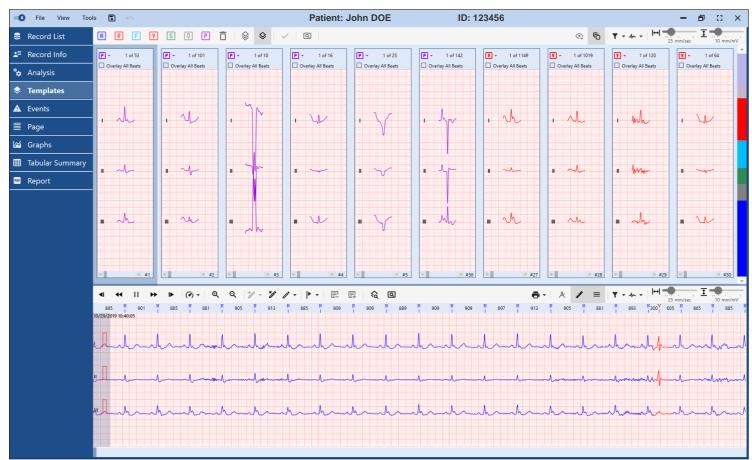


Figure 32: Reviewing and Editing ECG Recording

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Viewing Different Beat Morphologies



Figure 33: Analyzing ECG Data

Figure 33 shows different beat morphologies found during the beat analysis.

Each box is a template containing beats of similar morphology. Use the left or right arrow buttons, or the scroll wheel to go through the beats. When you click and hold the mouse on an arrow, the display automatically scans very fast through all beats in the template.

Reclassifying Selected Template(s)

N R F V S	P	Use these icon buttons to quickly reclassify the selected template or
		a group of templates. You can also use the drop-down menu at the top of each template box. Alternatively, you can change or delete a template using the keyboard (see available corrections in Table 8).

Action	Command	Keyboard Key
Classify the template as Normal		⇔ Shift + N
Classify the template as R on T	R	⇔ shift + R
Classify the template as Fusion	E	⇔ Shift + F
Classify the template as VPB	V	⇔ Shift + V
Classify the template as SVE	5	⇔ Shift + S
Classify template beats as Questionable	Q	⇔ Shift + Q
Classify template beats as Paced	P	⇔ Shift + P
Delete the template	Ō	⇔ Shift + Delete

Table 8: Reclassifying Template(s)

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Buttons on Top Pane

\	Template Mode
\$	Single Beat Mode
•	Show Checked Templates
ſ	Show Checked Templates Panel
EMG S Base Line S Mains S	Filter Selection
	Displayed Channel Selection
[↔] ↔	Use the two sliders to select the appropriate paper speed and amplitude for the display of the template boxes.

Going through large numbers of beats for ensuring that all beats have been annotated correctly and sorted to the right beat families takes very long time. The NH-301 Holter analysis system provides you not only with an extremely

accurate analysis algorithm but also with outstanding editing features that are described in detail below.

General Features

Note

The NH-301 software distinguishes between templates containing beats of the same morphology and editing templates containing dissimilar beats or templates that have been generated manually by editing single beats within templates.

The templates have a number at the bottom right corner reflecting the template number as it was generated during analysis and later during editing (see Figure 33).

You can scroll quickly through all beats forward and backward within a template using your mouse.

After changing a beat annotation type (single beat), you can copy this annotation to another beat by right-clicking on the beat.

When right-clicking the second time, the previous operation is canceled and the beat returns to its original annotation.

Using Ctrl or Shift key with the mouse allows selecting more templates.

- 1. Select a template for change, then press and hold the **Ctrl** key, while clicking the mouse on every template you wish to select.
 - Now you can (for example) change quickly the annotation for all selected templates.
- 2. If you wish to select many templates in series, click the first template.
- Press and hold the Shift key while clicking the mouse on the last template in the series.
 All templates between the first and the last are now selected and ready for a common operation.

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Edit Template Feature

This feature allows viewing every single beat within a template at a glance for the most thorough inspection possible.

In the relevant template box, right-click and choose the option **Edit Template** from the context menu or double-click the relevant template.

✓ X N R F Y 5 0 P T 	Crose By Reference Sample ← 11 11	⊞ - T - 4 →
1 Ah 1 Ah 1 Ah	I al I al I al I al	
	and	
		- I le I le I
	· · · · · · · · · · · · · · · · · ·	
· · · · · · · · · · · · · · ·	inter inter inter inter	- I when I when I
I alo I alo I alo I alo I alo I alo II alo II alo II alo	· ah · rh · ah · ah	- I the I the
■		
885 N 901 N 885 N 881 N 905 N 913 V/29/2019 10:40:05	N 885 N 909 N 909 N 889 N 909 N 897 N	25 mm/sec 10 mm/mV 913 N 905 N 881 N 893 N300V 605 N 865 N 885 N
International market	hand hand hand hand hand	hand hand hand hand hand hand hand hand
Here a second and a		hanne honor honor honor honor
	Much make a show the show	

The screen layout is changed automatically as follows (see Figure 34).

Figure 34: Editing Template

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

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Top Pane Controls

[↔] → 10 mm/mV	Use the slider controls to adjust paper speed and/or amplitude of the single displayed beats.
	Select the channel(s) for display from the drop-down list.
	Use this control to set how many beats are shown per row and how many rows should be shown in the window.
Order By Reference Sample Reference Sample Last Beat Distance	With these options you can view the beats sorted: by their RR interval duration or by beat prematurity.
	Use this control to select all beats with one click for renaming them in the template then you may use the option Select All .
NRFVS0P Î	Use these buttons to rename the selected beat(s). Alternatively you can change or delete a beat using the keyboard keys. To select more than one beat, use the Ctrl or Shift key with the mouse (see following Table 9 for available annotations).
✓ X	When you finish editing, click the 🖌 button to save your changes. If you wish to terminate without saving any changes, click the 🗙 button.

Table 9: Renaming Selected Beat(s)

Action	Command Button	Keyboard Key
Classify beat as Normal	N	N
Classify beat as R on T	R	R
Classify beat as Fusion	E	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	Ô	Delete

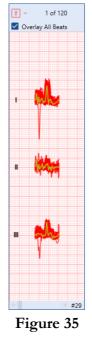
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Overlay All Beats Feature

To activate the **Overlay All Beats** feature, select the **Overlay All Beats** checkbox 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 the same pattern as seen in the template box (see Figure 35).



This template box example (see Figure 36) displays many beats with different shapes which are together in this template box example. This can happen if (for example) beats are manually renamed or if templates have been merged.

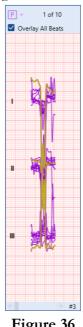


Figure 36

We recommend setting paper speed of the templates view to 100 mm/s, which enlarges the template view, and beat patterns can be inspected more easily.

You can quickly check all templates in **Overlay All Beats** mode.

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Merge Templates Feature

If you have a recording with many templates, it may be useful to merge templates that have almost identical morphology.

To merge templates, click on one of the two templates and drag the template box over the second template box.

During dragging the template box, it becomes transparent allowing to verify that the beat shapes fit together.

The **Merge Templates** feature does not affect the result of the beat analysis and the result of the arrhythmia analysis. It is used to reduce the number of templates when you do not want to view too many templates.

Note The NH-301 software can deal with many templates 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 (see Figure 37).

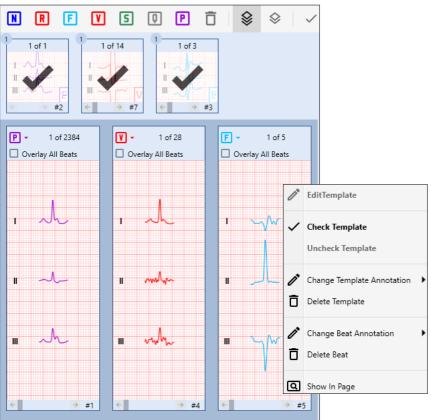


Figure 37

- 1. To select a template or a group of templates, press and hold the **Ctrl** key while clicking the mouse on the required templates, which are highlighted with dark frame (see Figure 37).
- 2. To mark the selected templates, right-click on a template, and then select <a>Check Template from the drop-down menu (see Figure 37).

The selected templates are marked and collected at the top of the screen (see Figure 37).

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ECG Detailed Strip View

This bottom pane of the screen displays an ECG Detailed Strip of the currently selected beat and the surrounding ECG (see Figure 38). 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 NH-301 Holter analysis system automatically adjusts all windows according to
 Note the computer graphics and the connected monitor. This 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.

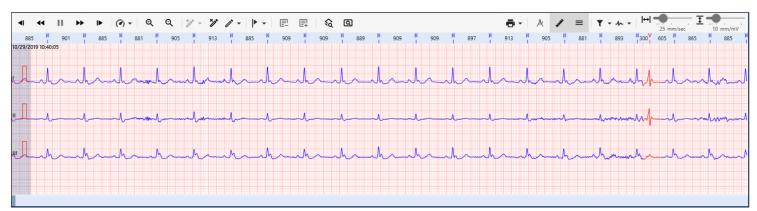


Figure 38

On the toolbar at the top of this detailed ECG view you can view some icons for additional functions as follows:

I II II II	Scan buttons:		
	To scan Step Backward, click I .		
	To scan Backward , click 4 .		
	To stop scanning, click III .		
	To scan Forward , click > .		
	To scan Step Forward, click D .		
X1 X2 X4 X8 X16 X32 X64 X128	To control the speed of scanning on screen, select the preferred speed of scanning from the drop-down menu.		
ଡ୍ ଦ୍	Zoom in and Zoom out buttons.		
+	To insert beats, press and hold the Alt key while right clicking .		
×J	Delete beats.		
1 -	Select beat annotation from the drop-down list.		
N R F V S 0 P			
	To create User Event, select from the drop-down list.		
e e	Exclude from Analysis and Include in Analysis buttons.		

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\$ 0	Show in Templates
٩	Show in Page
Print	To print the ECG, select your preference from the drop-down list.
Print with remarks	
æ	Toggle On/Off the calipers for measurement
	Click to display RR measurements/values above the ECG graph.
1 1001 1 1009 1 977 1 989 1 989	
	Click to display the channels at the left of the ECG graph.
EMG Base Line Mains	Select the filter(s) from the drop-down list
	Select the channel(s) from the drop-down list
[↔] → 10 mm/mV	To select the appropriate paper speed, use the \square slider. To select the ECG strip amplitude, use the $\boxed{1}$ slider.

When pointing to an ECG strip, you can drag the ECG strip to either side for viewing the very next beats to the ones shown in the strip.

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Changing or Deleting a Beat in the Strip View

Point to the relevant beat and then right-click to open the context menu (see Figure 39). Alternatively it is possible to reclassify or delete a beat by using the keyboard keys.

+*	
	Insert Beat
T.	Delete Beats
<i>I</i> *	Change Beats Annotation 🕨
•	Create User Event
E	Exclude from analysis
Ę	Include to analysis
\$2	Show In Templates
Q	Show In Page
	Figure 39
1. To delete Beats in the Strip View	
2. To change beats annotation, poi	int to Change Beats Annotation) and select the annotation
from 🛛 🖻 F 🔽 5 🔍 (P .
3. To create user event, point to	Create User Event and select from the drop-down
list (see Figure 40).	
	VPB Tachycardia
	SVE Tachycardia
	Atrial Fibrillation
	AtrialFlutter
	Pause
	VPB Couplet
	VPB Triplet
	SVE Couplet
	VPB Bigeminy
	VPB Trigeminy
	SVE Bigeminy
	SVE Trigeminy
	Tachycardia
	Bradycardia
	UnconductedPacer
	Custom
	Figure 40

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- To highlight the template that includes the beat, click Show In Templates
 It is displayed in the top pane the screen.
- 5. To highlight the beat on the page, click Show In Page

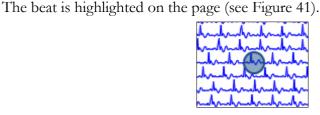


Figure 41

Measuring ECG

The caliper is available on **Templates**, **Events**, and **Page** screens.

Use the Caliper function to measure the RR interval or the amplitude at the cursor position. When you click the Caliper icon on the toolbar, you can notice two cursor lines (see Figure 42).



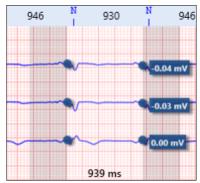


You can move each cursor separately.

- 1. Move the mouse pointer to the cursor line and the mouse pointer changes to \iff .
- 2. Drag and drop at the new position.
- 3. To maintain the caliper distance and move to a different spot for checking if the interval is identical, move the mouse pointer to the area between the two cursors (the mouse pointer is changed to (), and then drag and drop the caliper at the desired location.

For each channel in the strip, a small window adjacent to the right cursor displays the measured amplitude difference between both cursors (see figure below).

Below the cursors you see the distance in milliseconds **939 ms** (see figure below).



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Caliper Snapping and Keyboard Actions

- 1. Click the \bigwedge on the toolbar (see Figure 42).
- 2. To slightly move the caliper position, use the \leftarrow and \rightarrow keys.
- 3. To snap the boundary to **R-spike**, press and hold the Att key while dragging the caliper boundaries.
- 4. To snap the right boundary of the caliper to R-spike, press and hold the right At key while clicking the

 or → keys.
- 5. To snap the left boundary of the caliper to R-spike, press and hold the left Alt key while clicking the ← or → keys.

Editing the Annotations in the Caliper

Drag to the desired interval and then right-click.

A pop-up menu is displayed with the following options (see Figure 43).

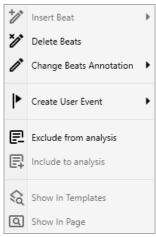
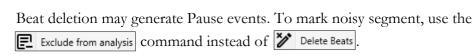


Figure 43

Delete Beats – The selected beat marks are removed and not counted in the analysis.



Note

- Change Beats Annotation – Use this command to manually reclassify all beats in the selected interval.
- Create User Event – Use this command to create a new user event.
- Exclude from analysis Use this option to mark a noisy segment that is excluded from the HR and RR calculations. Unlike beat deletion, it does not produce lower HR or generate wider RR intervals.

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Zoom In/Out

If you wish to view more details of the signal, you can zoom in on the ECG display (see Figure 44).

- Press and hold the Ctrl key while using the mouse wheel or click the Q icon.
 Turning forward zooms in and turning backward zooms out.
- 2. To return to the original size, click the \bigcirc icon.

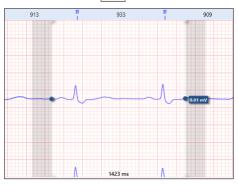


Figure 44

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Event View (Arrhythmia Overview)

The **Events** tab allows assessing arrhythmias that have been detected by the analysis software (see Figure 45).

You can quickly go through the example strips, see overall trend views, and use several editing functions explained below.

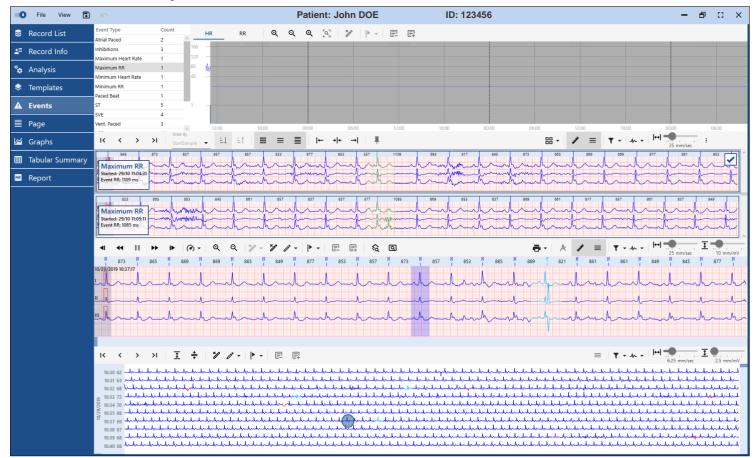


Figure 45

Event List

This list displays the different arrhythmia types that were found in the recording. (see Figure 46).

Event Type	Count	
Atrial Paced	61	\uparrow
Atrial Fibrillation	67	
AtrialFlutter	1	
AV Paced	45	
Bradycardia	59	
Capture Failures	1	
Inhibitions	185	
Sense Failures	30	
Maximum Heart Rate	1	
Maximum RR	1	. Le
• •		¥

Figure 46

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HR/RR Trends

On the top left of the trend display you can notice these buttons **HR** (see Figure 47).

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

If you wish to instantly view the ECG strip with the fastest heart rate, select **Maximum Heart Rate** from the Event list (see Figure 46).

_	HR	RR	ଭ୍ର୍ଠ	ર ્ગ્રે	► - E	Ę							
160		10/29/20	19		10/3	/2019			10/3	/2019		11/01/201	9
120 80	h sto	للعطيها	الألمنصيل	المسلط والمحالية	بىلى چىلىمى سىلىد	the land	مرد و المحدوق ما _{الع} الي كال	and a start a s	, processor of the part	والاستريط شرائع سرويها	and the	وروا والمحالية والمحالية والمحالية والمحالية المحالية المحالية المحالية والمحالية والمحالية والمحالية	Charles and
40													3
4													
1		:00 18:		:00 06	:00 12	:00 18:	0 00:	00 06		:00 18	:00 00	0:00 06:0	

Figure 47

The screen below is changed accordingly (see Figure 48).

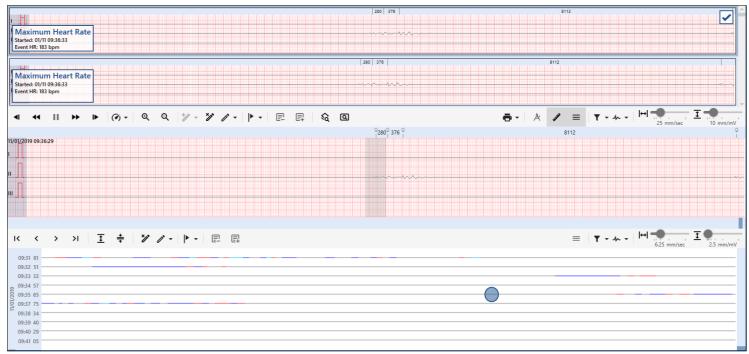


Figure 48

To view the ECG strip with the lowest heart rate, select **Minimum Heart Rate** from the Event list (see Figure 46).

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The screen below is changed accordingly (see Figure 49).

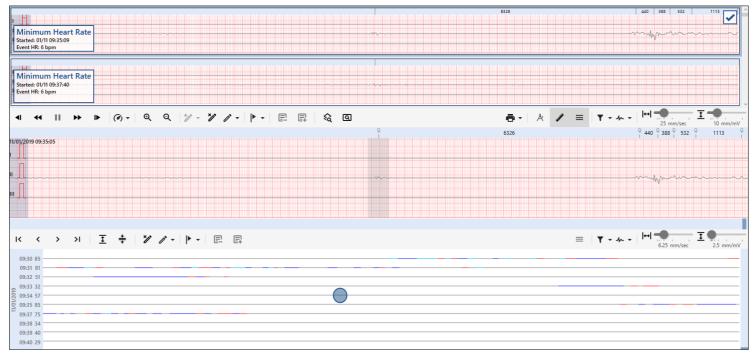


Figure 49

If you wish to view instantly the ECG strip with the longest RR interval, select **Maximum RR** from the Event list (see Figure 46).

The screen below is changed accordingly (see Figure 50).

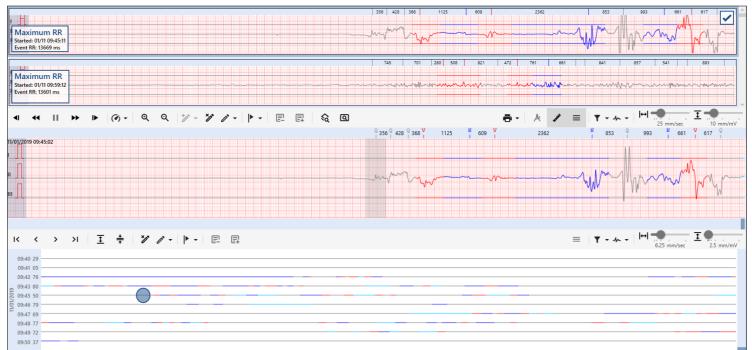


Figure 50

If you wish to view instantly the ECG strip with the shortest RR interval, select **Minimum RR** from the Event list (see Figure 46).

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The screen below is changed accordingly (see Figure 51).

384 496 637 360 444 508 689 484 432 388	557 621 605 348 565 80	15 388 593 765 661	805 573 669 549 1081	312 549 328
Minimum RR Started: 01/11 09:57:01 Event RR: 132 ms	way when we want was a start wat was the weak was	MMM		••••••••••••••••••••••••••••••••••••••
400 1129 348 569 593 360 368 593 821 Minimum RR Started: 01/1109:56:51 Event RR: 144 ms		440 520 729 404 384 496 	837 360 444 508 689 484 433 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
ब ब II ା ା । (?) - (२) २ (१) - ११ /	· • • • • • • • •		🖶 - 🙏 🥒 = 🛛 - 4	
404 ⁰ 384 ^V 496 ⁰ 637 ^N 360 ⁰ 444 ⁰ 508 ⁰ 689 ^N 484 ^N 432 ^V 388 ⁰ 01/2019 09:56:52		305 ° ° 388 ° 593 ° 765 ° 661 °	man and the second s	N Q Q312V 549 Q328Q
× < > > <u>∓</u> ≑ <i>∛ ∕</i> - + - =	Ę		≡ \▼ • 4	⊷ → H→I → , , , I → , , , , , , , , , , , , ,
09:51 100 09:53 100 09:54 111 09:55 105 09:56 112 09:57 107 09:58 95 09:59 94 10:00 91 10:02 102				

Figure 51

The \checkmark buttons allow scrolling the ECG strip to the next slower or faster heart rate or the next longer or shorter RR interval respectively.

If you do not agree with the example strips for maximum or minimum, you can select a different strip manually by using the mouse to move the marker and click the **T** button on the toolbar (see Figure 45).



Select the max/min values as final part of the review procedure. Otherwise, if changing something afterward (add/delete QRS etc.), the max/min values are automatically recalculated in the background, so it is necessary to assign max/min values again.

When you point with the mouse to a certain point within the trend, a small textbox appears (see Figure 52), displaying the values of either the heart rate or the RR interval duration.

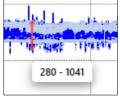


Figure 52

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Some actions are allowed directly on the trend when it is in RR mode. You can define an Event, exclude a noisy segment, or delete group of beats (see Figure 53).



Figure 53

To select the region on the trend, right-click and drag, and then choose the necessary action from the command menu (see Figure 53).

Histogram

Under the trend view you can see the histogram panel with the number of occurrences of the selected arrhythmia type (see Figure 54). The histogram is editable like the RR trend above.

You can select the interval by right-clicking and dragging, and then defining an Event, excluding a noisy segment, or deleting events in the selected range.

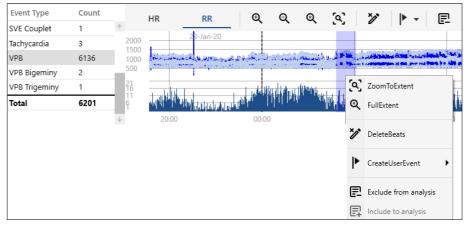


Figure 54

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Events Overview Panel

On top of the middle pane you can see a toolbar with several buttons allowing setting up the display of example strips and the lower pane. The button functions are explained below.

I< < > >I	Scroll through the example strips of the currently selected strip example. Use the K or M button to call up quickly the first or last strip.
Order By Duration	Use this drop-down list to select the order of the example strips that are sorted in the middle pane by StartSample, Duration, or HeartRate.
	This setting allows selecting the display layout of both the middle and lower panes. You can show Events in the middle pane and full disclosure, detailed strip view in the lower pane (as shown here), or any other combination.
	You can select the number of columns and lines using a simple selection tool as shown here.
и 1001 N 1009 N 977 N 989 N (Click to display the RR measurements/values above the ECG graph.
	Click to display the channels at the left of the ECG graph.
EMG C Base Line C Mains C	Select the filter(s) from the drop-down list
	Select the channel(s) from the drop-down list
I↔I I	To select the appropriate paper speed, use the $[H]$ slider. To select the ECG strip amplitude, use the $\boxed{1}$ slider.
Ō	Press this button to delete the selected event.
Your last setting	gs are stored automatically per arrhythmia type. The next time you

Your last settings are stored automatically per arrhythmia type. The next time you open the Event view, it displays the results as set up previously.

Note

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To select all strip windows for applying changes to all strips (like **Include in Report** for example), press and hold the **Shift** key while clicking the mouse on the first and last strip window, and then click the \checkmark button on the toolbar (see Figure 45).

To select a strip window, click the mouse on the window, and then click the \checkmark button on the toolbar.

To deselect the window, click the \checkmark button again on the toolbar.

1. To edit an event note, click the event, then click the **T** button on the toolbar or double-click the event (see Figure 45).

The Edit Event Note dialog box is displayed (see Figure 55).

T EDIT EVENT NOTE			
Event Note			
ОК	CANCEL		

Figure 55

2. Type the note and click **OK**.

To delete an event, click the mouse on the event, and then click the $\boxed{1}$ button.

Changing event type allows reclassifying selected events as a different event type.

To change the **Event Type**, click the mouse on the event, and then select the desired **Event Type** from the list (see Figure 46).

For instance, you can change an **SVE Run** event to **Atrial Fibrillation** or convert a **Triplet** to a **Couplet**, etc.



Use the **Ctrl**, **Shift** keys, and mouse to select and navigate between certain event strips or even to select a complete series of events.

Note

The textbox on bottom left of each event strip describes the start date and time, the duration, and heart rate value of the event (see Figure 56).



Figure 56

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ECG Preview Panel

The lower panel can display either a strip or a page (full disclosure) – see Figure 57.

You can preview and scan the ECG traces, create a user-defined event, reclassify or delete beats, exclude noisy segments, and print the ECG examples.

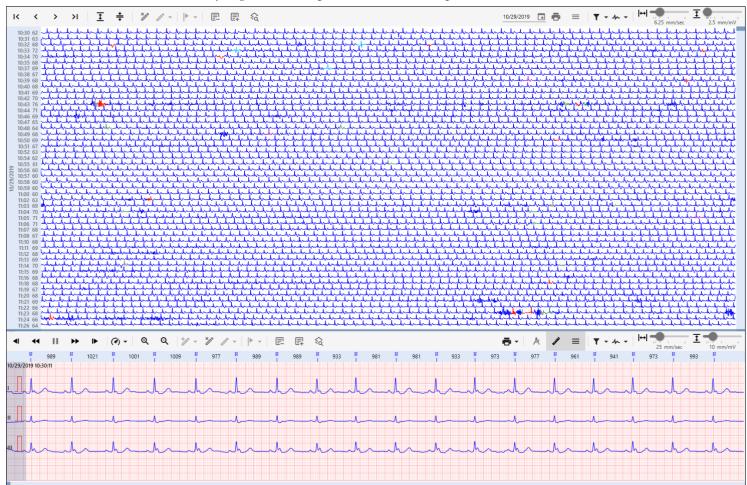


Figure 57

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Undo Changes

You can undo recent edits, additions and deletions of beats, events, and templates (see Figure 58).

To cancel the last change click the **Undo** button **n** on the main toolbar.

The process can be repeated to undo preceding commands.



- A Region is selected for beat deletion.
- **B** Beats are deleted from the region (the user decides this is a mistake).
- **C** 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

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Page View

The **Page** tab displays the entire ECG data as Full Disclosure and allows scrolling page forward and backward from the beginning to end of the study to review the complete recording (see Figure 59).

	ols 💽 🛌				Patien	t: John DOE	ID: 123456		- 8 0
😂 Record List	к < >	×ı <u>∓</u>	÷ %	· - ▶ - Ē				10/29/2019 🖬 🖶 🗮 🕇 🗸	
≟ ≡ Record Info	10:30 62 10:31 63 10:32 68				han				
🍫 Analysis	10:33 72				distanting a starting and a start of the sta			andar dan	ala antara da sa da sa da sa da antara da sa da sa Ana da sa da sa Ana da sa
Templates	10:37 69								
• Events	10:41 69	haihaihaihaihai daalaa haihaihai haihaihaihaihaiha		la da da da da da da da Martin da da da da da Martin da da da da da	haladadadadadada whaladada paljadjadjadjadja			- An	ika
E Page	10:44 71								
🗹 Graphs	10:49 68	ha da ha da da ha da ha ha ha ha da ha ha ha ha	-handrada da da da handrada da da da da handrada da da da da da	-h-h-h-h-h-h-h-h h-h-h-h-h-h-h-h-h wiji-h-h-h-h-h-h-h-h-					
🗄 Tabular Summary	10:54 62								
🔤 Report	610156 60 10:56 60 10:57 60 10:57 60 10:59 60 10:59 60 11:00 60	مار بار بار بار بار بار المسلم بار بار بار بار مار بار بار بار بار	- handra dan dan dan dar handra dan dan dan dar	hai hai hai hai hai hai Mandaraha Mandaraha Mandaraha daraha daraha	ha ha ha ha ha ha h nha ha ha ha ha ha h ha ha ha ha ha ha h	An An An An An An An An An An An An An An An	i da	ala andre al a calendar a la calendar a La calendar a la calendar a A calendar a la calendar a	ار شاور شاور شاور شاور شاور شاور شاور شا
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	N 989 10/29/2019 10:30:11	▶ ► ► N 1021	() - Q	1009 N 977	N 989 N	- LE+ ≺Q 989 № 933 №	981 N 981 N 933 N I I I 933 I	-	
	N 989		(0) • ~	1009 N 977		- E+ NQ	981 N 981 N 933 N		
	N 989		(0) • ~			- E+ NQ	981 N 981 N 933 N		

Figure 59

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 25 mm/s
1 .5 mm/mV	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 80 mm/mV .
↓ ▼ 1 11 11	Use this control to select the channel(s) for display.
<u>∓</u> ≑	To increase the number of the displayed ECG strips, click ‡ .
	To decrease the number of the displayed ECG strips, click I .

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Page Navigation

	The And d buttons allow scrolling Page up or Page down to view the next or previous page of the ECG recording. The And d buttons allow quick view of the end (final page) or the beginning (first page) of the ECG recording.
10/29/2019 Image: Content of the second	To scroll to the next day, click 💼 and then click the next date 🗿 or 📡.

ECG Detailed Strip

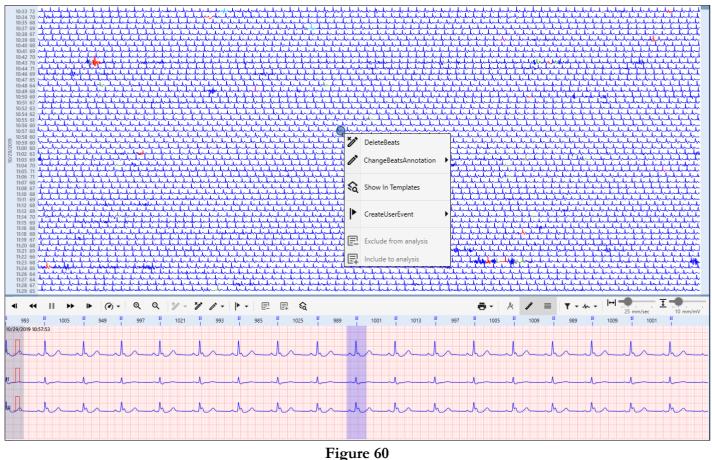
The bottom pane of the screen displays the ECG detailed strip view (see Figure 59).

Full Disclosure Page

The full disclosure ECG display area allows viewing large sections of one selectable ECG channel (see Figure 60).

The green circle in the middle of the page represents the current cursor position in the bottom ECG Detailed Strip view.

On the Page Panel you can use the mouse to highlight an ECG interval for creating Event, delete beats, exclude the noisy interval, or immediately print the ECG examples.



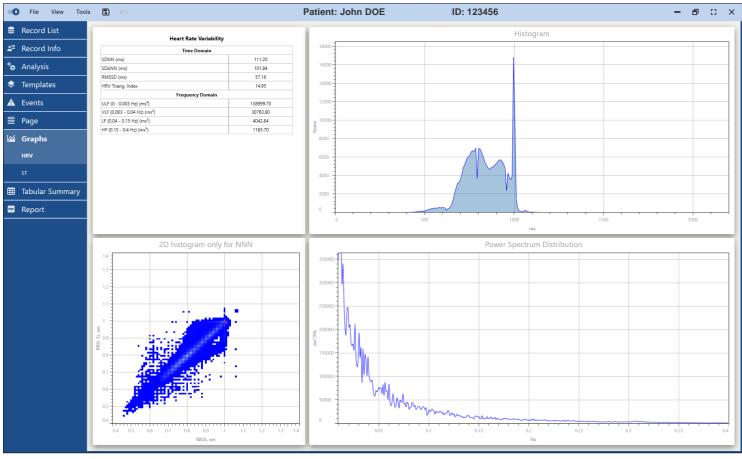
To print the highlighted section, click the 🔂 button on the toolbar. To create an event, see Step 3 and Figure 40 on page 51.

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Graphs View – HRV and ST

The Graphs view allows examining the results of HRV analysis and preview ST trends.

HRV graphs display all the results of the time domain analysis as well as the frequency domain spectrum (see Figure 61).





The **HRV** and **ST** buttons under **Graphs** allow selecting the page with HRV analysis, or displaying the ST trends.

HRV Analysis

- The Heart Rate Variability table lists the most common values of the HRV Time Domain and Frequency Domain analysis, such as SDNN, SDANN, RMSSD, etc.
- **Histogram** displays the numbers of RR Intervals with equal interval durations. The shape of the graph gives you the information about the variability at a glance.
- The Lorenz Plot or Scatter Gram (bottom left) is based on the RR Intervals of consecutive N-annotated beats (no S or V preceeding 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 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.

• The **Power Spectrum Distribution** displays the result of the frequency domain analysis.

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ST Trends

This page represents the ST calculations per each ECG channel. The top trend on the page represents the HR or RR intervals (see Figure 62).



Figure 62

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

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Tabular Summary

The Tabular Summary displays **Hourly Tabular Report** table with all arrhythmias detected by the software during the analysis.

This table is useful to predict whether certain arrhythmias appeared only under certain circumstances (see Figure 63).

	Patient: John DOE	ID: 123456	
Record List	Hourly Tabular Report: Day 1 - 2	2 (10/29/2019 - 10/30/2019)	
Record Info	e srage HR ximum al Beats ed Beat	VPB Couplet SVE Triplet SVE SVE Couplet Tachycardia	
Analysis	Minimu 0 0 Minimu 0 1030 2 0 9 0 9 0 9 9 10 0 9 9 9 0 9 9 9	o VPB O VPB O VPB O VPB O SVE O SVE	
Templates	10:59 60 69 108 4110 2 0 11:59 77 82 104 4924 3 0 12:59 63 71 83 4269 1 0	14 0 1 54 0 0 4 3 0 41 2 0 0 0 0 18 0 0	
Events	13:59 65 75 90 4468 5 0 14:59 71 79 94 4752 6 0 15:59 77 83 90 4956 2 0	9 1 0 98 0 0 4 0 0 34 0 0 203 0 0 456 5 1	
Page	16.59 75 83 100 500 15 0 17.59 75 80 91 4784 1 0 18.59 66 73 94 4344 0 0	1 0 0 15 0 0 3 0 0 6 0 0 0 0 0 171 1 0	
Graphs	19:59 63 68 82 4092 0 0 20:59 66 76 90 4530 9 0	2 0 0 265 0 0 4 2 0 294 2 1	
Tabular Summary	21:59 70 76 93 4539 11 0 22:59 65 77 99 4604 31 1 23:59 60 69 88 4098 2 0	6 1 0 19 1 0 4 0 0 325 0 0	
General	00:59 65 72 88 4311 4 0 01:59 61 67 86 4005 0 0 02:59 60 63 75 3801 0 0	67 0 0 800 0 0 223 1 0 88 1 0 1 0 0 72 2 0	
Pacemaker	03:59 60 61 72 3649 0 0 04:59 59 64 87 3851 0 0 05:59 59 64 84 3844 0 0	1 0 0 9 0 0 67 1 0 122 1 1 263 0 0 57 0 0	
Report	06:59 61 68 81 4081 0 0 07:59 66 77 95 4638 28 0 08:59 70 80 97 4781 22 0	333 0 0 178 0 0 28 0 0 882 1 1 42 4 0 772 0 0	
	09:59 62 71 87 4227 9 0	10 2 0 337 1 0	
		VPB Bigeminy Tachycarc Bradycarc Tachycarc ST Atrial Fibrillatic	
	10:30 60 67 92 1985 0 10:59 60 69 108 4110 0 11:59 77 82 104 4924 0	0 0 0 0.08:47 0:03:01 0 0 0:00:17 0:02:23 0 0 0 0:00:19 0 0	
	11:59 77 82 104 4924 0 12:59 63 71 83 4269 0 13:59 65 75 90 4468 0	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	
	14:59 71 79 94 4752 0	0 0 0 0 0 0.01:03 0 k00:25 0 0 0 0 0 0	
	16:59 75 83 100 5006 0	0 0 0 0 0	
	17:59 75 80 91 4784 0 18:59 66 73 94 4344 0	0 0 0 0 0 0 0 0 0 0 0	
	19:59 63 68 82 4092 0 20:59 66 76 90 4530 0	0 0 0 0 0 0 0 0 0 0 0 0:00:48 0	
	21:59 70 76 93 4539 0	0 0 0 0 0 0	
	22:59 65 77 99 4604 0 23:59 60 69 88 4098 0	0 0 0 0 0 0 0 0 0 0 0 0:07:43 0	
	00:59 65 72 88 4311 0	0 0 0 0 0:00:48 0	
	01:59 61 67 86 4005 0:00:19 02:59 60 63 75 3801 0	0 0 0 0 0 0 0 0 0 0 0 0	
	03:59 60 61 72 3649 0	0 0 0 0 0 0	
	04:59 59 64 87 3851 0 05:59 59 64 84 3844 0	0 0 0:00:11 0 0:11:28 0 0 0 0:00:10 0 0 0	
	06:59 61 68 81 4081 0	0 0 0 0 0 0	
	07:59 66 77 95 4638 0:00:06 08:59 70 80 97 4781 0:00:10	0 0 0 0 0:04:32 0 0 0 0 0 0:01:19 0	
	09:59 62 71 87 4227 0	0 0 0 0 0 0:00:31 0	

Figure 63

- When the recording duration exceeds one day and the table exceeds the page, scroll forward or backward through the pages using the or duttons.
- To export the table to Excel, click the $\mathbf{\overline{M}}$ button.
- To export the table to PDF, click the 🔤 button.
- To print the table, click the 📑 button.

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Pacemaker Analysis

When pacemaker detection has been enabled in the recorder, the **Pacemaker Tabular Report** represents the pacemaker-analysis hourly statistics (see Figure 64).

💶 File View Tools 🕃 🗠		Pat	tient	·.loh	n DO	F				1234	56				_	Ð	:: ×
Record List		Pacema					have 1	2 (10				/2010	`			-	
			iker i		аг кер	ort: L	ayı-	5 (10		- ero.	10/51	2013	,				
L≡ Record Info	e	Total Beat	ced Bea	ial Pac	nt. Pace	AV Paced	% Paced	% Atrial Paced	% Vent. Paced	% AV Pace	Sense Failure	Capture Failure	ibition				
😋 Analysis	道 10:30	1985	4 2	1¥ 2	2 1	0	0.2	0.1	0.1	0.1	0	0	2 1				
Templates	10:59 11:59 12:59	4110 4924 4269	3	1	2	0	< 0.1 < 0.1 < 0.1	< 0.1 < 0.1 < 0.1	< 0.1 < 0.1 0	< 0.1 < 0.1 < 0.1	0 0 0	0 0 0	0				
A Events	13:59 14:59	4468 4752	5	3	2	0	0.1	< 0.1	< 0.1	< 0.1	0	0	1				
≣ Page	15:59 16:59 17:59	4956 5006 4784	2 15 1	0 2 0	2 8 1	0 5 0	< 0.1 0.3 < 0.1	0 < 0.1 0	< 0.1 0.2 < 0.1	0 < 0.1 0	0 2 0	0	1 2 1				
🗹 Graphs	18:59 19:59	4344 4092	0	0	0	0	0	0	0	0	0	0	0				
I Tabular Summary	20:59 21:59 22:59	4530 4539 4604	9 11 31	1 4 8	7 7 16	1 0 7	0.2 0.2 0.7	< 0.1 < 0.1 0.2	0.2 0.2 0.3	< 0.1 < 0.1 0.2	1 1 5	0	3 6 11				
General	23:59 00:59	4098 4311	2	1	1	0	< 0.1	< 0.1 < 0.1	< 0.1 < 0.1 0	< 0.1	0	0	1				
Pacemaker	01:59 02:59 03:59	4005 3801 3649	0	0	0 0 0 0	0 0 0	0	0 0 0	0	0	0 0 0	0 0 0	0				
Report	04:59 05:59 06:59	3851 3844 4081	0 0 0 0	0	0 0 0	0	0	0 0 0	0	0	0 0 0	0 0 0	0				
	07:59 08:59	4638 4781	28 22	3	23 17	2	0.6	< 0.1 < 0.1	0.5	< 0.1 < 0.1	2	1	14 12				
	09:59 10:59 11:59	4227 4434 4360	9 3 2	2	6 1 2	1 1 0	0.2 < 0.1 < 0.1	< 0.1 < 0.1 0	0.1 < 0.1 < 0.1	< 0.1 < 0.1 0	1 0 0	0	4 1 2				
	12:59 13:59	4602 4679	3	0	3	0	< 0.1	0	< 0.1	0	0	0	0 4				
	14:59 15:59 16:59	4298 4162 4432	0 1 61	0	0 1 59	0	0 < 0.1	0 0 < 0.1	0 < 0.1	0 0 < 0.1	0	0	0 0 39				
	17:59 18:59	5461 5866	42	7	35 4	0	0.8	0.1	0.6	0.1	0	0	33				
	19:59 20:59 21:59	5561 5493 5553	1 0 14	0	1 0 11	0	< 0.1 0 0.3	0 < 0.1	< 0.1 0 0.2	0 < 0.1	0	0	1 0 7				
	22:59 23:59	5285 5266	1	1	0	0	< 0.1 < 0.1	< 0.1 0	0 < 0.1	< 0.1 0	0	0	0				
	00:59 01:59 02:59	5136 4860 4493	6 0 0	0	6 0	0	0.1	0	0.1	0	0	0	6 0 0				
	03:59 04:59	3845 3756	0	0	0	0	0	0	0	0	0	0	0				
	05:59 06:59 07:59	4034 3865 3829	1 0 0	0	1 0 0	0	< 0.1 0	0 0 0	< 0.1 0	0	0	0	1 0 0				
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						Of 2 🕽	- La	PDF	ē								
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Figure 64

- When the table exceeds the page, scroll forward or backward through the pages using the
 or buttons.
- To export the table to Excel, click the 🙀 button.
- To export the table to PDF, click the 🔤 button.
- To print the table, click the 📑 button.

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Report

You can customize your report with the address details and logo of your hospital or clinic (see Section Software Setup after Installation on page 10, and Figure 65).

	Page ^ Paper Size A4 General ^ Summary
	Paper Size A4 • General ^
Analysis	A4 • • • • • • • • • • • • • • • • • • •
Default Department	
	Summary
A Events Patient Information ID: 123436 Weight: Height: Last Nume DOIE Address: Statement	
Page First Name John Referring organization: Date Of Birth: 66131945 Age: 74 Referring Physician:	Conclusion
Graphs Order Number: MRN: Melications Indications Indications	Events
	Lvents
Holter Summary Report	Hourly Tabular Report
Recorded Analyzed Time Domain Frequency Domain (ms ²)	Pacemaker Tabular Report 📔 💶 🔵
Duration (hh.mm) 71:34 71:34 SDNN (m) 1111.2 ULF (0.0003 Hz) 139999.7	Diary Entry Index
Builder Stop 11/01/2019 10:05 PAISSD (ms) 57.16 LF (0,04 - 0.15 Hz) 4042 S4	Selected ECG Events
Designer Channels I, II, III I.HV into game 14.95 HF (0.15 - 0.4 Hz) 1165.7 Variationals Feedpy Heart State Hea	
Total Total	Charts ^
Beats (% of full beats) 3191 (1%) Total Beats 320036 Lolated 2592 Average HR 76	
1a0ated 2292 Average nat. /0 Bigeningv 48 Max ER 151 1101/2019 09:23	HRV 🛛
Triggeniny 96 Min HR 6 11/01/2019 09:35	ST 🛛
Couplet 74 Bindy-math (=6.0 kpm) 59 Traphet 2.5 Longest Bandy-condition 0.105 11.101/2019.09.04.5	RR Trend
	HR Trend
Fusion 866 Longest Tacycardia 0:04-23 11:01/2019 09:22	HR Irend
Supraventricular Ectopy 31961 (9.99%) Pause (> 2000 ms) 125	
Instand 21644 Jam R2 (ma) 0 1101/2019 09-35 Pair 5379 Max R2 (ma) 1569 1101/2019 09-45	Full Disclosure
Run (>=3) 0 Atrial Fibrillation 67 0.01% of analysed time	
Langert Atrial Fibrillation 0.00.45 10.29.2019 10.41	Full Disclosure
Relative ST Analysis Respiration	Start
Max Depression (> 1.00 mm) 2.47 Longert Sleep Apnea	10/29/2019 10:30 🜲
Reference ST: I - 0.44 mm II - 0.12 mm III 0.34 mm	End
	11/01/2019 10:05
	Channel
Conclusion	<u> </u>
	Page Duration 1 Hour
	Gain
	1.25 mm/mV 💌
-	

Figure 65

- The right pane allows including or excluding report sections in the final printed report. To include a section, turn ON the relevant switch . Any excluded section can always be reincluded and vice versa.
- The **middle pane** includes the report.
 - A. To preview a report, click Generate Report on the toolbar (see Figure 65).

It may take a few seconds while the software generates a comprehensive report.

- B. Click Confirm Report to finalize and save the report (see Figure 65).
- C. To zoom in to the report, click \bigcirc ZoomIn on the toolbar.
- D. To zoom out of the report, click \bigcirc ZoomOut on the toolbar.
- E. To export the report to PDF, click Export To Pdf on the toolbar.
- F. To print the report, click **Print Report** on the toolbar.
- The **bottom pane** includes the conclusion. Text can be entered using the keyboard.

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6. Recommended Workflow Options

The previous chapters explained what the analysis does and how you can adapt the analysis to your needs.

Further there is an overview of the various possibilities to edit analysis results, and finally how to obtain a printed report with your personal findings included.

Standard Workflow

- 1. Setup configuration
 - a. Template Sensitivity (see Figure 66)
 - 0 For N, Q, and P type annotations
 - **3** For **V** type annotations
 - **1** For **F** and **S** type annotations

🔯 Settings		×			
Defaults	1 ST Deviation				
General	Templates Sensitivity				
Algorithm	V 3 (Recommended: 3)				
Pacemaker	F - 1 (Recommended: 1) S - 1 (Recommended: 1)				
Symptoms	Q 🗣 0 (Recommended: 1)				
Activities	P • 0 (Recommended: 1)				
Medications	2000 ms				
Indications	IS Normal HR Range				
Records	(60 - 100) bpm				
Reports					
	Restore Defaults OK Cancel A	pply			

Figure 66

- To open the record, run the NH-301 Holter analysis system.
 After the program opens, double-click the selected patient record on the **Record List** panel.
- 3. When the patient data panel appears, click the 🍫 Analysis tab.
- 4. On the right of the Analysis screen, click the **START** button.
- 5. Upon completion of the analysis, click the **A** Events tab:
 - A. Select Maximum RR from the **Event Type** list (or use any other means to make sure the RR-trend and the ECG strip are displayed).
 - B. Using the RR-trend and the ECG strip, select regions to be excluded from analysis.

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- C. If there are events of Atrial Fibrillation type:
 - a. Select Atrial Fibrillation from the Event Type list.
 - b. Review Atrial Fibrillation events and delete events that are not truely Atrial Fibrillation (AFib).
 - c. If there are any AFib events remaining, select all, and then hover over **s** and click **N** (see Figure 67).



Figure 67

D. If required, create additional AFib events.

- 6. Click the S Templates tab.
- 7. Use the → 25 mm/sec slider at the top right of the page (see Figure 59) to set the paper speed for the template boxes to 100 mm/s, since this setting allows displaying more details of the beat morphologies.
- 8. Select the **Overlay All Beats** option for every template (see Section Overlay All Beats Feature on page 47).

Now you should see all beats overlaid in their relevant template boxes and you can quickly distinguish between templates to be handled as a whole and those requiring individual editing.

9. Examine the annotations of the templates that can be handled as a whole and correct the annotation if necessary (see Section Editing the Annotations in the Caliper on page 53). Always start with **V**, then **F**, and finish with **S**.

You can right-click on the relevant template and select *Ctrl+click* from the context menu. Using Windows[®] shortcuts (*Ctrl+click* or **Shift+click**) allows selecting beats that should be removed as artifacts. Proceed with the next beats.

Make sure to click the **Apply** button in the end to ensure saving your changes.

- 10. Click the **A** Events tab, and examine the example ECG strips for various arrhythmia types. To select an ECG strip for print, click the start of the ECG strip, press and hold the **Shift** key while clicking the end of the ECG strip, and then click **a**.
- 11. Click the Report tab. Verify that all report sections you want to include are selected.Click the Generate Report button and wait a few seconds until the final report is generated.
- 12. If you prefer, enter your personal findings in the **Conclusion** section below the report.
- 13. To finalize your review and prepare the PDF report, click Confirm Report.
- 14. Print the report and/or click the **Export to PDF** button to export the report to PDF file (or to create the Report in PDF format).
- 15. Close the study.

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Perfectionist Workflow

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

- 1. Setup configuration:
 - A. Templates Sensitivity:
 - **3** For **V** type annotations
 - **1** For all other annotation types
- To open the record, run the NH-301 Holter analysis system.
 After the program opens, double-click the selected patient record on the Record List panel.
- 3. When the patient data panel appears, click the 🍫 Analysis tab.
- 4. On the **Analysis** display:
 - A. Click the **I** button.
 - B. If there is no ECG visible on the page (only noise), click the **b** button repeatedly until ECG is found, while after each couple of times the **b** button is clicked, change the channel to see if any of the other channels has ECG.
 - C. When finding a channel with ECG traces, mark it as the point for the end of analysis.
 - D. Click the **START** button.
- 5. Upon completion of the analysis, click the \blacktriangle Events tab:
 - A. Select Maximum RR from the **Event Type** list (or use any other means to make sure the RR-trend and the ECG strip are displayed).
 - B. Using the RR-trend and the ECG strip, select regions to be excluded from analysis.
- 6. Click the Templates tab to review the algorithm decisions about the heart beat shapes but not the decisions about their prematurity i.e., reviewing whether heart beats annotated as N and S really have normal shapes and whether heart beats annotated as V and F really have abnormal shapes.

At this stage, there is no need to review wheter heartbeats annotated as **S** are really premature, which is done later (after AFib events are reviewed).

- 7. Use the → speed for the template boxes to 100 mm/s, since this setting allows displaying more details of the beat morphologies.
- 8. Select the **Overlay All Beats** option for every template (see Section Overlay All Beats Feature on page 47).

Now you should see all beats overlaid in their relevant template boxes and you can quickly distinguish between templates to be handled as a whole and those requiring individual editing.

Examine the annotations of the templates that can be handled as a whole and correct the annotation if necessary (see Section Editing the Annotations in the Caliper on page 53). Always start with V, then F, and finish with S.

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10. Click the \blacktriangle Events tab:

- A. If there are events of Atrial Fibrillation type, select Atrial Fibrillation from the **Event Type** list (or use any other means to make sure that the RR-trend and the ECG strip are shown).
- B. Review Atrial Fibrillation events and delete events that are not truely Atrial Fibrillation (AFib).
- C. If there are any AFib events remaining, select all, and then hover over **s** and click **N** (see Figure 67).
- D. If required, create additional AFib events.
- 11. Click the S Templates tab to review the algorithm decisions about prematurity of the heart beats.
- 12. Right-click on the relevant template and select **EditTemplate** from the context menu. Using Windows[®] shortcuts (**Ctrl+click** or **Shift+click**) you can select beats that should be removed as artifacts. Proceed with the next beats. Make sure to click the **Apply** button in the end to ensure saving your changes.
- 13. Click the **A** Events tab, and examine the example ECG strips for various arrhythmia types. To select an ECG strip for print, click the start of the ECG strip, press and hold the **Shift** key while clicking the end of the ECG strip, and then click **-**.
- 14. Click the **Report** tab. Verify that all report sections you want to include are selected.
- 15. Click the Generate Report button and wait a few seconds until the final report is generated.
- 16. If you prefer, enter your personal findings in the **Conclusion** section below the report.
- 17. To finalize your review and prepare the PDF report, click 🗸 Confirm Report.
- 18. Print the report and/or click the **Export to PDF** button to export the report to PDF file (or to create the Report in PDF format).
- 19. Close the study.

Clarifications and Explanations

• In both workflows, no selection of channels for analysis is done.

This is because the algorithm estimates usefulness of each channel at a specific time and acts accordingly. In the absolute majority of records, this leads to an additional channel being beneficial for the analysis even if it has low-quality signal.

- In the Standard workflow on the 🏠 Analysis display, all regions are included in the analysis and the start and end of analysis are not selected. This is because excluding regions from the analysis after the analysis is completed (RR-trend) is faster and easier and there is no advantage in 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 as the result of the combination of both:
 - Templates being enabled for annotations of type **N**, **Q**, or **P**.
 - Many hours with no channels having any ECG (detached electrodes).
- When both conditions occur, the algorithm attempts finding similar shapes where no such similarities can be found. Relatively short periods (up to tens of minutes) where no channels have ECG, do not create such a problem, and if at least one of the channels has ECG, the problem does not 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**, the end of the record should be examined and the end of the analysis should be selected.

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When SVEs are excluded from Atrial Fibrillation events (either hovering over s and clicking s (see Figure 67), 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 heart beat shapes should be done before any SVEs are excluded from Atrial Fibrillation (but after bad ECG regions were excluded from the analysis). However, the review of heart beats prematurity should be performed after SVEs are excluded from Atrial Fibrillation.

This is why the perfectionist workflow has multiple switches between the \blacktriangle Events and the \diamondsuit Templates displays.

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Appendix A – RR Trend Use and Explanations

The RR trend consists of blue vertical lines with light-blue dots on top of them. Each vertical line of pixels shows information regarding 1 to 2 minutes of the record (see Figure 68).

- The blue lines represent the connection between the maximal and minimal RRs within the 1-2 minute intervals.
- For each RR interval within 1-2 minutes, there is a light-blue dot at the height representing the interval duration. Frequently, there are various RR intervals with close values, resulting in many light-blue dots included in the same pixel (i.e., one light-blue pixel can represent multiple RR intervals).

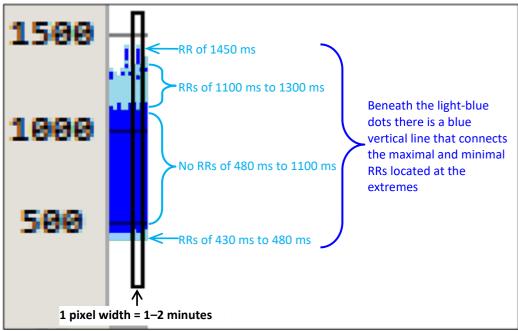


Figure 68

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The RR trend also includes three additional vertical lines (see Figure 69).

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

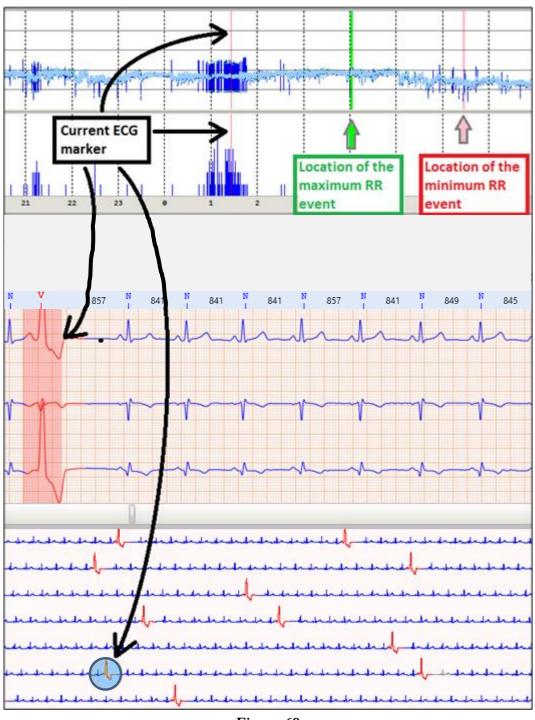
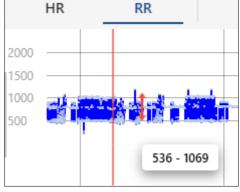


Figure 69

While hovering 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.

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Moreover, the actual values of minimal and maximal RRs are shown below in milliseconds (see Figure 70).





Clicking the mouse 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 column where the mouse was clicked.

The height at which the mouse is clicked is significant, since it determines the specific location inside that 1-2 minute period displayed.

The shown location is the RR location closest to the height at which the mouse was clicked. When clicked above the blue line, the maximal RR is displayed and if clicked below the blue line the minimal RR is displayed during the 1-2 minute period (see Figure 71).

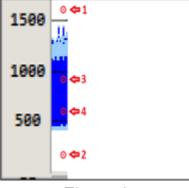


Figure 71

- 1. Shows maximal RR within the 1-2 minute period (1450 ms)
- 2. Shows minimal RR within the 1-2 minute period (420 ms)
- 3. Shows RR of 1120 ms, which is the shortest RR among RRs longer than 1000 ms. Explanation:

The mouse was clicked in an area without RRs (blue pixel, not light-blue), so the RR displayed is either the longest RR below the height of mouse click (450 ms) or the shortest RR above the mouse click (1120 ms). Since the mouse click is closer to the latter than the former, the RR of 1120 ms is displayed.

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

The mouse was clicked in an area without RRs (blue pixel, not light-blue), so the RR displayed is either the longest RR below the height of mouse click (450 ms) or the shortest RR above the mouse click (1120 ms). Since the mouse click is closer to the former than the latter, the RR of 450 ms is displayed.

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RR Trend Examples

Normal Sinus Rhythm (NSR)

See Figure 72.

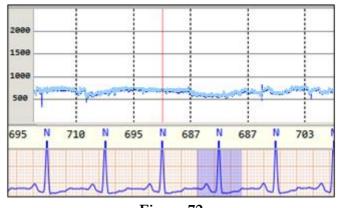


Figure 72

NSR with VPBs

See Figure 73.

- 1. Lower Line Ectopic RRs (N–V)
- 2. Upper Line Compensatory Pause RRs (V–N)
- 3. Middle Line NSR RRs (**N**–**N**)

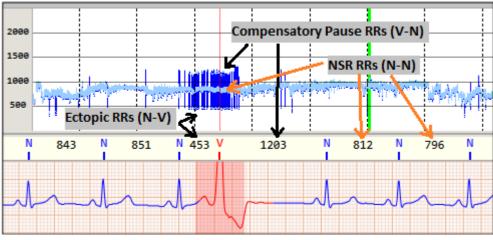


Figure 73

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Sustained Supraventricular Tachycardia (SVT)

See Figure 74.

- 1. Upper light-blue line NSR RRs
- 2. Depressed light-blue line SVT RRs

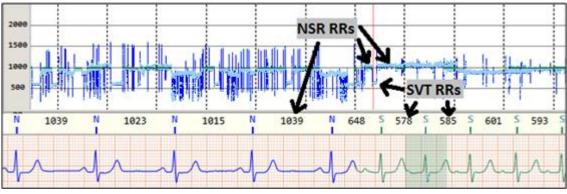


Figure 74

NSR with VPBs without Compensatory Pause

See Figure 75.

- 1. Upper light-blue line NSR (**N**–**N**)
- 2. Lower light-blue line Ectopic RRs (N–V)
- 3. Middle light-blue line RR after VPB (V–N)

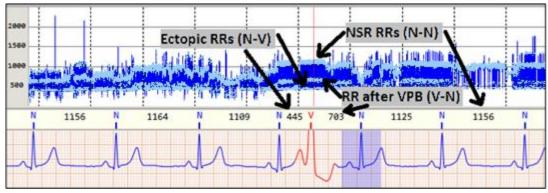


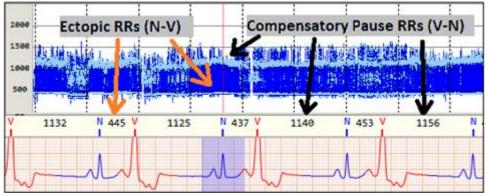
Figure 75

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Ventricular Bigeminy

See Figure 76 and Table 10.

- 1. Lower light-blue line Ectopic RRs (N–V)
- 2. Upper light-blue line Compensatory Pause RRs (V–N)







Mouse Click on	Display
White area below lower light-blue line	Shortest Ectopic RR (N–V)
Lower part of blue area	Longest Ectopic RR (N–V)
White area above upper light-blue line	Longest Compensatory Pause (V–N)
Upper part of blue area	Shortest Compensatory Pause (V–N)

Supraventricular Bigeminy

See Figure 77.

- 1. Lower light-blue line Ectopic RRs (N–S)
- 2. Upper light-blue line Compensatory Pause RRs (S–N)

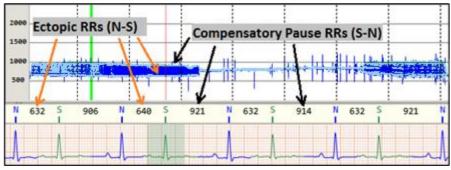


Figure 77

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Pacemaker Failure to Capture

See Figure 78.

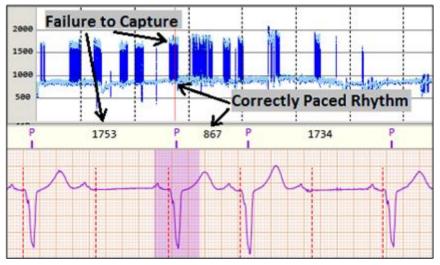


Figure 78

Atrial Fibrillation

See wide light-blue ribbon – Figure 79.

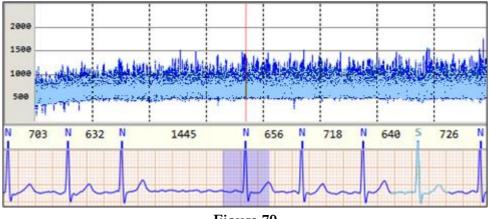


Figure 79

Wenkebach (Mobitz I)

In Figure 80 at the immediate vicinity of the red thin line, the RR-trend looks very similar to Atrial Fibrillation and other events, thus when the RR trend appears like a wide light-blue ribbon, the strip and page should be also consulted to differentiate between the different possibilities.

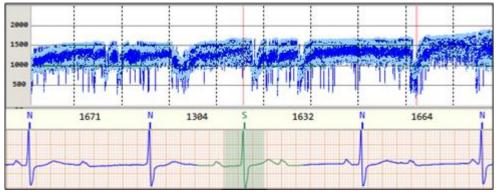


Figure 80

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Sick Sinus Syndrome

Wide light-blue ribbon (see Figure 81) – The RR trend may look similar to that of Atrial Fibrillation and other events, thus when the RR trend appears like a wide light-blue ribbon, the strip and page should also be consulted.

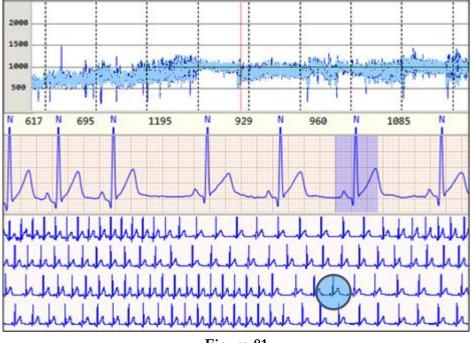


Figure 81

Atrial Flutter

Different horizontal light-blue lines correspond to different P:R ratios (see Figure 82).

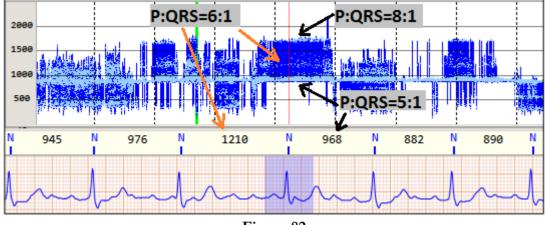


Figure 82

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NSR with High HRV

See Figure 83.

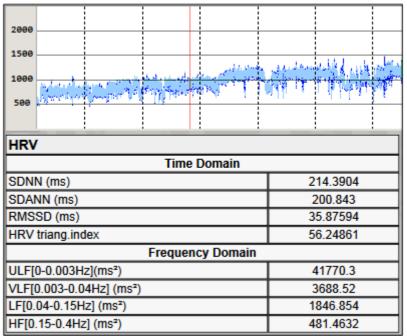


Figure 83

NSR with Low HRV

See Figure 84.

2000						
1500						
1000						
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](ms ²)	3704.025					
VLF[0.003-0.04Hz] (ms ²)	189.9941					
LF[0.04-0.15Hz] (ms ²)	70.07948					
HF[0.15-0.4Hz] (ms²)	20.47246					

Figure 84

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Appendix B – Holter Monitor Patient Diary Form

See Figure 85.

Institution:						
Referring Physician:						
Patient Name:						
Date of Birth:		Gender:	N	MRN:		
						-
Recording Period:	Hours	from:			to:	
Recorder:			Connected by	y:		

Figure 85

Dear patient,

While you are being monitored by a Holter monitor, it is 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 physician 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

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Appendix C – Patient Instructions



Caution

The physician is responsible for providing the patient with the following information required for a safe and effective ECG recording.

Patient Safety Cautions

- Notify the physician if skin problems develop. In rare cases, even when using biocompatible electrodes, allergic reactions may occur.
- > Do not expose the recorder to water in adverse weather or by taking a bath.
- Keep the recorder inside its pouch and wear it under a coat in adverse weather. Excessive humidity can damage parts of the recorder.
- Do not expose the recorder to extreme temperatures. In hot climates, stay in temperature-controlled environments as much as possible. In cold climates, wear the recorder under outer garments.
- Do not excessively bend or wrap the ECG cable around the recorder. The ECG cable can be damaged this way.
- > Keep distance from electrical equipment.
- > Do not use an electric blanket when you are wearing the recorder.

Recording Diary

According to the physician choice, the patient can maintain a Holter Monitor Patient Diary Form to record activities, symptoms, and the corresponding times during the ECG recording.

There are a few options for diary (depending on the recorder settings):

- Click the recorder **Event** button to note the time, and write symptoms/activities separately.
- Click the recorder **Event** button and select a reason from the predefined list.
- Click the recorder **Event** button and record a voice message about the event.

Marking a Patient Event

According to physician choice, the patient can use the recorder **Event** button to mark the times when feeling symptoms or performing particular activities, and selecting the activity from the list or using the voice message option (depending on the recorder settings).

To mark an event, the patient should press the **Event** button for 2-3 seconds until the recorder beeps.