R.TEST Evolution 4

User Manual

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1 Contents

2 Introduction

2.1 Description of the device

The R.Test Evolution 4 is a miniature automatic ECG arrhythmia detection device; it is quick and easy to fit to the patient. It is designed to detect and store the most important pathologic events (symptomatic or asymptomatic) as well as the patient's continuous heart rate, and is capable of up to 32 days of ambulatory monitoring.
The system consists of a unit weighing approximately 40 grams that can be worn by the patient unobtrusively and without any discomfort. The R.Test Evolution 4 is connected to the patient by a system of electrodes and a neck cable. Events stored by the R.Test Evolution 4 are then transferred to a computer for interpretation via a USB cable.
The use of a computer will allow:
- the programming of the conditions and criteria for each recording made by the R.Test Evolution 4.
- in addition, to select, organize and store the results of the examinations, then to print a customised report according to your needs.

2.2 This manual

This manual describes the physical operation, instructions, characteristics, technical specifications and the particular recommendations of use of the R.Test Evolution 4 and its accessories.
Although the greatest care was taken in its drafting, in order to make it as complete as possible, NOVACOR does not accept any responsibility for any errors, omissions or inaccuracies which it may contain.
The functionalities of the device and the accessories, as well as the contents of the manual, can be modified by NOVACOR without notice.

2.3 Safety information

Intended Users:
The R.Test Evolution 4 is intended for use by a licensed physician, or a person working under their supervision, after having read the R.Test 4 and RTSoft Ultima user manuals. No further training is necessary to use the equipment.
The patient is required to wear the device and should trigger recordings manually, the physician should ensure that the mental and physical condition of the patient is compatible with an R.Test procedure. The physician should inform the patient of the

nature of the test and any actions that are required (e.g. removal of the recorder for a shower, manual activation of recordings etc.).
The ECG strips recorded by the R.Test 4 during the procedure are then analysed to determine the presence (not the absence) of a pathological arrhythmia.
The R.Test 4 should not be used on patients with potentially life-threatening arrhythmias who require inpatient monitoring or on patients who the attending physician thinks should be hospitalised.

R. Test 4 is intended for use in an electromagnetic environment in which disturbances due to RF radiation are controlled.

Electromagnetic compatibility

This medical device complies with the applicable electromagnetic compatibility standards and will ensure that any electromagnetic interference, from radio frequency transmitters or other electronic devices, does not create an additional hazard.

The user of the medical device can help to avoid electromagnetic interference by maintaining a minimum distance, depending on the maximum power of the radio frequency transmission equipment.

Warning: RF portable communication devices (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of R.Test 4, including the cables specified by the manufacturer. Otherwise, the performance of these devices may be impaired.

Warning: The R.Test 4 should not be used next to other devices, or stacked with them, because this may cause a malfunction. If this is necessary, this unit and other devices should be observed for normal operation.

Warning: The use of accessories other than those specified or sold by NOVACOR as replacement parts may result in increased emission or decreased immunity of the medical device and may cause improper operation.

Recommendations and manufacturer's declaration		
The R.Test 4 is intended for use in an electromagnetic environment as specified below. The clinician and the user should ensure that the device is used in such an environment		
Electromagnetic emissions		
Emissions tests	**Conformity**	**Electromagnetic environment - remarks**
Impact of Electromagnetic field emitted by the device (Radiated emissions) (CISPR 11)	Group 1	R.Test 4 uses RF energy for its internal function. Therefore, its radiofrequency emissions are very low and are not likely to create any interference with nearby equipment.

Emissions from the power terminals (Emissions conducted) (CISPR 11)	Class B	R.TEST4 is suitable for use in all settings, including home health care environment and the environment of a professional health care facility.
Harmonic current emission (IEC61000-3-2)	Not applicable	
Voltage variations, voltage fluctuations and flicker (IEC61000-3-3)	Not applicable	

Electromagnetic immunity			
The R.Test.4 is intended for use in an electromagnetic environment as specified below. The clinician and the user should ensure that the R.Test 4 is used in such an environment			
Immunity test	**Test level according to IEC60601**	**Test level according to IEC60601**	**Electromagnetic environment / remarks**
Electrostatic discharge (ESD) (IEC61000-4-2)	8 kV in contact ± 15 kV to the air	8 kV in contact ± 15 kV to the air	Home health care environment and an environment of a professional health care facility.
Fast electrical transients in bursts (IEC61000-4-4)	± 2 kV for power lines	Not applicable (no relation to the public electricity grid)	Home health care environment and an environment of a professional health care facility.
Shocks (IEC61000-4-5)	± 1 kV in Differential mode ± 2 kV in common mode	Not applicable (no relation to the public electricity grid)	Home health care environment and an environment of a professional health care facility.
Magnetic field at assigned industrial frequency (IEC61000-4-8)	30 A/m	30 A/m	Home health care environment and an environment of a professional health care facility.

Electromagnetic immunity			
The R.Test.4 is intended for use in an electromagnetic environment as specified below. The clinician and the user should ensure that the R.Test 4 is used in such an environment			
Immunity test	**Test level according to IEC60601**	**Test level according to IEC60601**	**Electromagnetic environment / remarks**
Voltage dips, brief interruptions and voltage variations (IEC61000-4-11)	0% UT for 0.5 cycles At 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 ° and 315 ° 0% UT for 1 cycle 70% UT for 25 cycles at 50 Hz For 30 cycles at 60 Hz Single phase: at 0 °	Not applicable (no relation to the public electricity grid)	Home health care environment and an environment of a professional health care facility.
Voltage interruptions (IEC61000-4-11)	0% UT; for 250 cycles at 50 Hz for 300 cycles at 60 Hz	Not applicable (no relation to the public electricity grid)	Home health care environment and an environment of a professional health care facility.

Electromagnetic Immunity, Portable Radio Frequency Equipment			
Immunity test	**Test level according to IEC60601**	**Test level according to IEC60601**	**Electromagnetic environment / remarks**
WARNING: RF portable communication devices (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of the R.Test.4, including the cables specified by the manufacturer. Otherwise, the performance of these devices may be impaired.			
Electrostatic discharge (ESD) (IEC61000-4-2)	3 V/m 80 MHz at 2.7 GHz 80 % MA at 1 kHz 10 V/m 80 MHz at 2.7 GHz 80 % MA at 1 kHz	3 V/m 80 MHz at 2.7 GHz 80 % MA at 1 kHz 10 V/m 80 MHz at 2.7 GHz 80 % MA at 1 kHz	Home health care environment Professional health care institution

Proximity fields issued by RF wireless communication devices (IEC 61000-4-3 interim method)	9 V/m 710 MHz, 745 MHz, 780 MHZ, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	9 V/m 710 MHz, 745 MHz, 780 MHZ, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	Home health care environment and an environment of a professional health care facility.
Conducted disturbances, induced by RF fields (IEC610004-6)	3V 150KHz to 80MHz 6V in ISM band and band between 0.15 MHZ and 80 MHZ, amateur radio band included 80% MA at 1 KHz	3V 150KHz to 80MHz 6V in ISM band and band between 0.15 MHZ and 80 MHZ, amateur radio band included 80% MA at 1 KHz	Home health care environment and an environment of a professional health care facility.
The electromagnetic field strengths of fixed radio frequency transmitters, as determined by an electromagnetic environment measurement (a), shall be less than the compliance level for each frequency range. Interference may occur near equipment identified by the following symbol: 			

Note: These specifications may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection of structures, objects and people.

(a) The intensities of the electromagnetic fields of fixed radio frequency transmitters, such as base stations for mobile (cellular / wireless) telephones, mobile radios, radio amateurs, AM / FM radio transmissions and TV transmissions cannot be accurately determined theoretically. To evaluate the electromagnetic environment due to fixed radio frequency transmitters, an electromagnetic environment measurement must be performed. If the measured RF field strength in the immediate environment of use of the product exceeds the radio frequency compliance level (specified above), it is necessary to test the product performance to verify that it conforms to the specifications. If

abnormal performance is noted, additional measures may be necessary, such as reorienting or moving the R.Test 4.

Precautions for use must be taken with regard to electromagnetic compatibility (EMC) phenomena. The R.Test 4 must be installed and put into service in accordance with the EMC recommendations above.

Malfunctions can be caused by the proximity of portable or mobile RF communications equipment.

R.Test 4 is not protected from the effects of the discharges of an external defibrillator.

The minimal amplitude of the physiological patient signals is 0.5 mV. The use of the equipment close to this minimal level can generate incorrect results.

The equipment or system is under the responsibility of qualified staff. This equipment or system can be the source of radio interferences or be the source of abnormal operations of another apparatus located in the immediate vicinity. Some care over positioning could be necessary.

The equipment should not be used adjacent to, or placed upon other equipment. If this use is necessary, a check for good performance of the equipment in this configuration must be made.

2.4 Symbols

This sign on an apparatus indicates to the user that additional information, available in the accompanying documents, that must be consulted.

R.Test 4 works exclusively with an internal power source and complies with standards of protection for units in class BF.

IP24

Fitted with its ECG cable, R.Test 4 is classified IP24 (protected against water)
R.TEST 4 is not an apparatus of category AP nor APG
R.TEST 4 is designed for continuous service.

CEM

R.TEST 4 is in conformity with the Electromagnetic standard of Compatibility EN 60 601-1-2. However, if it is used in a very specific way, there can be some problems with interference

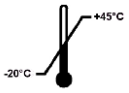
CE Mark, according to European Directive 93/42/CEE for medical devices

The device does not possess any specific protection against moisture, as a consequence, it is recommended to store it in a dry place.

Risk associated with the ESDs

The product must be disposed of through a suitable system to allow recovery and recycling

Store away from light



Storage Temperature Limits

Humidity Storage Limits

Pressure Storage Limits

Connecting the ECG cable to the patient:
When connecting it:
Always connect the cable to the recorder first, then to the electrodes on the patient.
When removing the unit:
Always disconnect the ECG cable from the electrodes on the patient before unplugging the cable from the recorder.

NOVACOR will provide electrical circuit diagrams and information about the nature of the materials for customers if required.

2.5 Guarantees

NOVACOR undertakes to deliver merchandise conforming to the technical specifications mentioned and to replace any merchandise recognised as being defective during the period of guarantee.

2.5.1 Specific Guarantees of the device

NOVACOR guarantees the unit for the period of one year from the date of delivery against any defect resulting in the unit functioning abnormally.

2.5.2 Specific Guarantees of the accessories

The parts or components not considered an integral part of the device, and in particular the accessories and cables, do not benefit from any particular guarantee.

2.5.3 Limits of guarantee

The guarantee does not apply:

1. if the device is repaired or opened outside of our workshops.
2. if the device is damaged following negligence, accident, or use that does not conform with the procedures described in the instruction manual.

If necessary, please contact your local distributor or our after-sales service directly.
We do not accept any return of goods without prior arrangement.

2.5.4 Responsibilities

NOVACOR will not, under any circumstances, be held responsible for physical or material damage of whatever nature, resulting either directly or indirectly from improper use of the unit or from failure to follow the instructions in the user manual. Although NOVACOR manufactures products to the highest standards, justifying customer confidence, it cannot guarantee or be responsible for the validity or accuracy of the measurements made with its units. Therefore, connection of the unit to the patient, interpretation of the ensuing clinical results and the diagnosis established from them are entirely the responsibility of the physician. No damage, either direct or indirect, resulting from the use of one of its units can be attributed to NOVACOR, excluding the repair of the unit within the limits of the guarantee.

2.5.5 Users information

All the customers duly recorded at NOVACOR or if necessary, by its distributors, will be kept informed as well as possible of various developments of R.TEST Evolution 4.

2.5.6 Copyrights

3 Description of the hardware

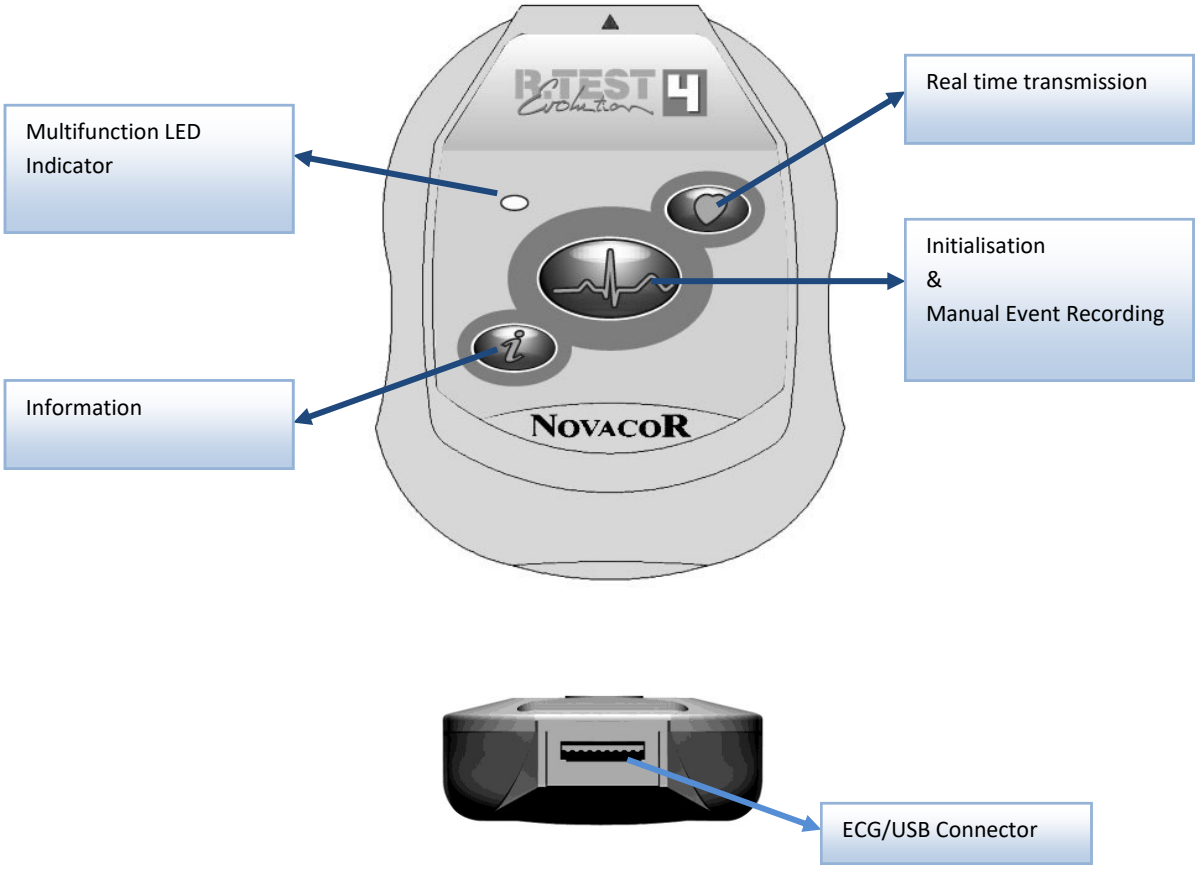
R.TEST Evolution 4 is a recorder / analyser of ECG events

- ambulatory,
- automatic or manual,
- single channel,
- long term,

Intended for asymptomatic and/or symptomatic patients.

3.1 The recorder R.TEST Evolution 4

3.1.1 The Device

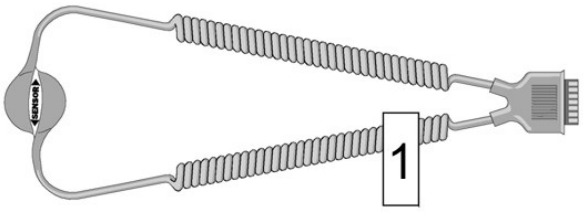


3.1.2 The Buttons

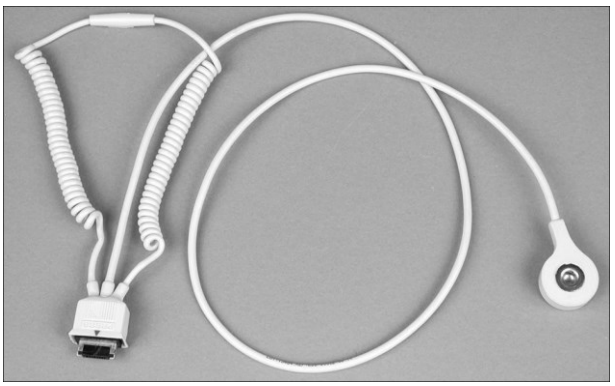
Button	Programmable	Description
	No	Start button, to start a procedure Patient activation button
	Yes	Activation of the modulated acoustic transmission of the real-time ECG signal A second press, starts the QRS beeps
	Yes	Indication of the memory state: - If red LED: memory full for one of the programmed events - If green led: no memory category is filled

3.2 R.Test-PC USB Cable

3.3 Accessories



Neck cable
(Connection Necklace)



CM5 Cable
(standard 40 cm or long
60 cm)

The use of accessories, sensors and cables other than those specified can induce an increase in the levels of electromagnetic emission or a reduction in the levels of immunity of the equipment.

4 Operation

4.1 Collection of ECG signal

The surface ECG signal is collected according to a bipolar configuration between two ECG electrodes especially adapted to the R.Test. The apparatus is integrated directly with one of the electrodes, in contact with the patient's sternum. The second electrode, placed either behind the neck or on the patient's side, is connected to the R.Test by using the supplied accessory.

The physician is free to choose between the "neck-sternum" and the "CM5 lead" configurations, there is a specially designed cable for each.

The neck-sternum configuration allows the collection of the ECG signal characterised by:

- a morphology and an amplitude of QRS similar to V2,
- significantly different right and left ventricular activations,
- generally optimal P waves amplitude.

The CM5 configuration allows collection of the ECG signal characterised by:

- a morphology and an amplitude of QRS similar to V5,
- an amplitude often greater than the 'neck-sternum' configuration

The CM5 cable may provide a better recording of ST changes and give more flexibility when the anatomy of the patient's sternum makes it impossible to connect the R.Test normally.

The R.Test stores significant ECG events in its memory.
The physician can pre-program the duration of these events and the mode in which they will be recorded:
- automatically (for asymptomatic problems), according to recognition criteria specific to each pathology,
- or by patient activation (pressing the recording key) (for symptomatic events, whether they be cardiac or not).

4.2 Recording modes

The clinician may decide to use one, or both, of the two options below, depending on the software options available:

4.2.1 Manual Recording

The ECG is recorded by the R.Test, for one predetermined length of time, without analysis or processing, when the patient presses on the manual event button on the device.
Each recording is obtained according to the pre and post event durations set in the current program, configurable by the clinician, via the software.

4.2.2 Automatic Recording (with the option of patient activated recordings)

The ECG signal is processed and analysed in real time, and the most significant pathologies are stored into the memory of the device.
Each recording is obtained according to the criteria and to the pre and post event durations set in the current program, configurable by the clinician, via the software.

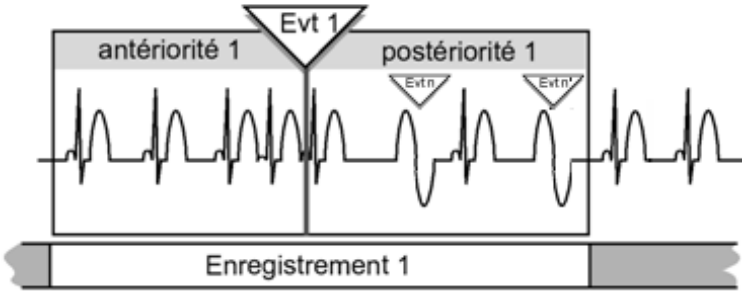
4.3 Operation in manual recording mode

This mode is intended for symptomatic patients, for whom one wishes to carry out a recording of an event or symptom, even if this symptom is not very frequent.

The patient simply has to press the R.Test recording key and the ECG recording will then be saved in the unit's memory. This recording is stored, without being analysed or interpreted, so that the physician can examine it later.

4.4 Operation in automatic recording mode

The R.Test monitors the ECG signal continuously and stores it in a loop memory, which therefore contains, at any given moment, the previous few minutes of ECG; this means that a given duration of the ECG preceding a detected event can be included in the recording. This duration, called the pre-event, can vary from 5 seconds to 5 minutes.
During the detection of an event, R.TEST Evolution 4 will store the ECG corresponding to the **pre-event** recording time defined for this type of event and will continue to memorise the ECG until the end of the **post-event** recording time defined for this type of event.
If during post-event, other events are detected, they will be simply marked on the ECG but the R.Test will not start a new recording (see also § 4.6.3 Multiple Events).



4.5 Automatic Signal Analysis

The analysis of the ECG takes place in real time in the R.Test: as the ECG signal is stored in the buffer, the R.Test's microchip, using a specific software algorithm, carries out the following operations automatically:

- identification of the QRS and possible elimination of artefacts,
- determination of the morphology of the QRS,
- calculation of R-R intervals and the basal heart rate,
- continuous storage of the heart rate,
- recognition and hourly counting of arrhythmic events,
- memorisation of selected episodes with date and time, QRS and events characteristics

4.5.1 Basal heart rate

The reference R-R interval, which corresponds to the basal heart rate, is obtained by continuous calculation of the average of the preceding few R-R intervals recognised by the R.Test as being "normal". Excluded from this average are R-R intervals considered not "normal", these include: periods of artefact, pauses, intervals preceding and following premature QRS (in order to also eliminate compensatory pauses).

By default this calculation is carried out on the last 8 "normal" R-R intervals collected (noted RR8N).

4.5.2 Storage of the heart rate

At regular intervals, the R.Test stores 3 values, enabling assessment of the patient's heart rate trend to be made: minimum rate, mean rate and maximum rate. The duration of this interval is chosen according to the length of time that the patient is connected to the unit.

The R.Test therefore also provides the physician with continuous monitoring of the minimum, mean and maximum heart rates for a period of up to 32 days.

Duration of examination	**< 48h**	**From 2 to 4 days**	**From 4 to 8 days**	**From 8 to 16 days**	**From 16 to 32 days**
Sampling of the HR	1'	2'	4'	8'	16'

4.5.3 Detection of rhythm disorders

Arrhythmias detected by the R.Test are classified in several categories. Some automatic functions of the R.Test Evolution 4 may be available only as additional options.

4.5.3.1 *Fast Rhythm disorders (premature QRS and salvos)*

A QRS is considered as premature if the R-R interval preceding it is lower by a given percentage (standard program 25%) compared to the base period (RR8N).
The R.Test characterises premature QRS according to:

- The morphology:
  - Normal or Narrow QRS as “Supraventricular”
  - Aberrant or Wide QRS as “Ventricular”
- Their organisation:
  - Isolated QRS, Couplets and Triplets (1, 2 or 3 consecutive premature QRS)
  - Runs (4 or more consecutive premature QRS).

This identification enables the R.Test to distinguish 8 subcategories of rapid events:

- Isolated Supraventricular Ectopic
- Supraventricular Couplets
- Supraventricular Triplets
- Supraventricular Runs
- Isolated Ventricular Ectopic
- Ventricular Couplets
- Ventricular Triplets
- Ventricular Runs

In the case of the isolated events, couplets and triplets of the same type, the reserved memory capacity is common. If the memory is full, a new event will replace another according to the following criteria of gravity: a triplet is more serious than a couplet, which itself is more serious than an isolated premature QRS.
Standard program: RR < RR8N - 25% * RR8N

4.5.3.2 *Absolute Pauses*

Characterised by an R-R interval exceeding a certain duration.
Standard program: RR > 2.0 seconds

4.5.3.3 *Relative Pauses*

Characterised by an R-R interval exceeding a given percentage of the mean reference R-R interval, providing that it does not follow a premature QRS complex, and that its duration is shorter than the absolute pause threshold.
Standard program: RR > 175% * RR8N

4.5.3.4 *Bradycardia*

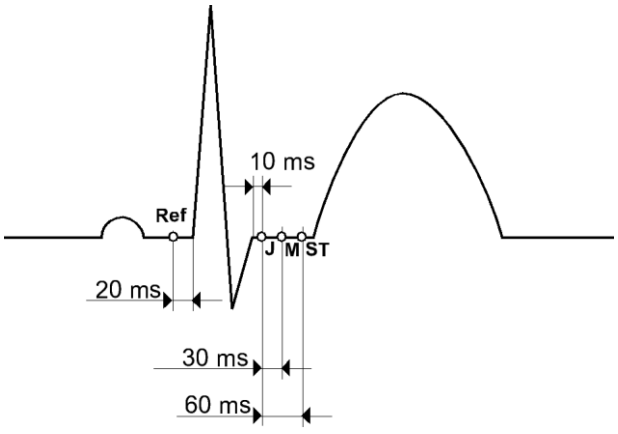
Characterised by the decrease of the reference heart rate below a threshold, with a minimum of 8 consecutive RR intervals.
Standard program: 8xRR < 40 BPM

4.5.3.5 *Sinus Tachycardia*

Characterised by the increase of the reference heart rate above a given threshold
Standard program: 8xRR > 140 BPM

4.5.3.6 *ST Segment Analysis*

The ST segment is characterised by its shift compared to the base line: it can be positive (elevation), or negative (depression). It is measured in millimetres (mm), the scale of the ordinates being of 1 mV/cm.



Location of the measurement points

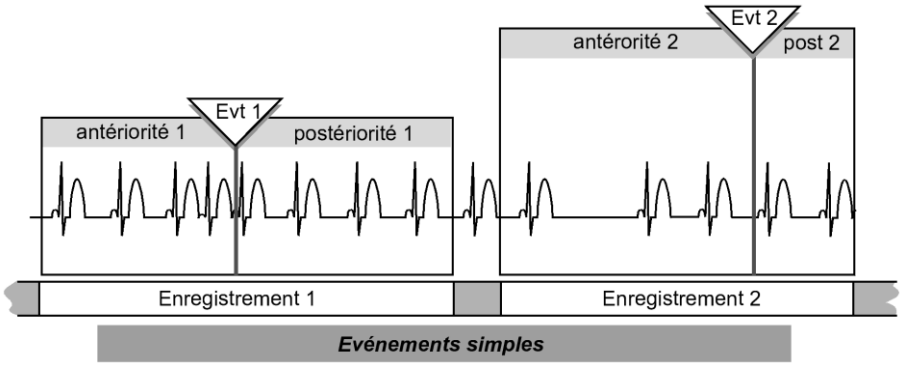
An ST episode can be recorded by the R.Test if, during 32 QRS, the shift is larger than the programmed threshold.
For the histograms, the R.Test computes the averages shift for each 30''period, and retains the maximum and minimum shift values.

4.5.3.7 *Atrial Fibrillation Analysis*

Atrial fibrillation is often associated with a fast and irregular heart rate. An analysis of the rhythm makes it possible to detect episodes of AF. The algorithm used analyses the width of the distribution of R-R intervals as well as the temporal stability of alternations between regular and irregular states.

4.6 Consecutive Events

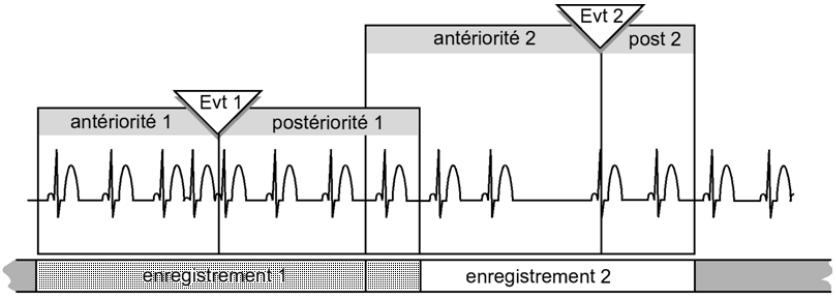
4.6.1 Simple Events



Simple Events

In general, two consecutive events detected by the R.Test are sufficiently far apart from one another for their recordings to be separate. These two events are therefore two single events.

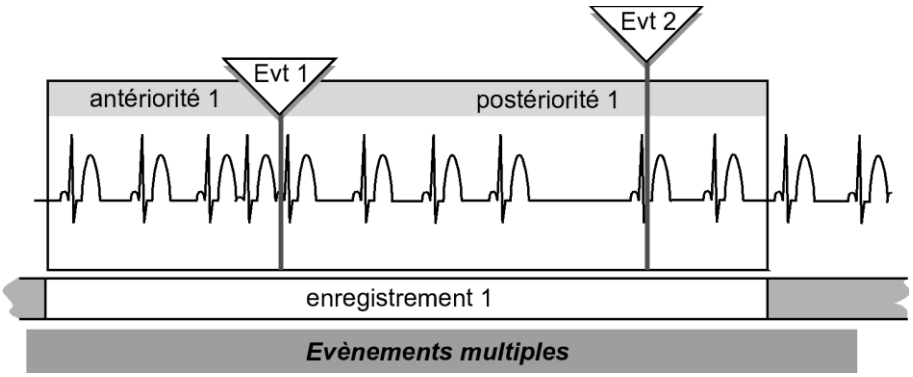
4.6.2 Superimposed Events



Superimposed Events

If the interval separating two events is lower than the post-event duration of the first + pre-event of the second, and the second event actually occurs after the post event of the first has finished, they will each be recorded normally, each one in its own category.
Contrary to the operation of R.Tests from preceding generations, the second recording will not be shifted in time: the concept of chain events no longer exists with R.Test Evolution 4. Each event respects its parameter settings of pre-event and post-event.

4.6.3 Multiple Events



Multiple Events

When two consecutive events are such that the second occurs in the post-event of the first, the second will not be recorded separately. However, if it is either an **absolute pause**, or a **run** (i.e. at least 4 consecutive premature QRS), the recording of this double event will be identified as a "multiple event".

4.7 Setting of the events in memory

When the R.Test is programmed, the total duration of its memory is divided up between the different types of pathologies.
The number of events of each type which can be stored in the memory of the R.Test depends on:
- the size of the memory allocated to that type of event and
- the duration of the recording period chosen for each episode (pre-event + post-event).

In addition to this, each time an event corresponding to one of the pre-defined pathologies is identified:
- the event counter for this type of pathology is incremented by 1 in the corresponding hour segment, and
- the severity of the event is measured; for pauses, according to their duration; for premature complexes, according to their number; and for Bradycardia/Tachycardia and runs, according to their rate.

The R.Test stores only the most serious detected events:
When the memory allocated for a given "type" of pathology is saturated, the R.Test does not memorise a new event of the same type unless it more serious than the least serious event it has already stored. In the case that a new event is more serious, in order to free enough memory for this new event, the least serious event is erased. This rule does not apply to the **multiple events**, which, once recorded, cannot be overridden.
In addition, it should be noted that the manually recorded events cannot be replaced when the allocated portion of memory is saturated by them. As a result the manual event button becomes inoperative until the R.Test is reprogrammed.

During the whole time it is connected to the patient, the R.Test also stores, hour by hour, the total number of events detected for each pathology, whether they are recorded or not. This enables tables and event histograms by pathology to be created for the whole monitoring period.

4.8 Default Program

Standard event	Pre-event (mm:ss)	Post-event (mm:ss)	Qty	Duration (S)	Criteria of detection
VT	00:15	00:45	6	360	
VEs (1 to 3)	00:15	00:15	9	270	
PSVT	00:15	00:45	6	360	Threshold < RR8N - 25% RR8N
SVEs (1 to 3)	00:15	00:15	9	270	Threshold < RR8N - 25% RR8N
Absolute Pauses	00:10	00:20	8	240	RR > 2.0 S
Relative Pauses	00:10	00:10	6	120	RR > 175% RR8N
Tachycardia	00:15	00:30	8	360	Threshold > 140 bpm
Bradycardia	00:15	00:30	8	360	Threshold < 50 bpm
ST shifts	00:15	00:15	4	120	Offset ≥ 2 mm
AF	00:45	00:45	6	540	
Manual Markers	00:40	00:20	10	600	

5 Connecting the patient

The R.Test Evolution is usually connected to the patient, using ECG electrodes, with the CM5 lead, although another lead (such as the “Neck-Sternum”) can be chosen.

The patient is connected, as described below, using ECG electrodes in most cases.

5.1 Order of connection

- Choice of lead
- Inserting new batteries
- Initialising the unit
- Connecting the patient cable to the R.Test
- Placing the electrodes on the patient and connecting the R.Test
- Start up and start up test

5.2 Choice of lead

5.2.1 Standard Configuration CM5

CM5 is the standard lead supplied with the R.Test Evolution 4.
It is the most reliable lead if the QRS amplitude is low, the patient has unusual anatomy or it is difficult to place an electrode on the sternum and to investigate ST changes.
This configuration is also more discreet for the patient

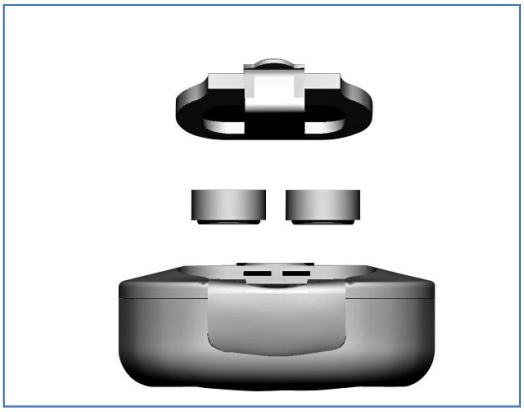
5.2.2 "Neck-Sternum" Configuration

This configuration, which gives an ECG signal of very good quality, in particular with clear P waves, requires the use of the `neck cable' (ref. ACC-0105-00).

5.3 Inserting new batteries

The replacement of the used batteries should be carried out just before the initialisation of the R.Test in order for it to function for the longest possible time.
The use of special NOVACOR batteries allows the operation of the R.Test for up to 16 days in automatic mode with all options activated.

The R.Test should be used only with Zinc-Air 1.4V batteries PR44 respecting the polarity of insertion.
Do not forget to remove the cover placed on the bottom of the batteries before use.



- Insert the new batteries by respecting the polarity indicated,
the + side (bottom of the batteries) directed upwards.

The R.Test then begins a cycle of battery checks for a few seconds ending with a double tone.

If the batteries are new, the LED illuminates green for 5 seconds
If the batteries are not new, the LED illuminates orange for 5 seconds
If the batteries are low, the LED illuminates in red for 5 seconds

5.4 Programming of the recorder

Connect the R.TEST Evolution 4 to the PC via the USB cable, then Program/Read via the software to choose the program to be used as well as to input patient information.

Note: it is not necessary to have inserted batteries to read or program and R.TEST Evolution 4 with the USB cable.

5.5 Connecting the Patient Cable to the R.Test

R.Test /cable

Make sure that the connector is lined up with the R.Test so that the logos on the connector and the front plate of the R.Test are visible at the same time.
Guide the connector into the unit until it is locked into position.

5.6 Placing the electrodes and connecting the R.Test

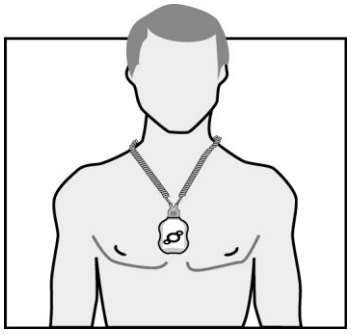
5.6.1 Preparation

Novacor recommends the exclusive use of the specially selected electrodes for R.Test monitoring, which are supplied in sealed pouches.
These electrodes are hypoallergenic (Ag-AgCl) and can normally be worn for several days without any side effects. However, people with sensitive skin may have a reaction (rashes, spots, etc.). These reactions will usually disappear spontaneously a few days after the electrodes are removed.

If the patient's skin is particularly sensitive, wait until the rash has completely disappeared before placing electrodes on them again, and take any other precautions that you consider necessary.

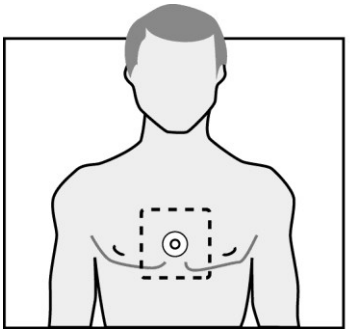
The installation of the electrodes for the R.Test requires careful preparation of the patients' skin: it is recommended to shave the site of the electrodes where necessary, and if clean the area with a suitable wipe and then thoroughly dry.

5.6.2 "Neck-Sternum" configuration with solid gel electrodes

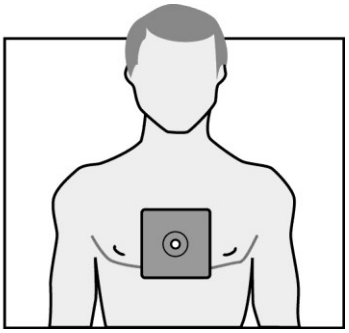


Neck-Sternum configuration

5.6.2.1 *Connecting the sternal electrode*



Sternal electrode

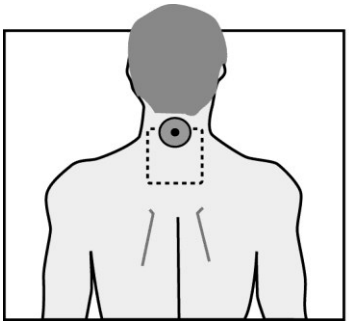


Electrode with reinforcement

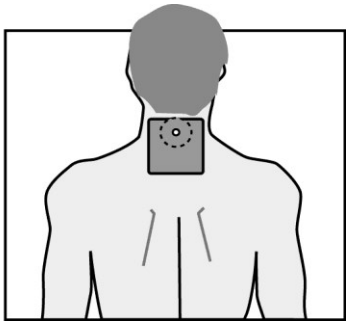
Place the sternal electrode first, on the lower third of the sternum, if possible, or, in any case, as low as possible (if the patient's chest is particularly large).

Adhesive patches can be used to make sure that the solid gel electrodes adhere properly, especially for patients who perspire heavily or who will be connected to the R.Test for more than 24 hours.

5.6.2.2 *Connecting the cervical electrode*



Cervical Electrode

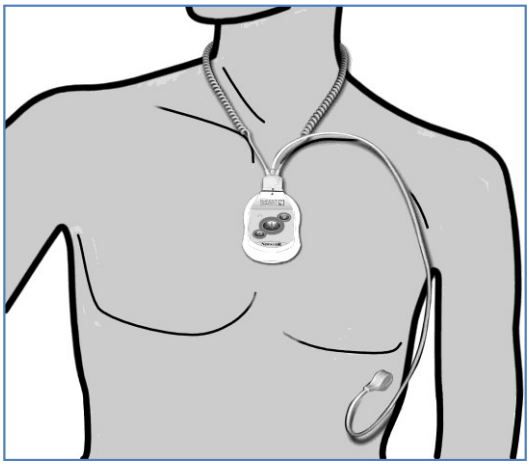


Electrode plus adhesive patch

Put the R.Test and cable around the patients neck like a necklace, without attaching the unit to the sternum, and let it hang naturally against the cervico-thoracic spine.

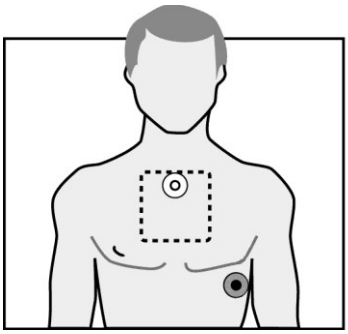
Locate the place where the neck electrode will be applied (round electrode), put it in place, then stick the adhesive patch over it (popper through a hole).
Then connect the neck electrode, followed by the sternal electrode to the R.Test by simply applying light pressure.

5.6.3 Configuration in CM5: pre-gelled electrodes

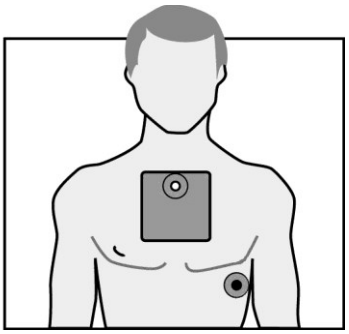


Configuration *in CM5*

5.6.3.1 *Placing the electrodes*



Sternal and V5 electrodes



plus adhesive patch

This is connected in the same way except that the sternal electrode is placed higher up, on the **sternal manubrium**, ideally at the angle of Louis.
Then place the electrode in V5 as indicated.

5.6.3.2 *Connecting the R.Test*

Plug the CM5 cable into the R.Test as indicated before for the neck-sternum cable, put the spiral support part around the patient's neck, then click the R.Test onto the sternal electrode and the distant connector to the electrode in the V5 position.

5.7 Start up and hook-up test

5.7.1 Start-up in continuous mode

- Press on the central key of the device to start.
The R.Test emits a signal modulated by the ECG. The modulation of the signal, during its 20 seconds duration, makes it possible to immediately detect with the ear, possible anomalies in the detection of the ECG.
- After these 20 seconds, the recording starts and R.Test emits a beep synchronised with each detected QRS. In the absence of visualisation of the signal a perfect synchronization of the beeps with the pulse of the patient during at least 30 seconds constitutes the best guarantee that the selected configuration is sufficient in amplitude (>1 mV).

In automatic mode, this check is imperative if you want to ensure a reliable detection. If it proves to be negative, it is advisable to check the quality of the connections and the positioning of the electrodes.
- Once you are happy, **press again on the central key to stop the beeps**. If you omit this step the recording will start automatically.

Throughout the entire recording, the LED emits a green flash every 5 seconds to indicate the status is 'recording in progress'.

5.7.2 Disconnection Test

If the disconnection alarm has been programmed (recommended), disconnect the unit or the cable from an electrode for a few seconds to activate it and explain what it means to the patient. The warning signal will be emitted every 15 minutes by the R.Test until the problem has been resolved, for example by replacing an electrode which has come unstuck or has dried out. (The patient should be provided with an extra set of electrodes in case they are needed).

5.8 Removing the R.Test

5.8.1 End of monitoring

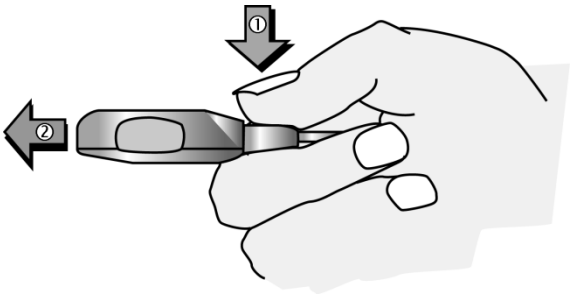
If the R.Test monitoring is not to continue after data transfer, simply disconnect the recorder together with its cable from the electrodes. The electrodes can then be removed and the patient's skin can then be cleaned and dried, if required, following any instructions given by the physician.

5.8.2 Temporary Interruption of the monitoring

You can choose:
- to proceed as previously described, and after the data transfer to replace the electrodes with new ones, or
- to leave the electrodes in place: disconnect the R.Test from its sternal electrode, and then unplug the cable from the R.Test as described below.

5.8.3 To Unplug the cable from R.Test

This operation must be carried out very carefully, so as not to damage the unit nor the cable. Training beforehand is essential:



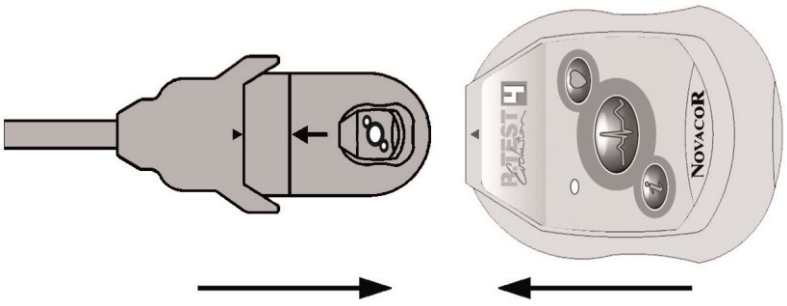
To disconnect the cable from the unit, **the connector must first be unlocked:** do not pull using brute force, the unit could be damaged!

① Press firmly on the two faces of the connector (marked PRESS), and
② pull straight until clear, as indicated in the picture above.

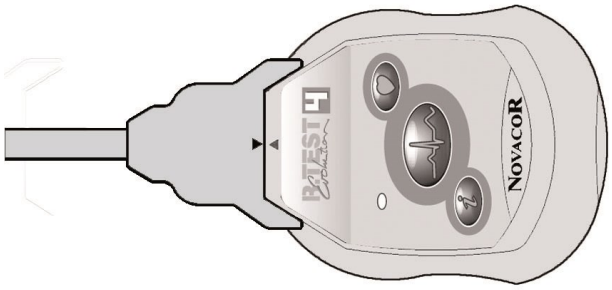
5.9 Connection to a computer

5.9.1 Connecting the R.Test PC cable

Completely engage the R.Test on the connector, in accordance with the symbol shown on the interior of the connector,



until the two red positioning triangles are exactly face-to-face:



Correctly connected R.Test and connector

5.9.2 Disconnection of the cable

To disconnect an R.Test from the cable:

After having turned over the R.Test-connector, it is necessary to:

- press firmly on the serrated part of the connector, using the thumb and forefinger, **before**
- releasing the R.Test from the connector by moving them apart.

5.10 Resuming monitoring

5.10.1 Without changing batteries

It is possible, after reading the R.Test data, to continue the recording for the same patient. Simply reconnect the R.Test and its cable to the patient electrodes, the procedure continues automatically.

5.10.2 Changing batteries

Change the batteries as indicated in §5.3 Inserting new batteries. After the start up, the led must flicker green once every five seconds. Then simply reconnect the R.Test and its cable to the patient electrodes, the procedure continues automatically.

6 Maintenance

6.1 Handling and use

The installation of the device on a patient must be carried out by a qualified person. Always press the centre of the recorder's keys with a finger; never use a blunt or pointed object or your finger nail.

The R.Test 4 is not designed for use on children under ten kilograms.

If you believe there is any risk of strangulation with the spiral cord of the CM5 cable, you can decide not to place it around the neck or alternatively make use of the V5 cable.

Operation in moist environment: The R.TEST Evolution 4 is water resistant to IPx4 and is protected from splashing water projections. However, the device does not have any specific protection against moisture when the ECG cable is not connected.

Do not use the R.TEST 4 if any part, including the cables, appears broken or damaged. Do not make any additions or modifications to the equipment, other than fitting a replacement Novacor branded cable, but return it to your dealer for repair.

6.2 Cleaning

Before carrying out cleaning, the cable must be connected and the batteries removed.
Regularly clean and disinfect the R.Test Evolution 4 and its accessories. We recommend gently wiping with surgical spirit (70%), never use very strong disinfectants such as nail polish remover or acetone.

Never leave the device in touch with liquid or a wet tissue

If you want to use another cleaning product, make a preliminary test to ensure there is no degradation to the coating.

In particular, it is recommended to thoroughly clean the ECG cables between patients.

6.3 After-sales Service

Maintenance is carried out in our workshop, as rapidly as possible. We are unable, however, to provide a unit on loan during the repair period or to provide compensation of any sort.
In all cases, including units under guarantee, transport costs are the customer's responsibility. If the unit is examined outside the guarantee period, there will be a minimum charge for administrative and testing costs.
An estimate will be sent by mail or fax upon receipt of the unit and completion of the diagnostic tests.
No repair can take place without a signed order from the customer.

6.4 Storage and dispatching

Take care to remove the R.Test Evolution 4 batteries if the device will be stored for more than a few days.

During shipping, the R.Test Evolution 4 is protected by its packaging. This should be kept in case it is needed at a later date; it also contains a Complaint Report form you will be able to use in the event of incident during the use of the device.

When disposing of used batteries use proper procedures, following any applicable local laws.

You must respect the current regulations concerning the disposal of the unit.

6.5 Preventive Maintenance

A preventive check-up of the recorder is recommended every two years. This check-up will reduce the number of potential break downs and prolong its useful life. The unit will be checked for its correct functioning, in particular ECG amplifiers and safeguard battery
The check-up must be carried out in our workshop, or by an approved distributor.
The invoicing covers the tests only, the quote for any necessary repair will be sent by mail or by fax. The repair can only be carried out upon reception of a customer order.

7 Specifications

	R.TEST EVOLUTION 4 Evolution
Overall Length	60 mm
Overall Width	48 mm
Overall Depth	28 mm
Weight with batteries	40 g.
Index IP (with ECG cable in place)	IP24
Conditions of storage/transport	Temperature - 20 °C to + 60 °C Humidity 10% to 93% (non condensing) Pressure 500hPA to 1060hPA
Operating Conditions	Temperature + 5 °C to + 40 °C Humidity 10% to 90% (non condensing) Pressure 700hPA to 1060hPA
Batteries Type	675 Zinc Air IEC - PR44 ANSI/NEDA - 7003ZD

Type of recorder	Automatic Recorder/ ECG Arrhythmia detection and Heart Rate trend. Manual Recorder of ECG episodes.
Type of events (automatic mode)	Supraventricular and Ventricular QRS, (Isolated, couplets, triplets and runs). Absolute and relative Pauses. Bradycardia, Tachycardia ST shifts, Atrial Fibrillation Manual Markers
Maximum Number of events	256
Duration of the events • automatic mode • manual mode only	Programmable from 10s to 60 min, with pre-event minimum 5s, maximum 5 min, post-event minimum 5s, maximum 59 min 55s (looping memory). pre-event 0 + post-event 30s to 60min
Total Duration of recording • ECG events • Heart rate and histograms trend	• 60 min • 32 days

Maximum Duration of an examination • automatic mode • manual mode only	 • 32 days • 2 months
Electrical Supply	2 x zinc-air 1.4 V - 640 mAh batteries
Number of channels	1
Data Storage	Non-volatile Stable Memory
Memory Lifetime	10 billion cycles
Sampling and analysis	200 Hz
Vertical Resolution	10bits
Precision of the ECG in duration	± 2.5 ms
Precision of the ECG in voltage:	± 6 µV
Storage	100 Hz
PC connection	USB2.0 Full compatible Speed
Lifetime of the device (estimate)	5 years
Lifetime of the accessories (estimate)	5 years

8 Accessories and consumables

The following accessories and consumables are available from your supplier:

Accessory & Consumables	**Reference**	**Details**
Special Batteries	ACC-0706-02	Box of 60 batteries
Pre-gelled Ag-AgCl Electrodes	ACC-2002-02	Box of 50 electrodes
Neck Cable (configuration neck-sternum)	ACC-0105-25	1 part
CM5 Cable standard 2pt 40 cm	ACC-0112-20	1 part
CM5 Cable long 2pt 60 cm	ACC-0112-21	1 part
V5 cable standard 40cm	ACC-0106-21	1 part
V5 cable long 60cm	ACC-0107-21	1 part
Battery Cover (RT4)	ACC-0603-04	1 part
R.Test - PC USB Cable	ACC-0159-00	1 part
Software RTSoft PC	LOG-0700-05	DVD Applications
User Manual R.TEST Evolution 4 (this handbook)	CDI-0201-00	CD Manuals

First placed on the market in 2011

CE 0459