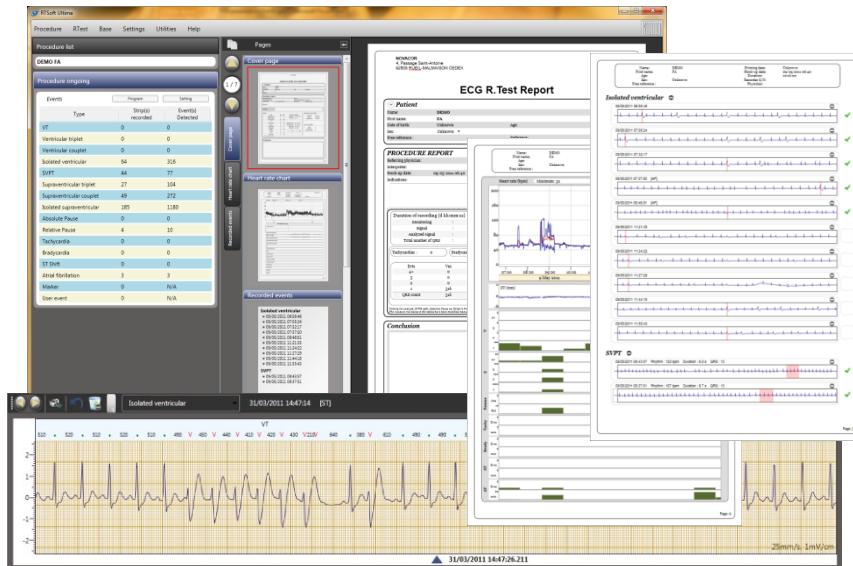




RTSoft Ultima v1.3.x

User Manual



(First available in 2011)



NOVACOR

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1. NOVACOR Licence Agreement

RTSoft Ultima software is sold under licence and must only be copied or used in accordance with it. By installing RTSoft Ultima software you agree to be bound by the terms and conditions of this licence agreement.

Please read this manual carefully before installing the software. If you do not agree to its conditions, you must not, under any circumstances, install the software. You should return it with the accompanying documents, accessories and packaging to the place of purchase, where you may be able to request a refund.

Using the software

The software is licenced "as is" for use on a single central processing unit and one terminal at a time. Using *RTSoft Ultima* on a multi-user system is possible, but is not allowed by this license, to do so you must have a written contract with NOVACOR SAS. In addition, NOVACOR SAS does not authorise the installation and use of this software on a Terminal Server type platform e.g. Citrix or equivalent.

It is strictly prohibited to rent or loan the software, except where agreed in writing with NOVACOR SAS. You can sell or transfer the licence, but it must be a permanent transfer and include the media (CD or DVD) and all other related hardware. The transfer causes you to lose the rights of use and obliges the recipient to abide by the terms and conditions described in this licensing agreement.

Copyright

An "Access Key" is required for the software to function without restrictions.

Any attempt to circumvent the "Access Key", could be considered an infringement of the copyright, punishable under the protection of French or EU copyright law.

Guarantee

NOVACOR SAS. guarantees that *RTSoft Ultima* functions in a way that substantially conforms with the supplied documents on its computers, that were used for testing. NOVACOR SAS. cannot guarantee good performance of the software on any specific computer.

NOVACOR SAS. guarantees the supplied hardware and documentation for *RTSoft Ultima* for 90 days following delivery. In particular, NOVACOR SAS. will, during this period, provide a replacement application CD or DVD if the one supplied appears illegible. After this period a fixed price, for the replacement, will be charged.

The software, and the manuals that accompany it, are sold as is, without guarantee concerning their quality, their performance, their accuracy or their ability to meet a specific need.

Consequently, the clinical use of the results and any diagnosis established from them remain the responsibility of the expert user. No loss or corruption of data, nor direct or indirect damage resulting from the use of the software, can be attributed to NOVACOR SAS. or its distributors.

Manual

This document is provided for information only, and does not represent a commitment, on the part of NOVACOR SAS., to provide any specific functionality. The company, NOVACOR SAS., does not accept any liability with respect to errors or inaccuracies that may appear in any manual.

The examples, values and figures shown in this manual are fictitious and provided for the sole purpose of illustrating the use of *RTSoft Ultima* software. They have no value for medical or scientific reference and therefore can't be used for purposes other than those of this manual.

The software, its features and any manuals can be modified by Novacor without notice.

Legal jurisdiction

In case of dispute, French courts will have jurisdiction. The applicable law is French law.

Rights

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R.Test, RTSoft Ultima, and their respective logos are registered trademarks of NOVACOR.

Windows is a registered trademark of Microsoft Corporation.

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2. Warnings



Intended Users:

R.Test Evolution 4 and its software *RTSoft Ultima* is intended to be used by a State Registered Medical Doctor or someone acting under their direct supervision after having read the R.Test 4 and *RTSoft Ultima* user manuals. No additional training is necessary to use the device.



In the event of poor performance or failure of the software related to an operating system, network or PC failure, the user must contact the system administrator who manages their computer system.



Novacor strongly recommends the use of up to date antivirus, firewall and operating system software on the PCs running *RTSoft Ultima*.

The purpose of this manual

It is intended to guide the user of *RTSoft Ultima* through the procedures required to use the software.

If you have never used a computer...

The techniques required to use *RTSoft Ultima* are very simple. They are standard actions used in the Microsoft Windows environment, using the mouse and keyboard to work with menus and windows or to modify text on the screen.

This manual assumes that you know the basics of using applications under Windows. If you are not accustomed to this kind of environment, take the time to familiarise yourself with it using the guide provided with your computer.

If you have never used your recorders...

This manual assumes that you already know how to use your recorders; if this is not the case, you must refer to the relevant instruction manual.

Hardware requirements

- A PC type computer running Windows and with a USB port
- A DVD and DVD-ROM drive for installation
- An Access Key

Installation of the hardware

RTSoft Ultima requires an access key, which was delivered to you with the software, to be installed on your computer. It is a special connector that has no effect on your PC other than to enable the use of *RTSoft Ultima*.

To connect the access key,



simply plug it in to a free USB port.



Do not connect the key until after the software has been installed

3. Installation of the software

Minimum Configuration

- A PC with 2GHz dual-core Micro Processor & 2GB of RAM
- DVD Drive
- 17-inch monitor with a minimum resolution of 1280x1024
- Windows 7*
- Hard drive with 1GB available
- Laser printer

Recommended Configuration

- A PC with a multi core Micro Processor e.g. Intel© i5 or i7 & 4GB of RAM
- DVD Writer
- 23-inch Monitor with a minimum resolution of 1920x1080
- Windows 10*
- 7200rpm Hard drive with 2GB available
- Fast Laser printer
- Backup system

*Windows 7, 8 & 10 are supported for as long as they are actively supported by Microsoft.

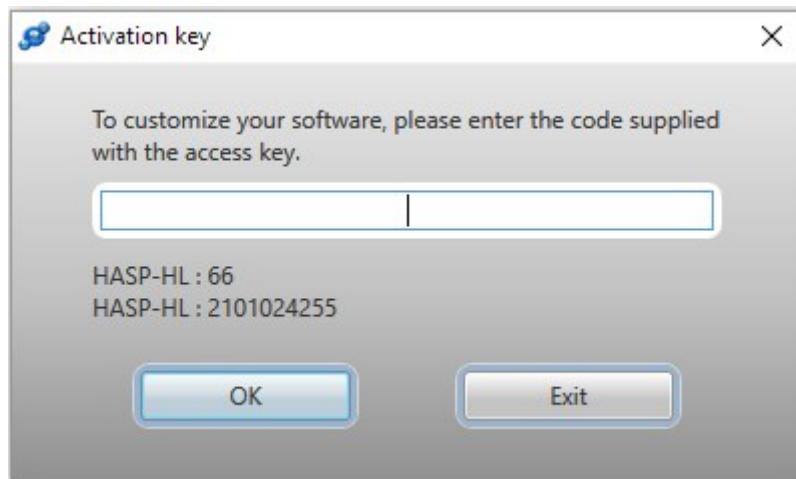
Installation Procedure

To install the software, simply run the installation files from the supplied DVD. If the DVD fails to auto run and load the user-friendly graphical interface simply browse to D:\Install\RTSoft_Ultima where D is the letter associated with your DVD drive and run setup.exe.

4. First use of the software

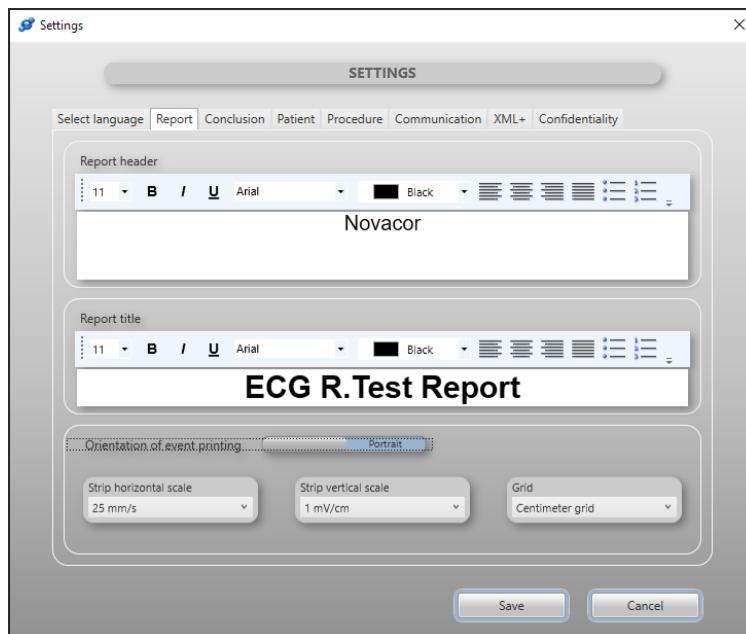
Entering the unlocking code

The first time you launch the software it is necessary to enter the unlocking code which was provided with the access key. This code will unlock the application and may activate certain optional functions of the software. A message confirms the successful activation.



Setting application preferences

From the 'Settings' menu, choose 'Settings...' and you will find a window allowing the application language to be changed and various other options to be configured including the report heading, title and scales.

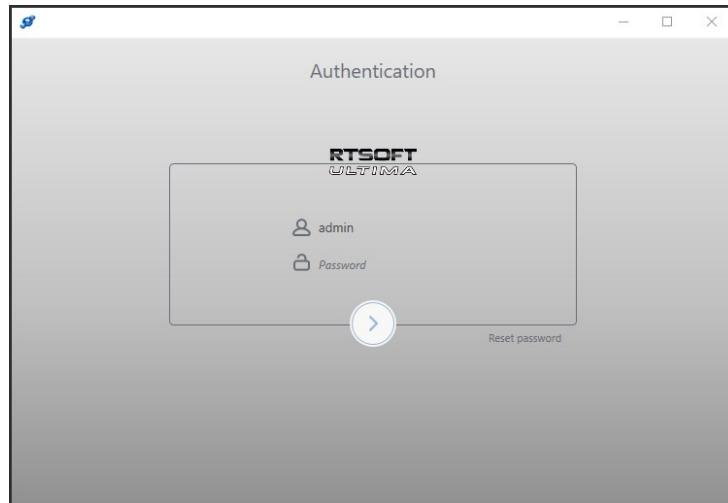


5. Authentication and user management (V1.3.X)

To protect access to the application and patient data, a user authentication system is available. Its use is optional, however **Novacor strongly recommends** using it for security reasons.

This feature can be activated using the '*Enable authentication...*' option in the '*Settings*' menu. The user must then enter the password of the "admin" account. This "admin" user who has a "SuperAdmin" role is unique and cannot be deleted.

After having entered this password twice, the user "admin" will be invited to login.

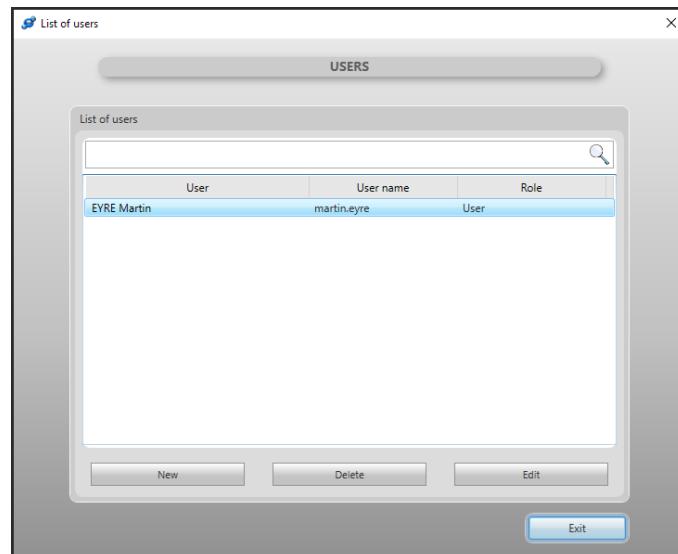


If the "admin" user forgets their password it can be reset via a link on the authentication window using the unlocking code provided with the software access key.

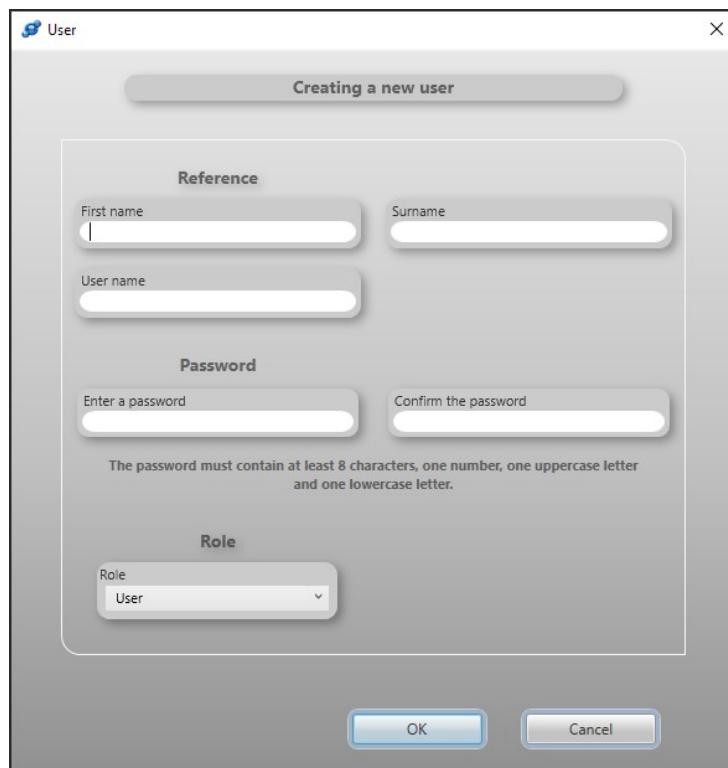
Passwords must contain at least 8 characters, one uppercase and one lowercase, and one number.

Creation and management of users

The "admin" user (role "SuperAdmin") can manage (create, delete, edit) the application's users from the '*Users...*' option on the '*Settings*' menu.



Specifically, it can create or edit a user and assign or modify their role.



When a new user is created, a temporary password is assigned to them. The user must change it on first login. They can modify it, at any time, from the 'User' window, accessed by clicking on the user name at the top of the application window.

After 5 minutes of inactivity, the user is automatically logged out. The software will prompt the user to change his password every 180 days. (Except for the user "admin")

There are 3 types of role:

- User
- Super user
- Administrator (The "SuperAdmin" role has the same powers as the "Administrator" users, but can also disable the authentication system from the 'Disable authentication...' submenu of the 'Settings' menu.)

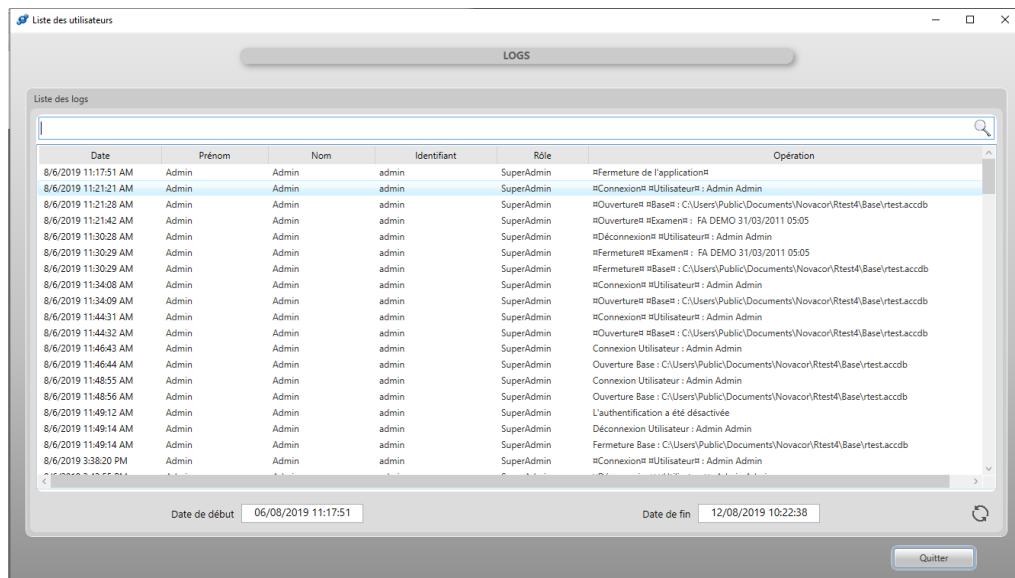
The application provides the following user management features for Administrators:

- Create a new user
- Delete a user
- Change the role of a user
- Reset a user's password
- Select a new "local database" for settings

User information is stored in the “local database”, a database of settings. However, this database can be shared by different *RTSoft Ultima* instances installed on computers connected to each other. In this way, within the same centre, it will be possible to share a common database of users. This sharing is managed from the ‘Select a new database for settings..’ submenu from the ‘Database’ menu.

Logging user actions

When authentication is enabled, the actions of the logged-in user are logged. This data is stored in the database and can be accessed, by an Administrator, from the ‘Logs...’ submenu of the ‘Settings’ menu.

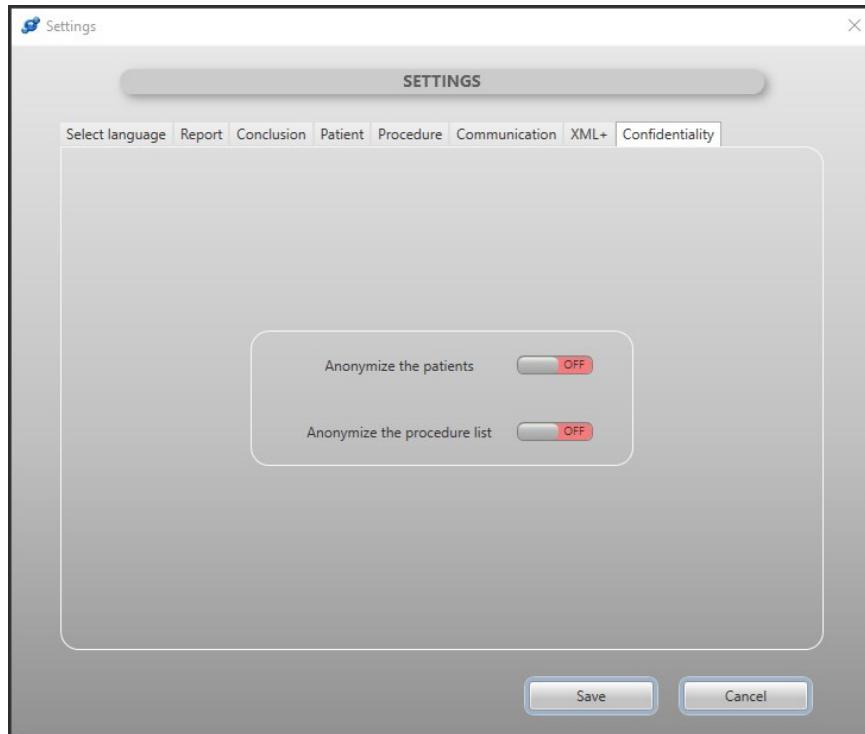


Date	Prénom	Nom	Identifiant	Rôle	Opération
8/6/2019 11:17:51 AM	Admin	Admin	admin	SuperAdmin	#Fermeture de l'application#
8/6/2019 11:18:21 AM	Admin	Admin	admin	SuperAdmin	#Connexion# #Utilisateur# : Admin Admin
8/6/2019 11:21:28 AM	Admin	Admin	admin	SuperAdmin	#Ouverture# #Base# : C:\Users\Public\Documents\Novacor\Rtest4\Base\rttest.accdb
8/6/2019 11:21:42 AM	Admin	Admin	admin	SuperAdmin	#Ouverture# #Examen# : FA DEMO 31/03/2011 05:05
8/6/2019 11:30:28 AM	Admin	Admin	admin	SuperAdmin	#Déconnexion# #Utilisateur# : Admin Admin
8/6/2019 11:30:29 AM	Admin	Admin	admin	SuperAdmin	#Fermeture# #Examen# : FA DEMO 31/03/2011 05:05
8/6/2019 11:30:29 AM	Admin	Admin	admin	SuperAdmin	#Fermeture# #Base# : C:\Users\Public\Documents\Novacor\Rtest4\Base\rttest.accdb
8/6/2019 11:34:08 AM	Admin	Admin	admin	SuperAdmin	#Connexion# #Utilisateur# : Admin Admin
8/6/2019 11:34:09 AM	Admin	Admin	admin	SuperAdmin	#Ouverture# #Base# : C:\Users\Public\Documents\Novacor\Rtest4\Base\rttest.accdb
8/6/2019 11:44:31 AM	Admin	Admin	admin	SuperAdmin	#Connexion# #Utilisateur# : Admin Admin
8/6/2019 11:48:32 AM	Admin	Admin	admin	SuperAdmin	#Ouverture# #Base# : C:\Users\Public\Documents\Novacor\Rtest4\Base\rttest.accdb
8/6/2019 11:48:43 AM	Admin	Admin	admin	SuperAdmin	Connexion Utilisateur : Admin Admin
8/6/2019 11:48:44 AM	Admin	Admin	admin	SuperAdmin	Ouverture Base : C:\Users\Public\Documents\Novacor\Rtest4\Base\rttest.accdb
8/6/2019 11:48:55 AM	Admin	Admin	admin	SuperAdmin	Connexion Utilisateur : Admin Admin
8/6/2019 11:48:56 AM	Admin	Admin	admin	SuperAdmin	Ouverture Base : C:\Users\Public\Documents\Novacor\Rtest4\Base\rttest.accdb
8/6/2019 11:49:12 AM	Admin	Admin	admin	SuperAdmin	L'authentification a été désactivée
8/6/2019 11:49:14 AM	Admin	Admin	admin	SuperAdmin	Déconnexion Utilisateur : Admin Admin
8/6/2019 11:49:14 AM	Admin	Admin	admin	SuperAdmin	Fermeture Base : C:\Users\Public\Documents\Novacor\Rtest4\Base\rttest.accdb
8/6/2019 13:38:20 PM	Admin	Admin	admin	SuperAdmin	#Connexion# #Utilisateur# : Admin Admin

6. Data privacy (V1.3.X)

All users of the application have the ability to anonymise the names of patients by displaying only the first 2 letters of the first name and surname of each patient.

This feature is available from the '*Confidentiality*' tab of '*Settings*' window.



Two possibilities are offered to the user, either to anonymise all the windows of the application as well as the printed report, or only the names of patients in the procedure list. (See § 11)

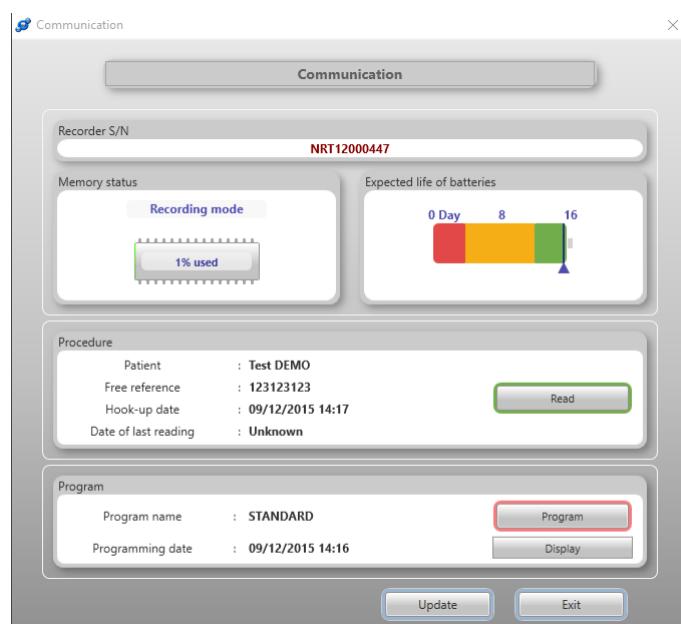
7. Programming the recorder

Connect the R.Test USB cable to the PC, then connect R.Test 4 to the cable.

Communication Window

To open the communication window, there are three possibilities:

- From the RTEST menu choose Program/Read R.Test4...
- By clicking on the icon: 
- By activating the automatic communication: choose 'Settings...' from the 'Settings' menu and in the communication tab turn on the option 'Automatic connection R.Test 4'

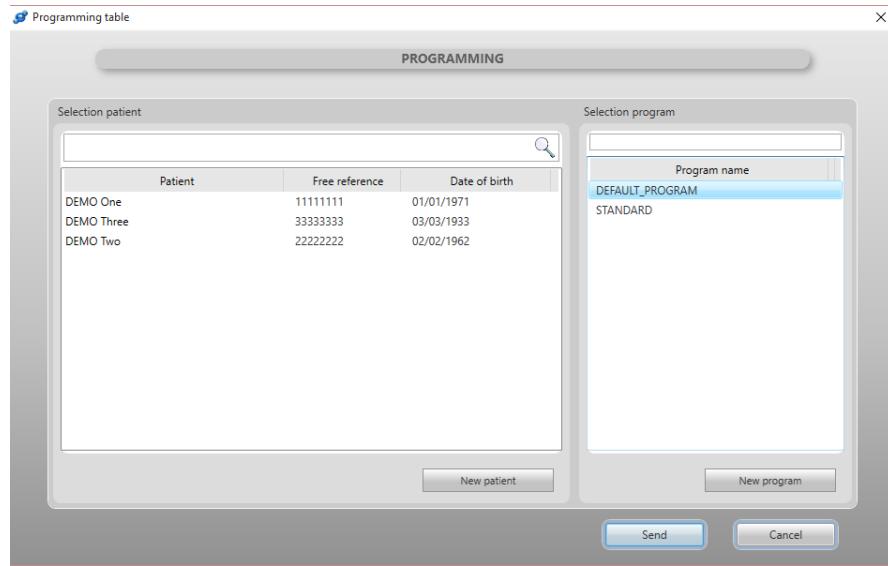


The communication window displays the state of the recorder:

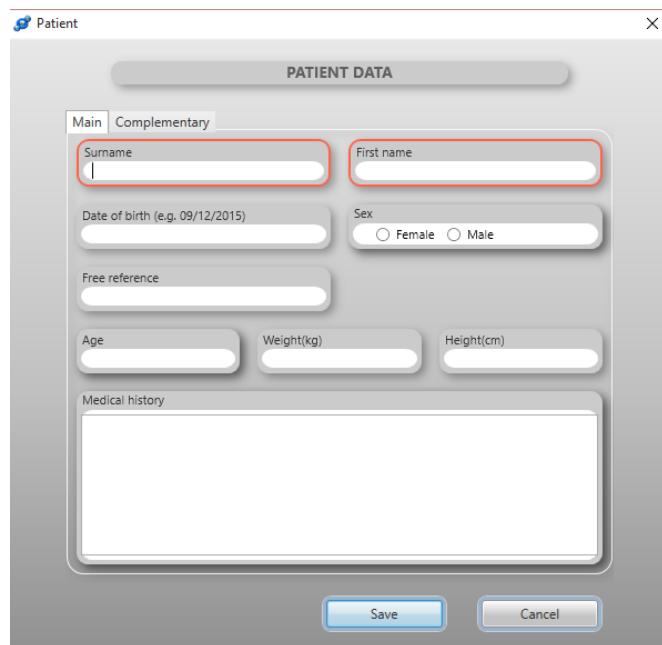
	Description	Options
Recorder S/N	Serial Number	
Memory status	The current state of the connected recorder's memory	<ul style="list-style-type: none">➤ Recording Mode➤ Memory usage
Estimated life of batteries	Estimated duration of monitoring available	<ul style="list-style-type: none">➤ No batteries➤ Endurance expressed in days
Procedure	Data currently contained in R.Test	
Program	Program currently contained in R.Test	

Click on the button

Program



If the patient does not appear in the list, you should create them by clicking on the 'New patient' button. Once you have entered the information, click 'Save'.



Select the desired patient and program then click

Send

Programs

A user with the "User" role cannot create or modify a program.

Programming table

Programming table

Program name: **DEFAULT_PROGRAM** | Memory available: **00:00:00**

Event types	Pre	Post	Events	Duration	Analysis Criteria	RAM
VT	00:15	00:45	6	360		<input checked="" type="button"/> ON
VEs (3 classes)	00:15	00:15	9	270		<input type="button"/> OFF
PSVT	00:15	00:45	6	360	Threshold < RR - 25	<input type="button"/> OFF
SVEs (3 classes)	00:15	00:15	9	270	Threshold < RR - 25	<input type="button"/> OFF
Absolute pauses	00:10	00:20	8	240	Duration > 2 s	<input checked="" type="button"/> ON
Relative pauses	00:10	00:10	6	120	Duration > 175	<input type="button"/> OFF
Tachycardias	00:15	00:30	8	360	Threshold > 140 bpm	<input type="button"/> OFF
Bradycardias	00:15	00:30	8	360	Threshold < 50 bpm	<input type="button"/> OFF
ST shifts	00:15	00:15	4	120	≥ 2 mm	<input type="button"/> OFF
AF	00:45	00:45	6	540		<input checked="" type="button"/> ON
Patient Events	00:40	00:20	10	600		

Faulty electrode alarm: OFF | Real time key: OFF | Spike detection: ON

Save | **Cancel**

Description:

Event types	Pre	Post	Events	Duration	Analysis Criteria	RAM
VT	00:15	00:45	6	360		<input checked="" type="button"/> ON

Column	Significance	Comment
Event types	Classes of events	
Pre	Duration to be recorded before the event	Duration in seconds, maximum 5 minutes
Post	Duration to be recorded after the event	Duration in seconds, maximum 59' 55"
Events	Number of events to be recorded	Maximum 99 per class
Duration	Total Duration allocated to class (not modifiable)	Duration in seconds, maximum 3600 seconds
Analysis Criteria	The criteria to trigger the recording of the event	See Arrhythmia detection in the R.Test 4 manual.
	Activation of the corresponding key on the recorder for a class of event	Indication of the memory state at the time of an activation of this button: - Red LED: memory full for one of the events programmed - Green LED: no memory full

Software Options

Display of the 'ST shifts' and 'AF' rows on the programming table are dependent on the presence of the optional 'ST software module' and 'AF software module' respectively. Recordings of ST events and AF events are controlled using the programming table.

Additional program options:

- Faulty electrode alarm: Causes a beep when that the recorder becomes disconnected from the patient (e.g. electrodes removed).
- Real time key: Activation of the  button, allowing the patient to trigger an audible tone modulated by the ECG in real time.
- Spike Detection: Activation of the detection circuit for electrical impulses of pacemakers (Spikes). These spikes are taken into account when detecting and classifying QRS complexes. This mode should be activated for patients with pacemakers.

8. Reading an examination

To open the communication window, there are three possibilities:

- From the RTEST menu choose Program/Read R.Test4...

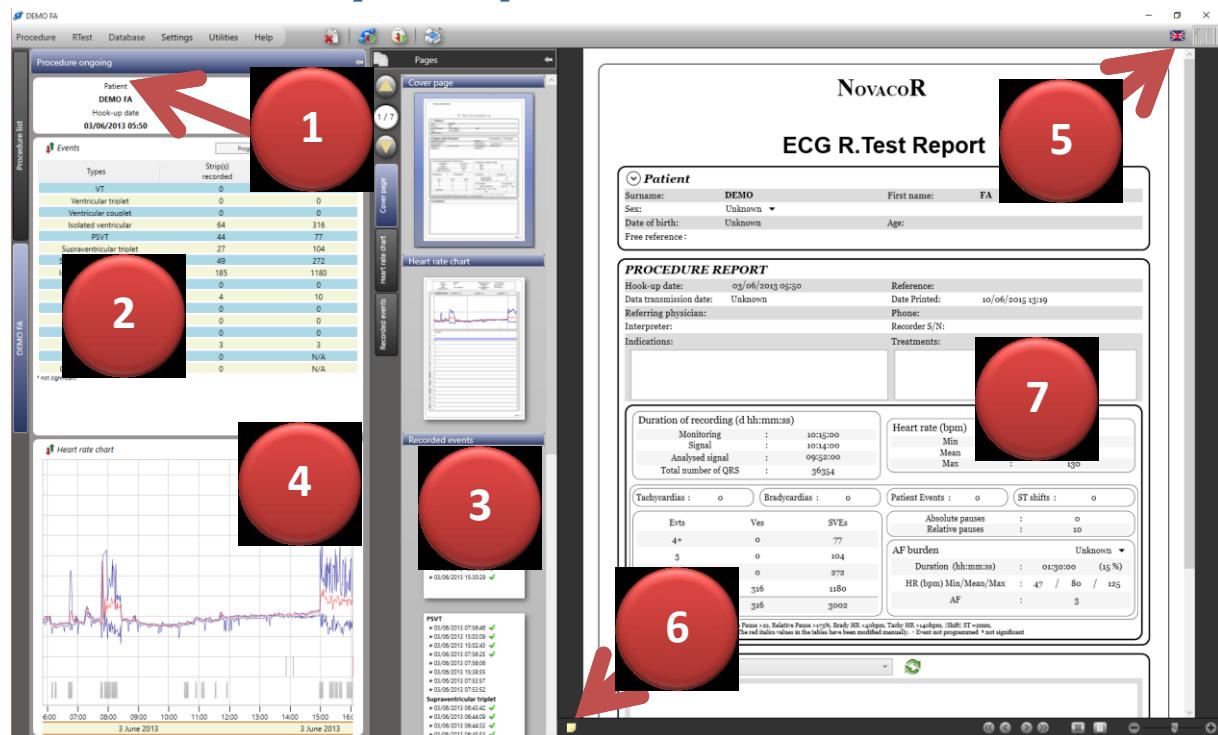


- By clicking on the icon:
- By activating the automatic communication: choose 'Settings...' from the 'Settings' menu and in the 'Communication' tab turn on the option 'Automatic connection R.Test4'.

Click on the Read button to read the procedure from the R.Test recorder.

You can then select from the list of the patients, which is displayed, or create a new patient if the correct details do not exist. The procedure will be opened automatically.

9. Review and report the procedure



Procedure list (1)

Initially allows access to a complete list of procedures that can be sorted or filtered, once a procedure has been opened just the current patient is displayed.

Events table (2)

This table displays the number of events, in the open procedure, detected and recorded for each category. It is possible to click on a line, to display the 1st page of corresponding ECG strips.

Program	Displays the program used to conduct the procedure
---------	--

Settings	Allows modification of the number of visible strips for each type of event.
----------	---

Pages of the report (3)

Provides rapid access to each page of the report.

Heart Rate Chart (4)

Displays the minimum, mean and maximum heart rate (HR) curve and the occurrence of events over time. The user can navigate in the examination report by clicking on the desired event. The vertical grey bands symbolize the day / night periods. The user can modify them by setting the bedtime and getting up times from the 'Procedure' tab of the 'Settings' window.

Status bar (5)

Displays:

- The logged in user's ID and access the User window by clicking on the ID
- The language of the application, that can be modified by clicking on the flag
- The state of the application icon 
- The state of the Internet connection of the application icon 
- A button allowing the user to Logout. 

Sticky Note pad (6)

Allows you to open a note, the user can take notes and quickly integrate them in the conclusion by copy / paste or from the context menu of the conclusion field.

Detailed Report (7)

Cover Page

Report Header and Title

The report header is directly modifiable on this page. It is possible to modify the size, font and colour of the characters and paste an image (using copy & paste) if required.

The title of the report can be changed using the 'Settings...' option from the 'Settings' menu.

Changes made to the report header and the title of the report will apply to all procedures.

'Patient' & 'Procedure Report' Sections

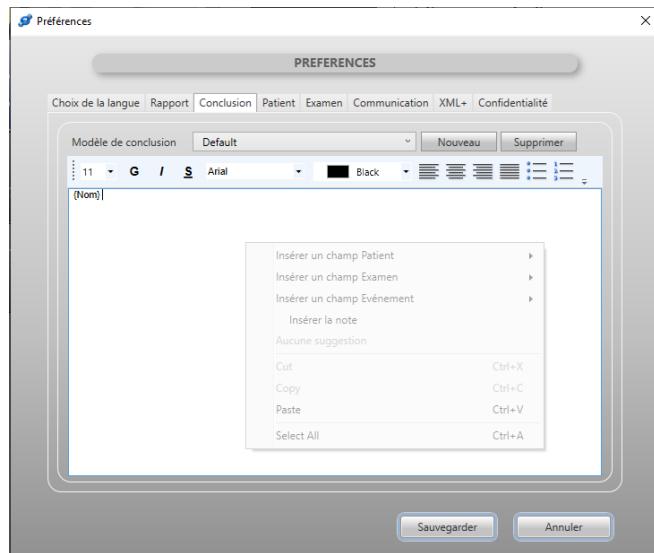
This area displays the details of the patient and procedure.

Where the user has modified the procedure data it will appear in red. It is possible to restore the initial value by clicking on the button located on the right of field: 

'Conclusion' Section

This area is provided for your comments; they can either be typed or pasted. The user also has the option to define custom conclusion templates from the 'Conclusion' tab of the 'Settings' window. A range of patient, procedure and event fields can be inserted into conclusion templates, together with

the contents of the Sticky note pad. When a template is applied to the conclusion window, the correct values will automatically be inserted in to the chosen fields.



Heart Rate & Histograms

Heart Rate Graph

This section provides a graphical representation of the minimum, mean and maximum heart rate (HR) curves for each measurement time interval (see the R.Test 4 manual for more information on calculation of the HR).

It is possible to zoom in on part of the HR curve by using the wheel on your mouse, to return to the whole graph simply right-click and choose “Adjust the width of the page”

The display of the minimum-maximum values can be modified by using a right click and changing the “Mini-Maxi” option.

Histograms

The histograms are synchronised with the Heart Rate graph and represent the number of occurrences for each type of event indicated in the left margin. The abbreviation ‘min’ on some histograms represents the number of minutes per hour that a given event was detected.

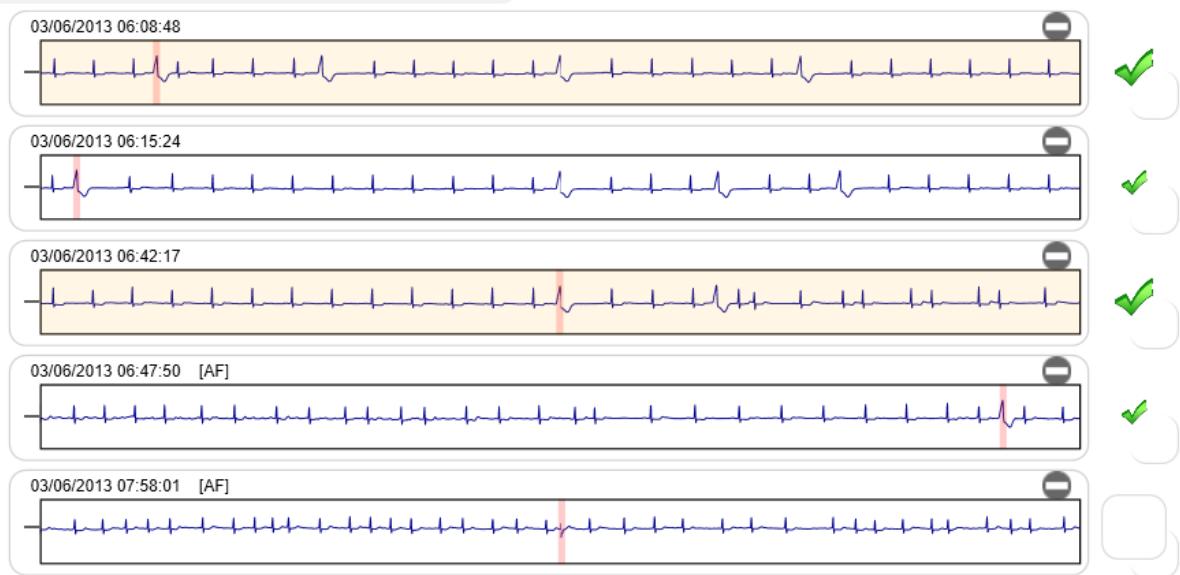
Hovering over the histograms with the mouse gives a tooltip that displays the number represented by the histogram.

Recorded Events

All of the events recorded by the R.Test, subject to the limits set by the user in the ‘visible events recorded in the procedure report’ will appear in this section.

Isolated ventricular

10 / 64



On the right of each strip there is a button that controls how the trace will be printed it in the report:

<input type="checkbox"/>	The strip will not be printed
<input checked="" type="checkbox"/>	The strip will be printed in compressed format only
<input checked="" type="checkbox"/>	The strip will be printed in compressed format and at full size (the strip also appears with a pink background)
<input checked="" type="checkbox"/>	The strip will be printed in compressed format and in full page.
<input checked="" type="checkbox"/>	The strip will be printed in compressed format, in full size (the strip appears with a pink background) and in full page.

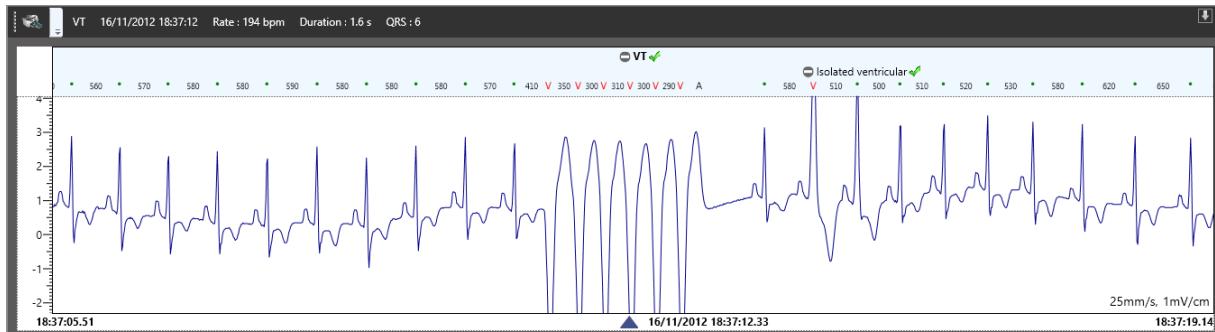
For each strip it is possible to remove it from the report by clicking on the minus symbol located above the top right corner of the strip. All the numerical counts for this type of event are decreased by 1.

All the events of a particular type can be removed (including the hidden events) by clicking on the minus symbol located to the right of the event title. The numerical counts are changed to 0* (* indicating that the events were removed by the user and are not clinically significant).

It is possible to move between the pages of the report either via the labels in zone ③, the 'Page up/Page down' buttons or by using the button bar below:



Double clicking on an ECG strip, opens a window to display that strip in more detail and allows the user to explore the context of the event:



The context menu contained in the top banner of the ECG strip allows you to add, remove, or modify an event.

The context menu accessed through a right mouse click in the window allows modification of:

- the Scale (horizontally and vertically)
- the type of grid displayed
- the QRS and RR interval annotations display
- the polarity of the ECG

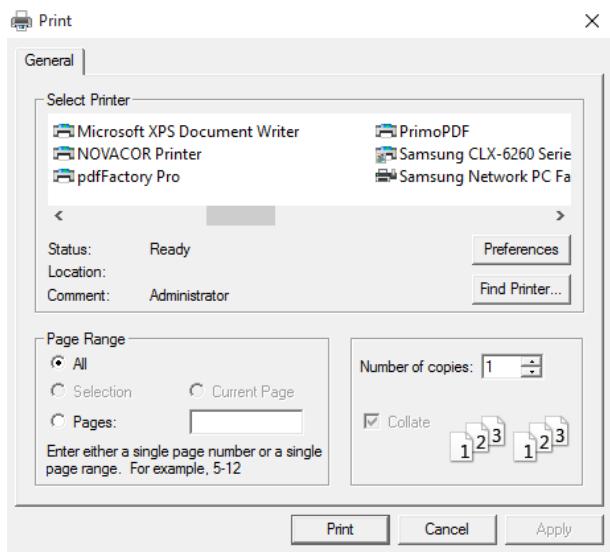
These choices will be applied automatically for this procedure.

The printer icon makes it possible to directly print a strip centred on the viewable section.

10. Printing the report

Printing

From the main printing icon, or starting from the 'Procedure' menu and the 'Print...' option.



The 'Print Range' area of dialog box provides control over which pages of the report are printed: for example, entering 5-8 will print only pages 5 to 8 of the report.

Preview

It is possible preview the report before you print it by choosing the 'Preview...' option.

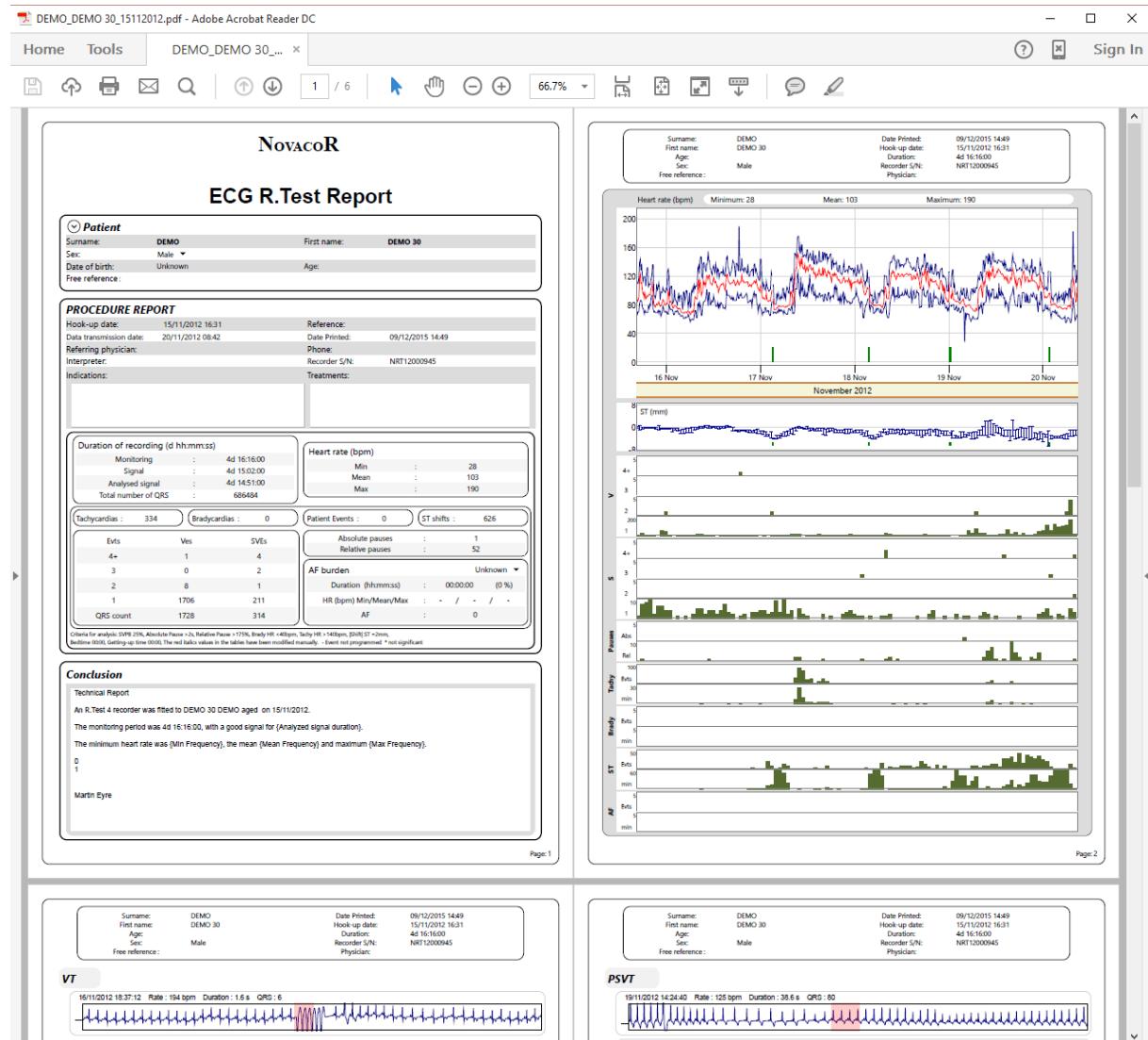
From this preview view, it is possible to print the report by clicking on the printer icon.



Export PDF

It is also possible to generate a PDF file by choosing 'Export PDF...' from the 'Procedure' menu.

All that is required is to choose a location and enter a filename.



XML export +

The user has the possibility to export the exam data in XML format. This option can be set from the 'XML+' tab of the 'Settings' window.

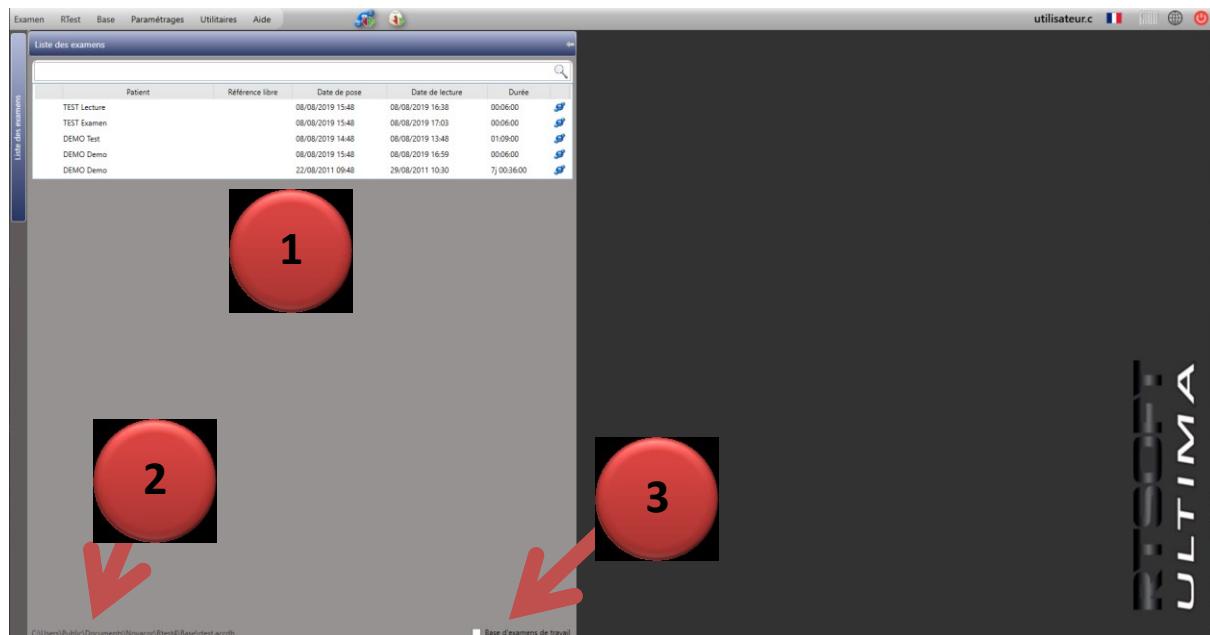
11. Procedure Management

The procedures read within RTSoft Ultima are stored in a database that can be shared by different instances of RTSoft Ultima installed on computers connected to each other. In this way, within the same centre, it will be possible to share a common database of procedures.

RTSoft Ultima gives the possibility from the 'Database' menu to:

- Create a new procedure database ("Super User", "Administrator")
- To open a database and to display the list of procedures
- Unlock it if one or more exams are locked
- To protect one or more databases with a password ("Super User", "Administrator")
- To repair it if it is corrupted.

List of procedures in database



List of procedures in the open database - ①

The user can search for a procedure in the list according to different criteria (Surname, first name and patient's ID). He can also sort the exams according to each column header.

From the context menu of the list, the user can:

- Delete a procedure ("Super User", "Administrator")
- Copy a procedure to another database ("Super User", "Administrator")

From the 'Procedure' menu, the user can:

- Delete a procedure ("Super User", "Administrator")
- Move a procedure from one patient to another ("Super User", "Administrator")

Display of the database path - ②

The database path information can help the user to quickly back up the database.

Selection of 'Default 'Read to' database' - 3

Any authenticated user can define a default 'Read to' database. If he reads a procedure in to another database, that is not his default database, a warning message will be displayed.

Back-Up your Database

To perform a backup, simply copy all the data (including all subdirectories) contained in the database folder from the specified path.

This process can be automated using any backup software on the market (including the backup software that is integrated into Windows).

The application's 'Local database' (Settings database) is by default in "C:\ProgramData\NOVACOR\Rtest4", it is advisable to also make a backup of this directory.



It is strongly recommended you regular backup your data.

CAUTION!



It would be damaging to your data to directly modify the files in the subfolders of the directory containing an *RTSoft Ultima* database. The act of moving, renaming or of deleting files or folder in this directory can seriously affect your database; it could result in the loss of all your data and even prevent the software from functioning.

12- Updating the Firmware of your R.Test 4 recorders (V1.3.X)

RTSoft Ultima allows you to update the embedded software of R.Test 4 recorders that are connected to the PC. This feature requires the PC to be connected to the Internet so that RTSoft Ultima can communicate with the Novacor Web Server. This communication is necessary for the EU regulation of medical devices which requires Novacor to track the updates.

Before RTSoft Ultima can access the Novacor Server through the Internet the user is prompted to activate this function from the 'Communication' tab of the 'Settings' window.

Update procedure

After connecting an R.Test 4 to the PC via the USB cable, the application will check the version of firmware on the device. If the recorder is in the 'Ready to Start' state, and needs to be updated, an update window will automatically appear. It can also be opened via the 'Update R.Test4...' option on the 'RTTest' menu.

Example of an update of C04n version to C04q:



After viewing the window, the user is prompted to click the 'Update' button. You must not disconnect the recorder from the PC during the update as it will be damaged.



R.Test 4 can be disconnected at the end of the procedure.



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