



USER MANUAL

Télécardia

12-lead Electrocardiograph



www.parsys.com

Copyright © 2022
by Parsys Télémedecine
5/7, avenue de Paris
94300 Vincennes - France

This document contains confidential information belonging to Parsys Télémedecine. No part of this document may be transmitted, reproduced, used or disclosed outside the organization for which it is intended without the express written consent of Parsys Télémedecine. (contact: info@parsys.com)

TABLE OF CONTENTS

1	TELECARDIA KIT CONTENTS	5
1.1	COMPONENTS	5
1.2	WARNINGS AND SAFETY RECOMMENDATIONS	7
1.2.1	Liability of the manufacturer	7
1.2.2	Responsibility of the client	7
1.2.3	Identification of the equipment	7
1.2.4	Copyright and trademark warnings	7
1.2.5	Warnings concerning the information in this document	7
1.2.6	Safety recommendations for the equipment user	8
1.2.6.1	Environmental warnings	8
1.2.6.1.1	Context of use	8
1.2.6.1.2	Compliance with the instructions for use	8
1.2.6.1.3	Electrical safety	8
1.2.6.1.4	Simultaneous use with another device	8
1.2.6.2	Warnings concerning the use of the device	9
1.2.6.2.1	How to use and start up the device	9
1.2.6.2.2	Using the main button	9
1.2.6.2.3	Direct cardiac use	9
1.2.6.2.4	Respecting the connection modes of the device and its peripherals	9
1.2.6.2.5	Contact of the device with the patient	9
1.2.6.2.6	Behavior of the patient	9
1.2.6.2.7	Cleaning the device and peripherals	9
1.2.6.2.8	Battery of the device	10
1.2.6.2.9	Recharging of the device	10
1.2.6.2.10	Special conditions of use	10
1.2.6.2.11	Conditions of storage and transport	10
1.2.6.3	Warnings concerning peripherals, accessories and other equipment	11
1.2.6.3.1	Equipment compliance	11
1.2.6.3.2	Risks about the peripherals	11
1.3	USER MANUAL CHANGE TRACKING	12
2	EQUIPMENT DESCRIPTION	14
2.1	GENERAL FEATURES	14
2.2	ELECTRODES POSITION	14
2.2.1	Precordial leads: dry fixed thoracic electrodes	14
2.2.2	Peripheral leads	15
2.3	DEVICE CONTROL BUTTONS	16
2.3.1	Switch on the device	16
2.3.2	Switch off the device	16
2.4	CHARGING BASE	17
2.5	ECG READING	18
3	INSTALLATION OF MEDCAPTURE PC SOFTWARE	19
4	BLUETOOTH PAIRING PROCEDURE OF THE TELECARDIA TO A TERMINAL PC	21
4.1	REQUIREMENTS	21
4.2	SPECIFICITY ACCORDING TO WINDOWS VERSIONS	21
4.3	PAIRING OF TELECARDIA WITH A WINDOWS TERMINAL PC	22
4.4	PAIRING OF TELECARDIA WITH THE MEDCAPTURE SOFTWARE	25
5	USING THE MEDCAPTURE PC SOFTWARE	31
6	ECG TRACE CAPTURE (ELECTROCARDIOGRAM	32
7	UPDATING THE PC SOFTWARE / DEVICE FIRMWARE	35
8	TECHNICAL FEATURES	36
8.1	GENERAL FEATURES	36
8.2	MECHANICAL FEATURES	36

8.3	ELECTRICAL SPECIFICATIONS	37
8.4	FUNCTIONAL FEATURES	38
9	ELECTROMAGNETIC EMISSIONS.....	39
9.1	SUITABLE ENVIRONMENTS	39
9.2	EQUIPMENT COMPATIBILITY	39
9.3	DEGRADATION OF EQUIPMENT PERFORMANCES.....	39
9.4	SPECIFIC CAUTIONS WITH EXTERNAL EQUIPMENTS	40
9.5	COMPLIANCE	41
10	USERS' TRAINING	42
11	MAINTENANCE.....	43
11.1	CLEANING / DISINFECTION	43
11.2	PROCEDURE IF THE DEVICE IS DROPPED OR FALLS.....	43
11.3	RESET PROCEDURE	43
11.4	METROLOGICAL CHECKS	44
11.5	DISCHARGED BATTERY	44
11.6	PRODUCT SCRAP TREATMENT	44
12	FAULT OR FAILURE	45
12.1	THE TELECARDIA ECG DOES NOT SEND ANY TRACE	45
12.2	THE SOFTWARE MODULE OF THE ECG TELECARDIA IS GRAYED OUT	45
12.3	THE ECG IS SUBJECT TO INTERFERENCE	46
12.4	THE TELECARDIA ECG IS NOT CHARGING	46
12.5	THE TELECARDIA ECG REMAINS BLOCKED.....	47
12.6	THE TELECARDIA ECG HAS LOST IS TIME STAMPING	47
13	TECHNICAL ASSISTANCE AND CUSTOMER CARE SERVICE	48

1 Télécardia Kit contents

We thank you for having chosen PARSYS Télémédecine equipment. We hope that it will bring you full satisfaction in your daily electrocardiography practice.

1.1 Components



Firstly, please **check the contents** of your **Télécardia** Kit (Ref: 100-004). It must contain the following items:

- 1 **Télécardia portable electrocardiograph (ECG)** Ref: 25-001
- 1 Bluetooth USB adapter Ref: 36-002
- 1 Peripheral 3-lead Patient cable - 4 mm banana secured plugs Ref: 23-029
- 3 Colored arm limb clips - 4 mm banana plugs (red, yellow and green) Ref: 36-007/8/11
- 1 Charging base DC 5V/1,1A Ref: 25-002
- 1 Medical (IEC 60601-1) 5V / EU power supply and cord Ref: 16-001
- 1 Water spray Ref: 36-006
- 1 Reset black cord (for device reset) Ref: 23-051
- 1 Carry case with foam Ref: 34-003
- 1 USB waterproof storage key containing: Ref: 25-050
 - 1 Warranty Card Ref: 37-003
 - 1 User Manual - Télécardia Ref: 37-021
 - 1 User Manual - MedCapture Software Ref: 37-080

If any of the items are missing, please contact the Customer Care Service of PARSYS Télémédecine at the address specified in this User Manual (see Section 12).

List of symbols used



Warning: consult attached documents



Please read the notice before use



BF type applied part



Do not dispose of in the bin but through the appropriate recycling channels
Product subject to the European WEEE Directive (2002/96/CE)



Non-ionizing radiation



Product complies with the European RoHS Directive (2002/95/CE)



Product manufactured by PARSYS Télémédecine



Date of manufacture



Device climatic range of use or storage



Serial number



Catalogue number



Medical device European compliance

IP21

IP22

Degrees of protection provided by the protective envelopes (Protection index or IP)



ON/OFF button icon

1.2 Warnings and safety recommendations

PARSYS Télémedecine draws the attention of the user on the following points regarding:

1.2.1 Liability of the manufacturer

PARSYS Télémedecine is responsible for the effects on safety and performance, **only if**:

- The assembly, upgrade, adaptation, modification or repair operations are carried out only by **agents authorized** by PARSYS Télémedecine.
- The device is **used according to the instructions for use**.

1.2.2 Responsibility of the client

The user of this device is responsible for establishing and **maintaining a satisfactory maintenance program**. The violation of this instruction may result in equipment failure and possibly **health hazards**. PARSYS Télémedecine systematically offers a maintenance program that the user can choose to contract at any time.

1.2.3 Identification of the equipment

PARSYS Télémedecine equipment is identified by a **serial and reference number** positioned directly on the device. Make sure these numbers are **always readable** outside of a maintenance program.

1.2.4 Copyright and trademark warnings

This document contains information protected by **copyright**. All rights **reserved**. This document, in whole or in part, may not be photocopied, reproduced or translated to another language without the prior written consent of PARSYS Télémedecine.

1.2.5 Warnings concerning the information in this document

The information in this document is **subject to change without notice**.

PARSYS Télémedecine makes no warranty for this device, including, but not limited to, warranties of merchantability and fitness for a particular purpose. PARSYS Télémedecine assumes no responsibility for any errors or omissions that may appear in this document. PARSYS Télémedecine does not undertake to update the information contained in this document.

Keep the original User Manual for future reference.

1.2.6 Safety recommendations for the equipment user

1.2.6.1 Environmental warnings

1.2.6.1.1 Context of use

The Télécardia ECG is an ambulatory electrocardiograph capable of capturing an ECG trace of 12 leads on 12 simultaneous channels. The dry electrodes fixed on the housing of the device replace the conventional adhesive electrodes. Télécardia is a digital and portable electrocardiograph integrating a battery and interfacing in Bluetooth with a PC terminal. It is used with software to preview the patient's ECG trace on the screen of a PC terminal.

This sensor does not integrate alarms.

The Télécardia device is operational for most patients. There are, however, some patient morphologies for which the device is not compatible:

- Children under 13 years old
- Extremely thin morphologies (anorexia, etc.)
- Morphologies in obesity higher than 200 kg
- Very strong breasts (women or men)
- Pectus carinatum and excavatum

Télécardia is intended for use in a hospital or controlled work environment and must be used and stored in accordance with the environmental conditions specified in this User Manual.



Make sure to use the device and its accessories under the limit conditions of use indicated in Section 8 of this User Manual.

1.2.6.1.2 Compliance with the instructions for use

This Manual provides important information on the use and safety of this device. Failure to follow procedures for use, **inappropriate use** or **misuse** of the device, or failure to comply with specifications and recommendations could result in **increased risk** to nearby users, patients and others, but also **damage the device**.

1.2.6.1.3 Electrical safety

For the protection of the device and the electrical safety of the patient, **use only the original charging system** which is provided with the Télécardia. If your original medical charger no longer works, please contact the Customer Care Service of PARSYS Télémédecine.

1.2.6.1.4 Simultaneous use with another device

The device **must not be used** simultaneously with an electric surgery instrument.

In the case where the device is used simultaneously with another one, **be careful** that the sum of the patient leakage currents to ground does not exceed the safety limits.

The device **is not intended** to be used at the same time as a **defibrillator** and **does not have** defibrillation shock protection. It is therefore **imperative to remove the device and all its accessories from the patient** before being able to apply a defibrillation shock.

1.2.6.2 Warnings concerning the use of the device

1.2.6.2.1 How to use and start up the device

This device is designed to be **used by hand in ambulatory mode**. Only slight pressure is needed on the green main button to **ignite the device and release its side arms** with fixed and dry electrodes.

To help prevent operational stress injuries, **do not try to release the arms of the device by force**. Their locking and release are only possible through the mechanical system of the green main button.

Check all the elements of the system after receipt it and before each use to confirm that none of the elements, and in particular the connectors, **have no apparent damage**. **Never use cords in poor condition** (bare, damaged sheath, deformed connectors, etc.).



Make sure to read and understand all of the instructions in this User Manual, and in particular the warnings, before using the Télécardia device on a patient for the first time.

1.2.6.2.2 Using the main button

To avoid damaging the green main button, **do not use sharp or hard objects** to push in, but only the fingers.

1.2.6.2.3 Direct cardiac use

The device **is not intended** for direct cardiac use (reserved for CF-class devices).

1.2.6.2.4 Respecting the connection modes of the device and its peripherals

For proper operation and for the safety of nearby users or patients and others, the equipment and accessories must be connected only as described in this Manual.

1.2.6.2.5 Contact of the device with the patient

When capturing an ECG trace, the device box **must be** in contact with the patient.

1.2.6.2.6 Behavior of the patient

Excessive movements of the patient may interfere with the operation of the device. Make sure that it remains as calm as possible.

1.2.6.2.7 Cleaning the device and peripherals

Do not attempt to clean the device or patient cable **by immersing them** in liquid or by autoclaving or steaming as this may damage the equipment or shorten its life. **Blot the outer surfaces** with a solution of mild detergent and warm water, then wipe with a dry towel.

The use of a cleaning method or disinfectants not specified in this manual, as well as failure to follow recommended procedures or contact with unspecified materials, could result in increased risk to nearby users, patients and patients, or **damage the device**.

1.2.6.2.8 *Battery of the device*

The built-in rechargeable battery is **lithium-ion** type and requires **no maintenance**. If the battery seems to be **defective, report it** to the Customer Care Service of PARSYS Télémedecine or its duly authorized agent.

1.2.6.2.9 *Recharging of the device*

Always charge the device after using its battery. This ensures that the battery will be automatically recharged the next time you use the device. A LED on the charging base indicates that the device is charging.

1.2.6.2.10 *Special conditions of use*

Do not open, crush, heat above 50°C or incinerate this device, otherwise there is a risk of fire and burns. Follow the instructions in this Manual.

If necessary, set aside the device, its components and accessories (charging base, batteries, cables, electrodes) and/or packaging materials in accordance with the current regulations.

1.2.6.2.11 *Conditions of storage and transport*

Refer to the limit conditions of storage/transport presented in the Section 8 and always check the device and its accessories after an extended storage period before use.



Do not expose the device and its accessories to the sun (UV) for a prolonged period of time as this may cause substantial and irreversible damage.

1.2.6.3 Warnings concerning peripherals, accessories and other equipment

1.2.6.3.1 Equipment compliance

To ensure the safety of the operator and the patient, the peripheral equipment and accessories used which are in direct contact with the patient must **comply with the requirements** of IEC 60601-1 and IEC 60601-2-25.

Only use the parts and accessories supplied with the device and available from PARSYS Télémedecine. The use of accessories (electrodes, cables, etc.) not supplied or not certified compatible by PARSYS Télémedecine **may negatively affect EMC or medical performance** of the equipment.

1.2.6.3.2 Risks about the peripherals

When capturing an ECG trace, electrodes that are not connected to the patient **must be protected** from contact with the ground or other exposed metal parts.

Do not pull on the patient cable as this may cause mechanical and/or electrical faults. Gently wrap the patient cable around one hand before storing.

1.3 User Manual Change Tracking

SECTION	PURPOSE OF THE AMENDMENT
4.3 Version - 02/28/2018	
All the document	Overall improvement of the layout
1.1	Technical details on electrical accessories
1.2	Modification of icons relating to the EN60601-1 standard
1.4	Adding the "User Manual Change Tracking" section
8	Technical details on electrical components and accessories
12.1	Improvement of didactic content
13	Modification of the address of the company (5 → 5/7)
4.4 Version - 09/21/2018	
8.1	New battery information update
4.5 Version - 07/19/2019	
All the document	Update graphic elements (logo, product photos, etc.)
1.2	Addition of RoHS elements
1.3	Addition of warnings and restructuring of the section
4	Modifications of the Bluetooth pairing procedure according to the new firmware version.
6	Addition of a warning related to the typology of patient morphologies
8	Modification of specifications in tables format
8.1	Addition of the lifespan of the medical device
8.5	Remove of the "Operating Flowchart" section
10.3	Modifications of the procedure according to the new firmware version.
12.4	Modifications of the procedure according to the new firmware version.
12.5	Modifications of the procedure according to the new firmware version.
13	Change of title and update of a table of useful contacts
4.6 Version - 09/02/2019	
1 st Page	ID bar code removing
1.2	Addition of new ISO icons
3	Addition of a MedCapture software section
5	Addition of a MedCapture software section
4.7 Version - 02/21/2020	
All the document	Update graphic elements (logo, product photos, etc.)
1.2	Switching "CF applied part" icon to "BF applied part" icon Addition of an IP and an ON/OFF icons
1.3.1.2.10	Modification of the maximal temperature
1.3.6	Precisions about the context of use and storage/transport conditions
2.3	Addition of 2 sections about switching ON/OFF the device
8.1	Addition of lifespans and precisions about the PSU in the features
8.2	Modification of the IP information
8.3	Addition of several electrical specifications of the device
9	Addition of 5 more sections about electromagnetic emissions compliance
11.1	Precisions about the device cleaning procedure
11.4	Addition of a Metrological checks table

4.8 Version - 09/23/2020

8.2	Correction of technical data errors
8.3	Correction of technical data errors

4.8.1 Version - 03/17/2022

All the document	Removal of mentions of Télécordialys software Télécordia pictures update
2.3.2	Add of the mention to the audio message when turning off the device Télécordia
2.5	Content update
4	Complete redesign of the section
6	Complete redesign of the section
7	Content update
8	Add of a new model of medical power supply Content update

2 Equipment description

2.1 General features

Télécardia represents a major advance in remote cardiac monitoring and portable medical equipment. It enables health professionals to rapidly capture and send a patient's ECG under any circumstances, without the constraints of a conventional device.

The trace captured is a digital, simultaneous 12-lead 12-second 12-channel ECG, in keeping with standard electrocardiographs usually used. It can be sent automatically to a care watch center or be viewed on a terminal PC next to the patient.

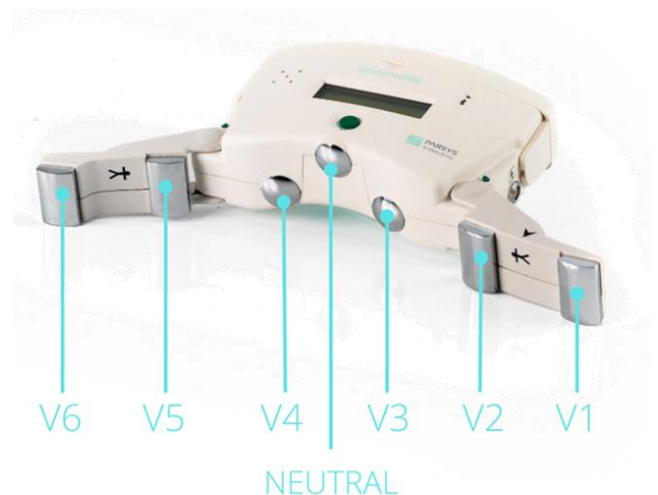
Télécardia has CE marking (CE 0459). This is an ECG device intended for temporary use, class IIa.



2.2 Electrodes position

Télécardia is an electrocardiograph:

- 12-lead,
- 12-second capture,
- simultaneous 12-channel,
- with fixed thoracic electrodes,
- with dry electrodes,
- no consumables.



2.2.1 Precordial leads: dry fixed thoracic electrodes

The shape of the unit enables capture of the **6 precordial leads** collected thanks to the 2 articulated arms. These thoracic electrodes are dry and fixed, from V1 to V6.

The Neutral, usually captured on the right leg, is captured in the thorax via the fixed electrode on the housing.

2.2.2 Peripheral leads

Télécardia contains a Patient peripherals cable to plug into the ECG box right-side. It enables the capture of **AvR**, **AvL** and **AvF** with limb clips dry electrodes (**R**, **L** and **F**):



Peripherals cable R, L and F - Arm Limb clips electrodes



Peripheral cable connection

The insertion mark, a red point on the cord, must be facing the device's top



Sensors and accessories are supplied with the device:

- DO NOT USE any other model of sensors and accessories without having previously validated compliance with PARSYS Télémédecine.
- The use of accessories (electrodes, cables, etc.) not supplied or not certified compatible by PARSYS Télémédecine may negatively affect EMC or medical performance of the equipment.

2.3 Device control buttons

To control the device and start all the functions, Télécardia has only one single button.

It's an **ON/OFF green** push button which ensure the release of the device's arms and switch the device **ON/OFF**, located on the front of the device and marked with a green circle crossed by a black line.

In addition, it allows the retransmission of the last captured ECG trace and the Bluetooth pairing procedure.



Télécardia ON/OFF Green button

2.3.1 Switch on the device

To switch on the device, briefly press the ON/OFF button to free the device's arms and then press again the button until the device's screen lights on (~ 3 seconds).

2.3.2 Switch off the device

The device automatically switches off a couple of seconds after an ECG trace capture but it's possible to switch off the device anytime by pressing on its ON/OFF button during ~ 3 seconds. A message displayed on the screen and an audio message then confirm that the device has been switched off.

2.4 Charging base

Télécardia is equipped with a separate power supply provided by a rechargeable Lithium/Polymer battery, allowing approximately 350 traces per charge. This battery is charged using the charging base, via 2 metal contacts integrated in the back of the device unit.

The charging base charges the device completely in approximately **2.5 hours** (150 min) using a 220V/50Hz source, via the mains adapter supplied.



Always use the mains adapter supplied to power the charging base; Otherwise, irreversible damage not covered by the device warranty is liable to occur.

To charge Télécardia:

- Connect your charging base to 220V power supply with the provided 5V medical charger.
- Put the Télécardia device upon its charging base in the correct side to ensure a good charging.



Check light indicators on the charging base's side to confirm the good contact of the device with charging contacts of the base.

Light indicators located on the side of the charging base indicate the device charging status, and whether the device is in contact with the support.



ON/OFF
indicator

Télécardia
charging indicator

The ON/OFF indicator **flashes BLUE** to indicate that the base **power is on**.

The CHARGING INDICATOR **does not light up** when Télécardia is **not correctly inserted** in its slot, without contact with the charging contacts, **or missing from the slot**.

The CHARGING INDICATOR remains **RED** as long as Télécardia is **charging**.

The CHARGING INDICATOR is **GREEN** when Télécardia is **charged**.



Not charging the device Télécardia for more than 1-year means losing the device's internal real-time clock: we recommend to regularly charge Télécardia battery.

2.5 ECG reading

Following capture, the data is sent to the terminal PC automatically via the Bluetooth radio link which has a free field range of approximately 100 meters.

This requires the presence of a Bluetooth USB adapter, supplied in the kit, connected to the terminal PC used to operate Télécardia. It is possible to do without the adapter if the terminal PC dispose of a 2.1 or more advanced Bluetooth feature. Then proceed with the pairing the Télécardia (see Section 4) or get in touch with the Customer Care Service of PARSYS Télémédecine.


On the operating terminal PC, MedCapture software allows many options:

- Dialogue with the device via Bluetooth;
- Display the captured ECGs;
- Archive, consult, print or send recorded ECGs in PDF format.

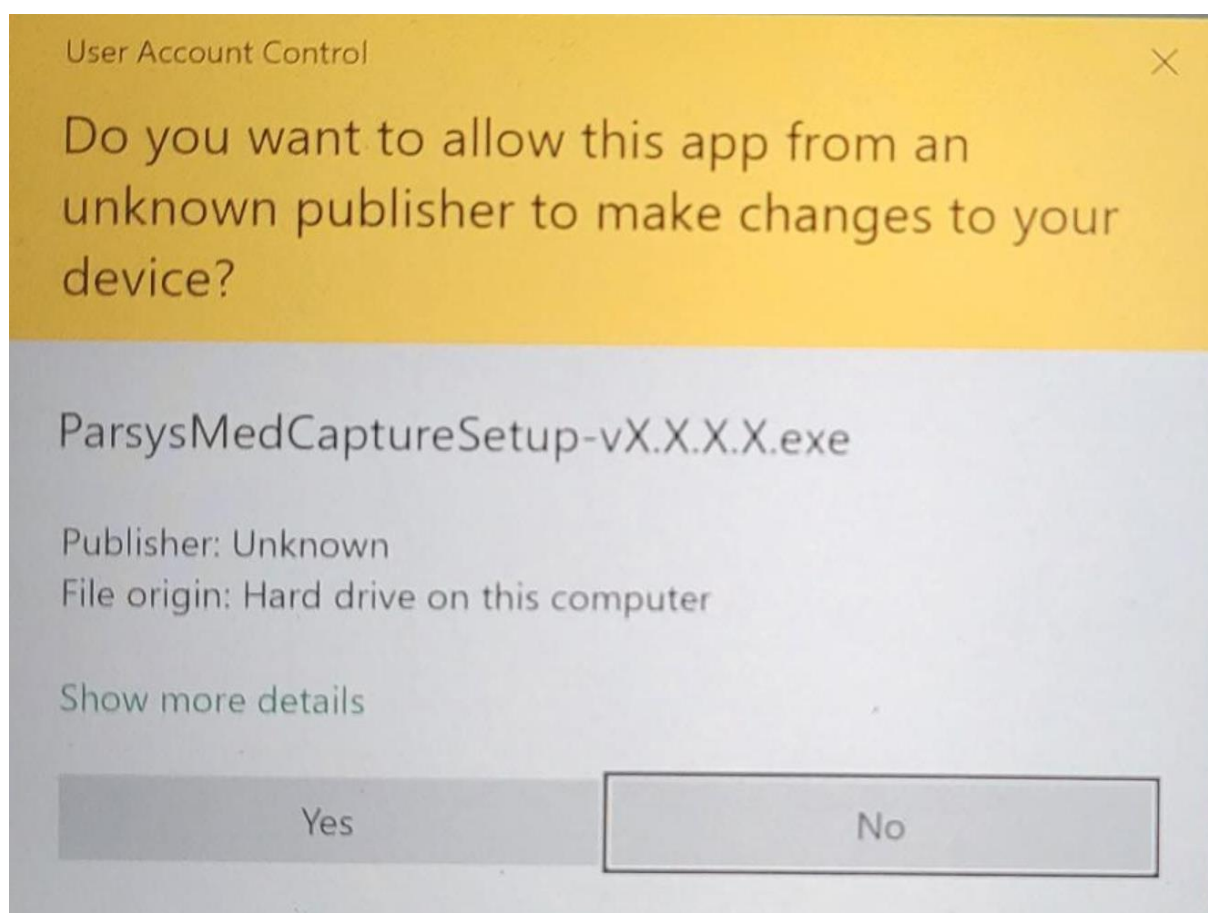


3 Installation of MedCapture PC Software

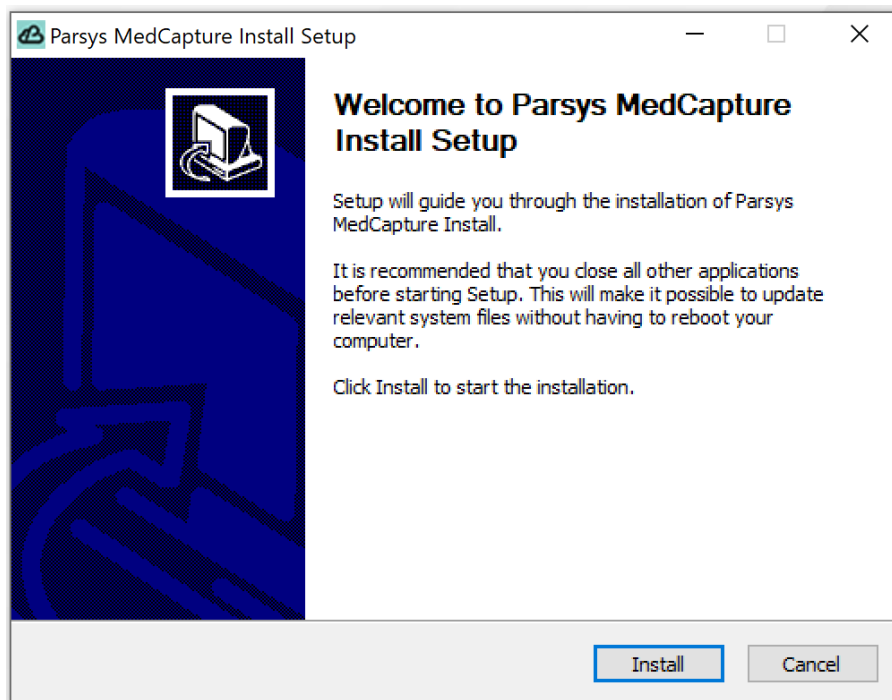
1. Insert the installation USB storage key into a USB port of the terminal PC.
2. Launch the executable by clicking on the **.exe** file.

<input type="checkbox"/> Name	Date modified	Type	Size
 ParsysMedCaptureSetup-vX.X.X.X.exe	1/28/2022 11:28 AM	Application	154,899 KB

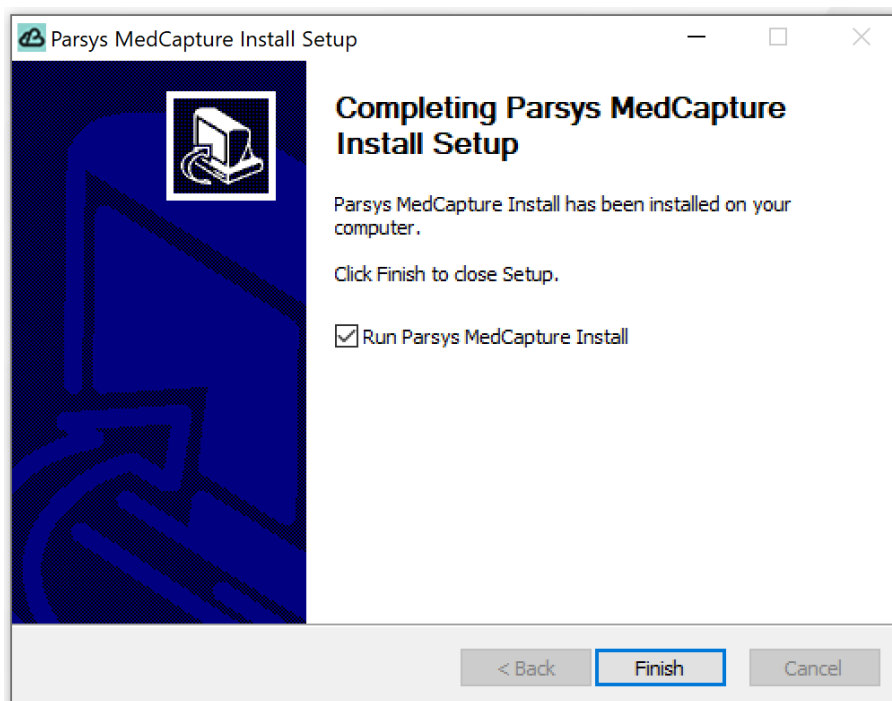
3. Authorize the third-party application to make changes to the computer (this operation requires having administrator rights on the terminal PC).



4. Follow the steps of the Parsys MedCapture installer.
5. Click on “Install” then wait a few moments for the installation to complete.



6. Make sure to uncheck the box for automatically launching the software then close the program by clicking on “Close”.



For more information, please read the User Manual MedCapture Software, provided with the ECG Télécardia Kit.

4 Bluetooth pairing procedure of the Télécordia to a terminal PC



The pairing procedure of the Télécordia ECG with a computer station (or PC terminal) is specific: it is essential to follow the procedure adapted to the operating system of your terminal PC. In case of doubt or blockage, please contact the Customer Care Service of PARSYS Télémédecine.

4.1 Requirements

Check if the terminal PC (fixed, laptop PC, Tablet PC, etc.) to pair with the ECG includes a preinstalled Bluetooth built-in module.

Note: In the case of a fixed PC, there is a good chance that there is no internal module; but mobile computers often have a preinstalled Bluetooth built-in module.

If no internal module is preinstalled, use the Bluetooth USB adapter supplied with your kit.

- It is fundamental that your computer **has an active Internet connection**.
- Just plug your Bluetooth USB adapter on a USB port, driver installation is automatic via the Internet.



In this case, your computer must be connected to the Internet to install the Bluetooth USB adapter (driver updating).

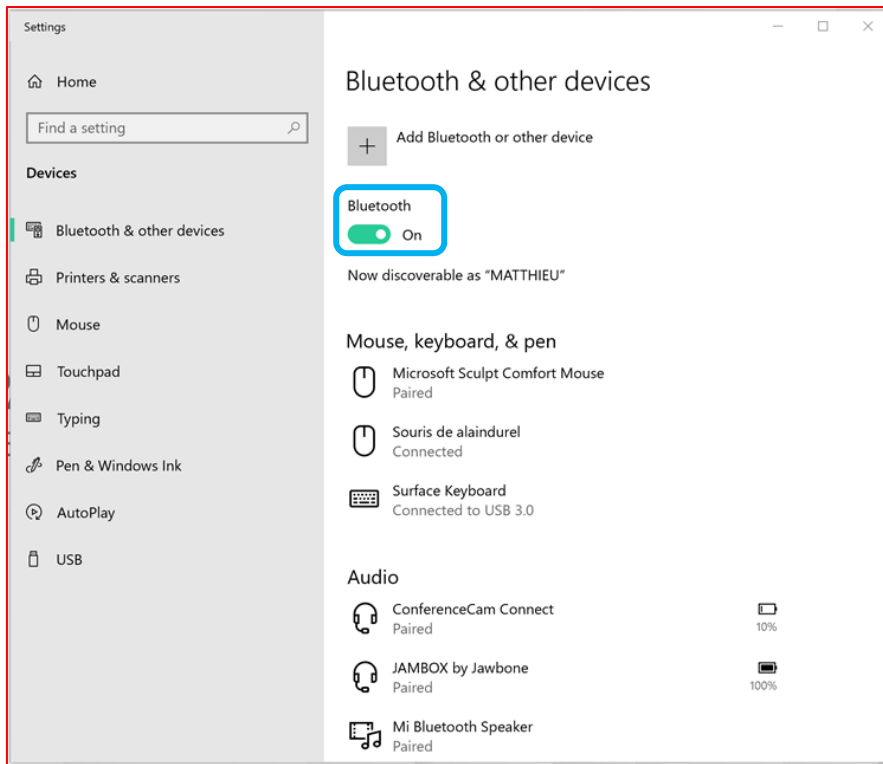
4.2 Specificity according to Windows versions

The different generations of Microsoft operating systems are not all compatible with PARSYS Télémédecine systems. If the terminal PC envisaged for using the Télécordia ECG has a Windows operating system lower than version 8.1, we strongly recommend that you contact the Customer Care Service of PARSYS Télémédecine.

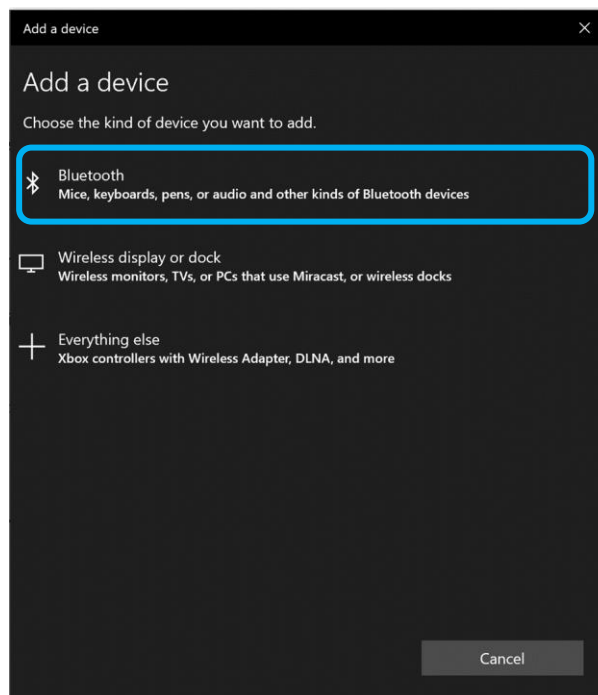
Similarly, if you facing difficulties when installing the MedCapture software while the terminal PC used is running on a Windows 8.1 or higher operating system, do not hesitate to contact the Customer Care Service of PARSYS Télémédecine.

4.3 Pairing of Télécardia with a Windows terminal PC

1. Open Windows “Settings” then go to the “Bluetooth and other devices” section.



2. Make sure Bluetooth is turned on.
3. Click on the “Add a Bluetooth device or other device” button.



4. Select « Bluetooth ».

5. Open the unit cover of the **Télécardia** device.



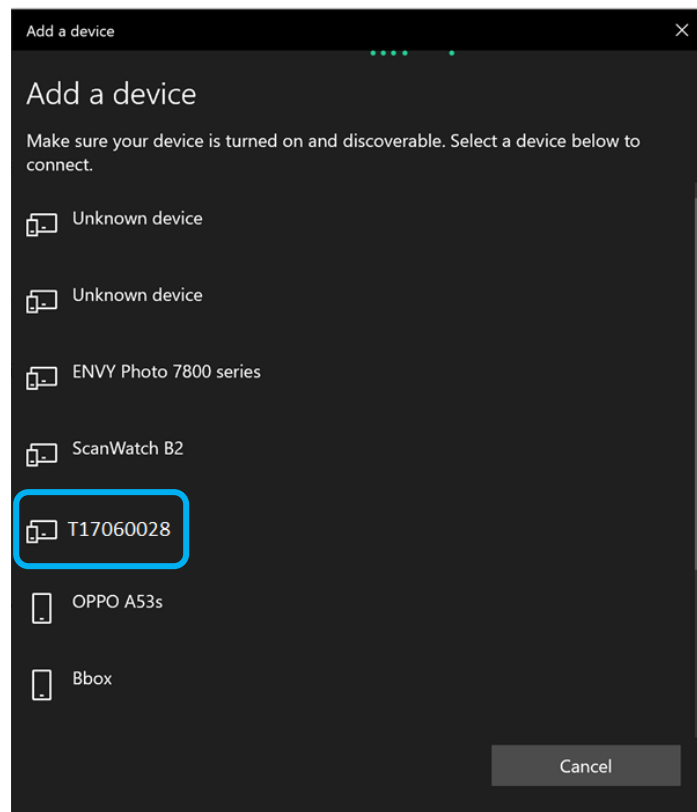
6. Note the serial number of the Télécardia device used: **No. starting with a T.**

7. **Make the connection.**



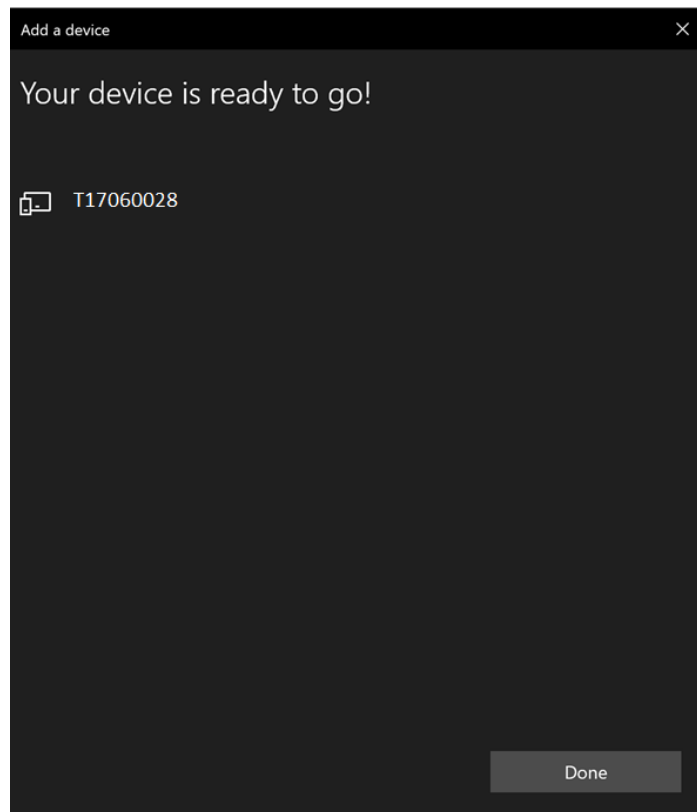
8. Press the **On/Off** button until the device turns on.
9. Press the button again when the message "**REPLAY ECG**" appears on the screen.

10. Select the **Télécardia** from the list using its serial number.



11. If Windows asks to enter a Bluetooth pairing key.

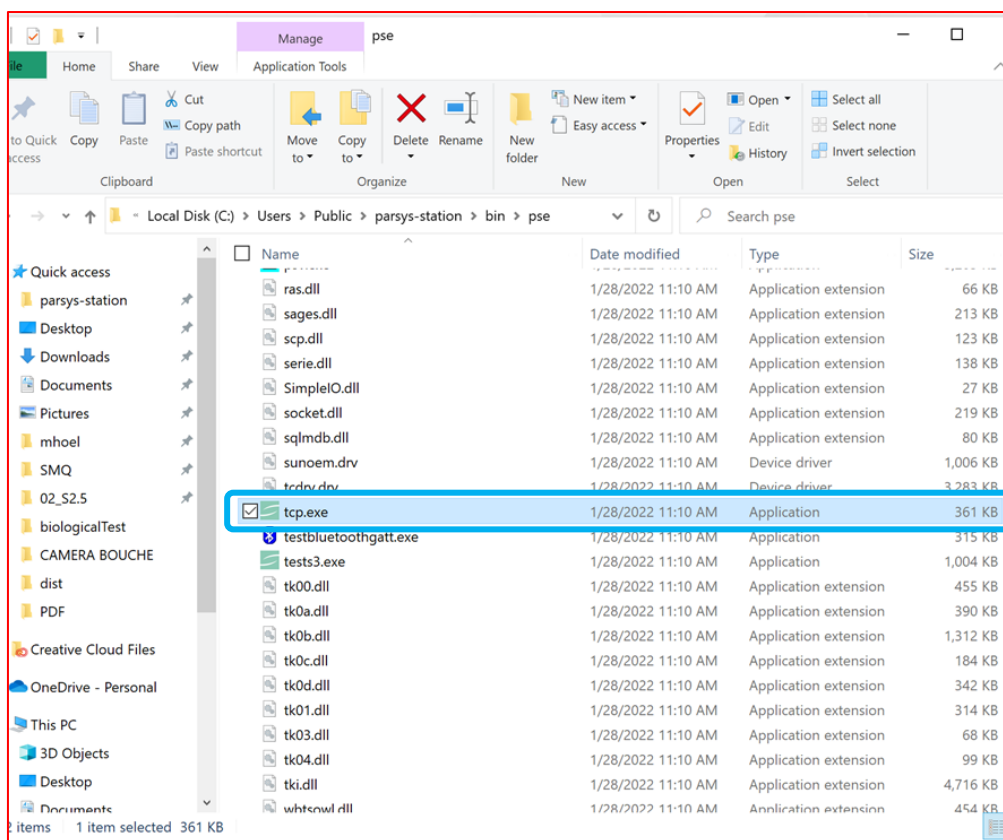
If the Bluetooth installer asks for an access key, this is fixed for all Télécardia devices. Enter the code: **02101124** and click on “Next”.



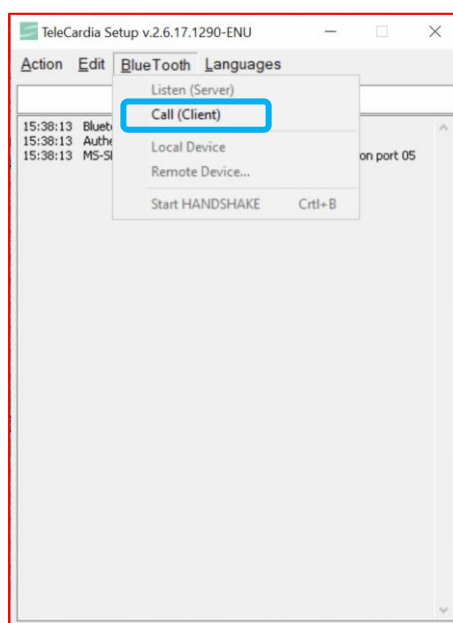
12. The ECG is now paired in Windows. The next steps are to pair it in the **MedCapture** software.

4.4 Pairing of Télécordia with the MedCapture software

1. Open the folder: « C:\Users\Public\parsys-station\bin\pse ».



2. Then, open the « Parsys » folder and launch the « TCP.EXE » software.
3. When the software opens, put the device in « Call (Client) » mode.



4. Open the unit cover of the **Télécardia** device.

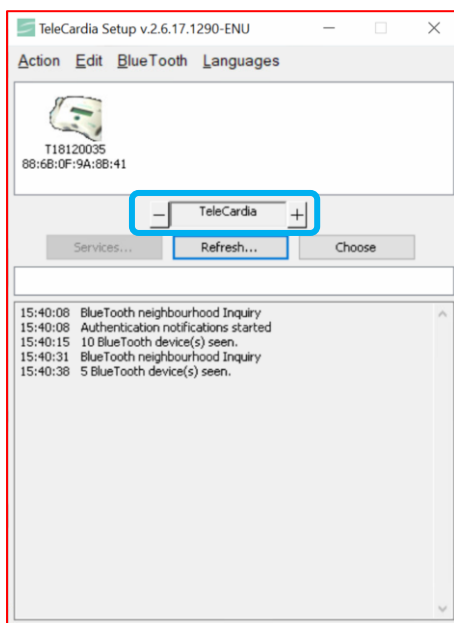


5. Note the serial number of the Télécardia device used: **No. starting with a T.**
6. **Make the connection.**

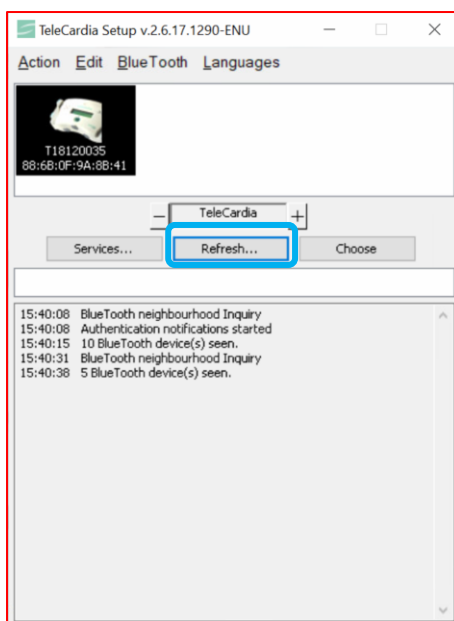


7. Press the **On/Off** button until the device turns on.
8. Press the button again when the message "**REPLAY ECG**" appears on the screen.

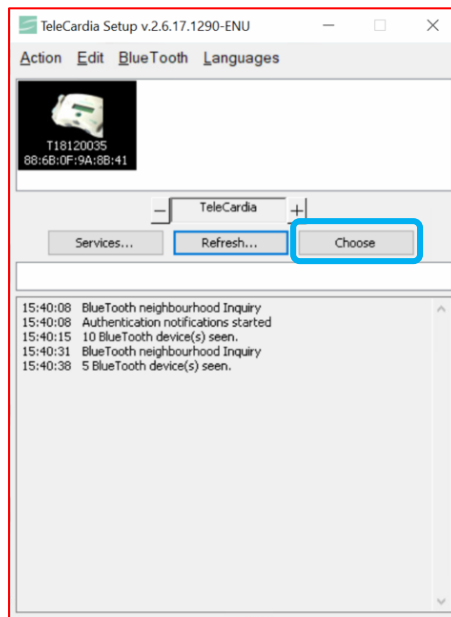
- The various devices that can be connected via Bluetooth are recognized by the system. It is possible to refine the search by type of device.



- If the search is unsuccessful, click on **“Refresh...”**, which will launch a new search.

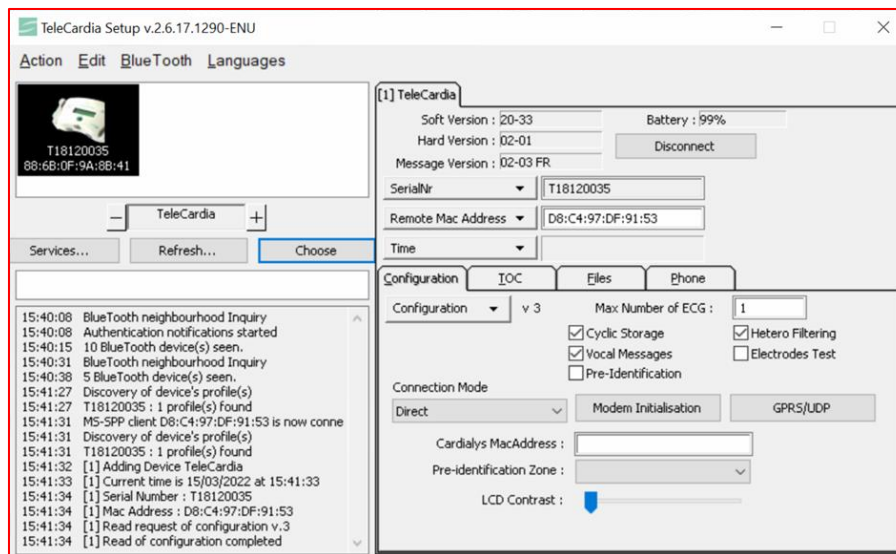


11. One the desired device is visible, click on the icon indicating it (check the serial number carefully).



12. Then, click on the « Choose » button.

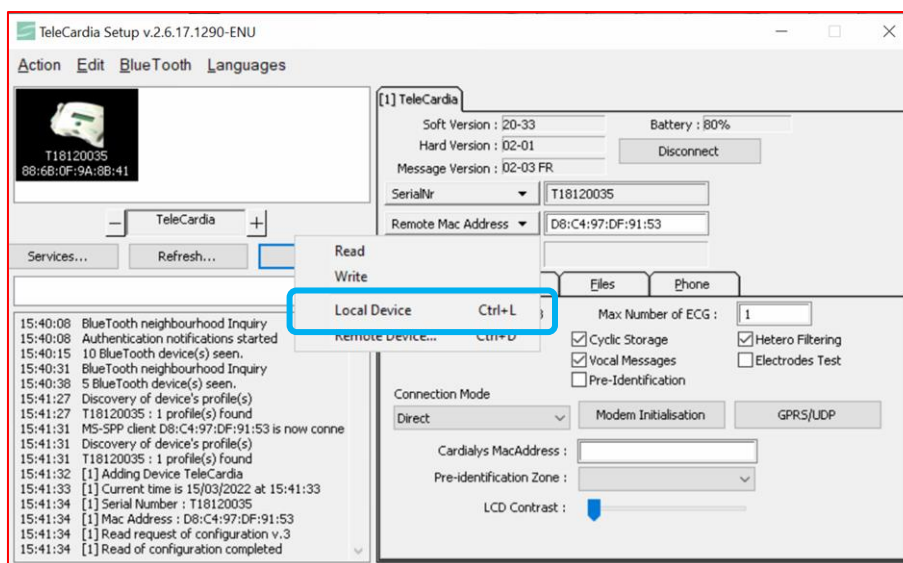
13. The interface window with the medical device is then visible.



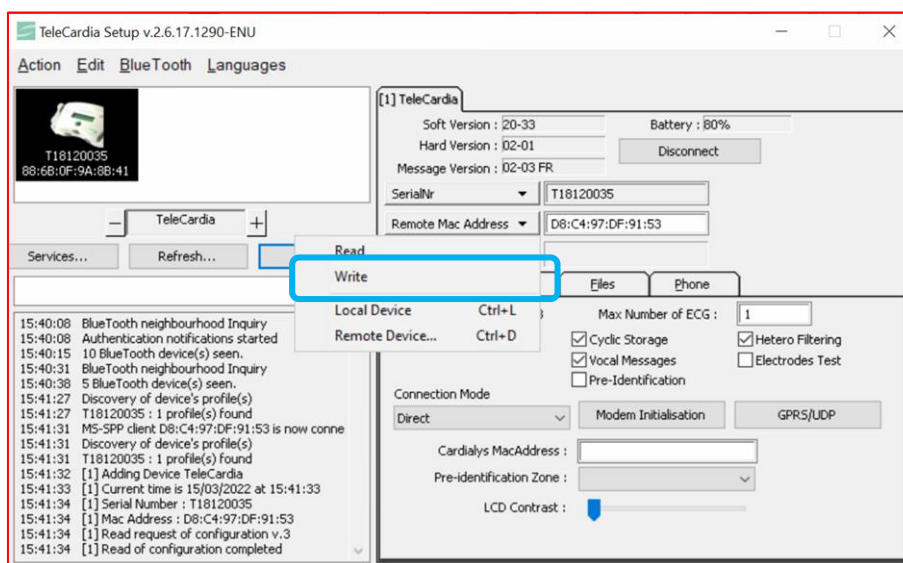
14. Click on « **Remote Mac Address** ».

15. Then, click on « **Local Device** ».

The Mac Address of the terminal PC will then be displayed in the right field.

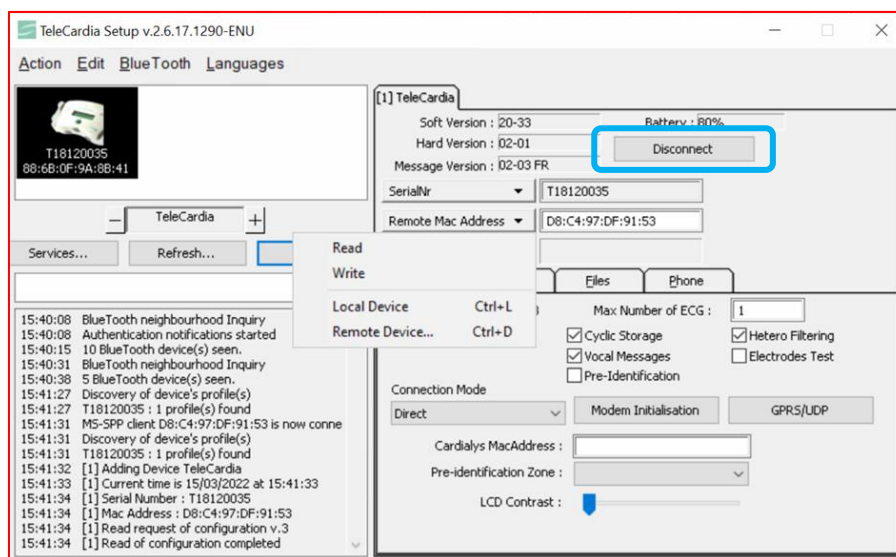


16. Click on « **Remote Mac Address** ».

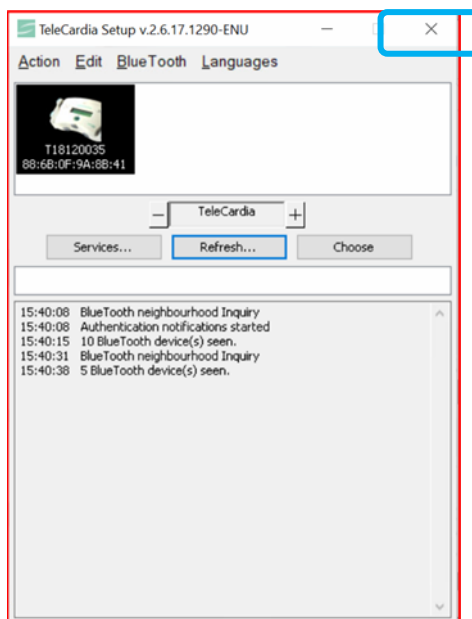


17. Then, click on « **Write** » to save the new Mac Address.

18. Click on the « Disconnect » button



19. Return to the « TCP » software startup window.



20. Close the window to quit the application.

5 Using the MedCapture PC Software



For more information, please read the User Manual MedCapture Software, provided with the Télécardia Kit depending on the client request.

6 ECG trace capture (electrocardiogram)

Take the Télécardia ECG and please follow the following procedures to capture a simultaneous 12-lead ECG trace in 12 seconds on the patient:

- Press the "**Start Télécardia (ECG)**" button on the software, the message "**ECG waiting**" appears.
- You can capture the ECG; the trace will be automatically transmitted to the terminal PC.



The ECG Télécardia is an ambulatory electrocardiograph that captures a simultaneous 12-lead ECG trace for most patients.

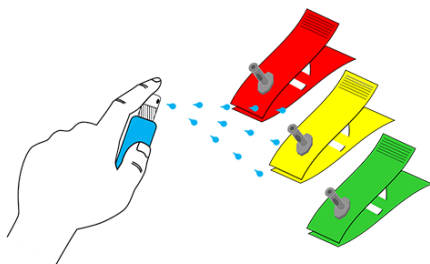
There are, however, some patient morphologies for which the device is not compatible:

- Children under 13 years old
- Extremely thin morphologies (anorexia, etc.)
- Morphologies in obesity higher than 200 kg
- Very strong breasts (women or men)
- Pectus carinatum and excavatum



Clear the patient's chest (removing the shirt is not essential) and roll-up sleeves and pants.

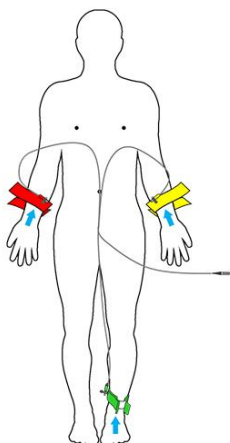
Remove any object that could interfere with the exam (watch, mobile phone, keys...).



Lay down or sit down the patient.

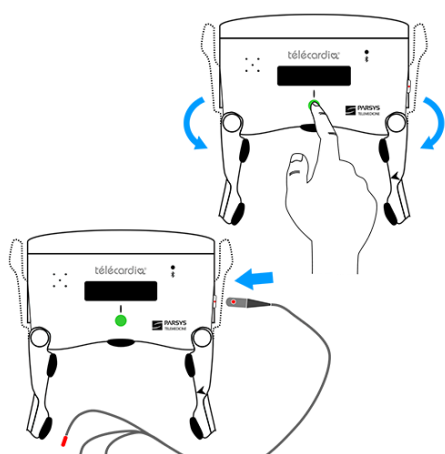
Connect the 3-lead ECG cable to the ECG limb clips according to the color.

Humidify the inside of the ECG limb clips with the water spray.



Place the ECG limb clips according to the protocol:

- Red:** right wrist
- Yellow:** left wrist
- Green:** left ankle



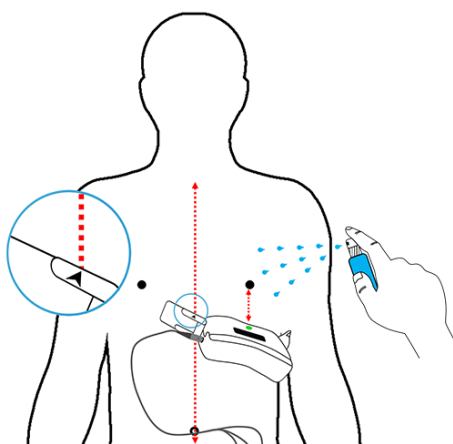
Press briefly the green button on the ECG to release both arms.

Never use the arms to deploy the device.

Plug the cable to the ECG on the right side.

The red dots must be aligned,

Do not force the connector.

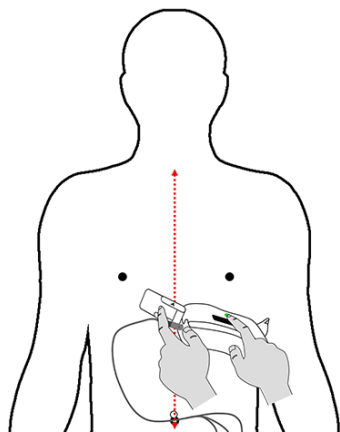


Humidify lightly patient's thorax.

Place the ECG unit on the patient.

Align the black arrow on the left arm with the sternum.

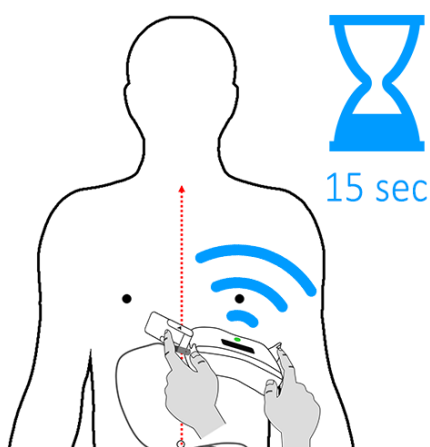
Align the green button with the patient left nipple.



Press ECG arms and device on the patient's thorax in order to maintain the electrodes in contact with the skin.

The device should have a light angle.

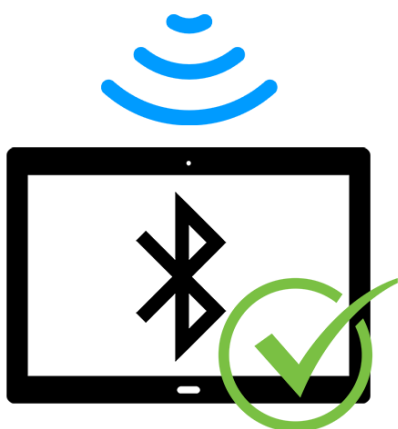
Press the green button until the device emits an audible signal then release the button to start the measure.



Keep the electrodes in contact with the skin until the end of the analysis.

The patient and yourself must remain calm and still during the analysis (15s).

An audible signal indicates the end of the capture.



Measurement is automatically transmitted to MedCapture by Bluetooth.



For more information, please read the software User Manual provided with the Télécardia.

7 Updating the PC software / device firmware

We shall contact you periodically by e-mail concerning download of updated software / firmware versions.

The updates are performed during maintenance.

You can also contact the Customer Care Service of PARSYS Télémedecine to obtain an update for your ECG device if applicable.

8 Technical features

8.1 General features

Manufacturer:	PARSYS Télémedecine
Model:	25-001
Class:	Ila
Type:	Portable, event-driven, 12-lead temporary electrocardiograph
Lifespans:	Télécardia device: 10-year Built-in battery: 2-year Patient ECG cable: 2-year Electrodes (clips): 2-year
Transmission:	Radio data transmission (Bluetooth)
Rechargeable battery:	Built-in Lithium polymer 3,7V / 3000 mAh
Charging base:	DC 5V/1,1A (contacts 2x)
Power supply:	2 modes (1 st and 2 nd generation) with no impact of use: <ol style="list-style-type: none"> 1. Medical mains charger 5V DC / 8W / 1,3A / 230V / 50-60 Hz / EU / IEC 60601-1 certified / Class II 2. Medical mains charger 5V DC / 11W / 2,2A / 230V / 50-60 Hz / EU / IEC/EN/UL 60601-1 3.1 Edition certified / Class II
Certification:	CE 0459

8.2 Mechanical features

Material:	Two half-body unit + one hinged hatch made of flame-retardant ABS v0
Color:	RAL 9002 white with pad printing marking
Surface condition:	26 arbours
Electrodes on unit:	Chest on lower section → VN - V1 - V2 - V3 - V4 - V5 - V6 (7/10μ chromium-plated brass)
Electrodes with cable:	VR, VL and VF peripheral limb clips cable
Protection index:	IP22 for the Télécardia ECG unit IP21 for the charging base
Folded overall dimensions:	210 x 100 x 50 mm
Weight:	500 g

8.3 Electrical specifications

Use:	Device intended for temporary use
Defibrillation:	Device not protected against defibrillation shocks
Device with internal electricity supply:	Rechargeable lithium polymer battery
Battery life:	350 peri-critical ECG captures and Bluetooth transmission in one battery charge
Shutdown:	Automatic shutdown after transmission
Internal protection:	Internal protection using 500mA resettable fuse
Measurement with internal electrodes, 9 simultaneous leads:	VR, VL, VF, V1 - V2 - V3 - V4 - V5 - V6 with reference to VN
Reproduction of 12 leads:	D1, D2, D3, VR, VL, VF, V1, V2, V3, V4, V5, V6
Input impedance:	10 MΩ
Sensitivity:	± 3%
Bandwidth:	0.05Hz to 150Hz at -3db
Measurement linearity:	0,01%
Measurement sensitivity:	4608 pt/mV
Sampling frequency:	539 pt/s
Common-mode rejection:	< 10mm
Noise level:	< 30μV
Channel crosstalk:	< 0.5mm
HF response:	± 10%
LF response:	Max. offset 100*V / Max. slope 50μV
Linearity:	< 5%
Saving:	Saving of the last ECG trace
Internal clock:	Real-time clock for ECG dating (autonomy of 1 year from full charging level under normal storage conditions)
Display:	2-line, 16-character screen Task procedure message display
Setting:	Operating mode setting (computer configuration): Voice prompt / Rotating stack/locking / Connection type

Bluetooth interface:	Bluetooth version 2.0 (EDR) - Class II 2,5mW	
Operating conditions:	Temperature:	+10°C to +35°C
	Relative humidity level:	30% to 75%
	Atmospheric pressure:	700 mb to 1060 mb
Storage and transport conditions:	Temperature:	-10°C to +50°C
	Relative humidity level:	10% to 85%
	Atmospheric pressure:	500 mb to 1060 mb

8.4 Functional features

Front panel:	<ul style="list-style-type: none"> 1 Start-up button 1 Blue/green LED indicating: <ul style="list-style-type: none"> ▪ steady green - device power on ▪ steady blue - Bluetooth transmission to PC or base 1 LCD 2 x 16-character line screen without backlighting
Curved lower section:	3 chromium-plated (7μ) brass convex round electrodes
Upper section:	Hatch opening outwards and used to support the unit
Upper section under hatch:	Serialization label
Rear panel (back):	<ul style="list-style-type: none"> Instruction label 2 charging contacts
Edges:	<ul style="list-style-type: none"> 1 folding articulated arm on either side, supporting electrodes V1, V2 and V5, V6 Under the right arm, 1 connecting socket for VR, VL and VF limb clips cable

9 Electromagnetic emissions

9.1 Suitable environments



The Télécordia is suitable only for professional and homecare environments including use in maritime environment. Using the Télécordia in a special environment including use in a home healthcare or similar environments may lead to reduced or loss of equipments performances.

NOTE: the emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals, and also in a residential environment (for which CISPR 11 class B is required). This equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

9.2 Equipment compatibility



- The mutual compatibility of equipments listed in this User Manual has been verified. Using other equipments may lead to unforeseen interferences that might lead to the decrease or loss of equipments performances.
- Use only the cables, plugs and other electrical spare parts specified for the Télécordia by PARSYS Télémédecine.

9.3 Degradation of equipment performances

Below are listed the performances of the Télécordia:

Parameter	Tolerance	Description
Display	Acceptable	Normal or small glitches
	Degraded	Significant display error and/or freeze; reboot or maintenance is required
Hard drive	Acceptable	Some functions are not available temporarily
	Degraded	Functions are lost and/or application stops; reboot or maintenance is required
Communication (Bluetooth, ethernet, WIFI)	Acceptable	Normal or small packet loss (<5%)
	Degraded	Significant packet loss or complete loss of communication; reboot or maintenance is required
Measurement (medical devices)	Acceptable	Intermittent communication errors with the terminal PC or monitoring temporarily not available
	Degraded	Permanent loss of monitoring or wrong measurement



In case any of the degraded performance is observed, first restart the device and remove all electrical or radio-emitting equipments in the vicinity of the device (e.g. mobile phone...). If the issue is still observed, please contact the Customer Care Service of PARSYS Télémédecine.

9.4 Specific cautions with external equipments



- When positioning the Télécardia, ensure it is not adjacent or stacked with other electrical equipments or installation as this may lead to unforeseen interferences.
- As a general caution of use, ensure to keep a minimum caution distance between radio-emitting equipments (e.g. mobile phone...) and the Télécardia or any of its components in service, according to below table of services.

If the power of the equipment is higher than the one specified, calculate the new caution distance according to following formula and values equal or changed from below table:

$$d = \frac{6}{E} \sqrt{P}$$

Band (MHz)	Service	Maximum power = P (W)	Distance = d (m)	Immunity test level = E (V/m)
380 - 390	TETRA 400	1,8	0,3	27
430 - 470	GMRS 460, FRS 460	2	0,3	28
704 - 787	LTE Band 13, 17	0,2	0,3	9
800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	2	0,3	28
1 700 - 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	2	0,3	28
2 400 - 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	2	0,3	28
5 100 - 5 800	WLAN 802 .11 a/n	0,2	0,3	9

9.5 Compliance

Standard: EN 60601-1-2:2014.

Test description	Reference test standard	Status
Emission		
Conducted RF	CISPR 11	Class B
Radiated RF	CISPR 11	Class B
Harmonic distortion	IEC 61000-3-2	N/A (<220V)
Voltage Fluctuations and Flicker	IEC 61000-3-3	N/A (<220V)
Immunity		
Electrostatic discharges	IEC 61000-4-2	Compliant
Radiated RF EM fields	IEC 61000-4-3	Compliant
Proximity fields from RF	IEC 61000-4-3	Compliant
Electrical fast transients / bursts	IEC 61000-4-4	Compliant
Surges	IEC 61000-4-5	Compliant
Conducted disturbances	IEC 61000-4-6	Compliant
Power frequency magnetic fields	IEC 61000-4-8	Compliant
Voltage dips and interrupts	IEC 61000-4-11	Compliant

10 Users' Training

It is **imperative** that the use of Télécardia ECG and its accessories be performed under the responsibility of a medical doctor.

In all cases, the user must have received prior training in the use of the Télécardia ECG.

11 Maintenance

11.1 Cleaning / Disinfection

The Télécardia device can be cleaned and disinfected by wiping the electrodes in contact with the skin and the plastic unit, except on the self-adhesive label at the rear of the device, with cotton wool or a wipe soaked in a product such as STERANIOS or equivalent (2% glutaraldehyde solution).

Any other product would not ensure proper cleaning without damaging the Télécardia components.



Never apply the cleaning product directly to the parts of the device, otherwise the components may be damaged by infiltrating too much of this product.

11.2 Procedure if the device is dropped or falls

Mechanical damage to the device necessarily implies discontinuation of use of the device and return to the Customer Care Service of PARSYS Télémédecine.

11.3 Reset procedure

If, when using the device, it **blocks for more than 1 min**:

- Use the provided reset cable or take a metal object (paper clip, scissors, etc.) and place it on and between the charging contacts, located under the device, for 1s. The device automatically switches off.



- Switch on again the device by pressing on the **Green ON/OFF** button until the display of the “**PARSYS Santé**” message on the screen.



If this procedure doesn't work, please repeat it at least once. If the problem persists, we recommend that you:

- NEVER attempt to repair the device by yourself;
- Contact the Customer Care Service of PARSYS Télémédecine.

11.4 Metrological checks

The device must be checked metrologically **every 3 years**.

Checks should be carried out by the PARSYS Télémédecine technical service, it alone being able to guarantee maintenance of the device's metrological performance.

Part	Preventive	Corrective
Battery	Check 1 year	Replaced if loss of autonomy < 100 ECG traces in full charge
Patient ECG cable	Check 3 year	Replaced if damaged
Electrodes (clips)	Check 3 year	Replaced if damaged/corroded
Device	Check 3 year	Repaired or replaced if NC to the compliance test

11.5 Discharged battery

We recommend not to let Télécardia discharged for more than 1 year to keep the device's internal real-time clock (see Section 12).

11.6 Product scrap treatment


According to the directive 2002/96/CE relating to DEEE electronic and electric devices, do not throw away in regular trash. Please bring waste to specialized collection points.



12 Fault or failure

12.1 The Télécordia ECG does not send any trace

After capturing the ECG, no ECG trace is received by paired terminal PC through the MedCapture software, which is certainly a loss of the Bluetooth® connection.

Make sure that the **blue** link light on the device lights up correctly and that the Bluetooth icon  in the software is active when attempting to transmit the ECG.

Also check that the device is not discharged by observing that the Télécordia display lights up when the device is opened (after pressing and holding the **green ON/OFF** button).


If only one or none of these indicators are working, please **do not attempt to modify** the device and contact the Customer Care Service of PARSYS Télémédecine.



We therefore advise you:

- NEVER ATTEMPT any direct manipulation of the installed software on the terminal PC;
- Contact the Customer Care Service of PARSYS Télémédecine.

12.2 The software module of the ECG Télécordia is grayed out

If the software module of the Télécordia ECG remains grayed out, make sure that the Bluetooth® icon  in the software is active.

If this is not the case, turn the terminal PC off and on again.

If the problem persists, please **do not attempt to modify** the device and contact the Customer Care Service of PARSYS Télémédecine.



For more information, please read the Software's User Manual, provided with the Télécordia.



We therefore advise you:

- NEVER ATTEMPT any direct manipulation of the installed software;
- Contact the Customer Care Service of PARSYS Télémédecine.

12.3 The ECG is subject to interference

Check the condition of the ECG Patient cable: it must not be **crushed** or **severed**.

Check that the capture protocol described in Section 6 has been followed, in particular:

- The correct connection of the ECG Patient cable;
- The positioning of the fixed electrodes of Télécardia on the thorax of the patient;
- The correct color code has been followed for the limb clips: **red on the right arm**, **yellow on the left arm** and **green on the left leg**;
- The electrodes and the skin have been humidified: **using the spray**.

In addition, patient and operator should be as **relaxed** and **calm** as possible to avoid any tense movements when capturing the ECG trace.



For more information, please read the Software's User Manual, provided with the Télécardia.

12.4 The Télécardia ECG is not charging

Check that the protocol described in section 2.4 has been followed, in particular:

- that the Télécardia is in the correct position on its charging base,
- that the red LED on the charging base is on during charging,
- that the charging base is correctly plugged into the mains.

Should you note a low battery level after 1 hour's charging, please contact the Customer Care Service of PARSYS Télémédecine.



We recommend that you:

- NEVER ATTEMPT a modification by yourself,
- Contact the Customer Care Service of PARSYS Télémédecine.

12.5 The Télécordia ECG remains blocked

If, when using the device, it **blocks for more than 1 minute**:

- Use the provided reset cable or take a metal object (paper clip, scissors, etc.) and place it on and between the charging contacts, located under the device, for 1s. The device automatically switches off.



- Switch on again the device by pressing on the **Green ON/OFF** button until the display of the “**PARSYS Santé**” message on the screen.



If this procedure doesn't work, please repeat it at least once.
If the problem persists, we recommend that you:

- NEVER attempt to repair the device by yourself;
- Contact the Customer Care Service of PARSYS Télémédecine.

12.6 The Télécordia ECG has lost its time stamping

If the Télécordia ECG has lost its time stamping:

- Place yourself near the Terminal PC paired with your Télécordia.
- Switch on the device by pressing on the **Green ON/OFF** button until the display of the “**PARSYS Santé**” message on the screen.
- When the screen displays the message “**REPLAY ECG**”, press again on the **Green ON/OFF** button to establish radio connection with the terminal PC in configuration mode to update the device's internal real-time clock.



If this procedure doesn't work, please repeat it at least once.
If the problem persists, we recommend that you:

- NEVER attempt to repair the device by yourself;
- Contact the Customer Care Service of PARSYS Télémédecine.

13 Technical Assistance and Customer Care Service

The Customer agrees to comply with the Warranty Conditions listed on the Warranty Certificate provided with the devices or in the General Conditions of Sales or Maintenance provided when ordering the devices.

The devices are supplied with a two-year (2) warranty during which period the Customer will be able to exchange devices found to have a latent defect and subject to the Customer having informed PARSYS Télémedecine thereof in writing and in detail.

In the event of a functional fault or failure of the devices, the Customer may contact PARSYS Télémedecine:

- by sending an e-mail to support@parsys.com,
- or by calling the Customer Care Service of PARSYS Télémedecine:
 - Monday to Friday
 - 10 a.m. - 12.30 p.m. and 2 p.m. - 6p.m. (in France - UTC+1)
 - Except for bank holidays
 - At: **+33 (0)1 60 31 51 71**
- or by sending a letter by recorded delivery with acknowledgement of receipt to:

**PARSYS Télémedecine - Customer Care Service
5, avenue de Paris 94300 Vincennes - FRANCE**

The Customer Care Service of PARSYS Télémedecine identifies the nature of the fault or failure of the devices before carrying out any repairs or replacing the defective devices.

Beyond the warranty period, the Customer has the possibility of subscribing to a maintenance contract with the PARSYS Télémedecine sales department.

USEFUL CONTACTS

Sales Support / Customer Relationship

Functions:	Devices, Accessories & Consumables quotes / Maintenance contracts / Training
Address :	PARSYS Télémedecine - Sales Department - 5, avenue de Paris 94300 Vincennes - France
Phone:	+33 1 60 31 51 63
Fax:	+33 1 64 02 31 93
E-mail:	sales@parsys.com

Technical Assistance / Customer Care Service

Functions:	Technical assistance 5 days a week (levels 1 - 2 - 3) / Calibration / Repair
Address:	PARSYS Télémedecine - Support Service - 5, avenue de Paris 94300 Vincennes - France
Phone:	+33 1 60 31 51 71
Fax:	+33 1 64 02 31 93
E-mail:	support@parsys.com

Quality / Material vigilance

Address:	PARSYS Télémedecine - Quality Department - 5, avenue de Paris 94300 Vincennes - France
Phone:	+33 1 60 31 70 40
Fax:	+33 1 64 02 31 93