Enter the Cardioline World

TouchECG HD+ Windows

HD+ Acquisition Unit

- Comfortable, lightweight, wireless full diagnostic 12 lead ECG acquisition unit.
- Extremely high with signal quality, very low noise. Exceeds the most stringent standards for ECG acquisition (AAMI, AHA).
- Continuous hardware detection for optimal pacemaker recognition.
- Water and dust protected (IP42 with silicon shell) and drop proof (1 meter).
- Low power consumption technology allows more than 10 hours (greater than 500 ECGs) continuous usage.

TouchECG Windows

- Next generation PC ECG application, designed for touch screen tablets and laptops.
- Allows simultaneous view of 12 lead high quality signals on ample screen, and rhythm strip of continuous acquisition (up to 30 minutes).
- Fully integrated with Hospital PACS and HIS through bidirectional DICOM data flow.
- Supports SCP, PDF, GDT data transfer, HL7 protocol (optional).
- Optionally integrates Glasgow algorithm for ECG interpretation for adult, pediatric and neonates. Extremely accurate STEMI detection.
- Extremely easy to use, 1 button, 1 led.

TECHNICAL SPECIFICATIONS

TouchECG HD+ Windows

ECG leads	12-leads (I, II, III, aVR-L-F, V1-6)
Patient cable	10 wire patient cable with replaceable leads
CMRR	115dB
DC input impedance	100MΩ
A/D converter	24 bit 32000 samples/second/channel
ECG Resolution	< 1µV/LSB - 1000 samples/second/channel
Dynamic range	+/- 400 mV
High frequency response	Performance equivalent to 0,05-300 Hz
Pacemaker detection	Hardware detection coupled with digital convolution filter
Filters	Linear phase digital diagnostic high-pass filter (according to 60601-2-25 2nd ed.) 50/60 Hz AC interference adaptive digital filter Digital low pass filters at 25/40/150 Hz, for display and printing only
Exported formats	SCP-PDF-XML-GDT Standard format DICOM Included in DICOM connectivity option HL7 Optional
Operating System	Windows 7, Windows 8.1, Windows 10
Sampling rate	1000 Hz
Data transfer	Bluetooth 2.1+ EDR with "secure pairing"
Memory	Internal archive stores up to 1000 ECG's

Advanced display, intuitive operator interface and functional design. Can be used with a Rugged tablet solution, ideal for emergency ap-plications. Instantly allows for sending a first patient diagnosis enroute to the emergency room.

Exam transmission from TouchECG to a repor-ting ECG center with ECG platform Managment Cardioline ECGWebApp or other ECG managment platforms that can be integrated for analysis and reporting. Ideal for Tele-Healthcare applications.

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touchECG

General Information

Product name	TouchECG
Generic name	TouchECG - Windows
Product code	81019579
Manufacturer	Cardioline Spa Head Office and Production: Via Linz, 151 38121 Trento Italy Sales Office: Via F.lli Bronzetti, 8 20129 Milan Italy
Description of Device	TouchECG is a software implementing a 12 channels diagnostic electrocardiograph which displays, acquires, prints and stores ECG traces for adults and children. It also calculates the principal global ECG parameters. The device can be supplied with the optional 12-lead Glasgow resting ECG interpretation algorithm, with specific criteria for patients of different age, sex and race. If this option is enabled, the algorithm can provide the physician of reference with an automatic interpretation, generating diagnostic messages in the ECG report. For further information on the resting ECG interpretation algorithm, see the Instruction Manual for doctors for its use with adults and children (see list of accessory equipment). The device can be configured with the DICOM® function. The device can be installed on any PC, tablet or notebook that complies with the minimum requisites listed. It prints out in the following formats: standard or Cabrera 3, 3+1, 3+3, 6 or 12 channel in automatic mode, and 3, 6 or 12 printout channels of the rhythm strip.
Intended use	TouchECG is designed to monitor and diagnose cardiac function. However, a Cardiologist must validate the results of the analysis run by the ECG. TouchECG is intended for use in hospitals, clinics and outpatient departments of any size. It is suited for use at home and in emergencies (ambulances). ▪ The device acquires, analyses, displays and prints out electrocardiograms. ▪ The device interprets the data for review by a doctor. ▪ The device must be used by a doctor or by specialised staff on behalf of an authorised doctor in clinical facilities. It is not intended as the only means for determining the diagnosis. ▪ The device's interpretation of the ECG analysis is only significant if used together with an additional analysis by the physician of reference and by an assessment of all the patient's important data. ▪ The device can be used on adult and paediatric patients. ▪ The device must not be used as a physiological monitoring of vital signs.

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Technical specifications

Minimum requirements for the computer

Operating System	Windows 7, Windows 8.1, Windows 10
Processor	Quad core 1.6 GHz or higher
RAM	2GB or more
Fr ee space on Hard Disk	8GB or more
Monitor	640 x 480 pixel or more
Bluetooth	Bluetooth 2.1 +EDR
Printer	Laser (colour/BW)
Additional applications	Email application which supports the EML format (only required for the email File Upload feature)

ECG acquisition (HD+ unit)

ECG leads	12-leads (I, II, III, aVR-L-F, V1-6)
Patient cable	10 replaceable wire patient lead
CMRR	115dB
DC input impedance	100MΩ
A/D converter	24 bit, 32000 samples/second/channel
Sampling rate of the input stage	32000 samples/second/channel
Sampling rate for signal analysis	1000 samples/second/channel
A/D conversion	20 bit
Resolution	<1 µV/LSB
Dynamic range	+/- 400 mV
Bandwidth	Performances equivalent to 0,05-300 Hz
Pacemaker detection	Hardware detection coupled with digital convolution filter
De fibrillation protection	AAMI/IEC standard
Front-end performance	ANSI/AAMI IEC 60601-2-25:2011
Data transfer	Bluetooth 2.1+ EDR with “secure pairing”

Processing

Operating system	Windows
Pacemaker detection	Hardware recognition in compliance with the requirements 60601-2-25 (HD+ acquisition unit)
Lead-fail detection	Independent for all leads
Cardiac frequency range	30 - 300 bpm
Sampling rate	1000 Hz
Filters	Linear phase digital diagnostic high-pass filter (according to 60601-2-25 2nd ed.) 50/60 Hz AC interference adaptive digital filter Digital low pass filters at 25/40/150 Hz, for display and printing only
ECG acquisition mode	Automatic (12 channels), Manual (3/6 channels), Review (12 channels)
Lead configuration	Standard, Cabrera

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ECG measurements	All leads, medians, corrected HR Average RR PR Interval QRS duration QT and QTc (Hodges formula) intervals QTc Bazett interval QTc Fridericia interval max R[V5];[V6] and S[V1] Sokolow-Lyon Index P, R, T axis.
ECG interpretation	Glasgow algorithm for adults, paediatric, STEMI (optional)
ECG interpretation parameters	Sex, age
Memory	Internal archive stores up to 1000 ECG's
Processing options	
Interpretation	Glasgow algorithm for adults, paediatric, STEMI
Connectivity	DICOM
Exported formats	
SCP-PDF-XML-GDT	Standard format
DICOM	Included in DICOM connectivity option
HL7	Optional
Connectivity	
USB-LAN-WiFi	Dependent on support device (computer)
Printing	
Resolution	Variable in relation to printer
Paper type	Variable in relation to printer
Sensitivity/gain	5, 10, 20 mm/mV
Automatic print speed	25, 50 mm/s
Automatic print	3, 3+1, 6, 12 channels; Standard or Cabrera;
Automatic print formats	12x1, 6x2, 3x4, 3x4+1, 3x4+3
Manual print speed	5, 10, 25, 50 mm/sec
Manual printing	3, 6, 12 channels; Standard or Cabrera;
Manual print formats	12x1, 6+6, 3x1
Calibration signal	Yes
Lead marker	Yes
External USB devices	
Bar-code reader	Optional
USB Printer	Optional
Magnetic cards reader	Optional

Regulations and Safety

Classification according to MDD 93/42/EEC

Class	Class IIa
Rational	Rule 10 annex IX Directive 93/42/EEC and its amendments
Notified Body	TUV (1936)

GDPR Compliance (General Data Protection Regulation)

Access control	Through the use of username and password at Operating System level and installing an instance (each one with its own database to which only the corresponding user can access) of touchECG for each user.
Data at rest protection	By the system administrator, activating the encryption functions of the operating system.
Audit trail	Through the log of the Windows operating system, which traces the operations performed on the system.
Patient data removal (right to be forgotten)	It is possible to delete the examinations from the archive and to activate the automatic cancellation of the examinations after the transmission (where the use scenario foresees it).

Classification according to FDA

510K Number	K160746
Product Code:	DPS
Classification:	Class II
Regulation Number:	21 CFR 870.2340

Classification according to IEC 62304 – Software

Class of risk	B

Performances (ECG display)

Standard	EN 60601-2-25:2011

Other classifications

GMDN	16231 - Electrocardiographs, Interpretive
CND	Z12050302 - ELECTROCARDIOGRAPHS FOR ADVANCED DIAGNOSIS
RDM (Medical Device Catalogue)	1369845

Applicable standards

EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 1041	Information supplied by the manufacturer of medical devices
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN 60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs. Partly applied – Applied in conjunction with HD+
IEC 60601-1-11	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical

	equipment and medical electrical systems used in the home healthcare environment. *Partly applied – Applied in conjunction with HD+*
EN 62304	Medical device software - Software life cycle processes
EN 62366	Medical devices - Application of usability engineering to medical devices

Product codes

Accessories

81018027	HD+

Cardioline TouchECG HD+ setup guide

Mobility, practicality & accuracy in one small device.

Box Contents

The Cardioline TouchECG HD+ is packaged nicely with several protective layers and includes the ECG device, cables, lead connections, instruction manual, 2 AAA batteries & protective rubber case for the HD+.

The TouchECG simplifies the monitoring process through Bluetooth connection with windows tablets, laptops & computers.

This system allows for seamless transmission of information between the patient, ECG and output device. Most beneficial of all is mobility. The **Bluetooth 4.0** capabilities allow for clinicians to move about freely whilst taking measurements from the patient. Furthermore, this ECG set-up allows for wi-fi printing on regular paper, meaning there is no longer a need for ECG specific paper.

Setting up your Cardioline touchecg HD+

Follow this step by step guide to set up your HD+ before clinical application. As the Cardioline package comes with a case, we recommend using it during practice to protect the device; but we will also show you how to set up without.

The walkthrough includes:

1) Physical set up of the product

2) Setting up a Bluetooth connection

3) Setting up Cardioline ECG software

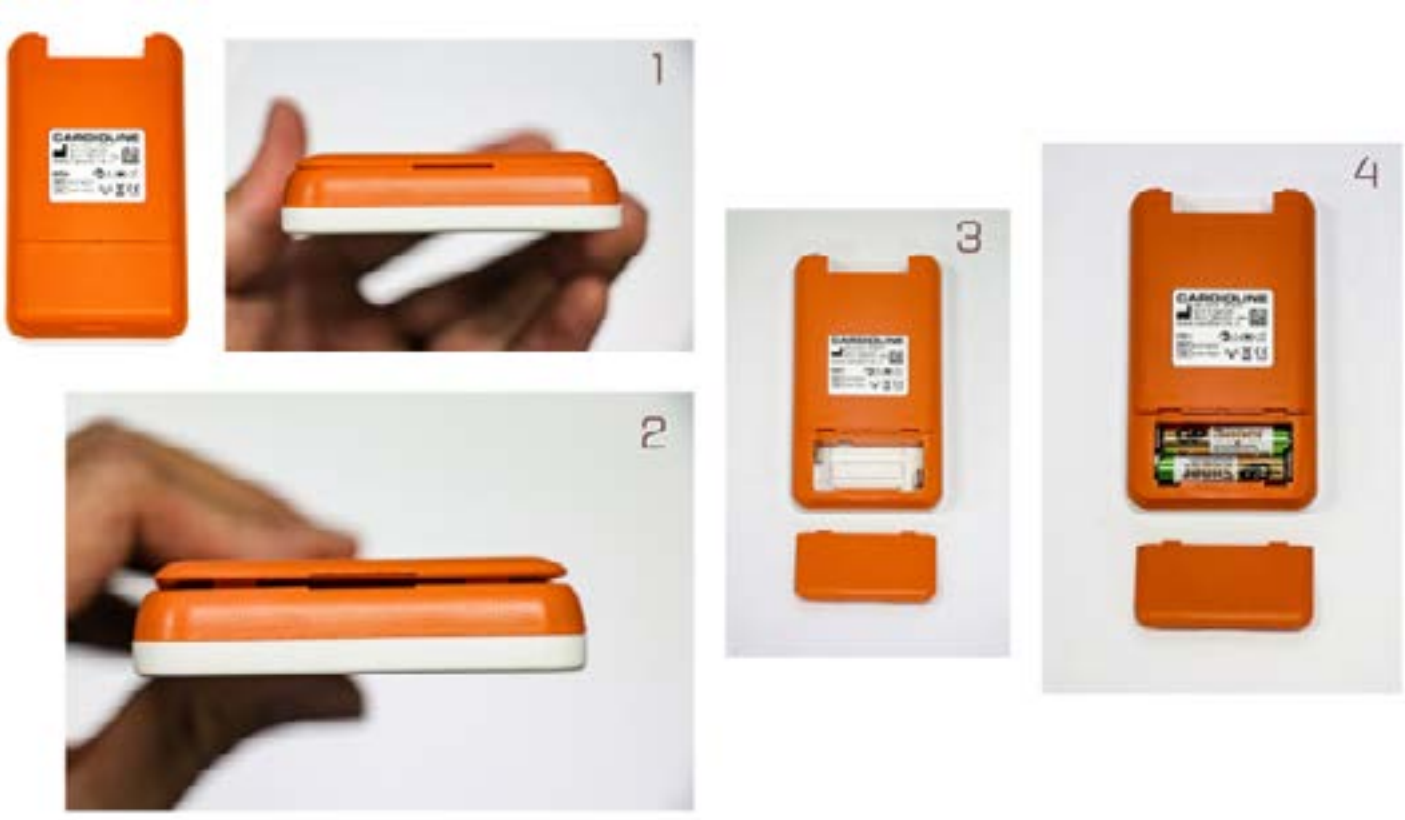
Setting up the HD+

First thing's first, batteries. Take the TouchECG out of the packaging and find the 2 AAA batteries included in the Cardioline box. If single-use batteries are a hassle, we recommend investing in USB rechargeable batteries.

Turn the device around and find the opening at the bottom of the device.

Pry open the water-resistant battery backing. This is do-able with nails, but it might hurt. We recommend using a thin plastic wedge as to not damage the device backing such as a Woolworths / Flybys rewards card - a small teaspoon also works.

Insert batteries & ensure the backing is secured tightly.



Caseless set up

For those who want to use the device as it is, follow these steps. First of all, take out the cables from the Cardioline box packaging.

1) Find the top of the HD+ with the cable connection slot.

2) Take the cable and insert it into the cable connection slot.

3) Push the cable firmly into place so that there is a little gap between the soft rubber edge of the cable and the HD+.

Rubber case set up

This method is similar to that of the above but has a few extra steps. First, you'll want to take the rubber case out of the plastic film.

1) Find the insertion point on the bottom of the rubber case.

2) Take the HD+ cable and insert the connection point through the bottom of the rubber case.

3) Pull the connection point through and grab your HD+.



4) Connect the cable to the HD+ the same as the caseless setup.

5) Push cable firmly and ensure that it is secured to the HD+.

6) Pull the cord through the rubber case and fit around the HD+.



Setting up your output device (Tablet / Laptop / Computer)

Some may find this set up process tedious, but we here at StarkMed strive to make it as simple as possible. A couple of things you will need before you start.

- A relatively modern windows device (windows 8 or newer). Android also works, but might not operate as smoothly - so we recommend sticking with a windows device.

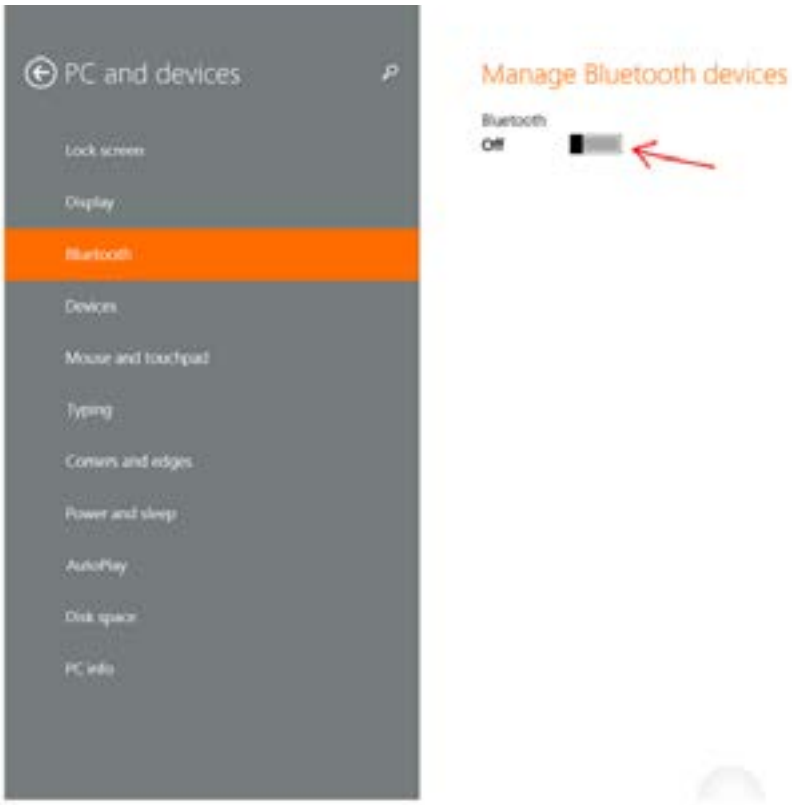
- Cardioline Software. This can be found in the user manual that comes in the box, but for your convenience - this information can be found on page 21 of the user manual or visit their website **update.cardioline.com/touchecg/**

For this demonstration, we will be using a DELL tablet with windows 8 installed. *Please note that the user interface may differ depending on your device and version of windows.

1) Turn on your device and go to the bottom right corner of the toolbar to find "Bluetooth".

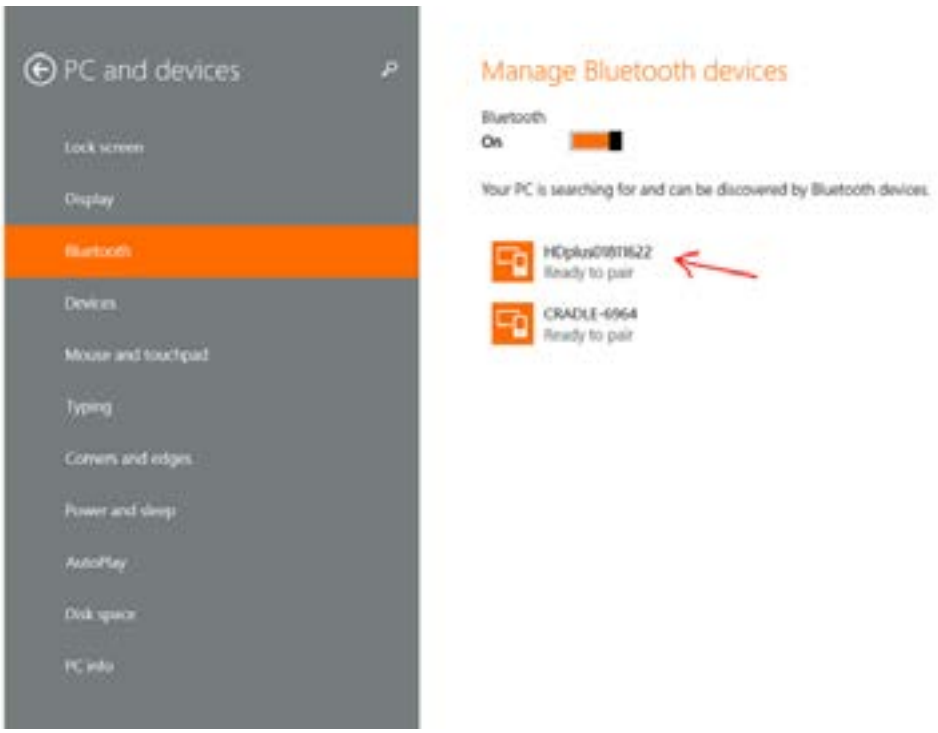
2) Press "Add a bluetooth device".

3) This should take you to the Bluetooth control panel. Turn bluetooth on by pressing the button / slider.

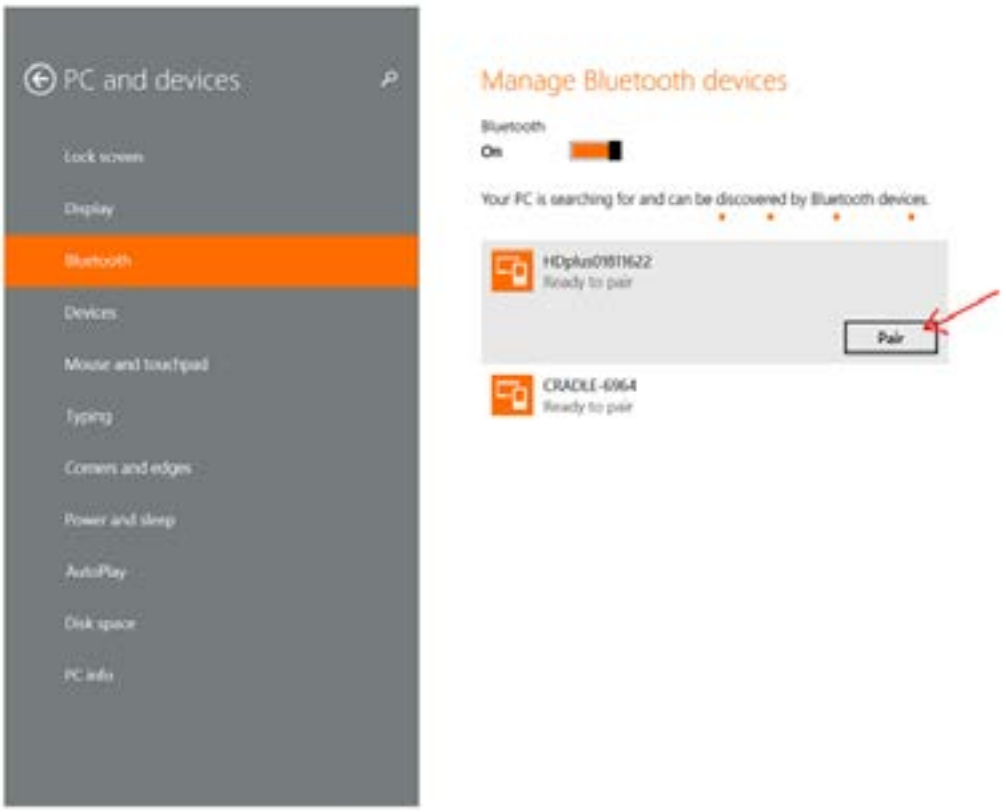


4) On the TouchECG HD+, Press the centre button. You should see a blue light turn on. The device will make a sound if it has connected to the tablet / laptop.

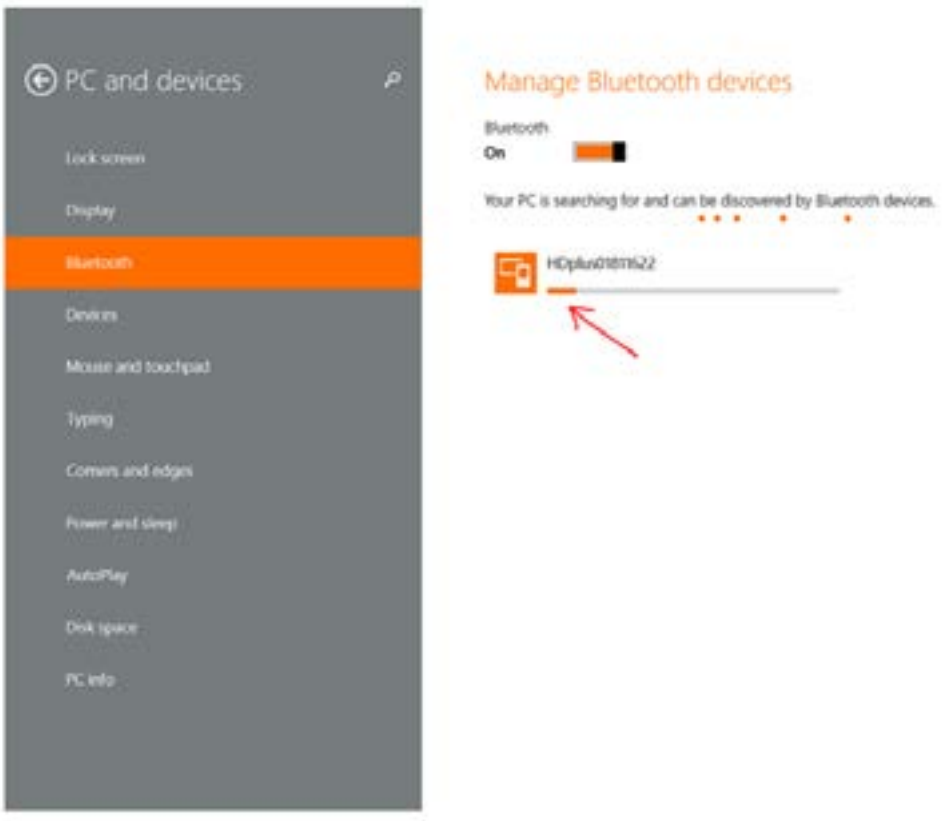
Your windows device should automatically search for available bluetooth connections. Press "HDplusXXXXXX" once it appears. (*The number will depend on the serial number of the device which can be found at on the back of the ecg).*



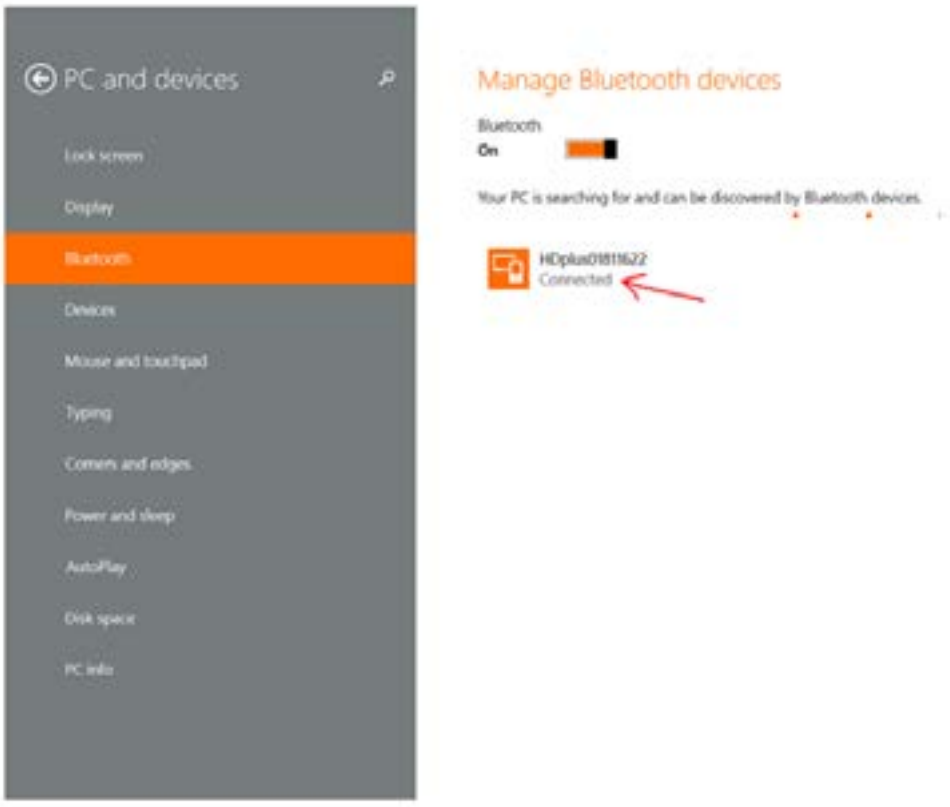
5) You should be able to see an option to "Pair". Press on this button to proceed - The button should turn grey, this is normal. Just wait a few seconds.



6) There might be a slight delay but wait for a loading bar to appear. Let the device do its thing in order to connect the devices. Do not close the window.



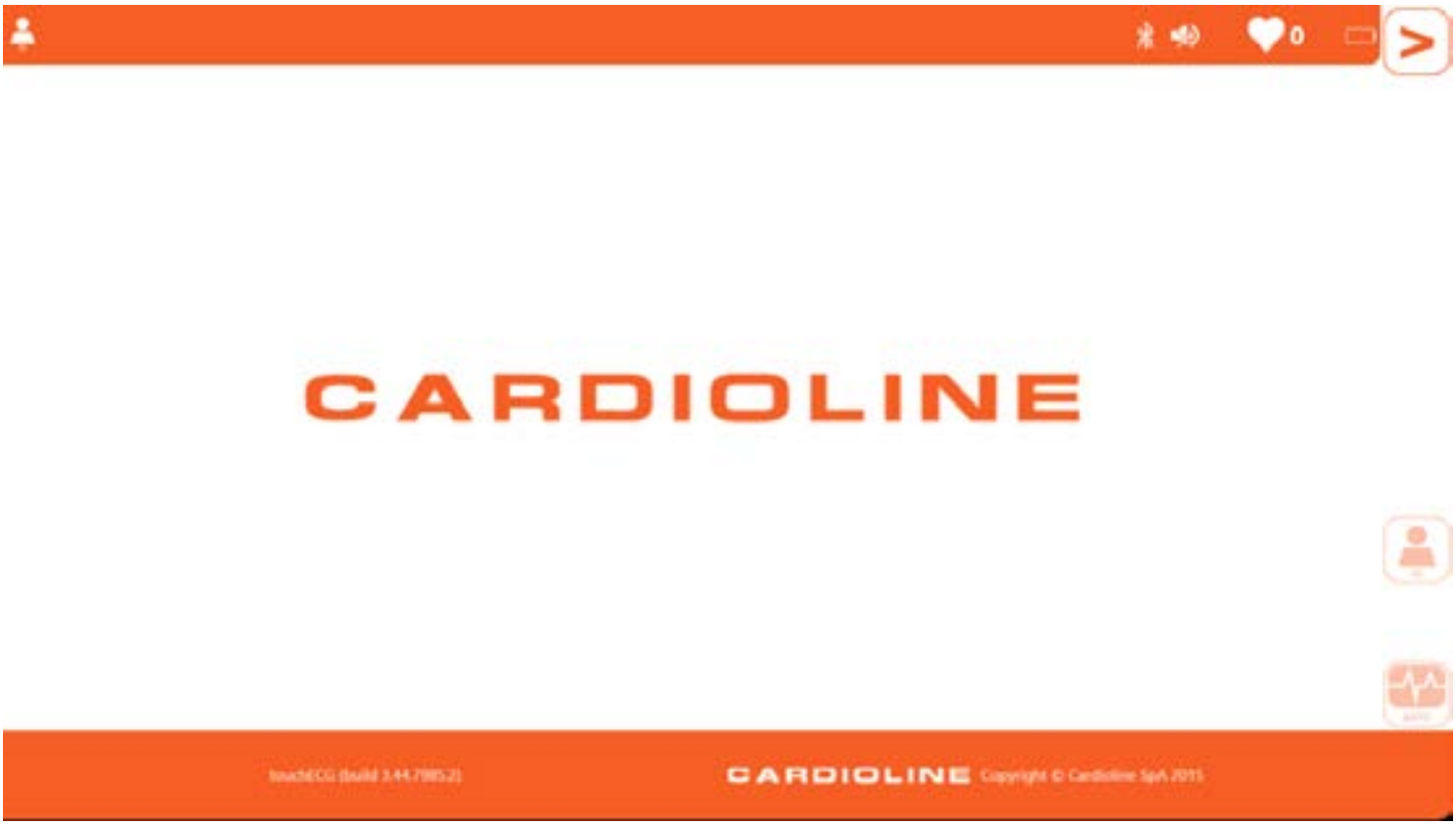
7) Once connected, the device will show "Connected". You may now return to the home screen. If the pairing is unsuccessful, please make sure no other bluetooth devices are connected (turn them off) and try again.



Using the Cardioline software

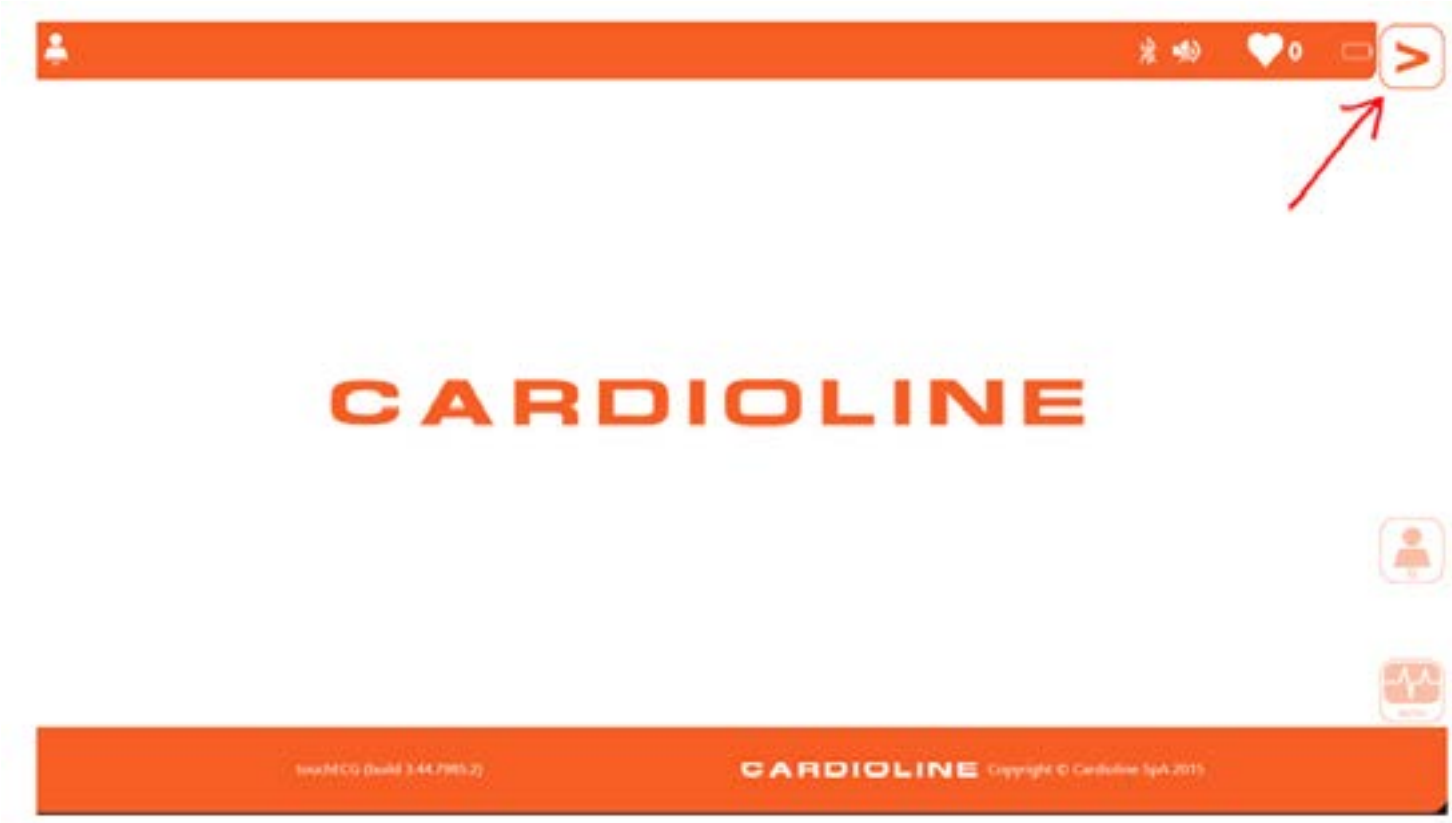
After your Cardioline software has been installed & your bluetooth settings have been configured successfully, we can continue with setting up the device.

1) When you open the software, you will see either this page or something similar.



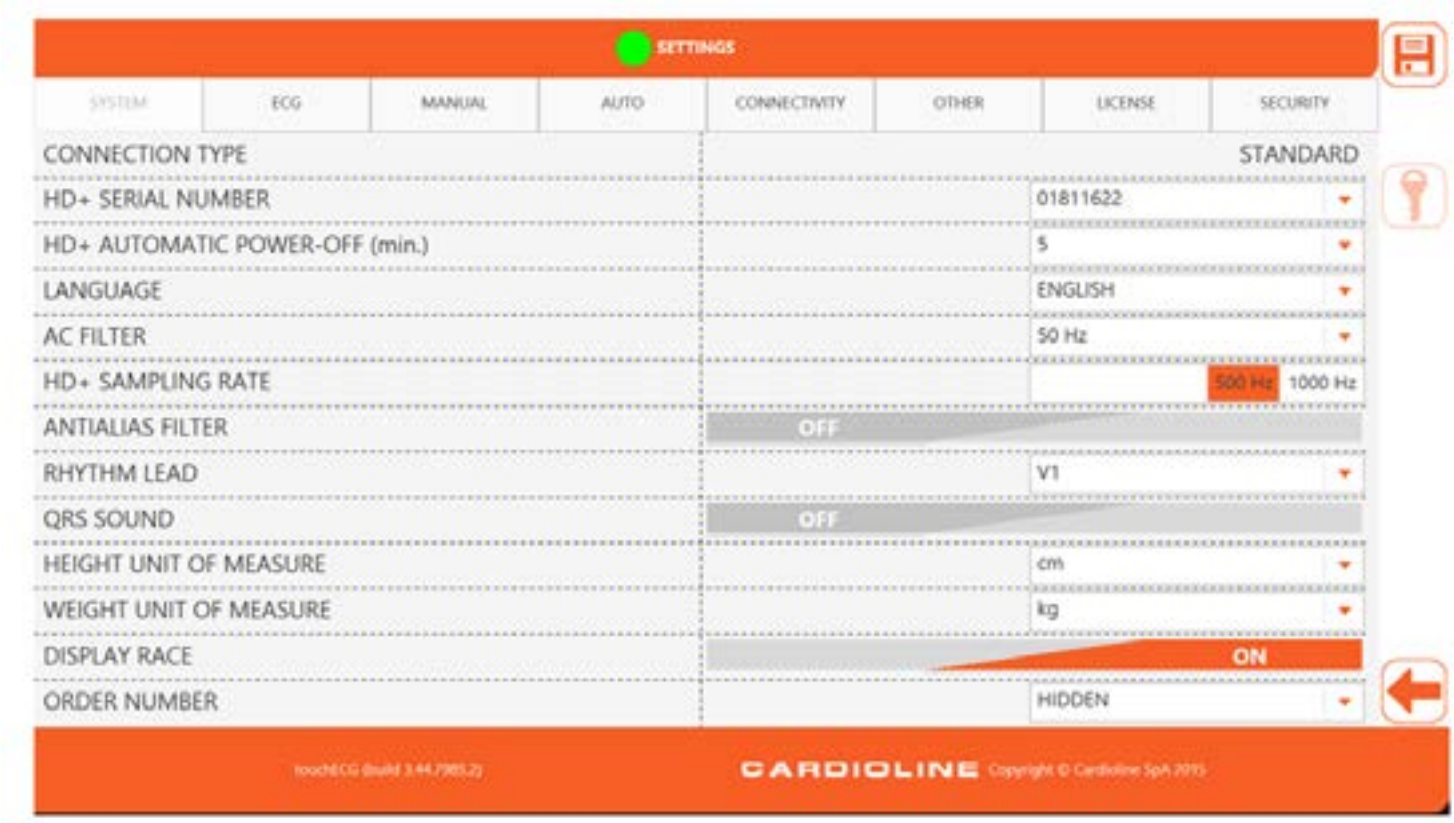
2) Notice the bottom bar changing text every few seconds. You may find that it says "HD+ NOT FOUND" or device is not connected. Do not worry, this is normal.

3) Press the arrow on the top right corner of the screen. This will display a drop-down menu.

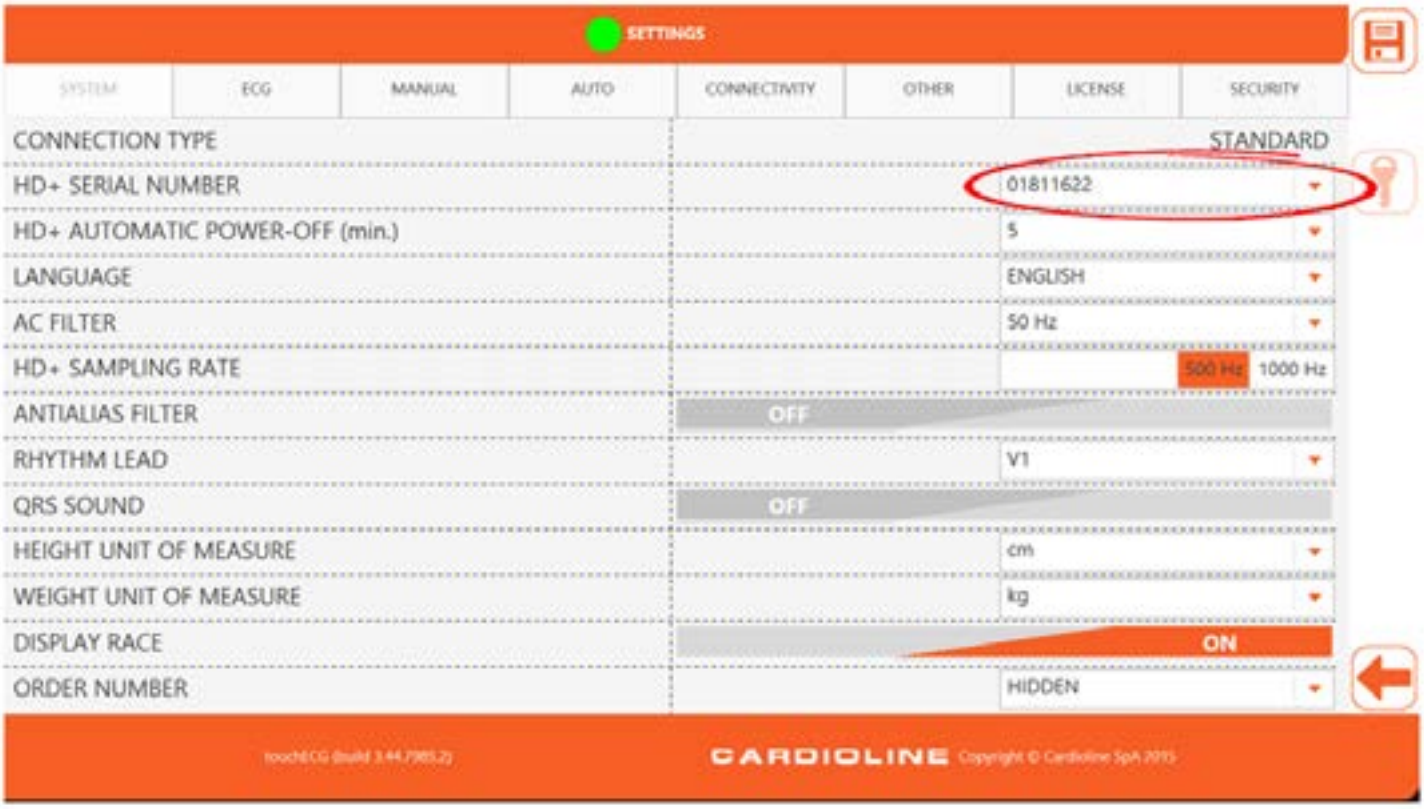


4) On the settings dropdown, go ahead and press the icon with the cogs to open up the settings menu.

5) This should take you to the first page of the settings menu. Here you can also modify several functions of the touchecg HD+.



6) We need the software to recognise the TouchECG HD+, so go to the row "HD+ SERIAL NUMBER" and press the dropdown menu to identify your HD+ and select it to connect.



7) After connecting successfully, **save your settings** using the *floppy disc icon* in the top right corner and return to the home screen by clicking the *arrow icon* in the bottom right corner.

8) Returning to the home menu, you should notice that the bottom bar is now green, meaning the device has been successfully been connected.

Using the Cardioline TouchECG HD+

Readings & Data

Now that your device has been connected – you can begin using it for your patients. Connect your adaptors if you haven't already. Once the device begins to take a reading from a patient. The data will automatically transmit onto the tablet/laptop output device.

If data does not automatically appear, press the bottom right button as displayed below to receive a reading.

Patient Information

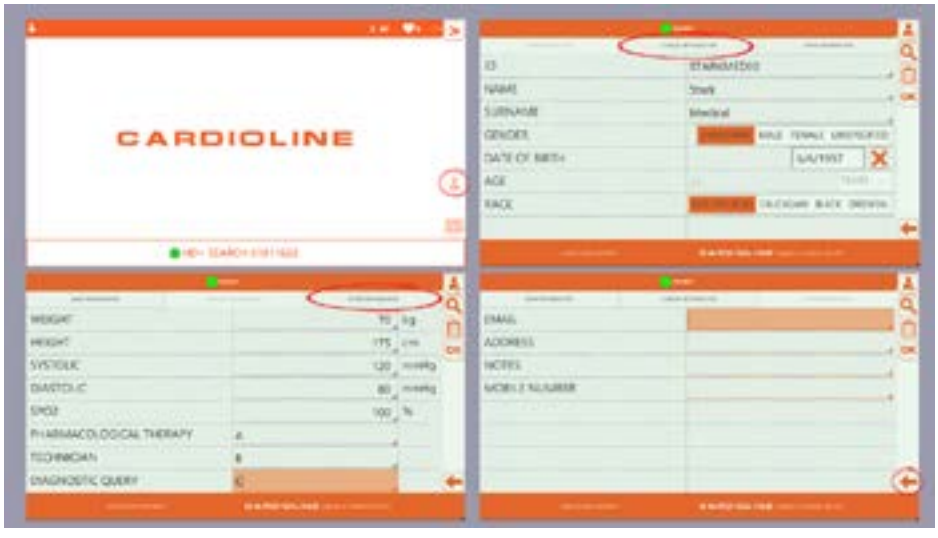
Patient data is important. The TouchECG HD+ makes it easy to record new patient data.

Click on the person icon on the right side of the menu. This should bring up a page which says **"Main Information"**. Fill it in as per your needs.

Notice the display bar on the right side of the page:

- Click the person icon to add a new patient.
- Click the magnifying glass to search for a patient.
- Click the checklist to bring up a checklist for the patient.

There are also the **"Clinical Information"** & **"Other Information"** tabs on the top of the page should you require it.



Other settings

If you wish to explore the settings of the device further, refer back to the ***"Using the Cardioline Software***" section. Here you can adjust settings such as Graph Format, Speed, Amplitude, Security settings and more.