



ECG EXPERT

Owner's Manual

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1. Product Description

ECGExpert includes the following equipment:

- 1 Acquisition Module
- 10 labelled ECG cables
- 1 USB Cable
- 1 Power Supply for battery charge



2. Intended use

ECGExpert is designed to measure ECG signals in routine reviews of patients in both, ambulatory or non-ambulatory, environments. An additional computer device (tablet-PC, smartphone or PC), with Bluetooth connectivity, is required to visualize the acquired signals. Data is stored on the computer device for further analysis by a medical practitioner.

The expected user has basic knowledge of ECG measurements and is able to place the electrodes on the patient body, as well as able to verify that these connections are correct and able to start the data

acquisition process of the signals obtained from the electrodes.

The expected user for the analysis of the reports generated by the device is a medical practitioner with expertise on ECG signal analysis.

3. Indications

This device is able to capture electrocardiograms from 6 or 12 signals, data forwarding and analysis, for later diagnosis by a qualified medical practitioner.

4. Counter indications

None detected.

5. Side effects

None detected.

6. Safety Information

In this manual, a **Warning** identifies conditions and dangerous actions that may result in injuries or fatal injuries. A **Caution** identifies scenarios and actions that may result in damages on the product or on the visualizing equipment, or cause data loss.



Contact:

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Warnings

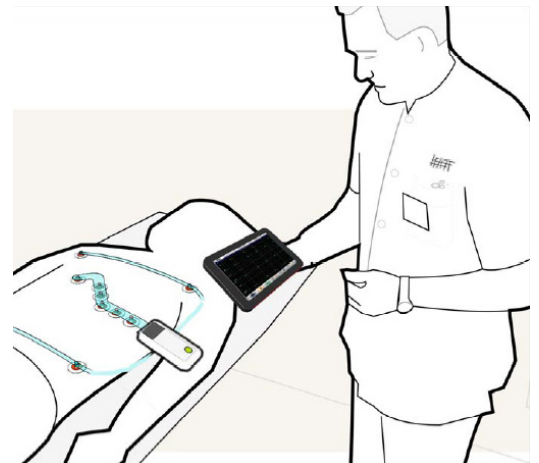
- The equipment must not be modified.
- Do not use if the device is damaged, the cables are damaged or the insulation is defective or damaged.
- Do not use any other ECG cables than those supplied with the device.
- The equipment must be sealed and all its inner parts inaccessible at all time.
- Prevent exposure to direct sunlight during extended periods of time.
- Remove cables with electrodes not needed for data acquisition.
- Do not use the equipment in environments with gases, containing explosive vapours, or in humid or wet environments. Protect the equipment from water, humidity, or salty/sulphuric environments.

- Do not operate the device while charging batteries.
- Read Safety Information before operating the product.
- Examine the product case before use. Verify that the device is not damaged. Carefully check the external insulation on the connectors and on the cables connected to the electrodes.
- Do not use sharp or piercing objects to operate the device.
- Prevent terminals and device to contact any conductive surface while in operation.
- Do not use the device close to high frequency power sources (microwaves) in operation.
- Ensure that no conductive part of the device (terminals, cables or electrodes) contact any exterior conductive element (cables, metal surfaces, conductive metal elements or plugs).
- Do not use the device in an operating room or during a surgical procedure.

7. ECGExpert User Manual

ECG expert will allow you to capture biological signal from a patient and to obtain an electrocardiogram (ECG) report, with an autonomous device of reduced dimensions powered by long lasting batteries.

The device is designed to be operated by users with minimal medical expertise. In order to correctly capture, ECG signals, it is only required to know the number of electrodes and the correct placement of these electrodes on the patient's body.



To visualize the results an additional computer or portable device (tablet-PC or smartphone), with bluetooth connectivity, is required. This visualizing device must have previously installed the ECGExpert application. ECGExpert device is suitable for direct cardiac applications.

8. Supplied equipment

The equipment supplied consists on the following elements:

- ECGExpert biomedical signal capturing device.
- 10 electrode connection cables.
- 1 USB-to-microUSB cable
- 1 Universal USB power supply for battery charging.
- 1 Card with the Identification QR code for the device with the web link of ECGExpert's manual.

9. ECGExpert Device

The device has a simple interface; the following figure indicates all relevant elements:

1. Electrode wires

2. Wire connectors

3. Wires and electrodes status signals

4. Battery level and on/off indicator

5. On/off button

6. Viewer link indicator

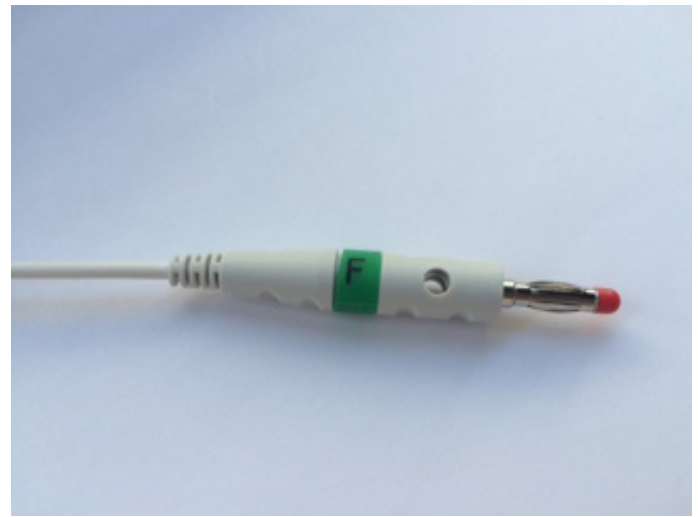
7. MicroUSB port battery charge port



To prevent misconnection of the electrode cables, all supplied cables have different terminal connectors that only fit in the intended connector.



End to be connected to your computer



End to be connected to the electrodes

Instrument Type	
Microprocessor augmented automatic handheld electrocardiograph with remote viewer interface (Bluetooth); 12-leadwire simultaneous acquisition with programmable lead configuration.	
Processing	
ECG Interpretation	Marquette 12SL ECG Analysis Program for Adults and Pediatrics
Computerized measurements	12-lead analysis
ECG analysis frequency	500 samples/second (sps)
Digital sampling rate	8000 samples/second/channel
ECG on-screen preview	Non applicable (Realtime view)
Acquisition mode	Realtime acquisition.
Dynamic range	TBD (AC differential +/- 5mV, DC offset +/- 300mV)
Resolution	24bits/channel
Frequency response	-3dB @ 0.02Hz to 150Hz
Low cut-off frequency	0.02Hz (-3db Limit)
High cut-off frequency	configurable to 40Hz or 150Hz
Adaptative AC filter	47Hz to 53Hz for european line, 57Hz to 63Hz for American line.
CMRR	> 105dB
Input impedance	>100MHz and defibrillator protected.
Patient Leakage	TBD
Hear rate meter	TBD
Start-up time	3 seconds.
Patient Information	
Supported Patient information	Name, Patient ID, birth date, gender, and medical notes.

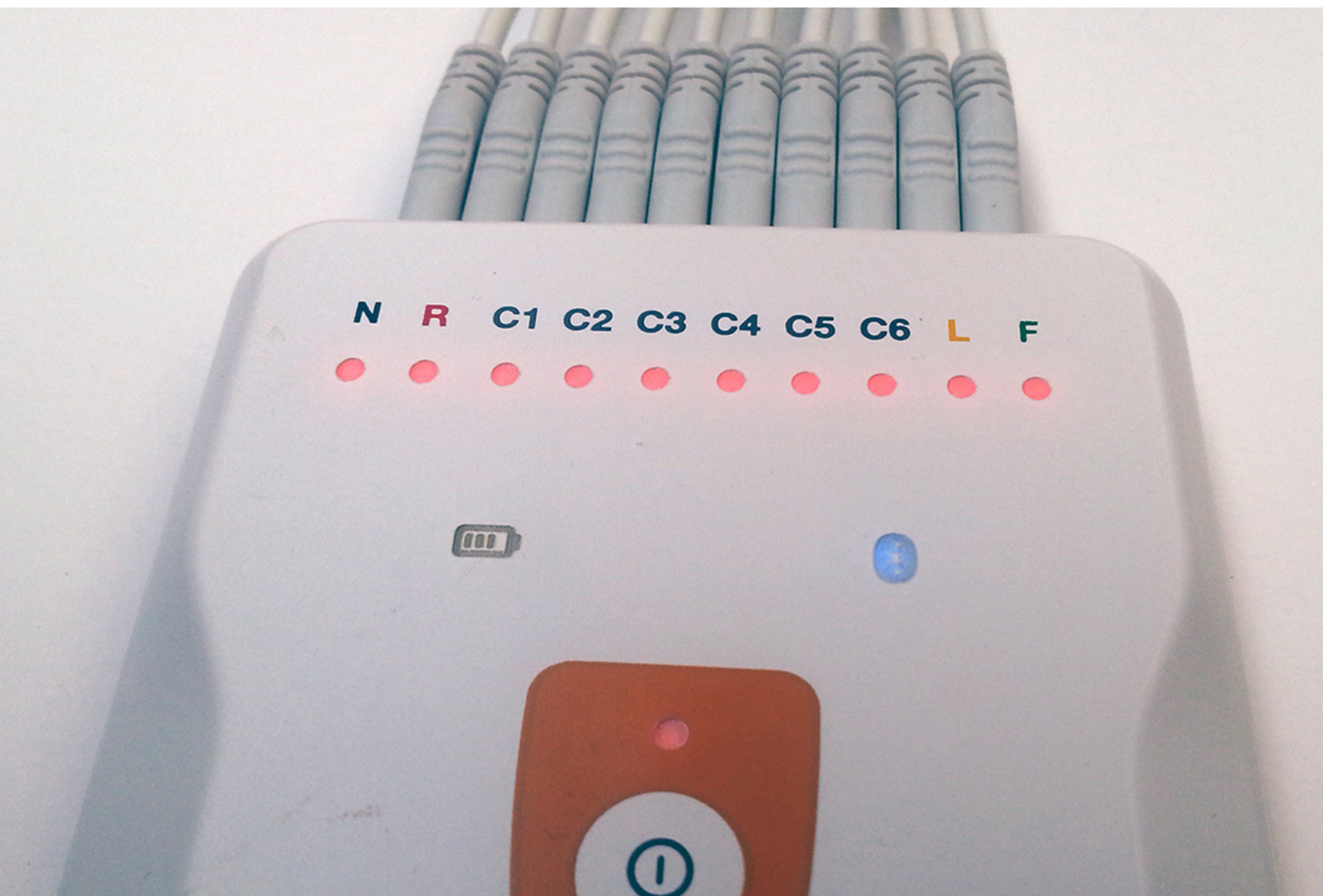
Patient Information	
Supported Patient information	Name, Patient ID, birth date, gender, and medical notes.
Display	
Display type	Depending of handheld bluetooth device
Display resolution	
Display data	Patient ID, Name, ECG's battery level indicator, waveforms, Lead labels, 12-leads standard display. Filter settings on report output.
Writer	
Writer technology	Any graphical printer attached to a PC or with Bluetooth interface accessible from a handheld device.
Keyboard	
Type	Handheld device's Touch screen
Software Standard	
Resing ECG Mode	Records and prints 12-lead resting ECG with 10-second duration as standard feature
Hookup advisor	TBD
Multi-language support:	TBD
Software Options	
Measurements	Supports Marquette 12SL ECG analysis Program
Interpretation	Marquette 12SL ECG Analysis Program
Color	Color for each channel
External storage	Storage in handheld device.
Transmission	Handheld device transmission channels
Communications	
Bluetooth	2.1 Class I
Report Formats	
Thermal printer report formats	
Accesories	
Electrical	
Power supply	USB 2.0 Standard 5V@500mA max
Battery Specifications	Rechargeable , Pol-lithium
Battery capacity	3V7 820mAh
Battery charger time	< 2h
Physical Specifications	
Height	14
Width	71,2
Depth	114,74
Weight	TBD
Environmental Specifications	
Temperature Operating	5°C 40°C
Storage Humidity	-15°C 50°C
Operating	25% 95,00% Non-condensing
Storage	25% 95,00% Non-condensing
Pressure	
Operating	1atm
Storage	1atm
Certification	
TBD	

10. Technical Specifications

To obtain the required technical documentation to repair the device, please contact our **TECHNICAL SERVICE**, central offices (contact information at the end of this document).

EMC information

Guide and Statement from the Manufacturer – ELECTROMAGNETIC EMISSIONS		
This device is to be used in the electromagnetic environment specified in this document.		
The user of the device must ensure that the device is operated in the specified environment.		
Emission test	Compliance	Entorno electromagnético Guía
RF Emissions CISPR 11	Group 1	ECGExpert uses RF energy only for its internal operation. Resulting in very low RF emission and not likely to cause any interference with surrounding electronic equipment.
RF Emissions CISPR 11	Class B	The device is suitable to be operated in all kind of facilities, including domestic (non industrial) buildings and, also, in those with direct connection to a public low-tension electrical grid such as in buildings for domestic use.
Harmonic Emissions IEC61000-3-2	Class A	
Tension fluctuation / Flickers IEC61000-3-3	Complies	



Guide and Statement from the Manufacturer – ELECTROMAGNETIC IMMUNITY

This device is to be used in the electromagnetic environment specified in this document.

The user of the device must ensure that the device is operated in the specified environment.

Immunity Test	IEC 60602 Standard Compliance Level Test Level	Compliance Level	Reference Electromagnetic Environment
Electrostatic discharge (DES) IEC61000-4-2	±6kV by contact ±8kV aerial	±6kV by contact ±8kV aerial	Floors should be conductive (wood, concrete or ceramic tiles). If the floor is covered with a synthetic material, relative humidity must be over 30%.
Transient / fast flashes IEC 61000-4-4	±2kV for power supply lines from public grid ±1KV for input/output lines	±2kV for power supply lines from public grid	The power grid quality must be as good as in a standard commercial environment or as in a hospital
Shock Wave IEC 61000-4-5	±1kV in line to ground line ±2kV in line to ground	±1kV in line to line ±2kV in line to line	The power grid quality must be as good as in a standard commercial environment or as in a hospital.
Power cuts, interruptions or variations voltage variation in power feed lines IEC 61000-4-11	<5% U_T (caída >95% en U_T) para 0,5 ciclos <40% U_T (caída >60% en U_T) para 5 ciclos <70% U_T (caída >30% en U_T) para 25 ciclos <5% U_T (drop >95% en U_T) for 0,5 cycles <40% U_T (drop >60% en U_T) for 5 cycles	Normative Compliance	The power grid quality must be as good as in a standard commercial environment or as in a hospital. If continuous operation is required, the device is to be powered by a continuous power source.
Magnetic field at grid frequencies (50/60Hz) IEC 61000-4-8	3 A/m	3 A/m	The magnetic fields at grid frequencies must be between the typical values from a typical commercial or hospital environments.

11. Symbols

The following table lists all the symbols used in this product:



European Union Standards Compliance



BF-type equipment, defibrillation protected



Operation Instructions



Caution



Manufacturing Date



Manufacturer



Protect from Sunlight



Continuous Current



Serial Number



Electronic/electrical Waste



Serial Connection

<i>Electrocardiografo / Electrocardiograph</i>			
REF ECG-EXPERT	SN EYYWWNNNN		
 YYYY-MM			
CUSTOM SOFTWARE & ELECTRONICS, SL Parc Tecnològic Bcn Nord/ Marie Curie, 8-14, 08042 Barcelona - España		 1639	

- **Equipment without protection against harmful particle entry or water:** IPX0
- **Electrical Shock Class of the device:** Powered by BF-type battery, defibrillation protected as in EN 60601-1 standard.
- **Operation mode:** Continuous.

12. Connecting the electrode cables

The connection of the device to the electrodes placed in the patient's body is extremely simple, without needing any specific training by the user.

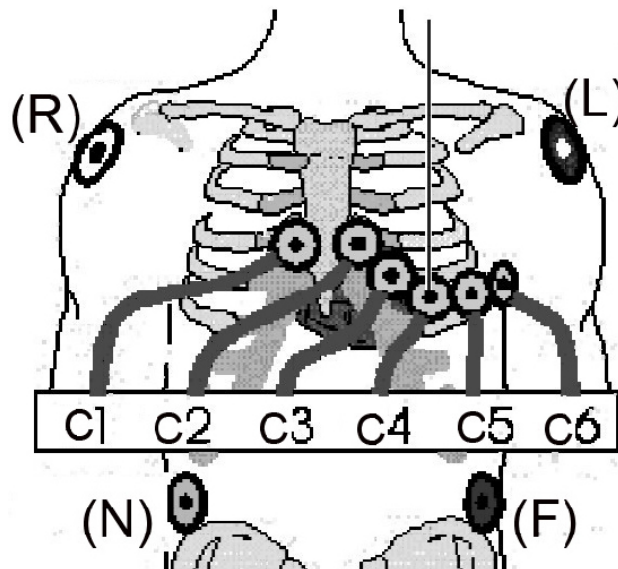
The cables to connect the electrodes to the device are asymmetrical; one end of the cable has a terminal that fits nicely in the correct connector on the device.



Notice the cable connection order, a letter and colour code indicate the correct slot on the device.

User must be aware of which electrode is connected to each cable depending on its colour and indicative letter.

Take the following diagram as reference:



The electrode connection is as shown in the pictures below.



13. Electrode Selection

The cables supplied with the device are designed to use with PIN-type electrodes or with commercially available adaptors to this connection type.

Use pre-gelated, Ag/AgCl, latex free and complying with CE standards electrodes with the following specifications:

- **Impedance (typ.):** 650 ohms
- **DC offset voltage (typ):** 0,2mV
- **Recovery from a desfibrillation charge (typ):** 9,9mV
- **Polarization potencial variation:** 0,2mV/s

14. Turning ON the device

Once all cables are correctly connected to the device and to the electrodes on the patient body, the user can proceed to the switching on procedure¹:

1. Verify that the device is not connected via micro-USB to any device.
2. Press the On/Off button. A blinking light above the power button indicates the device is ON.
3. A second after pressing the On/Off button, the battery/operation LED turns on². If the battery/operation LED colour is green the battery is fully charged. If the battery/operation LED colour is orange, indicates that the battery has enough power to capture ECG signals. On the contrary, if the battery/operation LED

colour is red, the battery needs recharging for the device to operate in optimal condition, and data acquisition is not recommended.

4. When the battery/operation LED is ON the blinking LED above the On/Off Button turns on. Release the Power button.

5. A blinking blue LED at the right side of the device indicates that the Bluetooth module is on but without connection. The device is in operation awaiting connection to visualize data.



Turning device ON



Device ON

1. The connection of the electrodes to the device can be done while in operation without affecting the device or risking neither the patient nor the user.
2. If the LED doesn't turn On the battery is fully discharged and it is needed to connect the device via USB to a power supply to charge the battery before use.

15. Turning OFF the device

To switch OFF the device proceed as following:

1. Push On/Off button. Notice the LED light above the button begins to blink.
2. Hold for few seconds until both LEDs, battery/operation and On/Off button LEDs³, are off indicating that the device is OFF.



Turning OFF the device

16. Inspection, Cleaning, Storage and Transport

1. Preventive inspection

A preventive inspection is required before using the ECG device to verify the absence of any visible damage in the device or cables that could affect the proper operation of the device.

The visual inspection must include the device and all the cables, in order to notice any damaged or worn areas, including, but not limited to, breakage, cuts, decolouration or oxidation of any part or component. If a cable or any other accessory shows any of these symptoms, replace before using the ECG device.

2. Cleaning and disinfection

Clean the exterior of the device with a mild solution of detergent and water on a soft cloth. Avoid any excessive amount of cleansing solution to avoid any leakage through the connectors or slots of the ECG device. If necessary, use a solution of water with low-alcohol sterilized detergent, as those used in hospitals.

Verify that all the equipment, including accessories, is completely dry before use.

The supplied cables are reusable but are not previously sterilized. To clean and disinfect the equipment proceed as follows:

1. Disconnect the cable by pulling from the connector.
2. Proceed carefully, avoid pulling with excessive force, twisting or bending the connection cable.
3. Clean cables using a soft cloth with cleaning solution.
4. Wipe the cable with a dry soft cloth.

3. During data acquisition the device cannot be turned OFF and will not react to pressing the On/Off button. End the data acquisition process before switching the device OFF.

3. Storage

To prevent any damage to the battery, storage the device between -15°C to 50°C.

To avoid any internal cuts in the conductor or damaging the outer insulation, do not bend the cables excessively.

4. Transport

If the device or one of its components is to be transported used the original packaging.

If the original packaging is not available, protect the elements from crashes, humidity, dust and electrical static.

5. Cautions

DO NOT INMERSE THE EQUIPMENT IN ANY LIQUID.

Follow strictly the cleaning instructions stated in section 16.2.

Do not use any aggressive or strong cleaning agents:

A prolonged exposure to alcohol can affect the mechanical properties of the protective case and to the cables.

N-Propyl alcohols or sodium hypochlorite are to be avoided as disinfection agents for both cables and the device.

17. Maintenance

The following actions are recommended as maintenance of the device. These actions include from metrological testing to safety checks of the medical device.

1. Maintenance

Due to the 100% digital technology of our ECG, it does not need any kind of mandatory maintenance once it is put on sale. We recommend, however, keeping the equipment and cables in perfect condition for proper operation of the equipment.

2. Metrological Testing

These check-ups must be carried out by authorized technical expert and taking the necessary actions as indicated by CSE.

3. Safety Check-ups

The device must be safety-checked by an authorized technical expert after any repair, modification or conversion is made on the ECGExpert device.

18. Interferences and EMC requirements

Radio Interferences, Television, Electrical Grid or Electrical Equipment

As in any electronic device, external electromagnetic fields can affect the normal operation of the device or any electromagnetic field generated within the device interfere with other devices.

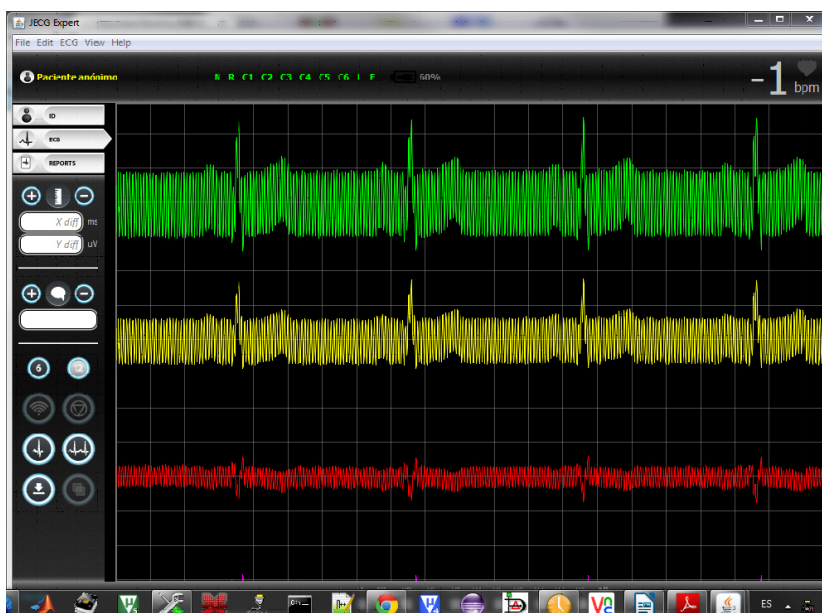
In order to prevent these interferences, the device is been robustly designed to avoid alterations in the signals from the ECG electrodes by external EM fields in standard environments (away from High Voltage Power lines o Electromagnetically noisy equipment such as washing machines, power generators, microwaves

or operating TV sets). Due to the nature of the radio electric link between the equipment and the visualizing equipment (tablet.PC, Smartphone or PC) it is possible that an intense electromagnetic field can affect the connection speed between these two devices, extending the waiting time to obtain a complete biometric capture. Under extreme electromagnetic conditions, the communication link between these two devices can be broken but it doesn't affect the quality or the shape of the obtained signal.

In order to avoid undesired effects, it is important to ensure that the device is operating within an EM field lower than 3V/m and 3A/m. It is NOT recommended to operate the device:

1. Closer than 10m from a High Voltage Power Line
2. Closer than 2.5m from industrial equipment, microwaves or operating TV set.

If the communication between devices is fluid but a signal like the one shown on the next figure appears:

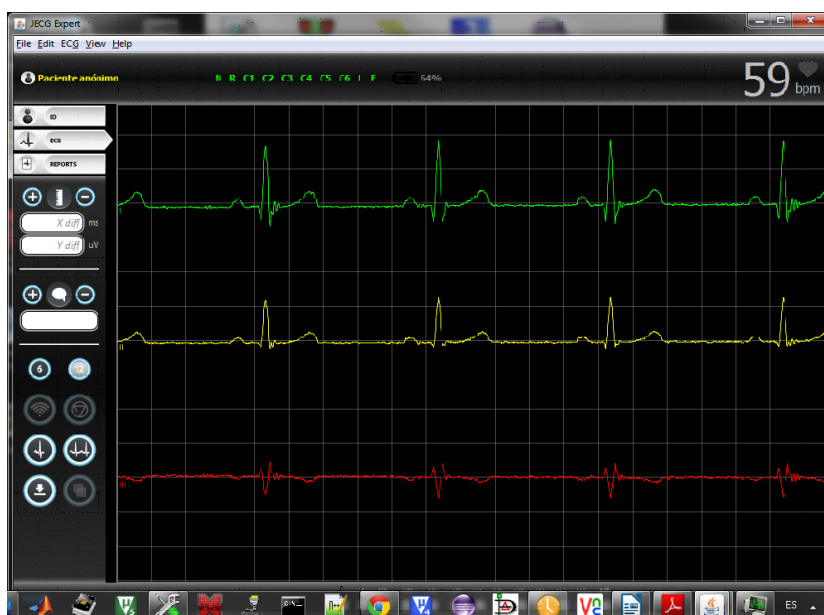


The device is suffering interferences from the electrical grid of the country where the measurement is being taken.

To eliminate such interference proceed as follows:

1. Activate the corresponding filter to eliminate Power grid interferences, according to the country where the measures are taken (See “Filter Configuration” Section).
2. Repeat Biometric Signal capture.

A new capture with the correct filter activated, will obtain a signal without the noise of the previous measurement, as shown in the next screenshot:



19. Use with defibrillator

ECGExpert is been designed to be used as diagnosis device and must not be used for monitoring during defibrillation.

The device is protected from the action of a defibrillator and communications via USB cable are galvanically insulated.

In any case, it is recommended to disconnect the device from the patient before operation the defibrillator, to facilitate the use of the defibrillator and the discharge.

20. Pacemakers

ECGExpert can be used in patients with pacemakers or any other implanted stimulators without any risk.

The device can detect the presence of pacemakers. As a biomedical monitoring device, ECGExpert does not affect the correct operation of pacemakers.

In case of suspecting a device malfunction, it is recommended to stop data acquisition and to contact technical assistance for repairing or adjustment (contact information at the end of this document).

21. ECGExpert

ECGExpert application can be installed on Tablet-PC or Smartphone and also on Computers.

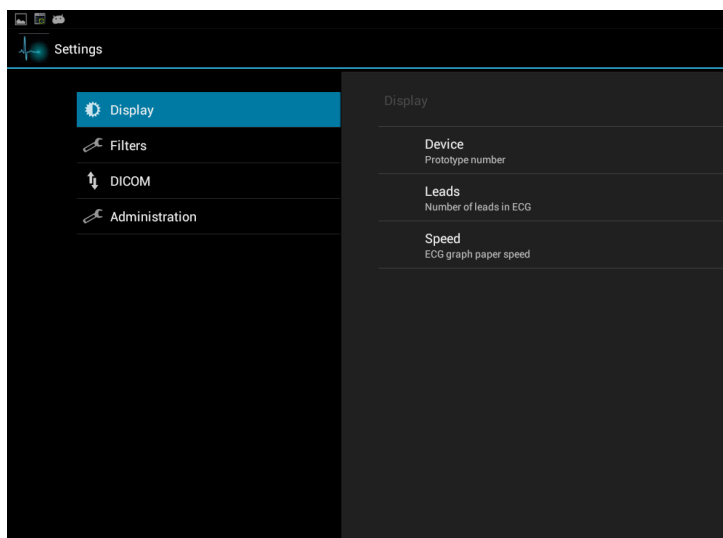
Once installed the application is shown on the App Menu of the Operating System.

Turn on, and pair, Bluetooth Comm. from both the ECGExpert Device and

the visualizing device. Check the User Manual of the visualizing device for further reference on how to correctly pair Bluetooth connections with the ECGExpert Device before running ECGExpert Application.

22. ECGExpert - Configuración

Go to “Settings” in the menu, use user and password credentials to log in⁴.



Screenshot of “Settings”

Visualization Configuration

- **Device:** Select the corresponding ECG device, by default PF1.
- **Leads:** Select the number of ECG Leads to capture, 6 or 12. By default 6 Leads.
- **Speed:** Select the desired timeline for the ECG graphic visualization, can be set to 10 mm/s, 25 mm/s or 50 mm/s. By default 25 mm/s.

Filter Configuration

- **Low pass filter:** Select the Low Pass filters depending of the requirements of the later analysis. Select 40 Hz for captures without Pacemaker detection or 150Hz for captures for later detection of Pacemakers. By default 40Hz is selected.
- **Line frequency:** Select the corresponding Power line frequency of the country where the measurements are taken. The following link lists the information on the Power line frequency used in each country: http://en.wikipedia.org/wiki/Mains_power_around_the_world

4. The first time running the application, the default username is “admin” and without requiring typing any password.

Admin Configuration

- **Change password:** Set a new password to access configuration. By default no password is set.

23. ECGExpert version - ECG capture

In order to capture a standard ECG signals follow these steps:

1. Connect the electrodes to the device using the supplied cables as explained on Chapter 4.
2. Turn on the ECG device as explained in Chapter 5.
3. To include a new patient:
 - 3.1. Go to **"Patients"** Tab and select **"Add"**.
 - 3.2. Fill all required fields in the dialog window (Patient's Name and Patient's ID are the only required Fields), and press OK button.
 - 3.3. Select the corresponding New Patient from the list.

If the patient is already on the Patient's List select the corresponding Patient.

4. Select the Capture Mode. Select **"10-seconds"** for a single 10-second ECG capture or **"Continuous Mode"** for a continuous ECG Monitoring. The ECG captures finishes when the Start/Stop capture button on the device is pressed or if the application button is pressed.
5. Push Start/stop button to start ECG capture.
6. Push Start/Stop Button or wait 10 seconds (if 10-seconds Mode is selected) to finish capture.
7. Press **"Save"** button to save a report with the captured data on the visualizing device. This information can be accessed from the **"Reports"** list.



AndroidOS Version Screenshot



Screenshot of ECGExpert Application PC version

Electrode status

The status of the electrodes can be monitored from the ECGExpert device or from the ECGExpert Application, using the following colour code:

- **Red:** Disconnected.
- **Green:** Signal OK.
- **Yellow:** Signal not OK or incorrect signal level.
- **Gray:** Unknown. "N" electrode is always in this status.

Tools

While capturing ECG as well as during "Reports" the following "Tools" can be used:

- **Chest/Limbs electrodes:** Changes views between terminals I,II,III, aVR, aVL, aVF and V1, V2, V3, V4, V5, V6 if available.
- **Ruler:** measures distance between two points in the graphics in both, X and Y, axis.
- **Zoom leads:** Zoom in graphic window.
- **Annotations:** Add or eliminate text annotations on the selected point in the graphic.

Fast ECG

A Fast ECG can be done without requiring Patient's identification. Select on the main window the ECG tab and capture a standard ECG. Notice at the upper left corner the message "Patient not selected".

When attempting to save the capture a message will indicate: "Select Patient identity first". Go back and select the Patient Id from the Patient's list and press "Save" button.

24. ECGExpert version - Patients

The "Patients" tab includes the following options:

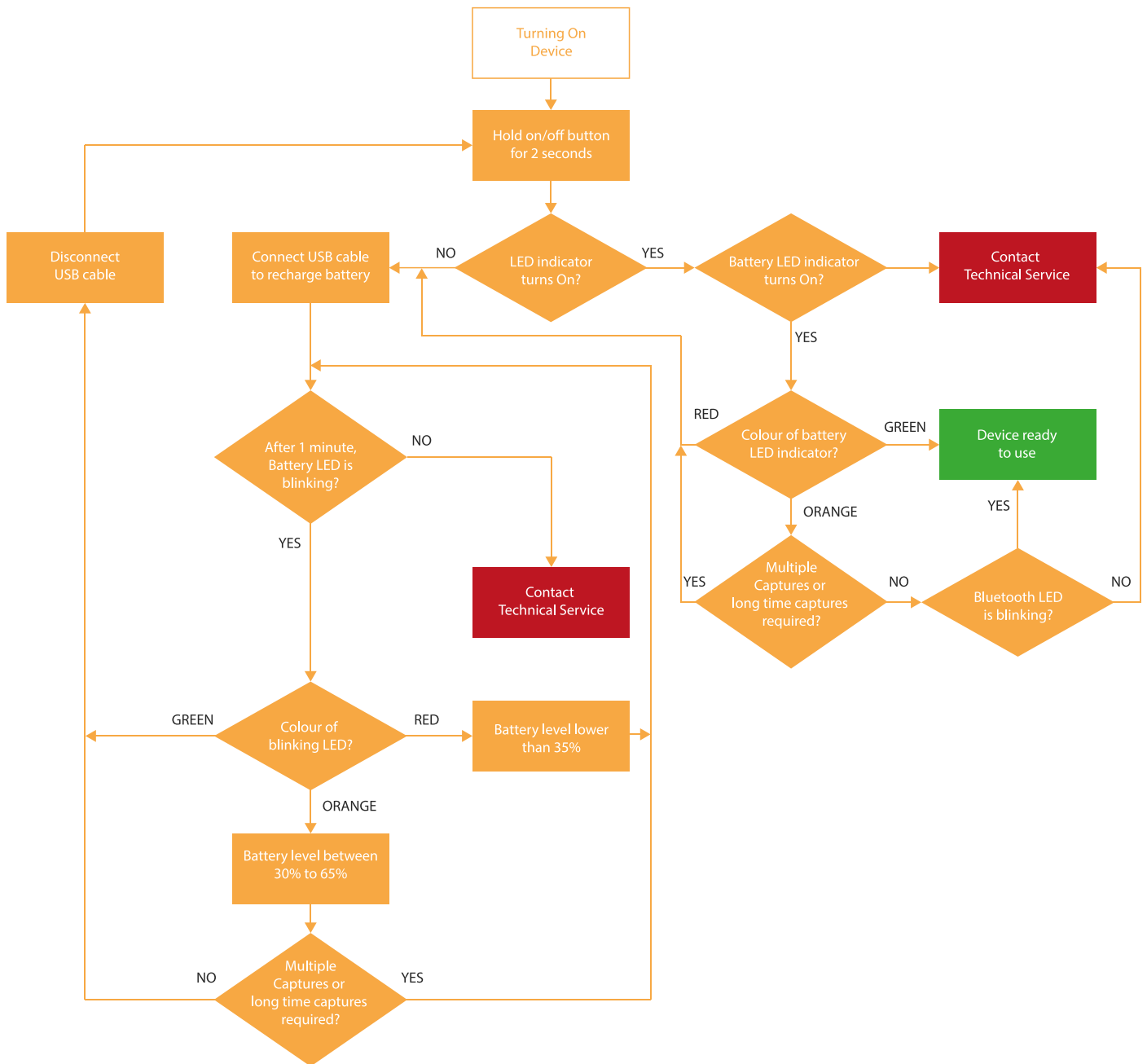
- **Search:** Searches within the Patient's List.
- **Add:** Shows the Add New Patient window.
- **Scan ID:** Starts Bar Code scanner to select a patient and start ECG captures.

By pressing any of the option buttons for a long period of time various items can be selected and a menu will show up with the following options:

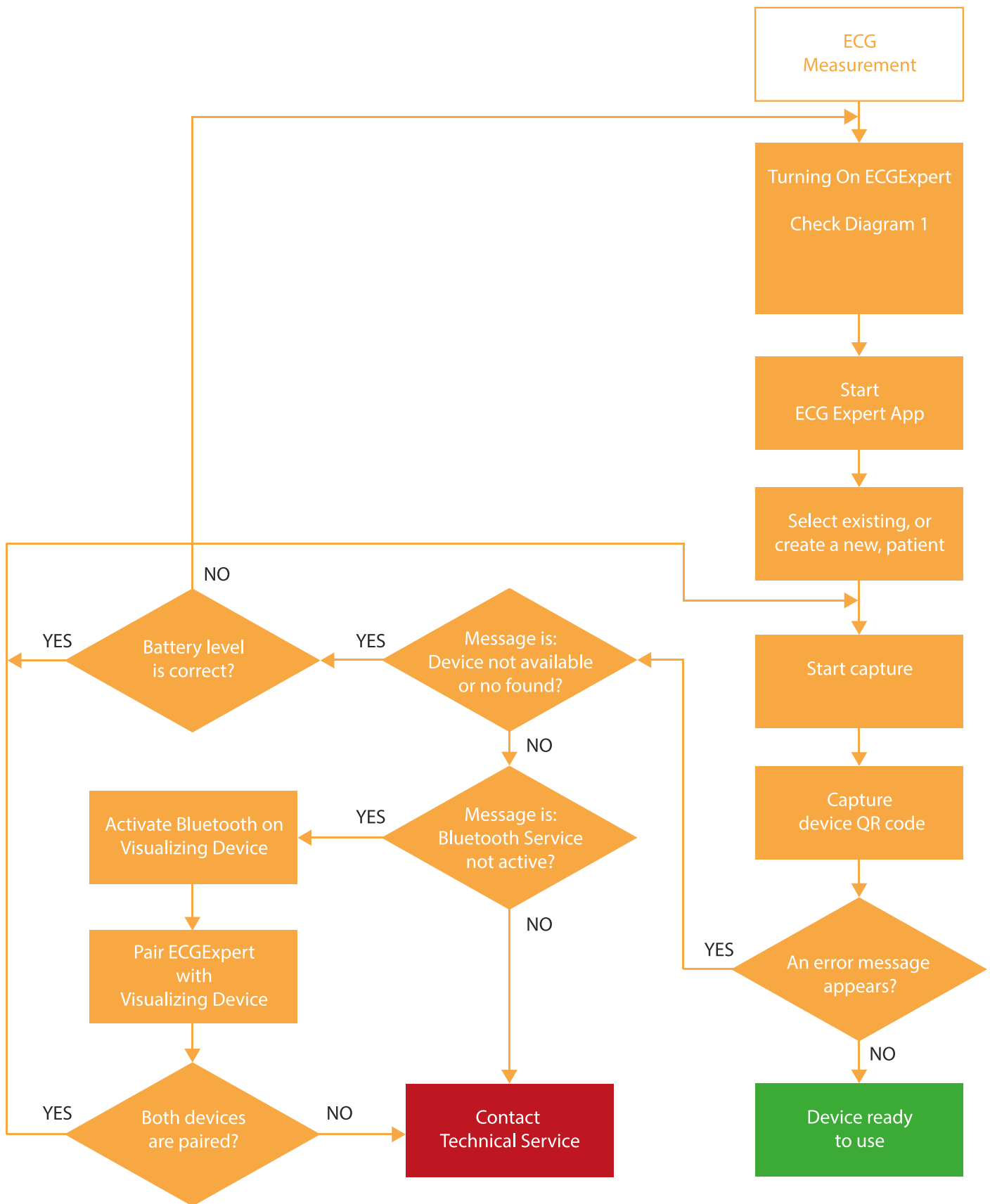
- **Edit:** Press to edit Patients data.
- **Delete:** Press to eliminate a Patient from the list.

27. User Guide and Trouble Shooting

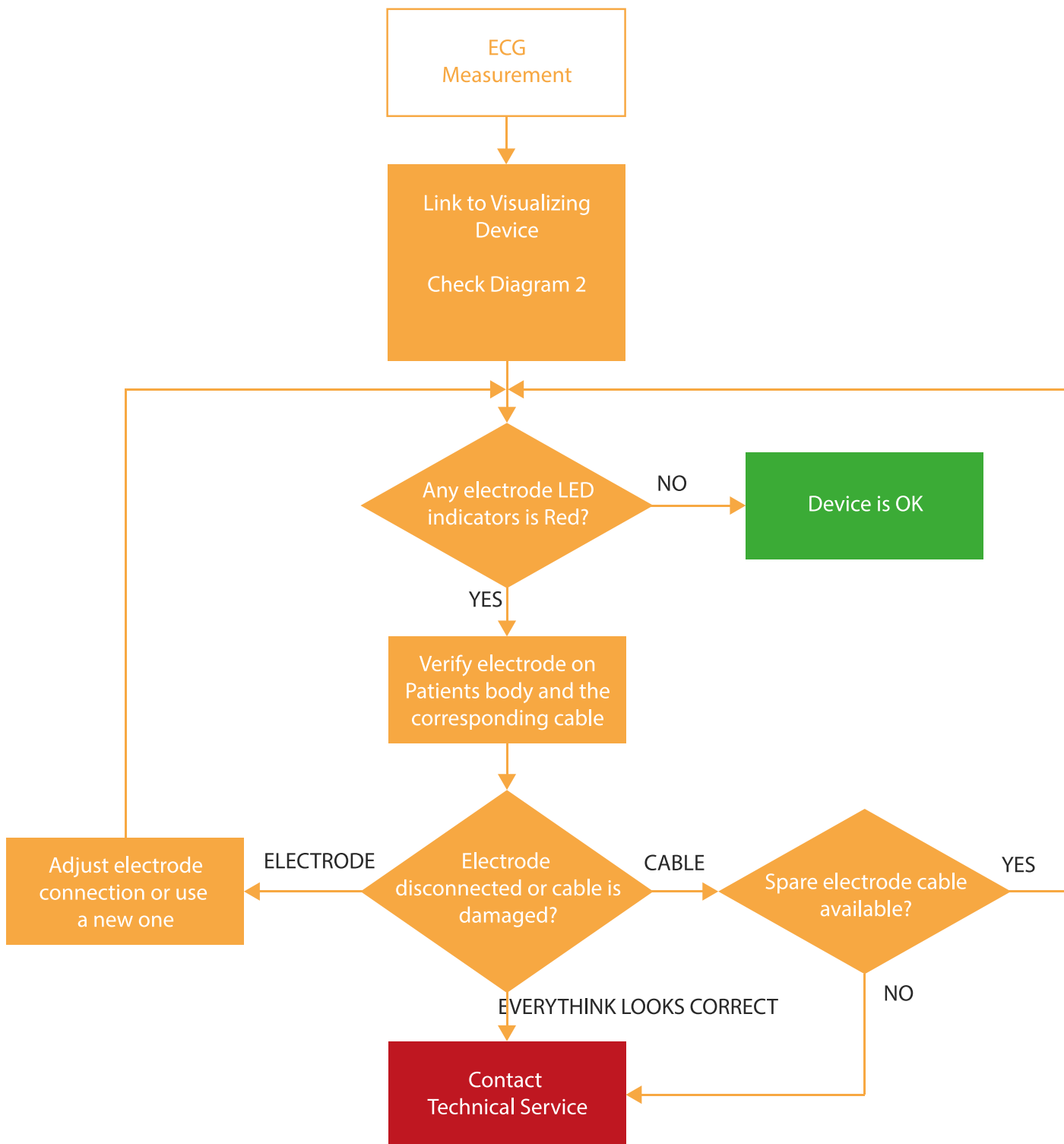
Device Initialization:



Pairing with visualizing device:



ECG Capture:



28. Requirements for a good Wireless network link

The device to be used to show and analyze the signals will be capable to made Bluetooth 2.1, or higher, links using Android 4.4 or less and Windows 7.0; and the SPP (Serial Port Profile) is implemented. That communication must be able to work at minimum data rate of 115200bps and, ideal, at 230400bps.

If the data link is lost during the operation the device, the ECGExpert disconnects immediately and waits for a 60 seconds for new data link, if not itself will power down automatically.

The software running on the computer for display signals, ECGExpert, also disconnects and finalize data collection, but keep running waiting to the user to start a new connection.

An upgrade of the operation system on the device used to show the signals could affect in an unknown way the behavior of the system. In that case, if you detect any kind of abnormality after a system upgrade, contact to CSE.

Are considered data link changes the following:

- Any evolution of the Bluetooth protocol (higher that 4.0).
- Any new device used on the Bluetooth link (multi device link).
- Any device removed on the Bluetooth link (multi device link).
- Upgrade the operating system on the signal viewer device (Android, Windows, IOS, MAC, Java version).

It's responsibility of the qualified user accept or refuse the set of captured data to be used as valid information for diagnosis.

The data links between the viewer equipment and the ECGExpert are exclusive point to point (one Bluetooth cannel for each ECGExpert), that is, is not possible share the Bluetooth link with other device.

The verify device's right behavior with future revisions of the Bluetooth higher than 4.0, please, contact with CSE.

The link between ECGExpert device with the viewer one, that enables to share the data link with other device could affect in an unknown way the signal capture and it's graphical representation.

Is device buyer's responsibility evaluate that potential risks.

All changes made over the data link could affect to the right behavior of the device, in that case ask to CSE to verify the right behavior of the device with the new data link.



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