Heart app Service Manual

Maritime Medical Applications BV (MMA)

“You are the captain of a vessel
In the middle of the night - there’s a knock on your door
One of your crewmembers is seriously ill
There’s no doctor: it is up to you to make the right calls
You were trained for this and you might have remote support
But in the end: it's up to you…”

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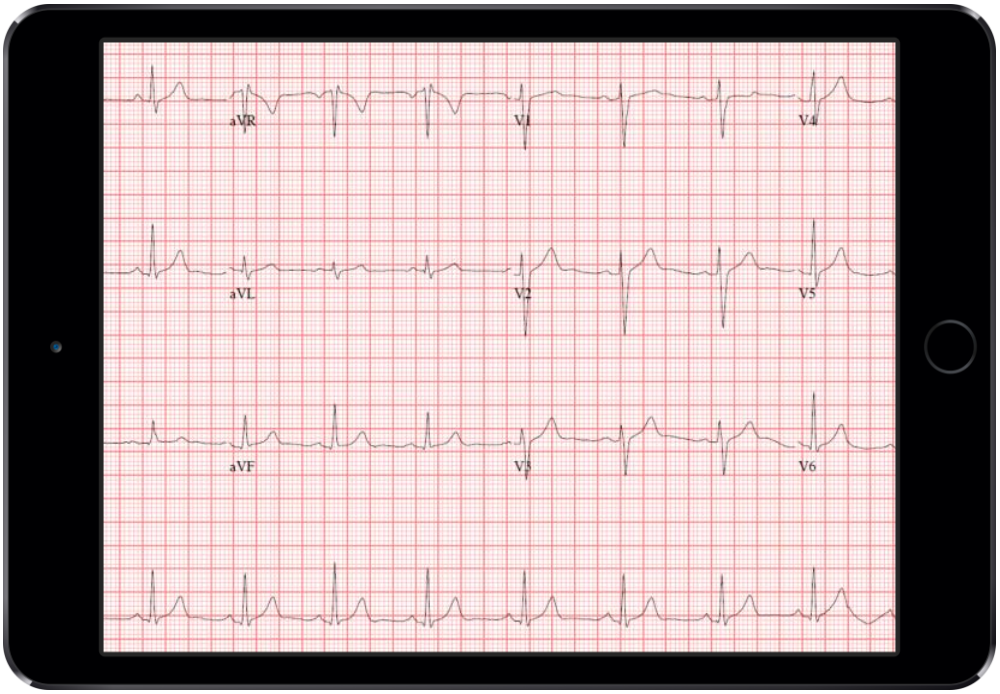
1 Introduction

The MedAssist.online Heart app enables people in remote locations, for instance captains and senior officers on a ship, to create a 12 lead hospital quality ECG.

An ECG is a recording of the electrical activity of the heart through a simple, non-invasive procedure. Electrodes are placed on the skin of the chest and connected in a specific order to a device that, when turned on, measures electrical activity all over the heart. This ECG is intended for remote interpretation by medical professionals. It can help in making a reliable diagnose.



The ECG is created using a Bluetooth enabled device with sensors, and a tablet.

It is captured as a PDF file. In short, you can record, view and interpret resting ECGs.

You can send ECGs by email for sharing with a qualified medical professional for interpretation.

2 Purpose

This document provides

- A delivery confirmation
- A service agreement
- An instruction manual for the Heart app.

3 Service Agreement

This product is not intended for use as a life sustain or life support device. This product is not intended for intracardiac use. This product is not intended for use in operating room or ICU.

For Support purposes, MedAssist.online can be contacted via www.MedAssist.online/support.

MedAssist.online Heart Application licenses and associated hardware will be for professional use aboard ships and includes Bluetooth sensors. Pads and medical gloves will be provided throughout the duration of the licenses.

Licenses are per ship and can be moved from any certain ship to any other ship (e.g. after being sold off), providing maximum flexibility.

Intellectual Property Rights where applicable remain with MMA or where applicable with the original holders.

Licenses can be transferred at no cost to other (or second) devices, as long as they are used onboard the agreed (number of) ships.

Licenses can be put on hold for a certain time - e.g. when on dock -, for a maximum of one year but cannot be sold back to MMA.

MMA will not use, store or keep any data that is collected by the application(s). This information is not available to MMA. It can only actively be made available by the Customer when saved or sent to MMA (or anyone else) for instance when testing or for support.

Customer accepts MMA terms of use (see: https://medassist.online/terms) of the MedAssist.online software applications, as would every individual user when accessing the application. This pertains to the specific (medical) content of the software and its use.

Some of the hard- and software we provide is produced by third parties (like Apple Inc). Their terms and agreements of use of this hard- and software are still applicable. To the best of our knowledge, this will not interfere with the services as provided, when used as instructed. If any change or interpretation thereof in these underlying terms might make it necessary to make any kinds of changes to our services, we will inform you accordingly.

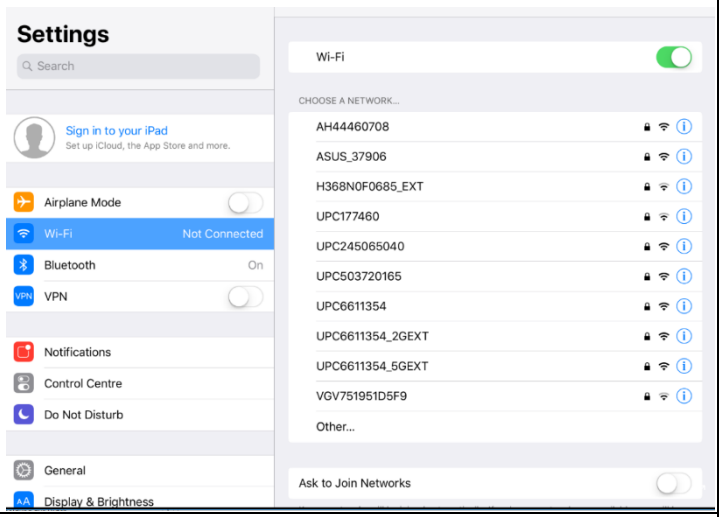
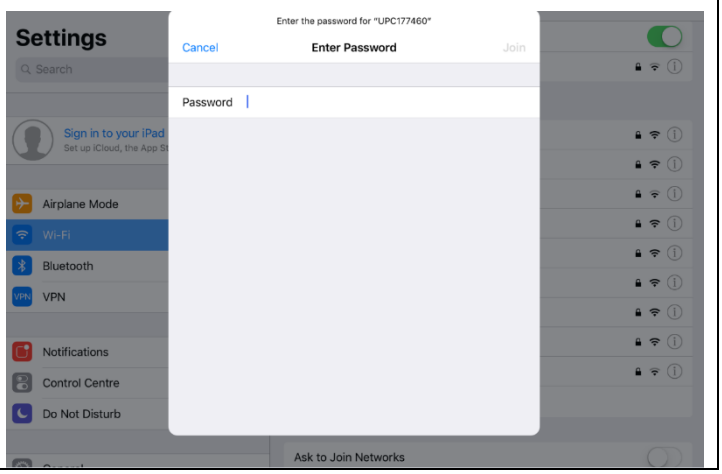
While MMA did its utmost to make sure all advice and instructions are accurate and in line with current (medical) practice and IMO and STCW regulations, MMA will not be held responsible or liable for the use of and results of any kind of action taken based on the software, information or output. That is the sole responsibility of Customer and the user.

A standard two year guarantee terms apply to the hardware. Only when there would be a defect, that is not covered by Apple under their terms, or after the 2-year guarantee period expires, MMA would have to charge Customer, for (direct) cost involved only.

4 User Manual

4.1 Initial Set up (Wi-Fi connection)

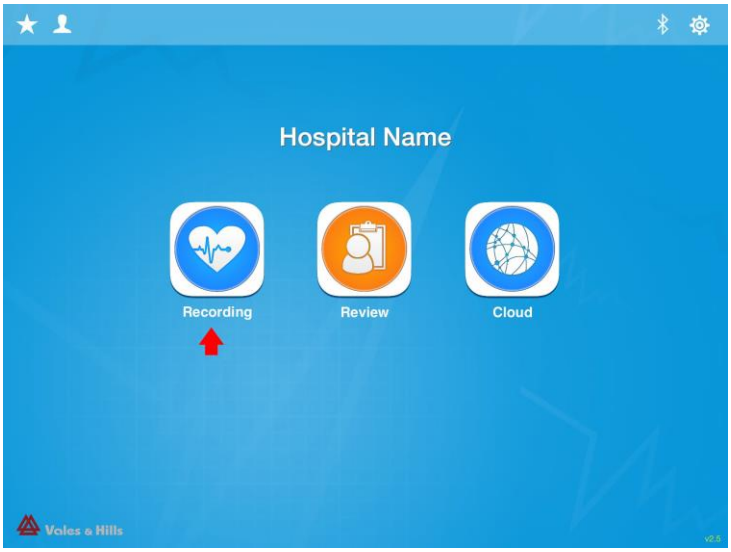
Set up of the Wi-Fi connection is required to enable the iPad to connect and send the ECG report.

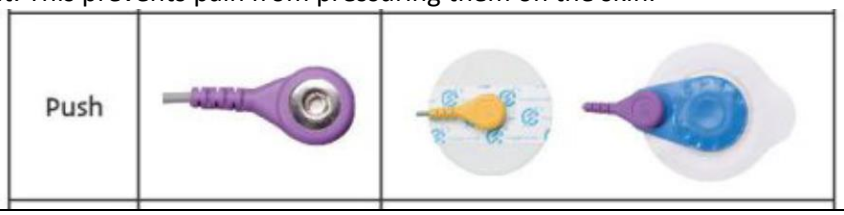
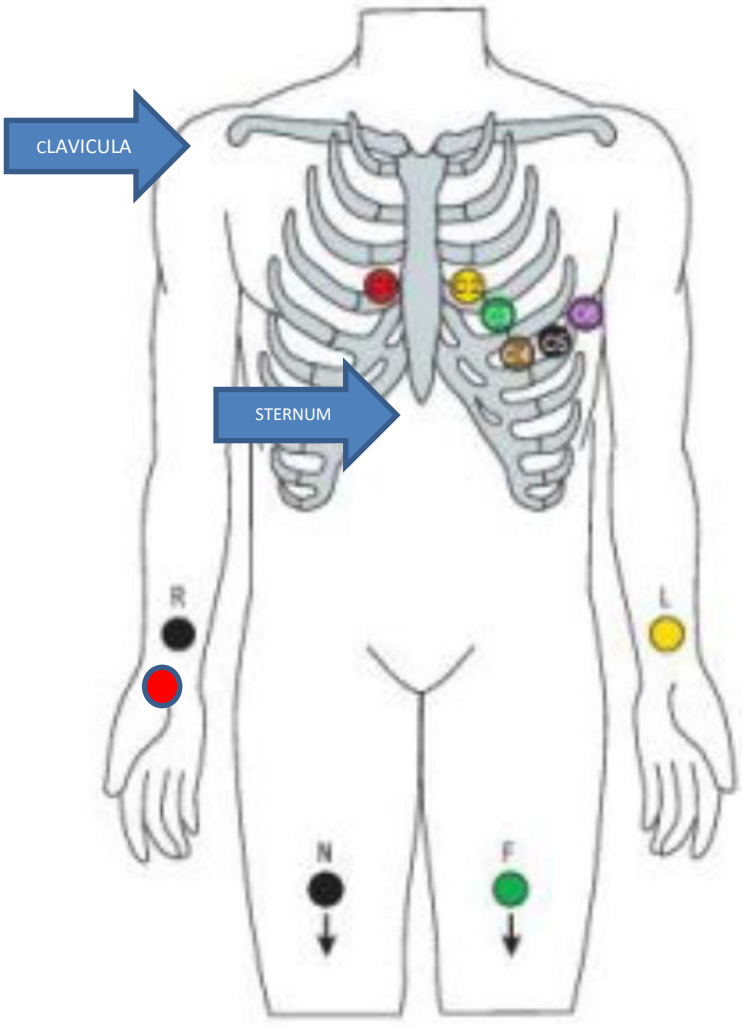
1	Switch the iPad with the switch at the right top.	
2	Choose Settings	
3	Enable Wi-Fi. Choose the Ship's Wi-Fi channel.	
4	Enter the Wi-Fi password Ensure there is a Wi-Fi connection. Press <Done> Return to the Main Screen By Pressing the <Home> button	

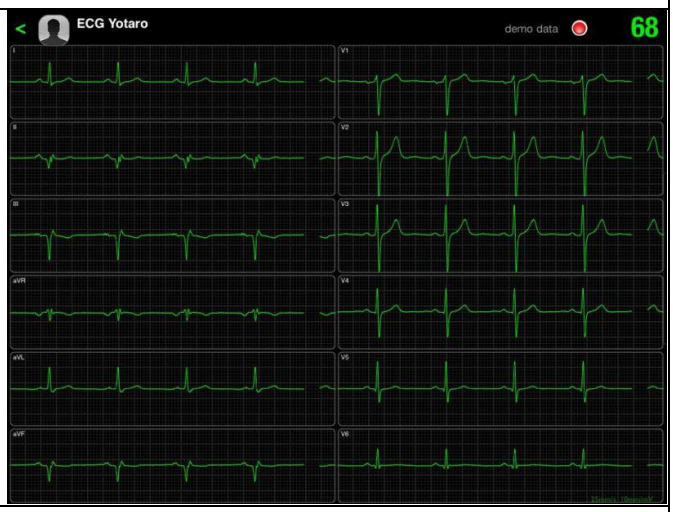
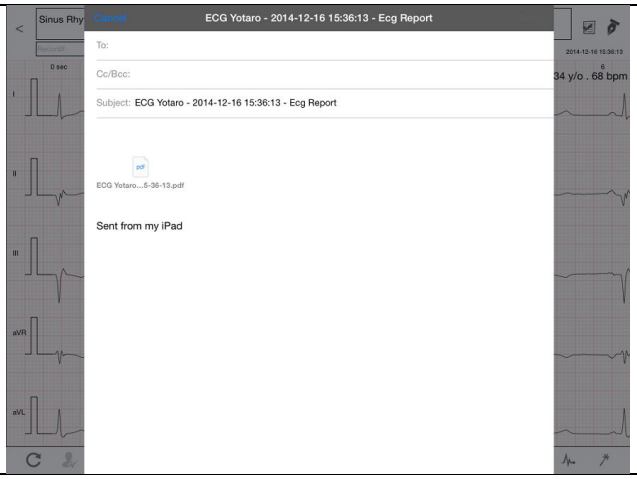
4.2 Making an ECG

To make a quality ECG it is required to have an iPad, with the Heart app installed, a Bluetooth sensor device with sensors and gel pads, which are connected via a button to the sensors.

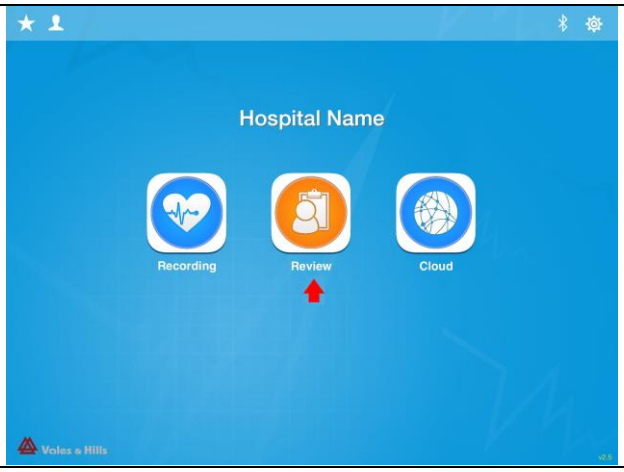
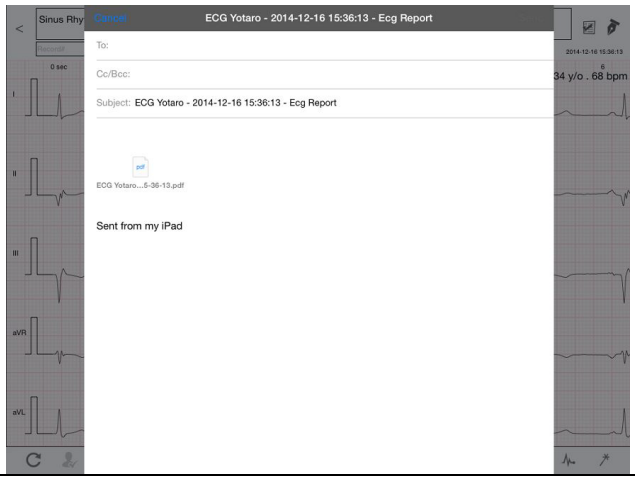
The quality of an ECG is dependent on the resistance between the skin and the electrode. Remove any blockers (e.g. hair) between the gel pads and the skin to enable optimal registration.

Step	Action
1	Take out the Bluetooth sensor device from the bag. Press the button on the device. A light turns green on top. If the light does not turn on, take out the batteries. Put them back in and try again. If it is still not working replace the batteries. 
2	Switch on the iPad: Press the on / off button on the backside of the iPad, above the camera lens
3	Your iPad is either **unlocked** or you have to enter the PIN code : **0000**
4	Choose /click the Heart App and wait for the App to start The ECG device is set up to auto connect with the iPad via bluetooth.. Main screen will indicate the connection with the Sensor device "Connected"  If auto connect for some reason does not work, check in 'Settings' (of the App) in right corner of screen under Connections if 'Device SN last digit' corresponds with the last digit of the SN on the unit.
5	Choose “Recording” to make a new ECG. 
6	Put the (test) patient on the ground and make sure only arms, legs and chest are uncovered.
7	Separate long and short sensors. Long sensors are for arms and legs (Red, Yellow, Black, Green). Put them alongside the body.

	Short sensors are for the chest. Keep them together centrally. Tip : Separate the long (4) and the short sensors (6) before applying the sensors to the skin.
8	Tip : Click the gel pad on the electrodes on the sensor wires ***before*** putting them on the patient. This prevents pain from pressuring them on the skin. 
9	Put the gel pads as indicated on the graph. Note : Start with the extremities (arms and legs), before applying them to the heart area. Note: To ensure a good quality, take care of the following: 1) Ensure that the patient is **warm** and -as much as possible- also **relaxed**. Movement and muscle activity adversely affects quality. 2) Shave electrode area before cleaning if needed 3) Thoroughly clean the area with alcohol  • On the chest: count down from the clavicula to the space between the 3rd and 4th rib (the fourth intercostal space) and place the red short sensor. Note the first intercostal space cannot usually be easily sensed/determined! • Mirror the red sensor on the right side of the sternum between the 3rd and 4th rib and connect the yellow sensor

	• Go down one intercostal space for the green and again for the brown sensor. • Follow on with the last two sensors in the 6th intercostal space, moving further to the end of the 5th rib. The purple one is to the side of the patient • Sensors N and F (Black and Green) should be placed on the inside of the ankles, left and right).
10	The screen should show this after placing the sensors. Each flat line will go live after placing the sensor. 
11	Press the Red button on the screen to record the ECG (it will take approx. 10 seconds to turn to bright red = recordable) 
12	From the option shown choose 'Preview' to check if the ECG looks good. If it does you can send it to any email address: • choose the 'send' symbol on the right bottom of the screen (the middle one with the arrow coming out) • Choose the (email) envelope from the options shown (second from below)
13	You will see a choice of Print, Email and some other options (question mark, social media). Choose **Email** – you will see the following screen Finally: send the email to your medical service provider/RMS 

4.3 Sending an ECG

1	Choose “Review”	
2	Choose the recorded file (based on the date).	
3	Choose Send at the right bottom part of the screen – you will see a choice of Print and Email and social media. Email is second from below, the closed envelope. This screen of a very familiar one will show up.	
4	Send the email to your medical service provider/RMS.	
5	Deletion of ECG PDF • Delete the email with the ECG PDF file from Sent Files in the email application • After 24 hours, the email will also be auto-deleted from the email server. • You can also delete the original ECG (pdf) from the Heart App by going to 'Review' choosing the files to delete and press delete if you choose so.