VH-JS-08(63F) Version A/0

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Preface

Copyright

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The information contained in this manual is subject to change without notice. All changes will be in compliance with regulations governing manufacture of medical equipment.

General Description and Intended Use

iCV200S is a portable ECG system with CardioView family. It includes a data acquisition recorder and iPad with vhECG App. The system is designed and manufactured by V&H for patient ECG recording with automatic measurements and interpretations.

- This product is not intended for use as sustain or support life devices.
- This product is not intended for introcardiac use.
- This product is not intended for use in operating room or ICU
- This product is not intended for infant.

The device is intended to provide reference for medical diagnosis, not intended for a replacement of diagnosis clinicians.

Precautions

Radio Frequency (RF) interference between the iCV200S recorder or electrocardiograph and any existing RF transmitting or receiving equipment at the installation site, including electrosurgical equipment, in close proximity to the electrocardiograph should be evaluated before the equipment is operated as they may seriously degrade performance.

The iCV200S is susceptible to interference from RF energy sources (lowered RF immunity) which exceed the IEC 60601-1-2 limits, such as power line bursts, other medical equipment, cellular products, information technology equipment and radio/television transmission.

To reduce EMC interference the cardiograph shall be separated from the emitting sources as much as possible. If assistance is needed, call V&H service.

Artifact on the ECG caused by electromagnetic interference should be evaluated by a physician or physician authorized personnel to determine if it will negatively impact diagnosis or treatment.

Like all electronic devices, this electrocardiograph is susceptible to electrostatic discharge (ESD). ESD typically occurs when electrostatic energy is transferred to the patient, the electrodes, or the electrocardiograph. ESD may result in ECG artifact that may appear as narrow spikes on the cardiograph display or on the printed report. When ESD occurs, the electrocardiograph’s interpretation may be inconsistent with the physician’s interpretation.

V&H assumes no liability for failures resulting from RF or ESD interference between V&H CardioView series and any RF or ESD generating equipment when these levels exceed those established by applicable standard.

Warnings

The electrocardiograph has not been designed for use with high frequency (HF) surgical equipment and does not protect against hazards to the patient.
Ensure the location of the electrode and associated cables provides maximum separation away from all sources of HF energy. The best way to ensure patient safety is to completely remove all electrodes and cables from the patient when exposed to HF energy.
Other medical equipment, including but not limited to defibrillators, ultrasound machines, pacemakers, and other simulators, may be used simultaneously with the electrocardiograph. However, such devices may disturb the electrocardiograph signal.
Cannot touch the patient during Defibrillation.
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This device complies with Part 15 of the FCC Rules.
Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Warranty and Service

V&H provides a one-year warranty and life-time service to all CardioView series products. Repairs on products under warranty must be performed or approved by V&H. Unauthorized repairs will void the warranty. In addition, whether or not covered under warranty, any product repair shall exclusively be performed by V&H certified service personnel.

Limited warranty statement

The warranty will not cover the damages caused by:
1) Use or maintenance contrary to labeled instructions
2) Alteration or repair by anyone not authorized by V&H
3) Accidents.

Troubleshooting

Most of the problem can be solved by contacting V&H service department support@vhmedical.com. To get the prompt and efficient response you will provide:

- Product name and its serial number.
- A complete problem description
- The complete name, address and phone number of your facility
- For out-of-warranty repairs or spare parts order, a purchase order
- For parts order, the required spare or replacement part number

Product return

If the product has to be returned for service, V&H recommends these parking instructions:

- Wherever possible, use the original shipping carton and packing materials.
- Including a packing list.
- Including a problem description report.

It is recommended that all returned goods be insured. Claim for loss or damage to the product must be initialed by the sender.

Unit disposal Instructions

Disposal of battery and the unit after the end of device life in municipally approved recycling area. The life of device is 4 years.

Classification

Degree of protection against electrical shock	**Type CF, defibrillation-proof**
The power supply of ECG Acquisition box	**2XAAABattery**
Degree of protection against harmful ingress of water	**Enclosed equipment without protection against ingress of water**
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	**Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.**
Method(s) of sterilization or disinfection recommended by the manufacturer	**Sterilization: not applicable disinfection: see user manual**
Mode of operation	**Continuous operation**
The defibrillation-proof recovery time	**10s**

List of Symbols

Symbols	Meaning
	Caution, consult accompanying documents.
SN	Serial Number(xxxxxxxxxxxxxxx)
	Manufacturer
	Date of manufacture
EC REP	Authorized representative in the European community
CE0197	The CE marking with the Registration Number of the Notified Body. This denotes the compliance of European Medical Device Directive 93/42/EEC
	Waste Electrical and Electronic Equipment (WEEE) It is the responsibility of the end user to dispose of this equipment at a designated collection point for recycling.
	DEFIBRILLATION-PROOF TYPE CF APPLIED PART
	Bluetooth
	Function switch button
	Keep dry
5℃ 35℃	temperature limits
0 85	Indicates the range of humidity to which the medical device can be safely exposed.
IPX0	Against ingress of water with harmful effects : non-protected

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Warning: Warning statements describe conditions or actions that can result in personal injury or lost of life.

Caution: Warning statements describe conditions or actions that can result in damage to the equipment of software.

Note: Notes contain additional information on iCV200S usage.

1. iCV200S

- *iCV200S Rest ECG for iOS (iPad, iPad-mini and iPhone)*

Thank you for your purchase of iCV200S Resting ECG System and we hope that you will enjoy working with it. If you have any comments or suggestions, we would appreciate hearing from you. Please contact support@vhmedical.com

1.1 About iCV200S

iCV200S is a portable ECG system. It includes a data acquisition recorder and patient cable. The system is designed and manufactured by V&H, The ECG Acquisition System is capable of sampling, recording and analyzing patients resting ECG. This system is applicable to the heart disease analysis for the medical treatment institution.

Fig1.1 iCV200S Rest ECG Composition

1.2 List of packing

The ECG Acquisition Systems consists of the following items:

Part No.	Description	**QTY**
CV060F-010	ECG Acquisition Box	**1**
	iCV200Ssoftware (Note1)	**1**
M0201120	ECG cable	**1**
CV060F-060	User manual	**1**

Note1: About the software download please see 2.2 Download vhECG HD from Apple App Store.

1.3 Accessories

Item No.	Description	Intended Use
CV-022010-M0201120	ICV200S patient cable	Cables allow connection to the electrode leads, which adhere to the patient for detection of ECG signals
CV-021010-M0201044	Standard Patient Cable	
CV-040002	Battery	Power for ECG acquisition box

Note：

1. If any lead wire of lead part is failure, the user is unable to replace the lead wire, please contact with V&H.

2. If any lead wire of lead part is failure, the user can replace the standard 6511ECG cable, the ECG cable safety requirements tested for compliance with 93/42/EEC, should have the CE certificate. Vales & Hills recommends Qingdao Bright medical, the model is M0201020.If use the manufacturer approval attachment may reduce the safety of the products.

3.iCV200Sis powered by two AAA LR03 batteries.Insufficient of power may affect the communication between the recorder and iPad.Check the batteries with adequacy of power before using. If the power is low,the user can replace the new battery, Vales & Hills recommends the battery model is AAA LR03.

4. For the sake of environmental protection, please recycle disposal of the battery.

5. For products and accessories that are no longer used, it will be the cause of environmental pollution, it should be properly treated.

6. Do not include standard Patient cable and battery when we sale.

7. If you find anything above is not included in the packing, please contact us by the following address:

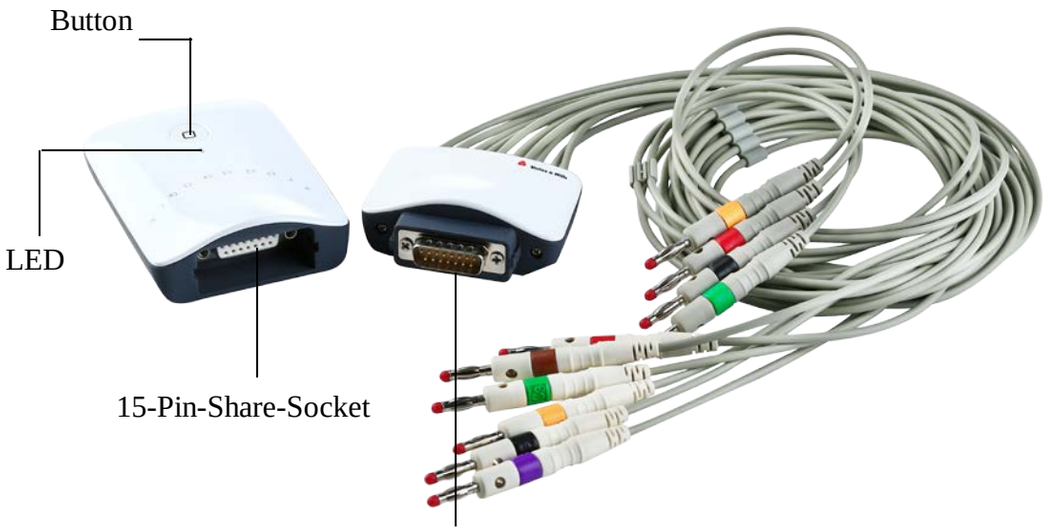
Technical Support Dept. of Vales & Hills Biomedical Tech. Ltd.
Tel:0086-010-51665548
E-mail:service@vhmedical.com
Website: http://www.vhecg.com
Fax:0086-010-67856343

2. Installation

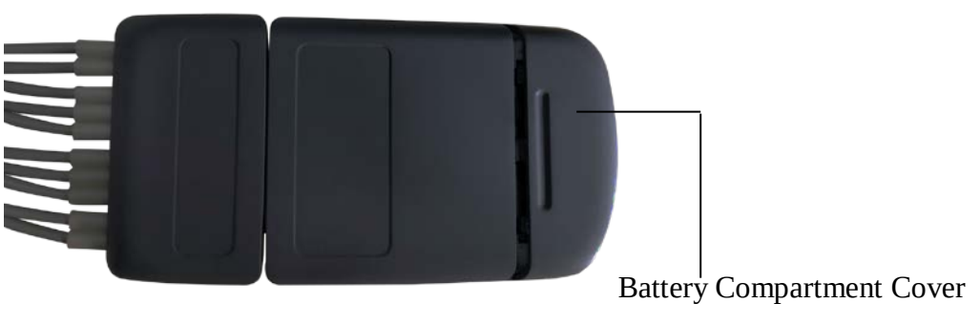
A complete iCV200S system consists of iCV200S data acquisition recorder and iPad or iPad-mini with Apple App – vhECG HD. This section will guide you iCV200S recorder composition and vhECG HD installation.

2.1Hardware Connection

iCV200S ECG Acquisition Recorder



iCV200S Recorder Frontside



iCV200S Recorder Backside

Fig 2.1 iCV200S Recorder

iCV200S Connecting further accessories

The illustration on the Fig2.2 show further accessories and the interface where they are connected.

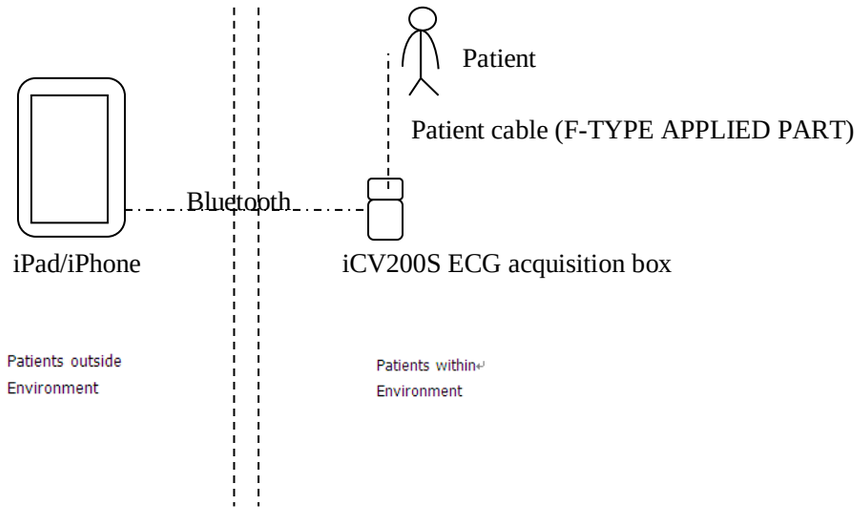


Fig 2.2

2.2. Download vhECG HD from Apple App Store

iCV200S Resting ECG System has its software running on iPad or iPad-mini named vhECG HD approved by Apple.

Purchase
Find vhECG HD in App Store and download it wth your Apple ID and registered credit card.

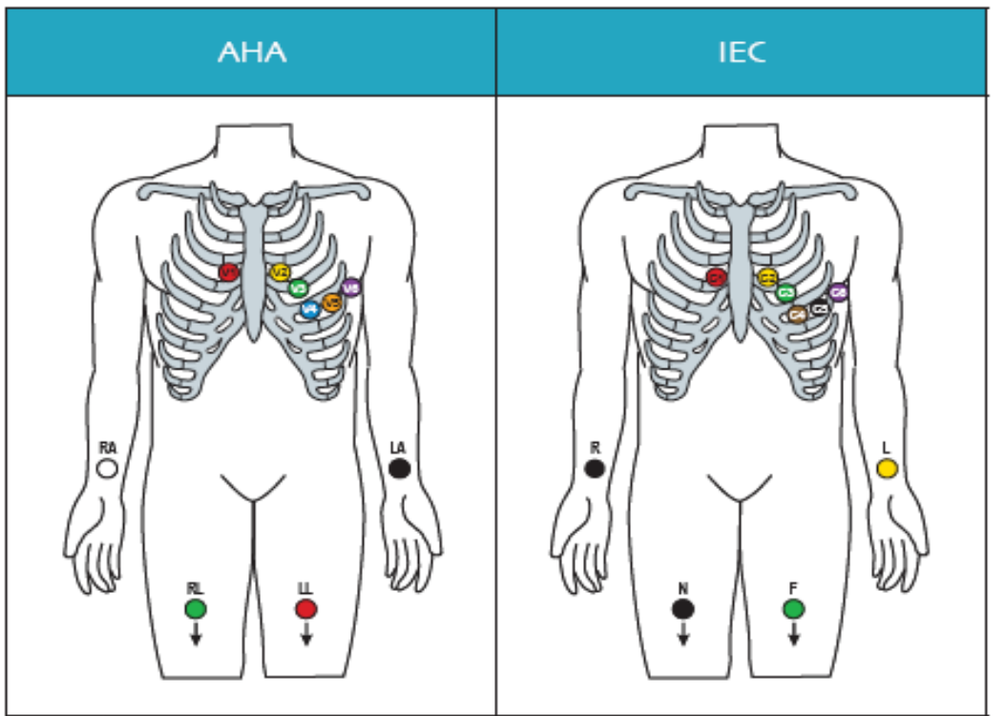
Free Download
If you have got a promotion code from V&H, you can use it to download vhECG HD to your iPad or iPad-mini free as following steps:

Step 1. Login with your Apple ID (Settings → Store). If you do not have an Apple ID, you can create one with your e-mail address.
Step 2. In AppStore, scroll to the bottom and find <Redeem> button.
Step 3. Click <Redeem>, and then enter your promotion code in the popup dialog.
Step 4. After step 3, you will be asked to enter your Apple ID password again.
Step 5. Download in process and you get vhECG HD

Note: The promotion code is valid within four weeks.You should download vhECG HD within this period.
If you have any questions about vhECG HD download, please contact support@vhmedical.com.

3. Electrodes Hookup

3.1 Hookup



V1	Fourth intercostal space at the right border of the sternum.	C1
V2	Fourth intercostal space at the left border of the sternum..	C2
V3	Midway between locations V2 and V4.	C3
V4	At the mid-clavicular line in the fifth intercostal space.	C4
V5	At the anterior axillary line on the same horizontal level as V4.	C5
V6	At the midaxillary line on the same horizontal level as V4 and V5.	C6
RA	Right arm	R
LA	Left arm	L
RL	Right leg	N
LL	Left leg	F

4. Getting Start

The communication between iPad and iCV200S Recorder is through Bluetooth.

iCV200S Resting ECG System for iPad is vhECG. It currently runs with the following languages:

- English
- 简体中文
- 繁體中文
- Français
- Español
- 日本語
- Türkçe

The running language of vhECG depends on your iPad language setting. The default language is English, that means if your iPad sets the language not belong to above selections, vhECG will run in English. vhECG will support more languages in progress. V&H appreciates your participations in vhECG development.

4.1 Recorder Setting

Referring to 2.1 to get the <terms> explaining.
The communication between iCV200S recorder and iPad is through Bluetooth.

Battery: Set two AAA batteries into the recorder.

<Button> Control:
Turn on: Click <button> to turn on the recorder.
Turn off: Keep press (two seconds) <button> to turn off the recorder.

<LED(Green)> State:
Off: The recorder is off.
On: The recorder is on.
Slow Flash (once four seconds): Power insufficient -- change the batteries.

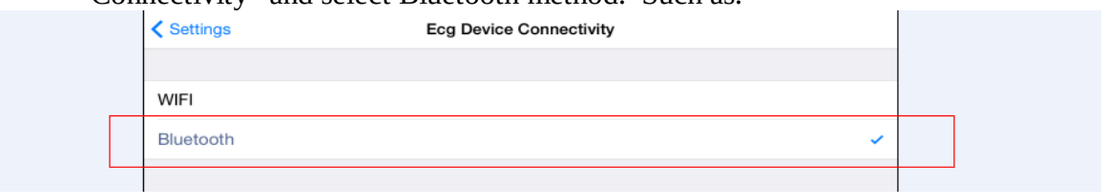
4.2 Communication between Recorder and iPad

Step 1: Turn on the recorder.

Step 2: Click " " on iPad to enter settings.

Step 3: Click " Bluetooth " on iPad. To enable bluetooth function of the iPad device.

Step 4: Open the vhECG software . Click to enter vhECG settings, then click " ecg Device Connectivity" and select Bluetooth method. Such as.



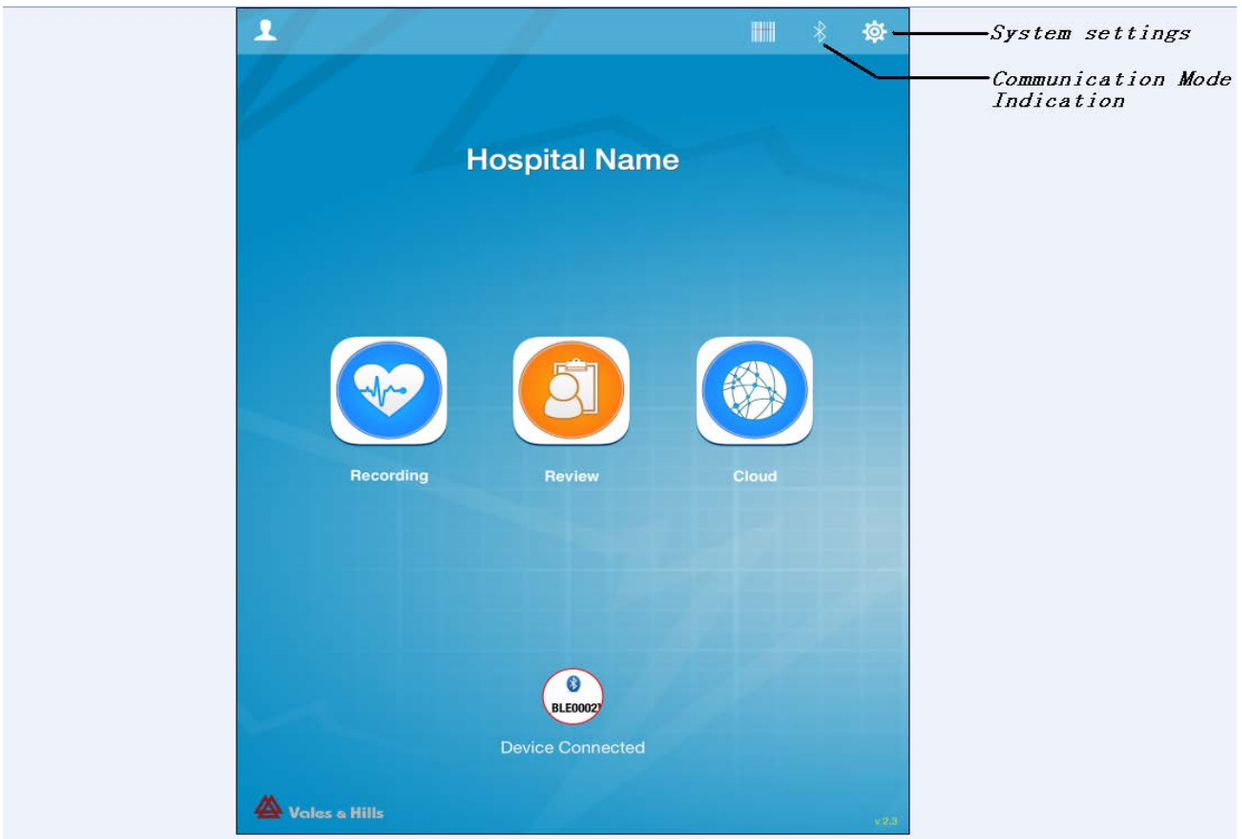
Step 5: Come back to the home page ,click on the top-right corner of your iPad.
When the connection is successed, you will see "Device Connected" at the bottom of your iPad.
Click the round icon with numbers to start work.

Note: the last five digits of the device will show on the bottom of your iPad, you need to select the same device number on the iPad with your recorder.

5. vhECG Rest ECG System

vhECG is designed as an easy using application program which offers professional ECG tools and fantastic user experience. Most of its usages follow to iOS operating style. If you are familiar with any Apple App and have a general knowledge of ECG, you will have no problem and be happy working with vhECG.

Click iPad App icon to enter vhECG Resting ECG System.



5. 1 System Settings

You can customize your vhECG to your own preference. Click Fig 5.2 to enter vhECG Settings which consist of four parts:

1. General
Hospiomtal Name - Input your hospital or organization name, etc. ①
Doctor Name - vhECG user's name

2. Live Monitor
Use Demo Data - ON/OFF: Use DEMO data in monitoring
New Born Baby Mode – Select a set of chest leads for newborns
Recording Time – Time of recording: 10-30 seconds
Lowpass – Cutoff frequency of low-pass filter: 30-250Hz, default: 70Hz
AC Notch – OFF/50/60(Hz): to eliminate power-line interference
Baseline Wander Erase – ON/OFF: to keep the baseline stable②
EMG Filter –ON/OFF: to remove muscle noise from ECG signal③
Patients Queue Mode –ON/OFF: ON for patients collected recording④

3. Communication
ECG Device Connectivity – BLE
Device SN Last Digit – the last digit of your iCV200S recorder's serial number
ECG Cloud / FTP Address – ECG Network (e.g. www.vhcloud.net)

4. Report
To custom the printing form:
Report Title – Title on the print report
Report Format – PDF or JPEG
Lead Layout – 1×12 or 2×6
Paper Orientation – A4 or B5, Portrait or Landscape
Print Grid – ON / OFF: with or without grid in printing report

① If you have registered in an ECG Network (e.g. vhCloud) group, the group name has its priority. To restore the input name you should exit from the group.
② This function can efficiently remove baseline wandering due to respiration or body movement without impacting ECG frequency response, such as ST segment. The function works only to ECG signal with QRS complex exist, that means it is not applicable to signals like square or sine waves, etc.
③ Patented by V&H. Muscle noise can be removed by setting LPF with low cutoff frequency but it will severely affect ECG high frequency component such us QRS complex. vhECG EMG filter can effectively remove muscle noise with little affection to ECG signal.
④ With Patient Queue Mode, vhECG asks you to pre-collect a queue of patients, from HIS or manual input, before recording. It is for a convenient using when there is a set of patients' ECGs to be recorded and sent to ECG Network for diagnosing. When you click, you will get fig5.2 to set up your patient list.

Fig. 5.2 Patients List

5.2 Patient Records Archive

This section shows how to create a new patient record or assign the recording ECG data to an existing patient. You can do it either in ECG "Recording" or "Reviewing" at any time by click or in fig5.1.
Create a new patient record:

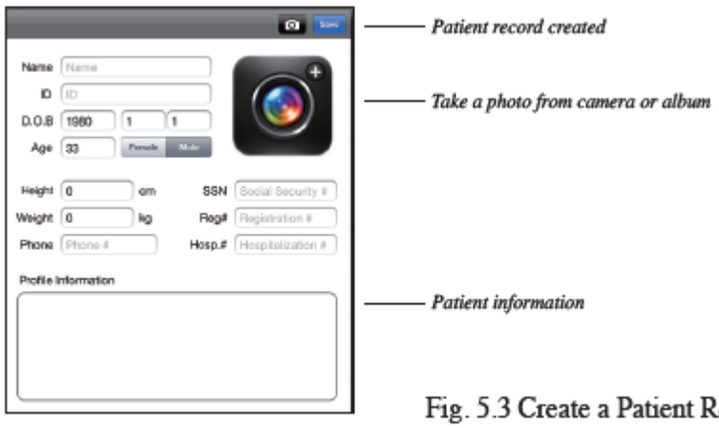


Fig. 5.3 Create a Patient Record

5.3 Monitoring and Recording

This section shows how to record ECGs.
1. Place the electrodes on the patient
2. Turn on the recorder and make sure it is connected to iPad with BLE.
3. Click to start recording

Fig. 5.4 Recording

Display Layout: 12×1, 6×2 and 3×4 display formats switch. In 3×4 format there is a rhythm strip (default: lead-II) at the bottom. You can switch to any other lead as rhythm strip by click the lead window.

Display Gain: You can change the ECG gain (5mm/mV, 10mm/mV and 20mm/mV) by two fingers sliding.

Recording and Save: Click ● to start recording while the ECG signal displayed stably. When the recording finished, you get a window pop-up with three selections:
*** Record Next:** Record the next ECG while #numerical order plus one
*** Review Now:** Enter "5.4.2 ECG Reviewing" page to review the current ECG recorded
*** Return:** Return to the main menu

Note: The duration of the record for 8s.

Restart Recording: Double click the screen to restart recording when you find the ECG signal not good.

Leadoff: iCV200S has the function to detect electrode disconnect. When there is any electrode disconnected, the color of the lead name in its related window(s) will turn in red with a mark [×] and the trace shows zero-line.

5.4 Records Review

5.4.1 Patient Records State

Click to select a record to review when at "Select Mode", or select records to delete when at "Cancel" (Top-Right corner button)

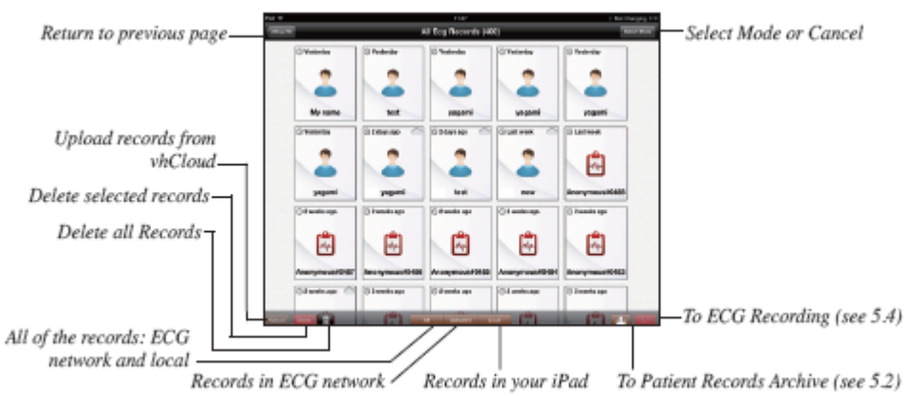


Fig5.5 Recorder List

5.4.2 ECG Reviewing

vhECG offers various views on an ECG with automatic parameter measurements and diagnostic interpretations. vhECG also offers effective tools for you to measure parameters and edit interpretations.

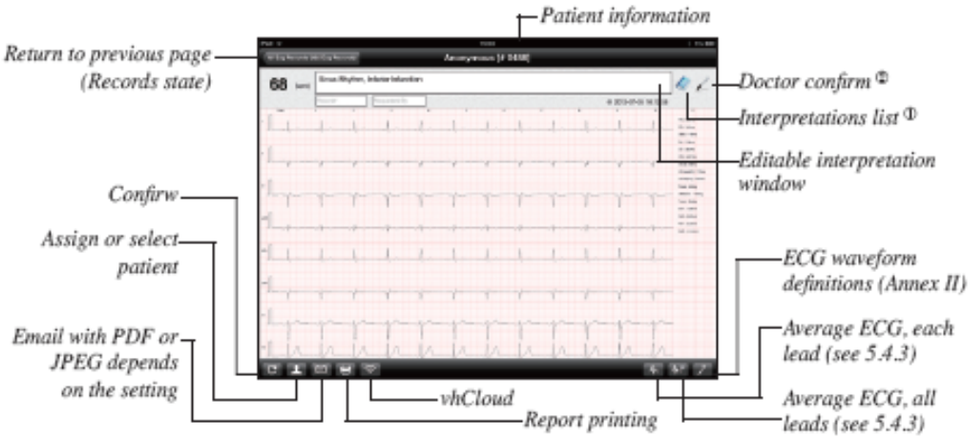


Fig. 5.6

①Interpretations list:You can select the diagnostic terms from the list when you edit your ECG diagnosis（See Fig.5.7）.

②Doctor confirm: Sign your name to confirm the diagnosis. The signature is keeped for printing and email(See Fig.5.8).

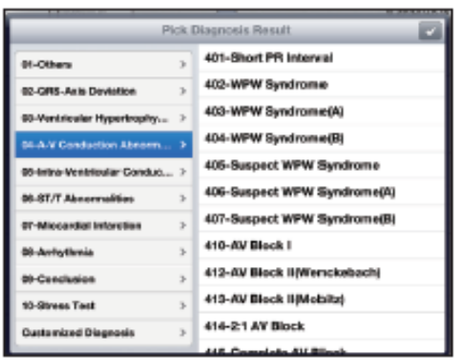


Fig. 5.7 Interpretations List

Fig. 5.8 Signature

Tips:

1.) Zoom: With two fingers sliding to zoom in and zoom out ECG display.
2.) Gain: Double click the screen with one finger to change the ECG gain.
3.) Speed: Double click the screen with two fingers to change the ECG speed.

5.4.3 Average ECG

Average ECG is calculated the dominant beats of the recorded ECG based on QRS complex morphology. vhECG offers two forms of average ECG, single lead average ECG and superimposition average ECG of 12 leads for your convenient using.

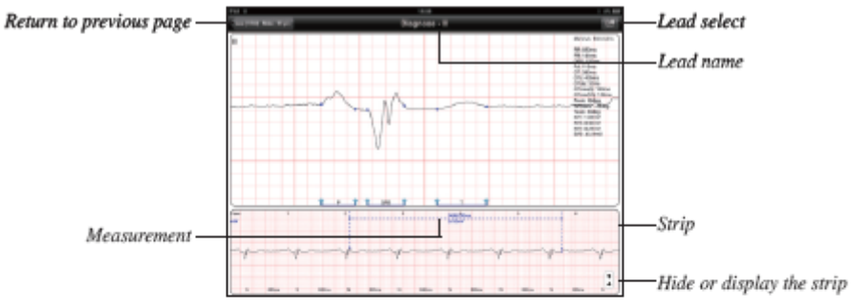


Fig. 5.9 Single Lead Average ECG

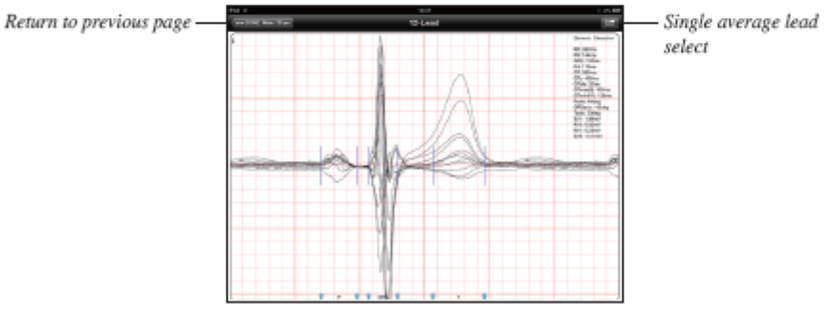


Fig. 5.10 Superimposition Average ECG

Marks positioning:
There are three sets of marks: P(onset, offset), QRS(onset, offset) and T(offset). You can adjust the mark by moving your finger. To delete a set of marks: move it to the rightmost of the screen. To add a set of marks: move your finger from the rightmost to left. The related parameters will be corrected simultaneously while the mark position(s) in changing.

Measurements:
You can measure the distance (in ms) and the gain (in mV) of the two points either on average ECG or ECG strip conveniently by sliding your two fingers (V&H patented). See Fig. 5.9

5.5 vhCloud

vhECG is a full functional ECG network designed on group permissions by V&H. Depends on your authority in the group you are belonging, you can store, achieve, diagnose and share the ECGs in the group. For more information, please contact support@vhmedical.com

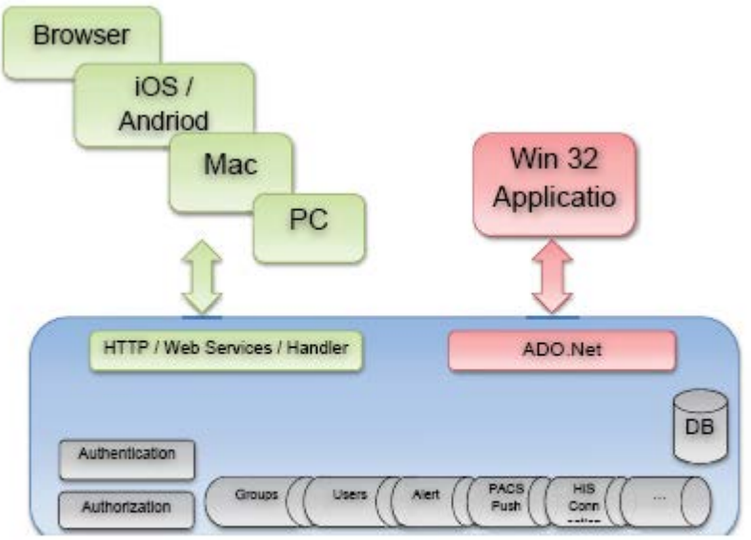


Fig. 5.11 vhCloud Architecture 1.0

6. Cleaning and Maintenance

It is recommended to check your iCV200S regularly to keep it in perfect condition.
Note: Only the qualified personnel authorized by V&H may service iCV200S.

Cleaning

- Use a moist cloth to wipe the recorder surface and patient cable cleaning. Do not allow liquids to enter the recorder. All cleaning agents and disinfectants without alcohol commonly used in hospitals are suitable. If liquids have entered the recorder, notify Service to have the system inspected for damage before it is used again.
- DO NOT use disinfectants with a phenol base or peroxide compounds to disinfect the external surfaces.

Note: When pull off the cable from the recorder, be sure to hold the plug, not the cable.

Battery Care

If a longer period of time without using ECG acquisition box, remove the battery to avoid battery leakage risk.

Important: For environment protection, please disposal the used batty to the recycling bin.

Operating Environment
Temperature: 5℃～35℃
Humidity: 25%～95%
Pressure :860hPa～1060hPa
Transport and Storage
Temperature: -20℃～55℃
Humidity: <93%
Pressure :860hPa～1060hPa

Troubleshooting

The following table contains a list of iCV200S recorder troublesome scenarios accompanied by suggestions for problem solving.

Trouble	Responses to the trouble
Cannot Start	Check the batteries to have sufficient power.
Cannot connet to iPad	● Check your iPad setting statues at the correct mode. ● Keep your iPad and Recorder in a reasonable distance, recommend visual distance: five meters, but it is some extent dependent on the environment around. ● Check the router if the recorder at Net-work mode.
With a fixed ECG signal	Your vhECG is in DEMO mode. Enter your iPad vhECG's setting part and set "Use Demo Data" OFF.
Without ECG signal or with too much noise	● Check the connection between the recorder and patient cable ● Check the connection between the patient cable and electrodes ● Check the connection between the electrodes and patient skin ● Skin treatment if necessary ● Check if there are forceful electrical power or strong magnetic field around

7. Guidance and Manufacture's Declarations

Declarations:

- iCV200Sneeds special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the User Manual;
- Portable and mobile RF communication equipment can affect iCV200S.

Electromagnetic emissions

iCV200S is intended for use in the electromagnetic environment specified below. The customer or the user of iCV200S should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	iCV200Suses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	iCV200Sis suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Electromagnetic immunity

iCV200S is intended for use in the electromagnetic environment specified below. The customer or the user of the ECG Acquisition Systems should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = [\frac{3,5}{3}]\sqrt{p}$ 80 MHz to 800 MHz $d = [\frac{7}{3}]\sqrt{p}$ 800 MHz to 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the iCV200S is used exceeds the applicable RF compliance level above, iCV200S should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ECG Acquisition Systems. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			

Recommended separation distances between portable and mobile RF communication equipment and iCV200S

iCV200S is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of iCV200S can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and iCV200S as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150Hz to 80MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3,5}{E_1}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.117	0.117	0.2333
0.1	0.36999	0.36999	0.73681
1	1.17	1.17	2.33
10	3.69986	3.69986	7.36811
100	11.6667	11.6667	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Annex I: iCV200S ECG Recorder Technical Specifications

- Sampling Rate:
  A/D: 24K/SPS/Ch
  Recording: 1K/SPS/Ch
- Quantization Precision:
  A/D: 24Bits
  Recording: 16Bits
- Resolution: 0.4μV
- Common Mode Rejection: >90dB
- Input Impedance: >20MΩ
- Frequency Response: 0.05-150Hz
- Time Constant: ≥3.2 Sec.
- Maximum Electrode Potential: ±300mV
- Dynamic Range: ±15mV
- Defibrillation Protect: Build-in
- Data Communication: BLE
- Power: 2×AAA(LR03)
- Recovery time after defibrillation：≤10S

Annex II: Definitions and Rules for ECG Measurements

1. ECG Waveform and Contour Classification

The ECG waveform consists of P-QRS-T complex which measured as:

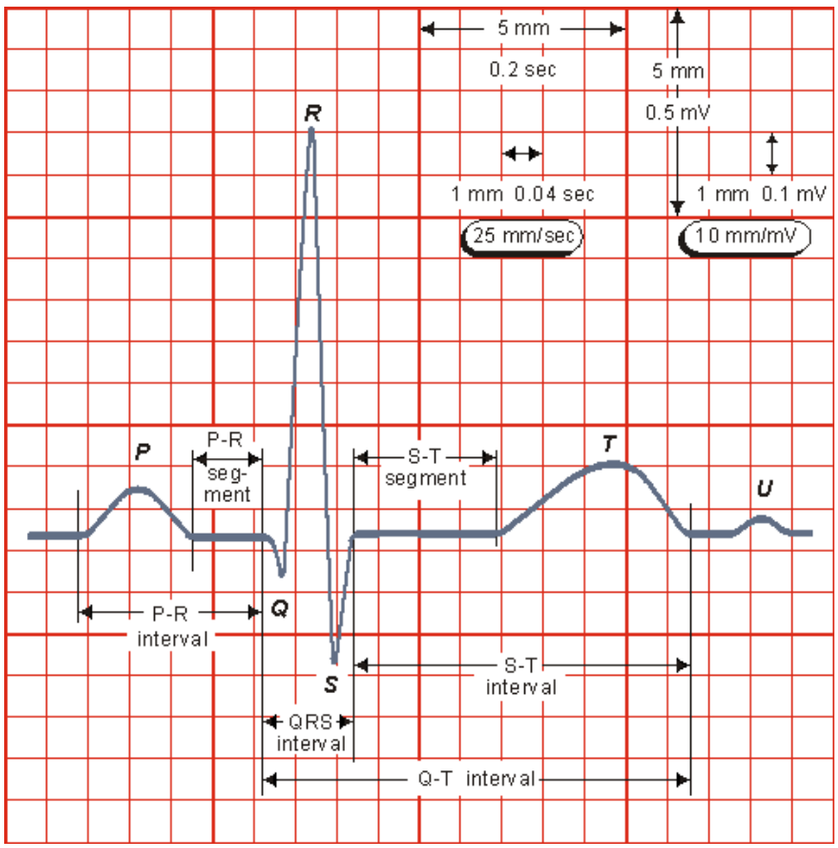
P-onset, P-offset：	Pb, Pe
QRS- onset, QRS- offset：	Qb, Se(J)
T- offset：	Te

Note: Globally, i.e. for all LEADS valid, Durations or intervals of P-QRS-T are defined, based on physiological reasons, by the earliest onset (for ST interval, the latest offset) of any LEAD to the latest offset (for PR interval, the earliest onset) of any other LEAD.

All parameters used in the diagnostic criteria of the contour classification are measured in the representative P-QRS-T complex. The lead-independent, overall parameters are presented in the table bellowing:

Name	**Descriptions**
Heart Rate	Ventricular rate (in beats per minute, bpm)
P duration	From P-onset to P-offset (in ms)
PR interval	From P-onset to QRS-onset (in ms)
QRS duration	From QRS-onset to QRS-offset (in ms)
QT interval	From QRS-onset to T-offset (in ms)
Corrected QT interval	QT interval correct for heart rate: QTc=QT*√(HR/60) (in ms)
P/QRS/T axis	Axis of P, QRS or T wave (in degree, from -180°to 180°)

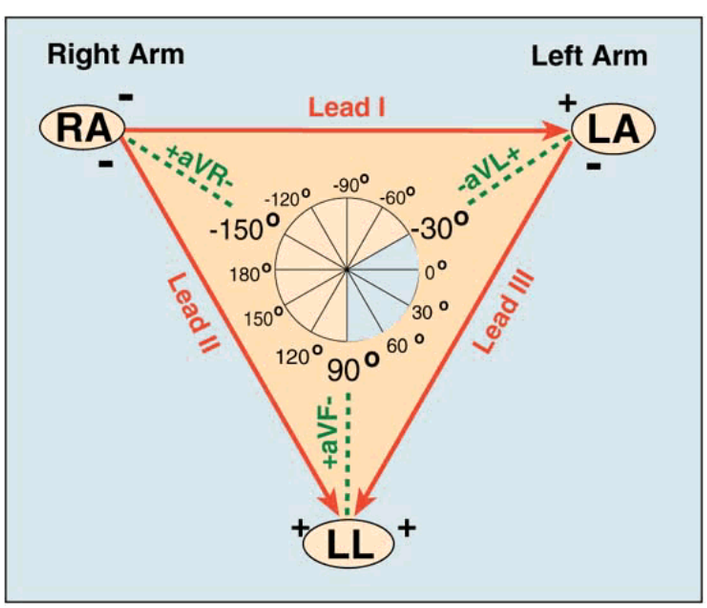
2. Duration and Amplitude Measurements



Normal electrocardiogram

Isoelectric segment: value of midpoint between P-offset and QRS-onset

3. ECG Axis



P/QRS/T axis is calculated based on Einthoven Triangl

4. Acceptance of minimum waves

The labeling of the QRS complex depends by definition on the first wave detected. A tiny positive wave at beginning is called r or R following Q and may mask a true. The acceptance criteria of initial waveforms should be clearly defined and standardized. The rule for acceptance of minimum waves is: the signal with amplitudes smaller than 20uV cannot be accepted.

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: 1) this device may not cause harmful interference, and 2) this device must accept any interference received, including interference that may cause undesired operation.
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.