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K152384

Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120, China

FDA/CDRH/DCC
AUG 24 2015
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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66 G609
10903 New Hampshire Avenue
Silver Spring, MD 20993 0002

08/04/2015

RE: Premarket Notification Traditional Section 510(k) Submission
Shenzhen Biocare Bio-Medical Equipment Co., Ltd(***the Sponsor***)
Digital Electrocardiograph, ECG-2000(***the Device(s)***)

Dear Madam/Sir,

In accordance with Section 510(k) of the Federal Food and Drug Cosmetic Act, and in conformance with Title 21 CFR, Part 807, this Pre-market Notification is being submitted at least ninety (90) days prior to the date when the sponsor proposes to introduce its device(s) into interstate commerce for commercial distribution.

The CD-ROM provided with the submission is the eCopy of the submission; the eCopy is an exact duplicate of the paper copy.

If you have any question, please contact me vie email at info@mid-link.net or via fax at (240) 238-7587.

Thanks for your help.

Best Regards,

Lee Fu

for Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

Enclosures

Template Rev 1.0 03/26/2013

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MID-LINK
www.mid-link.net info@mid-link.net

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2	FDA FORM 3514 CDRH Premarket Review Submission Cover Sheet
3	FDA FORM 3674 Certificate of Compliance for Clinical Trials
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5	Cover Letter
6	FDA FORM 3881 Indications for Use
7	510(k) Summary
8	Truthful and Accurate Statement
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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
SHENZHEN BIOCARE BIO-MEDICAL EQUIPMENT CO., LTD #A735 SHENZHEN MINGYOU INDUSTRIAL PRODUCTS EXHIBITION & PROCUREMENT CENTER BAO'AN 518105 SHENZHEN CHINA CN	Wang Li 2.1 E-MAIL ADDRESS xiuli.wang@mid-link.net 2.2 TELEPHONE NUMBER (include Area code) 86-21-64264467 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****6539	

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD155220

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE

EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 14-Jul-2015

Form FDA 3601 (05/13)

"Close Window" Print Cover sheet

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0616. Expiration Date: 2/28/2015. See PRA Statement on page 2.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
Shenzhen Biocare Bio-Medical Equipment Co., Ltd

2. Date of the Application/Submission Which This Certification Accompanies
07/27/2015

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
No. 168 Baoyuan Road, Baoan

Address 2 *(Apartment, suite, unit, building, floor, etc.)*
Room A735, Floor 7, Tower A, Shenzhen Famous Industrial Products Procurement & Exhibition Center

City: Shenzhen
State/Province/Region: Guangdong
Country: China
ZIP or Postal Code: 518102

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*
(Tel): +86-755-36615333
(Fax): +86-755-27960643

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

Common Name: Electrocardiograph

Classification: II

Trade Name: Digital Electrocardiograph, ECG-2000

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(If number previously assigned)*

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(J)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. *(Add continuation page as necessary.)*

NCT Number(s): _____ _____ _____ _____ _____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Hongbo Zhong	R&D Director

12. Address

Address 1 *(Street address, P.O. box, company name c/o)* No. 168 Baoyuan Road	
Address 2 *(Apartment, suite, unit, building, floor, etc.)* Room A735, Floor 7, Tower A, Shenzhen Famous Industrial Products Procurement & Exhibition Center	
City: Shenzhen	State/Province/Region: Guangdong
Country: China	ZIP or Postal Code: 518102

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): +86-755-36615333

(Fax): +86-755-27960643

14. Date of Certification

07/27/2015

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative *(Sign)*

Sign

Hongbo Zhong

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*****DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*****

The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-2-25 (Edition 2.0) 2011: medical electrical equipment - part 2-25: particular requirements for the basic safety and essential performance of electrocardiographs. (Cardiovascular)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#3-105	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☒
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-2-25 (Edition 2.0) 2011: medical electrical equipment - part 2-25: particular requirements for the basic safety and essential performance of electrocardiographs. (Cardiovascular)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.4	General requirements	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
201.5	General requirements for testing of ME EQUIPMENT	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
201.6	Classification of ME EQUIPMENT and ME SYSTEM	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-2-25 (Edition 2.0) 2011: medical electrical equipment - part 2-25: particular requirements for the basic safety and essential performance of electrocardiographs. (Cardiovascular)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.7	ME EQUIPMENT identification, marking and documents	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
201.8	Protection against electrical HAZARDS from ME EQUIPMENT	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
201.12.1	Accuracy of controls and instruments	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
201.12.4	Proctection against hazardous output	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-2-25 (Edition 2.0) 2011: medical electrical equipment - part 2-25: particular requirements for the basic safety and essential performance of electrocardiographs. (Cardiovascular)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
202	Electromagnetic compatibility- Requirements and tests	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

Tab #5 Cover Letter

1. Date of Submission: 08/04/2015

2. Sponsor Identification

Shenzhen Biocare Bio-Medical Equipment Co., Ltd.
Room A735, Floor 7, Tower A,
Shenzhen Famous Industrial Products Procurement & Exhibition Center,
No. 168 Baoyuan Road, Baoan, Shenzhen, 518102, P.R. China

Establishment Registration Number: 3008457078

Contact Person: Mr. Hongbo Zhong
Position: Director
Tel: +86-755-36615333-8856
Fax: +86-755-27960643
Email: hb-zhong@tom.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Lee Fu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 240-238-7587
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Digital Electrocardiograph
Model: ECG-2000
Proposed Device Common Name: Electrocardiograph

Regulatory Information:
Classification Name: Electrocardiograph
Classification: II;
Product Code: DPS;
Regulation Number: 21 CFR part 870.2340;
Review Panel: Cardiovascular;

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Intended Use:

Digital Electrocardiograph is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

Table 1 Design and Use of the Proposed Device

Question	YES	NO
Are the devices intended for prescription use (21 CFR 801 Subpart D)?	X	
Are the devices intended for over-the-counter use (21 CFR 807 Subpart C) ?		X
Do the devices contain components derived from a tissue or other biologic source?		X
Are the devices provided sterile?		X
Are the devices intended for single use?		X
Are the devices the reprocessed single use devices?		X
If yes, do these devices type require reprocessed validation data?	N/A	
Do the devices contain a drug?		X
Do the devices contain a biologic?		X
Do the devices use software?	X	
Does the submission include clinical information?		X
Are the devices implanted?		X

5. Submission Type

Traditional;

6. Basis of the submission

Additional or Expanded Indications

7. Prior Related Submission

There was a pre-submission (510(k)) submission related to the proposed device, K133985. During the previous submission, the reviewer requested that:
In the performance test report that you have provided you used CAL30000 for calibration (p.10/18 Tab 16. performance). Per the IEC 60601-2-25 standard digit 3 characterizes the QRS-form (0 = RS, 1 = R, 2 = QS, 5 = small RS (approx. pediatric ECG); hence CAL20500, and CAL20502 are the calibrations for pediatric use (please refer to the standard Annexes GG and HH). Moreover you marked the pediatrics applicable subclasses mentioned in Table GG.1 for pediatric test cases as N/A

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The requested test was not completed at that time, therefore, the target population of pediatric patients was removed from the previous submission.

The test has been completed and this submission is filed to include the pediatric patients into the intended use of the device.

Except for the intended use, the proposed device is **exactly identical** to the device cleared under K133985, concerning both hardware and software.

8. eCopy Statement

The CD-ROM provided with this submission is the eCopy of the submission; the eCopy is an exact duplicate of the paper copy.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Tab #7 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. Date of Preparation: 08/04/2016

2. Sponsor Identification

   Shenzhen Biocare Bio-Medical Equipment Co., Ltd.
   Room A735, Floor 7, Tower A,
   Shenzhen Famous Industrial Products Procurement & Exhibition Center,
   No. 168 Baoyuan Road, Baoan, Shenzhen, 518102, P.R. China

   Establishment Registration Number: 3008457078

   Contact Person: Mr. Hongbo Zhong
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   Tel: +86-755-36615333-8856
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3. Designated Submission Correspondent

   Ms. Diana Hong (Primary Contact Person)
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   P.O. Box 120-119, Shanghai, 200120, China

   Tel: +86-21-22815850,
   Fax: 240-238-7587
   Email: info@mid-link.net

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4. Identification of Proposed Device

Trade Name: Digital Electrocardiograph
Model: ECG-2000
Proposed Device Common Name: Electrocardiograph

Regulatory Information:
Classification Name: Electrocardiograph
Classification: II;
Product Code: DPS;
Regulation Number: 21 CFR part 870.2340;
Review Panel: Cardiovascular;

Intended Use:

Digital Electrocardiograph is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

Device Description

Digital Electrocardiograph, ECG-2000, is intended to acquire ECG signals from adult patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease.

It consists of the acquisition box, optional accessories, installation CD, and USB dongle. The acquisition box is connected with ECG electrodes, and intends to acquire ECG signals from patient. The acquired ECG signal is filtered and amplified, then transferred to the working station. The acquisition box is powered by the working station via a USB line. The working station is a Personal Computer installed with ECG-2000 Software, it intends to receive the processed ECG signal from the acquisition box, and further display and record the signals. Optional accessories include lead wires, limb electrodes and chest electrodes, and general-purpose printer (with USB interface, support PCL language, such as HP1010, P2035, and P2055d series). The CD contains Digital Electrocardiograph installer and dongle installation program module.

5. Identification of Predicate Device(s)

Predicate Device 1
510(k) Number: K092010
Product Name: PC ECG
Manufacturer: Edan Instruments, Inc.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Predicate device 2
510(k) Number: K133985
Product Name: Digital Electrocardiograph, ECG-2000
Manufacturer: Shenzhen Biocare Bio-Medical Equipment Co., Ltd.

6. Non-Clinical Test Conclusion

This submission is filed for extension of intended use, the device, including its hardware and software, has not been changed from the one cleared in the previous submission, K133985; therefore, only the following standard was tested to verify that the device can meet its additional intended use:

IEC 60601-2-25: 2011, Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device1	Predicate Device 2
Product Code	DPS	Same	Same
Regulation Number	21 CFR 870. 2340	Same	Same
Class	Class II	Same	Same
Intended Use	Digital Electrocardiograph is intended to acquire ECG signals from adult patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.	Same	Similar
Configuration	Chest Electrode and Limb Electrode	Same	Same
ECG Lead	Standard 12-lead	Same	Same
ECG Gain	1.25, 2.5, 5, 10, 20, 10-5, 20-10 (mm/mV)	Similar	Same
Sampling rate	1000Hz	Same	Same

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Input circuit current	≤0.1 μA	Similar	Same
Noise level	<15μ Vp-p	Similar	Same
Electrical Safety	Comply with IEC 60601-1	Same	Same
EMC	Comply with IEC 60601-1-2	Same	Same
Patient-contact Material	Chest Electrode: Metal Limb Electrode: ABS	Same	Same

The proposed device provides more options for gains than those of the predicate device 1, therefore, this difference will not affect the safety and effectiveness;

The proposed device provides a wider range of bandwidth than that of the predicate device 1. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

The noise level and input circuit current of the proposed and predicate device 1 are different, however both the specifications comply with IEC 60601-1.

9. Substantially Equivalent (SE) Conclusion

The proposed device, Digital Electrocardiograph EG-2000, is determined to be Substantially Equivalent (SE) to the predicate devices, PC ECG (K092010) and Digital Electrocardiographs ECG-2000 (K133985), in respect of safety and effectiveness.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Tab #8 Truthful and Accurate Statement

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as R&D Director of Shenzhen Biocare Bio-Medical Equipment Co., Ltd. I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Hongbo Zhong

Authorized Signature
Hongbo Zhong
R&D Director
Shenzhen Biocare Bio-Medical Equipment Co., Ltd
July 27, 2015

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Tab #9 Device Descriptions

1. General Description 2
2. Device Illustrations and Design Drawing 3
3. Design Description 4
   - 3.1 Design Description of Acquisition Box 4
   - 3.2 Design Description of Working Station 6
4. Accessories 7
   - 4.1 Description of Chest Electrode 7
   - 4.2 Limb Electrode 8
   - 4.3 Cables 8
5. Specifications 11

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1. General Description

Digital Electrocardiographs, ECG-2000, is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease.

There is no specific contraindication identified for the proposed devices.

The proposed model acquires ECG electrical signals from patient body surface by ECG electrodes. After been amplified, filtered and transferred, the ECG signal waveforms are displayed on the LCD and recorded on the paper through thermal printer.

The illustration and design drawing is provided in ***Section 2 Illustration and Design Drawing.*** The illustration and design drawing of accessories are provided in ***Section 4 Accessories.***

Digital Electrocardiograph consists of two components, which are (1) Acquisition Box and (2) Working Station. The acquisition box is connected with ECG electrodes, and intends to acquire ECG signals from patient. The acquired ECG signal is filtered and amplified, then transferred to the working station. The acquisition box is powered by the working station via a USB line. The working station is a Personal Computer installed with ECG-2000 Software, it intends to receive the processed ECG signal from the acquisition box, and further display and record the signals. In addition, it also provides the power supply to the box. The detail description of the two components is included in ***Section 3 Design Description.***

Digital Electrocardiograph consists of the acquisition box, optional accessories, installation CD, and USB dongle. Optional accessories include lead wires, limb electrodes and chest electrodes, and general-purpose printer (with USB interface, support PCL language, such as HP1010, P2035, and P2055d series). The CD contains Digital Electrocardiograph installer and dongle installation program module.

The accessories include limb electrodes and chest electrodes, which are detail discussed in ***Section 4 Accessories.***

The proposed device does not have any automated analysis and measurement feature, and other unique feature compared with other legally marketed Electrocardiograph.

The device can be programmed by the end user, who can only operate the device via the keys per the instructions specified in User Manual.

Device specifications are presented in ***Section 5 Specifications***.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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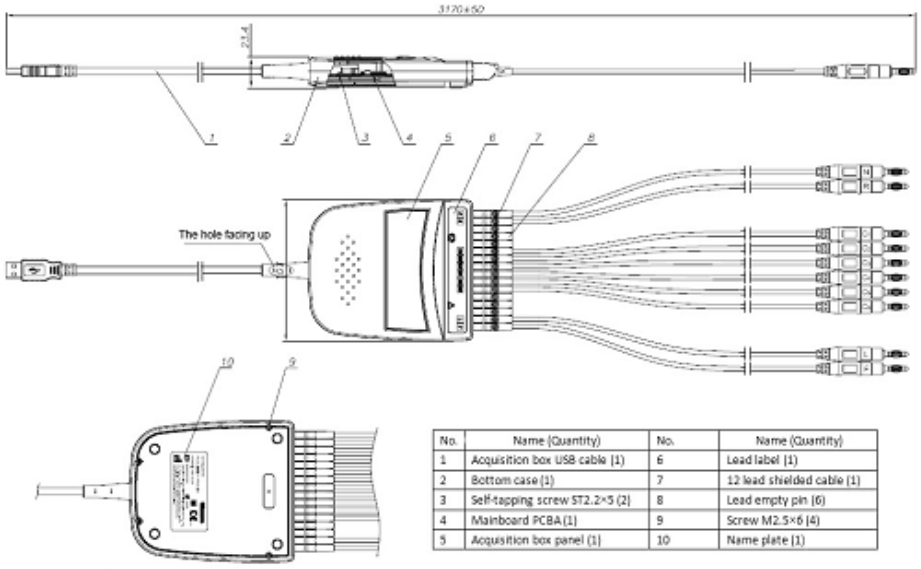
2. Device Illustrations and Design Drawing

Fig 1 Device Illustration, ECG-2000

Fig 2 Design Drawing, ECG-2000



No.	Name (Quantity)	No.	Name (Quantity)
1	Acquisition box USB cable (1)	6	Lead label (1)
2	Bottom case (1)	7	12 lead shielded cable (1)
3	Self-tapping screw ST2.2×5 (2)	8	Lead empty pin (6)
4	Mainboard PCBA (1)	9	Screw M2.5×6 (4)
5	Acquisition box panel (1)	10	Name plate (1)

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3. Design Description

3.1 Design Description of Acquisition Box

The acquisition box consists of three parts, which are power supply, analog circuit and microprocessor (MCU);

The box can be connected with working station via the USB interface, where it obtains the power supply. The power will be converted by isolated DC/DC, and then be transferred to analog circuit and digital circuit. In addition, the box can be connected with ECG electrodes via lead. The bio-electrical signal collected from the human skin by electrodes will be converted into digital signals through the analog circuit, and then be transferred to the MCU. The MCU will further process the signals and then transfer the signals to the working station through the isolation and USB interface.

Fig 3 Block Diagram, Acquisition Box

(b)(4)

Description of Power Supply

DC/DC isolated power supply is supplied by USB 5V power supply provided by the working station, which can produce +5V power supply.

+5V isolated power supply can supply +3.3V digital power supply to the digital circuit of acquisition box through digital power supply circuit. At the same time, it can supply two sets of analog power supply of +2.5V and -2.5V to analog circuit of acquisition box as shown in Fig 4 Block Diagram of Power Supply.

Fig 4 Block Diagram, Power Supply

(b)(4)

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Description of Analog Circuit

Analog circuit of acquisition box consists of input protection circuit, low-pass filter, driven-right-leg circuit and electrical analog integration chip. The ECG analog signals will be transferred to the input protection circuit and the low-pass filter circuit through lead cables, and then be input into ECG analog integration chip, which will transfer the signal into digital form, and transfers the digital ECG data to microprocessor through SPI interface.

Fig 5 Block Diagram, Analog Circuit

(b)(4)

Description of MCU

The microprocessor system consists of microprocessor, reset circuit, and clock circuit and data memory. The reset circuit provides reset signals for microprocessor; clock circuit provides clock signals for microprocessor; while the data memory provides the memory space for data calculation. Microprocessor obtains the ECG data from ECG analog integration chip through SPI interface and performs pre-processing, then transfer the signal to working station.

Fig 6 Block Diagram, MCU

(b)(4)

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3.2 Design Description of Working Station

The ECG 2000 software is installed in a PC complied with the following requirements:

Computer
CPU: P4 2.0 GHz or above;
HDD: 80 GB or above;
Memory: 512 MB or above;
High-resolution color display: 1024 x 768 or above;
Printer: resolution ≥ 600 dpi, laser printer or high-quality inkjet printer is recommended (dot matrix printers are not compatible);

Software environment
Windows Vista.
DirectX 9.0c drivers
OFFICE 2000 ACCESS
OFFICE 2000 WORD

The software has the following function:

a. It can set patient record;
b. It can receive the ECG signals from the box;
c. It can store the collected signals;
d. It can playback the stored signals;
e. It can process the signals for diagnosis convenience, e.g. zoom in, etc. but it will not change the actual stored signal;
f. It can NOT do the automated diagnosis.

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4. Accessories

The accessories of the proposed device include chest electrode, limb electrode and cables, as illustrated in *Fig 7 Device Illustration, Accessories*.

Fig 7 Device Illustration, Accessories

4.1 Description of Chest Electrode

The chest ECG electrode is placed on the chest of the patient.

Fig 8 Design Drawing, Chest Electrode (Unit:mm)

(b)(4)

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4.2 Limb Electrode

The limb ECG electrode is clamped on the limbs.

Fig 9 Design Drawing, Limb Electrode (Unit: mm)

(b)(4)

4.3 Cables

Patient Cable includes two parts, main cable and lead wires with associated electrode connectors. The electrode connectors which are intended for connecting with the Chest Electrodes or Limb Electrodes can be distinguished from the color and identifier on them in Table 1 Identifier and Color Code of Electrodes. The design drawing is presented in *Fig 10 Design Drawing, Cables.*

In addition, the patient cable of the proposed device complies with the mandatory performance standard (clause 56.3(c) of IEC 60601-1) as specified in Title 21, Code of Federal Regulations, part 898, Performance Standard for electrode Lead Wires and Patient Cables.

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Table 1 Identifier and Color Code of Electrodes

Sites for electrodes	Identifier for electrodes	Electrode Connector color of Patient Cable	Color code for electrodes
Right arm	RA	Beige	White
Left arm	LA	Beige	Black
Right leg	RL	Beige	Green
Left leg	LL	Beige	Red
Chest	C1	Brown	Red
	C2	Brown	Yellow
	C3	Brown	Green
	C4	Brown	Blue
	C5	Brown	Orange
	C6	Brown	Violet

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Fig 10 Design Drawing, Cables

(b)(4)

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5. Specifications

Table 1 Specifications

Classification of protection against electric shock	Class II, specific power supply (powered by computer USB port)	
Degree of protection against electric shock	Type CF applied part, and is defibrillator-proof.	
Electromagnetism compatible	Group I Class B	
Defibrillation recovery time	＜ 10 s	
ECG signal sampling rate	1000 Hz	
DC power supple	5 V±5 % (by USB interface)	
Smallest signal detection	≤20 μV(10 Hz)	
Polarization resistance voltage	±500 mV	
Input impedance	>2.5 MΩ	
Input circuit current	≤0.1 μA	
Calibration voltage	1 mV±5 %	
Noise level	≤15 μVp-p	
Anti-jamming capability	CMRR	>89 dB
	Suppression of 10V interfering signal	The record amplitude should not exceed 10 mm
	50Hz interference suppression filter	≥20 dB
Normal sensitivity	10 mm/mV±2 %	
Time constant	≥3.2 s	
Amplitude frequency characteristics	At 10 Hz, (+0.4-3.0+0.4-3.0$^{+04}_{-30}$ dB) in (0.05 Hz ~ 250 Hz); high frequency function requires higher frequency response, more than 250 Hz	
Sensitivity	1.25 mm/mV，2.5 mm/mV，5 mm/mV，10 mm/mV，20 mm/mV，10-5 mm/mV，20-10 mm/mV	
Waveform speed	5 mm/s, 6.25 mm/s , 10 mm/s, 12.5 mm/s，25 mm/s，50 mm/s	
Maximum trace deflection amplitude	≥25 mm	

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Tab #10 Proposed Labeling

1. General Description 2
2. Package Label 3
3. Device Label 5
4. User Manual 6

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1. General Description

The proposed labeling of the proposed device contains:

a) Transportation Package Label;
b) Device Label;
c) User Manual.

The above identified proposed labeling complies with Title 21, CFR Section 801 labeling.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2. Package Label

Fig 1 Package Drawing (Unit: mm)

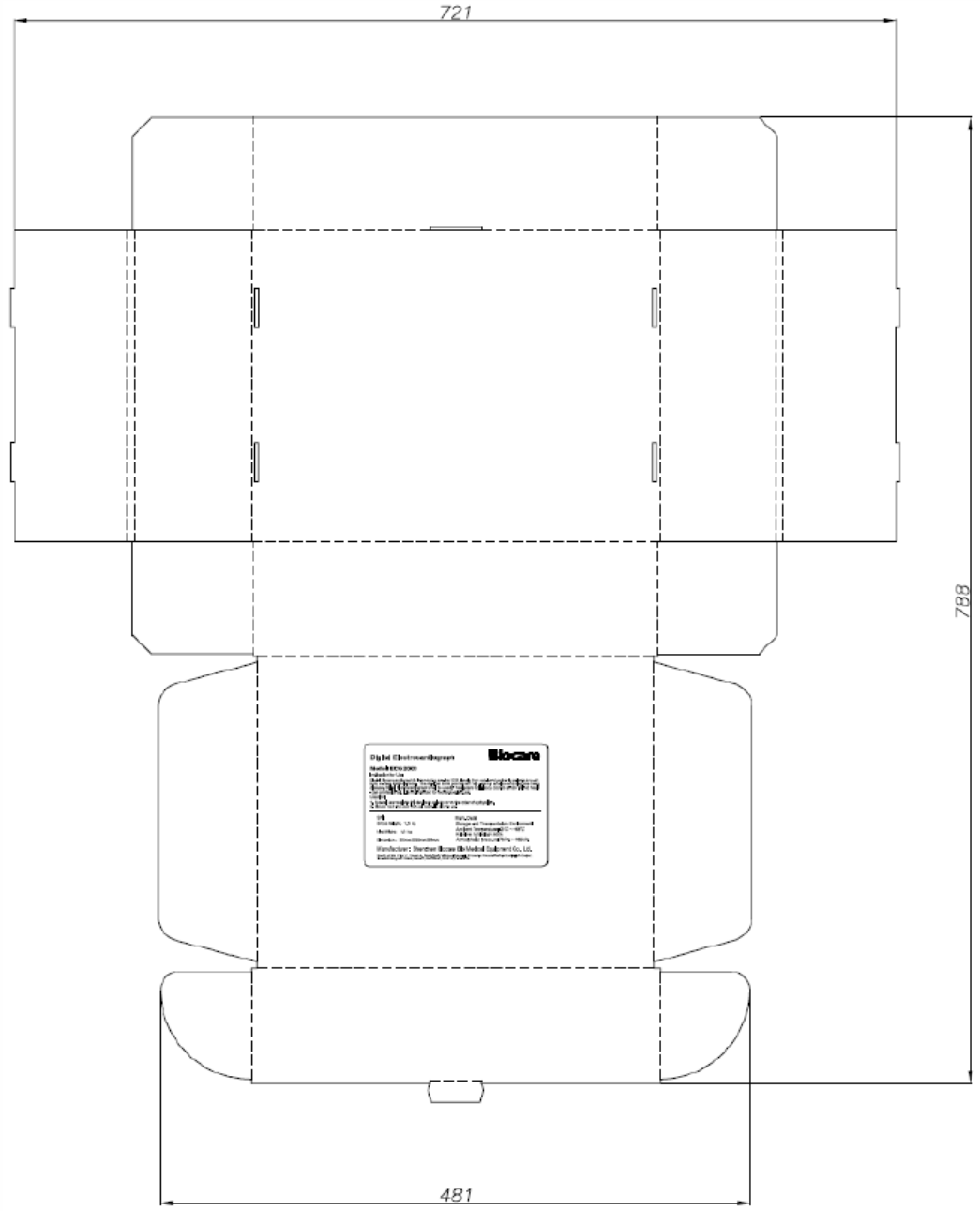

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Fig 2 Label on the Package

Digital Electrocardiograph

Biocare

Model: ECG-2000

Indication for Use:

Digital Electrocardiograph is intended to acquire ECG signals from adult patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

Caution:

1. Federal Law restricts this device to sale by or on the order of a physician.
2. Please read the user manual carefully prior to use.

SN:

Gross Weight: 1.3 kg

Net Weight: 1.0 kg

Dimension: 335mmX255mmX94mm

Manu.Date:

Storage and Transportation Environment:
Ambient Temperature:-20℃～+55℃
Relative humidity:≤95%
Atmospheric pressure:70kPa～106kPa

Manufacturer: Shenzhen Biocare Bio-Medical Equipment Co., Ltd.

Room A735, Floor 7, Tower A, Shenzhen Famous Industrial Products Procurement & Exhibition Center, No.168 Baoyuan Road, Baoan, Shenzhen, 518102,P.R.China

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3. Device Label

Fig 3 Label on Device

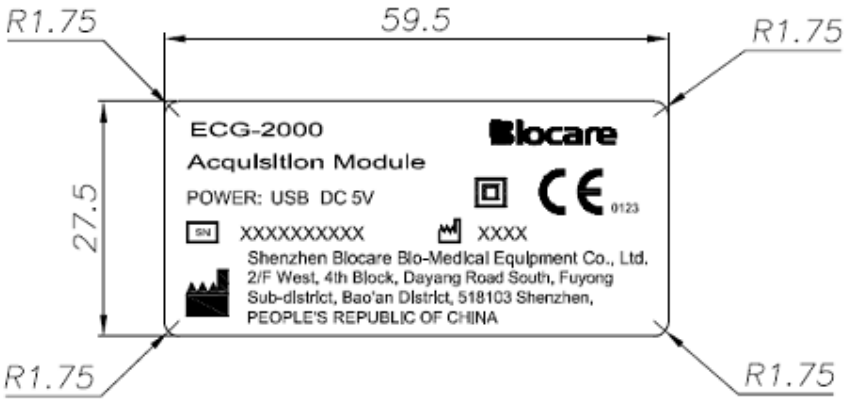
Biocare®

Digital Electrocardiograph

Model: ××××-××××
Safety: Class II– Type CF
Power: ~ 100 ~ 240V 50/60Hz ××VA
=14.8V / ×× mAh

Serial Number: ××××××××××
Date of Manufacture: ××××

Manufacturer:
Shenzhen Biocare Bio-Medical Equipment Co., Ltd



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4. User Manual

The User Manual is provided in ***Tab # 16 User Manual***.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Tab #11 Substantially Equivalent Discussion

Tab #11 Substantially Equivalent Discussion 1
1. Predicate Device Identification 2
2. Substantially Equivalent Comparison 3
3. Conclusion 8

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1. Predicate Device Identification

Predicate device 1

510(k) Number: K092010
Predicate Device Name: PC ECG
Manufacturer: Edan Instruments, Inc.

Intended Use:
SE-1010 PC ECG is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. SE-1010 PC ECG is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by SE-1010 PC ECG can help users to analyze and diagnose heart disease. However the ECG with measurements and interpretive statements is offered to clinician on an advisory basis only.

Predicate device 2

510(k) Number: K133985
Predicate Device Name: Digital Electrocardiograph, ECG-2000
Manufacturer: Shenzhen Biocare Bio-Medical Equipment Co., Ltd.

Intended Use:
Digital Electrocardiograph is intended to acquire ECG signals from adult patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

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2. Substantially Equivalent Comparison

Table 11-1 General Comparison

ITEM	Proposed Device	Predicate Device 1 K092010	Predicate Device 2 K133985	Remark
Product Code	DPS	DPS	DPS	SE
Regulation No.	870.2340	870.2340	870.2340	SE
Class	II	II	II	SE
Intended Use	Digital Electrocardiograph is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.	SE-1010 PC ECG is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. SE-1010 PC ECG is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by SE-1010 PC ECG can help users to analyze and diagnose heart disease. However the ECG with measurements and interpretive statements is offered to clinician on an advisory basis only.	Digital Electrocardiograph is intended to acquire ECG signals from adult patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.	SE
Intended Population	Adult and pediatric patients	Adult and pediatric patients	Adult patients	SE
Intended Environment	Healthcare facilities	Healthcare facilities	Healthcare facilities	SE
Configuration	Chest Electrode and Limb Electrode	Chest Electrode and Limb Electrode	Chest Electrode and Limb Electrode	SE
Contraindication	Not specified	Not specified	Not specified	SE
Programmable	No	No	No	SE
Components	• PC ECG software • ECG sampling box • Patient cable • Electrodes • USB Dongle (Sentinel) • USB cable	• PC ECG software • ECG sampling box • Patient cable • Electrodes • Sentinel • USB cable	• PC ECG software • ECG sampling box • Patient cable • Electrodes • USB Dongle (Sentinel) • USB cable	SE

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Table 11-2 Specifications Comparison – ECG

ITEM	Proposed Device	Predicate Device 1	Predicate Device 2	Remark
ECG Performance				
Leads mode	Standard 12-lead	Standard 12-lead	Standard 12-lead	SE
Acquisition mode	Simultaneous 12-leads	Simultaneous 12-leads	Simultaneous 12-leads	SE
Connection with PC	USB port	USB port	USB port	SE
Power supply	DV 5V from USB port	DV 5V from USB port	DV 5V from USB port	SE
Sampling rate	1000Hz	1000Hz	1000Hz	SE
Time Constant	≥3.2s	≥3.2s	≥3.2s	SE
Gain	1.25, 2.5, 5, 10, 20, 10-5, 20-10 (mm/mV)	2.5, 5, 10, 20 (mm/mV)	1.25, 2.5, 5, 10, 20, 10-5, 20-10 (mm/mV)	Analysis 1
Input impedance	>2.5 MΩ	50MΩ (10Hz)	>2.5 MΩ	SE
Input circuit current	≤0.1 μA	≤0.05μA	≤0.1 μA	Analysis 2
Calibration voltage	1 mV	1mV	1mV	SE
Noise level	<15μ Vp-p	<12.5μ Vp-p	<15μVp-p	Analysis 3
CMRR	>89 dB	≥100dB	>89 dB	Analysis 4
Recording				
Recording Paper	A4, Letter	A4, Letter	A4, Letter	SE
Paper Speed	5 mm/s, 6.25 mm/s, 10 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s	5mm/s, 10mm/s, 12 5 mm/s, 25mm/s and 50mm/s	5 mm/s, 6.25 mm/s, 10 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s	Analysis 5
Memory				
Memory	Storage amount depends on PC	Storage amount depends on PC	Storage amount depends on PC	SE
Power Supply (AC)				
Rated Frequency	50/60Hz	50/60Hz	50/60Hz	SE
Rated Voltage	110-240V	110-240V	100~240V	SE

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Analysis 1 - Gain

The gain of proposed device and predicate device 1 are different, because the proposed device provides more choices of gain for users. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Analysis 2 - Input circuit current

The input circuit current of proposed device and predicate device 1 are different. But both of them comply with IEC 60601-1 and IEC 60601-1-2. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Analysis 3 - Noise level

The noise level of proposed device and predicate device 1 are different. But the difference is very slight, and both of them comply with IEC 60601-1 and IEC 60601-1-2. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Analysis 4 – CMRR

CMRR is the ability for ECG common mode rejection, the higher the CMRR is, the more noise is reduced. IEC 60601-2-25 has a requirement for Common Mode Rejection, after calculation, CMRR of 89dB could comply with the standard requirements, which is:

Clause 201.12.4.105.1 in IEC 60601-2-25

A 10 V r.m.s. signal at mains frequency with 200 pF source capacitance, connected between earth and all LEAD WIRES connected together shall not produce an output signal greater than 10 mm peak-to-valley at a GAIN setting of 10 mm/mV for not less than 15 s.

The test result demonstrated that the proposed device complies with the requirement, which means, although, the CMRR of predicate device is better than the proposed device, the CMRR of the proposed device is applicable to clinical application as it comply with the standard.

Following is the calculation of CMRR according to this clause:

Per Fig 201.105 in the same clause, the total input signal is 20 Vrms, which should be 28280mV (Peak-Valley Voltage), the output signal shall not greater than 10mm peak-to-valley, which should be 1mV at maximum (1mm=0.1mV), then the CMRR is calculated as the following equation:

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$20*\log(Vinput/Voutput)$ =20* $\log(28280mV/1mV)$ =89dB.

Therefore, CMRR of 89dB could comply with the standard requirement and clinical application.

Analysis 5 – Paper speed

The paper speed of proposed device and predicate device 1 are different. But the paper speed will not affect the ECG measurement of the device. And the difference is caused by the proposed device providing more choices of paper speed for users. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

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Table 11-3 Safety Comparison

ITEM	Proposed Device	Predicate Device 1	Predicate Device 2	Remark
Electrical Safety and EMC				
Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Comply with IEC 60601-1	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Biocompatibility				
Patient Material	Chest Electrode: Metal (same with those of FDA approved chest electrode (K133985)	Chest Electrode: Metal	Chest Electrode: Metal	SE
	Limb Electrode: ABS (Acrylonitrile Butadiene Styrene) / Copper Alloy (same materials with those of FDA approved limb electrode (K13985)	Limb Electrode: ABS (Acrylonitrile Butadiene Styrene) / Tin Alloy	Limb Electrode: ABS (Acrylonitrile Butadiene Styrene) / Copper Alloy	SE
Software				
Level of Concern	Moderate	Moderate	Moderate	SE
Labeling				
Labeling	Comply with 21 CFR 801 and IEC 6061-1, IEC 60601-1-2	Comply with 21 CFR 801 and IEC 6061-1, IEC 60601-1-2	Comply with 21 CFR 801 and IEC 6061-1, IEC 60601-1-2	SE

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3. Conclusion

Based on the comparison and analysis above, the proposed devices, Digital Electrocardiograph, ECG-2000, is determined to be Substantially Equivalent (SE) to the predicate devices.

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Tab #12 Sterilization and Shelf Life

1. Sterilization

   The proposed device is provided non-sterile, and not to be sterilized by the user prior to use.

2. Shelf Life

   There is no shelf life of the proposed device, because it is provided non-sterile, and storage conditions could not affect device safety or effectiveness.

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Tab #13 Biocompatibility

1. Patient Contact Material(s)

The direct and indirect patient-contact component(s) along with the material(s) for the proposed devices are identified as follows:

Table 1 Patient Contact Material Identification

Components	Material	Contact Level	Contact Duration
Chest / Limb Metal Electrode	Copper Alloy	Surface	Limited (<24 hour)
Limb Electrode Clamp	ABS	Surface	Limited (<24 hour)

NOTE: The contact level and contact duration are determined according to Annex A of ISO 10993-1:2009 Biological evaluation of medical devices — Part 1 Evaluation and testing within a risk management process.

2. Biocompatibility

The patient contact materials of the proposed device as identified are identical to those of the legally marketed device, Digital Electrocardiograph, ECG-2000, as cleared in K123816 at 01/22/2015. Biocompatibility Statement is provided in ***Tab #26 Biocompatibility Statement.***

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Tab #14 Software

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1. General Description

Two software are included in this submission, which are Acquisition Box Software and Management System software used in ECG-2000.

2. Acquisition Box Software

Per FDA Guidance entitled "GUIDANCE FOR THE CONTENT OF PRE-MARKET SUBMISSIONS FOR SOFTWARE CONTAINED IN DEVICES", dated May 11, 2005, Table 3 Documentation Based on Level of Concern the following documents are presented for review:

This software is determined as **Moderate Level of Concern**.

Determination is made based the answer to the following questions:

Table 1 Level of Concern Determination

Key questions	Answer
Does the Software Device qualify as Blood Establishment Computer Software?	No
Is the Software Device intended to be used in combination with a drug or biologic?	No
Is the Software Device an accessory to a medical device that has a Major Level of Concern?	No
Does the Software Device control a life supporting or life sustaining function?	No
Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?	No
Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?	No
Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?	No
Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	No
Major Level of Concern?	**No**
Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?	No
Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?	No
Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	Yes
Moderate Level of Concern?	**Yes**

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2.1 Software Description

Table 2 Software Description

Software Name	ECG-2000 Acquisition Box Software
Current Version	(b)(4) Draft
Hardware Platform	
Software Capability	
Programming Language	
Operating System	No Operating System;
Off the Shelf Software	No OTS Software;
Software Function	Coordinate ECG analog front-end circuit to acquire, process and transmit digital ECG data.
Unsolved Problem	None

2.2 Device Hazard Analysis

The proposed device, Digital Electrocardiograph, was subject to risk analysis and management per ISO 14971:2007. The risk analysis method is FEMA (Failure mode and effects analysis). The risk analysis report is presented in ***Tab #17 Software Risk Analysis Report***.

2.3 Software Requirements Specifications

The software requirements specifications is included in ***Tab #18 Acquisition Box Software Requirements Specifications***.

2.4 Software Development Specifications

The software development specifications is included in ***Tab 19 Acquisition Box Software Development Specifications***.

2.5 Architecture Design Chart

Fig 1 Architecture Design Chart, Acquisition Box Software

(b)(4)

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2.6 Traceability Analysis

Tab 3 Tractability Analysis, Acquisition Box Software

(b)(4)

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(b)(4)

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(b)(4)

[redacted]

2.7 Revision History

Ver 1.0, 1st version release

2.8 Software Verification and Validation Documentations

The software verification report is included in ***Tab #20 Unit Test Cases for ECG-2000 Collection Box Software***.

2.9 Unresolved Anomalies

NONE

2.10 Software Development Environment

Software Development Environment is included is included in ***Tab #21 Software Development Environment Description***.

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3. Management System Software

Per FDA Guidance entitled "GUIDANCE FOR THE CONTENT OF PRE-MARKET SUBMISSIONS FOR SOFTWARE CONTAINED IN DEVICES", dated May 11, 2005, Table 3 Documentation Based on Level of Concern the following documents are presented for review:

This software is determined as **Moderate Level of Concern**.

Determination is made based the answer to the following questions:

Table 3 Level of Concern Determination

Key questions	Answer
Does the Software Device qualify as Blood Establishment Computer Software?	No
Is the Software Device intended to be used in combination with a drug or biologic?	No
Is the Software Device an accessory to a medical device that has a Major Level of Concern?	No
Does the Software Device control a life supporting or life sustaining function?	No
Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?	No
Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?	No
Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?	No
Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	No
Major Level of Concern?	**No**
Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?	No
Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?	No
Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	Yes
Moderate Level of Concern?	**Yes**

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3.1 Software Description

Table 4 Software Description-PC (Management System)

Software Name	ECG-2000Management System
Current Version	(b)(4)
Hardware Platform	
Software Function	Use PC and acquisition box to acquire, display, store, print and transmit ECG information.
Unsolved Problem	None
Programming Language	(b)
Operating System	There is Operating System
Off the Shelf Software	There is OTS Software: (b)(4)

3.2 Device Hazard Analysis

The proposed device, Digital Electrocardiograph, was subject to risk analysis and management per ISO 14971:2007. The risk analysis method is FEMA (Failure mode and effects analysis). The risk analysis report is presented in ***Tab #17 Software Risk Analysis Report***.

3.3 Software Requirements Specifications

The software requirements specifications is included in ***Tab #22 ECG Management Software Requirements Specifications***.

3.4 Software Development Specifications

The software development specifications is included in ***Tab 23 ECG Management Software Development Specifications***.

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3.5 Architecture Design Chart

Fig 2 Architecture Design Chart, ECG Management Software

(b)(4)

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3.6 Traceability Analysis

Table 5 Traceability Analysis

(b)(4)

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(b)(4)

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3.7 Revision History

V1.006, 1st released version.

3.8 Software Verification and Validation Documentations

The software verification report is included in ***Tab #24 Functions Test Report***.

3.9 Unresolved Anomalies

NONE

3.10 Software Development Environment

Software Development Environment is included is included in ***Tab #21 Software Development Environment Description***.

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Tab #15 Testing

This submission is filed for extension of intended use, the device, including its hardware and software, has not been changed from the one cleared in the previous submission, K133985; therefore, only the following standard (part items) was tested to verify that the device can meet its additional intended use:

IEC 60601-2-25: 2011, Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.

The items tested are listed as follows using CAL20500 to address deficiency in previous submission:

201.12.1.101.2
201.12.1.101.3.1
201.12.4.107.1.2

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About User Manual

This user manual only applies to the operation of this instrument; we are not responsible for the consequences and liabilities if it is used for any other purposes.

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Due to technical improvements or file updates, the content of the Manual is subject to changes without prior notice.

Due to technical updates or special requirements of users, please note that certain functions may be different with the standard configuration in this Manual on the premise that do not affect the performance of the instrument.

⚠ Warning: This is not therapeutic equipment.

Tips:

- This equipment isn't intended to be used at home.
- Before interventional treatment, be sure to check the observations on ECG-2000 with the clinical observations of patients at the bedside.

Corporate information

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CE 0123

The CE mark is a protected conformity mark of European Community.
The products herewith comply with the requirements of the Medical Device Directive 93/42/EEC

EC REP

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Chapter 1 Overview

1.1 Product overview

The ECG-2000 is used together with ECG acquisition box, and controls the ECG acquisition box to acquire ECG and display on the screen, generates a variety of types of ECG reports in accordance with the needs of users.

1.2 Intended use

Digital Electrocardiograph is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in health care facilities by doctors and/or trained healthcare professionals.

1.3 Features

The main features include:

1) Medical records and management
   a) Establish the new cases of patients;
   b) Inquire the patient's clinical data and modify patient information;
   c) List the medical records within a specified time;
2) ECG examination function: achieve ECG signal acquisition, display of the following items:
   a) 12-lead ECG
   b) VCG
   c) VLP
   d) HRV
   e) HFECG
   f) FCG
   g) HRT
   h) QT
3) Storage and playback of ECG signals;
4) ECG report printing

Note: It’s optional for VCG, VLP, HRV, HFECG, FCG, HRT and QT. It means if the user did not purchase the function, the function will not be available.

1.4 Operating environment

This equipment requires 5 V± 5% DC power supply provided by a standard USB interface. The equipment operates in intermittent loading continuous working mode.

Transport and storage conditions:

1) Ambient temperature range: transport:

-20 ℃~ +55 ℃, storage: -20 ℃~+55 ℃;

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2) Relative humidity range: transport: ≤ 95%, storage: ≤ 95%;

3) Atmospheric pressure range: 70 kPa ~ 106 kPa.

Normal working condition:

1) Ambient temperature range: 5 ℃~40 ℃;

2) Relative humidity range: ≤ 95%;

3) Atmospheric pressure range: 86 kPa ~ 106 kPa.

1.5 Safety precaution

Caution:
Federal Law restricts this device to sale by or on the order of a physician.

★ This product should be operated by qualified health care professionals in the medical units;

★ The medical staff shall analyze the ECG waveform and present diagnostic results; to use the equipment safely and effectively, please read the user manual carefully, in order to fully understand the correct method of operation.

★ This instrument is not intended for internal use and direct cardiac application.

★ This instrument shall not be used within a Magnetic Resonance (MR) environment.

◆To ensure proper use of the equipment, please carefully read this section.

This Manual uses the symbol ⚠ to remind users to pay special attention: the content following this symbol is related to safety. Please be sure to obey by, in order to avoid personal injury or damage to the equipment.

◆ Description of graphical symbols and text

Class II: Class II equipment with insulation shell.

There is a durable insulation shell, which has no space and surrounds all conductive parts, excluding some small parts, such as nameplates, screws and rivets.

Type CF application part:

The parts directly used for the heart are CF type.

⚠ The icon represents CF-type anti-defibrillation logo, which indicates that F-type parts have higher degree protection against electric shock than BF type (in particular, allow leakage current), and should have defibrillation effect protection.

Note:

- The applied part of circuit works in a floating ground condition, and the design conforms with the safety standard for Type CF, thus it is able to record and display the electrical signal of body surface generated by the activity of cardiac, but cannot directly used in heart.
- In order to trace the ECG more accurately, the equipment should be placed in a quiet, comfortable environment.
- The limb electrodes and chest electrodes can be reused, but should be cleaned or disinfected with medical alcohol prior to use.
- To clean and disinfect the lead electrodes and lead wires, please wipe gently with gauze dipped in medical alcohol. Do not pull the lead wires forcibly.

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- The measurements provided by the Digital Electrocardiograph can only serve as the diagnosis basis, and the final diagnosis should be made by the doctor.
- At the end of its useful life, the equipment and its accessories should be processed in accordance with the relevant laws and regulations. If there is any doubt about the processing, please contact the manufacturer or agent.
- If the provided accessories are damaged and can't be repaired or the service life expires, please scrap the accessories according to the local regulations.

⚠ Warning:

When it is used in combination with the cardiac defibrillator, the contact with patient or hospital bed should be avoided. All the electrodes which are connected or unconnected to the patients as well as the patients themselves are not necessary to be grounded .All the electrodes for use should be the Ag-Cl（single use） electrodes provided by our company . The patient cable specially provided by our company should also be used for ensuring the protection against the charging of the cardiac defibrillator. It is not recommended to use this instrument in combination with the other electric stimulators. However, if necessary, they should be used in the presence of professionals and under the appropriate directions. When the instrument is used in combination with the cardiac defibrillator or the other electric stimulators (such as HF surgical units), it is recommended to use the disposable chest electrodes in the shape of plate to prevent the adhesive metal electrodes from burning the skin of patient.

⚠ Warning:

Be cautious when the patient is connected with more than one instrument, because the total leak current may be harmful to the patient. Only the Class I devices in compliance with the standard of IEC60601-1 are allowed to be connected to this instrument, and the total leak current should be measured by the users to determine that if it meets the requirement and can be used after connection.

⚠ Warning:

If a cardiac pacemaker is implanted in the patient, it may influence on the ECG detection accuracy. In this case, the doctor is suggested to identify and analyze according to the waveform; in addition, the potential hazards are increased. In this case, pay particular attention to safety issues while recording ECG, and take appropriate measures to ensure that the leakage current is at a safe level.

⚠ Warning:

To prevent burns, the high-frequency electrotome contact point should be kept away from the electrodes, and the resistance between the high-frequency electrotome and the patient's body should be as small as possible. Plate electrodes can be used when necessary, because there is a large contact area, and the high-frequency current density can be restricted within the acceptable range.

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⚠	Don't use in the places with anesthetic gases, flammable gases such as oxygen, hydrogen or other flammable chemicals, or else it may cause explosion or fire.
⚠	Don't use in medical hyperbaric oxygen compartment, or else it may cause explosion or fire.
⚠	Where relevant, the EQUIPMENT is needed to be protected against malfunction caused by electro surgery.

◆ **Description of equipment safety**

This equipment meets the requirements of IEC60601-1 standard, and the type of protection against electric shock is Class II, CF application part (including neutral electrodes) and the conductive parts of the connectors shall not be in contact with other conductive parts nor grounded.

1. The parts of the equipment that should be disassembled with tools shall be disassembled and repaired by qualified personnel.
2. Lead wires, electrodes and electrode holders shall be original products.
3. When using this equipment to examine a patient, do not connect other medical devices to the patient.
4. It won't cause any danger when the patient is using a pacemaker.

1.6 Operation Precautions

★ This instrument is intended for usage by qualified medical personnel only.

★ Please read the precautions carefully before operating this instrument.

⚠ When install or store the instrument, take the following measures:

- Avoid contact with water, and avoid using and storing in spaces with too large barometric pressure, humidity and temperature beyond the prescribed standards, poor ventilation, or with excessive dust, sulfur, salt, alkali gas and chemicals;
- Place the instrument on a stable plane, and avoid vibration and mechanical shock while moving;
- Select a room with intact infrastructure (grounding facilities, etc.).

⚠ Warning:

- Avoid placing in places with chemicals or gas leak hazard;
- ECG machine should not be surrounded by high-voltage cables, X-ray, ultrasound equipment, electrotherapy machines and other high-power equipments;

⚠ Before the operation:

- Check if the instrument is in good condition;
- Check if the instrument is placed properly;
- Check if all wires are properly connected and if the instrument is properly grounded;

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- When the instrument is used together with other instruments, pay special attention to avoid misdiagnosis and other issues;
- All circuits directly contact with the patient must be inspected;
- When operate with battery, check the battery voltage and if the state is appropriate.

⚠ In operation:

- When the instrument is in operation, the doctor should not leave away from the operation site; instead, carefully observe the patients; if necessary, turn off the power or remove the electrodes in order to ensure the safety of patients;
- In addition to the electrodes, also avoid the patient contacting other parts of the instrument part or other conductors.

⚠ After operation:

- Set all function states back to the initial state, and turn off the power;
- Gently remove the electrodes; do not pull the wires;
- Clean the instrument and all accessories for the next use.

⚠ Warning:

The maintenance and repair of the instrument must be carried out by experienced professionals. When the instrument malfunctions, mark clearly to avoid instrument operating with trouble.

⚠ Warning:

Do not remodel or rebuild the instrument in any way.

⚠ Warning:

Maintenance and repair:

- Perform regular maintenance and inspection for the instrument and all its accessories (at least once every six months);
- ECG machine is measuring instrument; the user shall send it to statutory measurement authority in accordance with the requirements of the national metrological verification regulations of ECG machine for test and inspection; the cycle should not exceed one year;
- The electrical schematic diagrams and parts list are only provided to a qualified repair station or persons recognized by the Company.

⚠ Warning:

Treatment of discarded products: for the treatment of packaging materials, exhausted batteries and discarded products, please follow local laws and regulations and the decree requirements of authorities to handle the discarded products and materials properly, classify and recover as much as possible.

Note:

For all dated reference documents in this manual, its subsequent amendments (excluding corrections) or revisions do not apply to this manual; for undated reference documents, the latest version applies in this manual.

★ EMC Considerations

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This instrument complies with IEC60601-1-2 safety standards of medical electronic equipment or system electromagnetic compatibility; the electromagnetic environment exceeding IEC60601-1-2 standard limit or level will cause harmful interference to the instrument or make the instrument cannot achieve the expected function, or the performance is reduced. Therefore, in the process of using, if the function of the instrument does not match with the intended function, be sure to confirm and exclude adverse impact before continuing to use. In view of this situation, the corresponding preventive measures are given in this manual.

- Influence of electromagnetic wave radiation:

The use of mobile phones may affect the operation of this instrument. When medical electronic equipment is installed, be sure to remind people around to turn off mobile phones and small radio equipment.

- Influence of impact and conductive electromagnetic waves:

High frequency noise emitted by other equipment may enter into the instrument through the AC outlet. Please confirm the noise source, and stop using the equipment if possible. If the equipment cannot be stopped, use noise-cancellation equipment or other measures to reduce the impact.

- Influence of static electricity:

Static electricity in dry environment (indoor) may affect the operation of the instrument, especially in winter. Before using this instrument, humidify the indoor air or release the static electricity in the cable and ECG recording personnel.

1.7 Equipment classification

1) By the type of protection against electric shock:
   Class II, specific power supply (powered by computer USB port)
2) By the degree of protection against electric shock:
   CF type application part
3) By the degree of protection against harmful liquid:
   Common equipment (enclosed device without liquid intake protection)
4) By the safety degree using with flammable anesthetic gas and air mixture or oxygen or nitrous oxide mixture:
   Equipment cannot be used in the environment with flammable anesthetic gas and air mixture or oxygen or nitrous oxide gas mixture
5) By the working system:
   Continuous operation equipment

1.8 Operating environment

1.8.1 Hardware composition

Computer: recommended configuration: CPU: P4 2.0 GHz or above, HDD: 80 GB or above, memory: 512 MB or above.

a) High-resolution color display: 1024 x 768 or above;

b) Printer: resolution ≥ 600 dpi, laser printer or high-quality inkjet printer is recommended (do not use dot matrix printers);

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c) High-performance ECG acquisition box, including lead wires;

d) Chest electrodes;

e) Limb electrodes.

1.8.2 Software environment

a) Windows Vista or Windows 7 or later.
b) DirectX 9.0c drivers.

c) At least OFFICE 2000 ACCESS.

d) At least OFFICE 2000 WORD.

1.9 Structure

Digital Electrocardiograph consists of the acquisition box, optional accessories, installation CD, and USB dongle. Optional accessories include lead wires, limb electrodes and chest electrodes, and general-purpose printer (with USB interface, support PCL language, such as HP1010, P2035, and P2055d series). The CD contains Digital Electrocardiograph installer and dongle installation program module.

1.10 Symbols

CF Application Part, with defibrillation protection

Attention! Please refer to the provided document

Acquisition interface

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Chapter 2 System Installation and Hardware Connection

This chapter aims to provide the installation overview of the system. In order to avoid damage to the system and inconvenience to the user due to improper operation, please ask qualified personnel to re-install the system. The following content is intended for the users that have some understanding of computer.

Digital Electrocardiograph requires installing the software on the host first, and then connecting the acquisition box to the host.

2.1 System installation

1. Before installing Digital Electrocardiograph, make sure the following software has been installed to the host.
   - Windows 2000 SP4 or Windows XP SP2 or later
   - DirectX 9.0c drivers
   - At least OFFICE 2000 ACCESS
   - At least OFFICE 2000 WORD
2. Turn on the power to enter the operating system desktop, double-click the ECG-2000 installer in CD-ROM root directory (the installer name may be different depends on user custom functions; refer to Readme.txt on the CD for details), and follow the screen prompts to install.

a. Double-click "ECG-2000 V1.0.2.0.exe" to run the program, select the installation language “English”, and click on "OK":

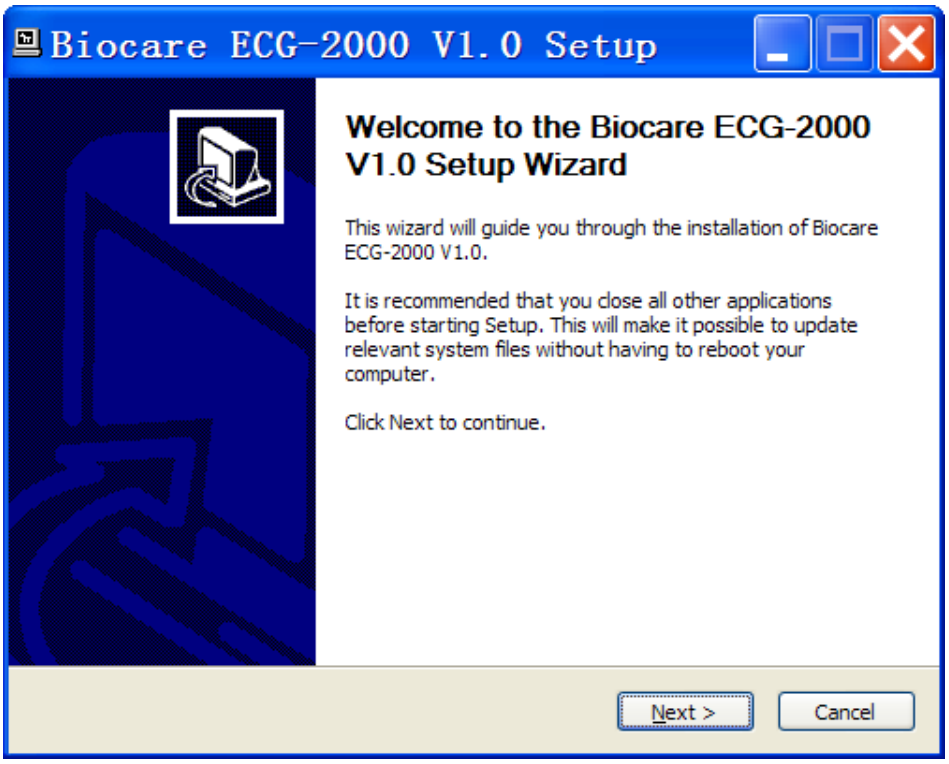

Fig. 2.1.1 Installation Step 1

b. Click "Next", as shown below:

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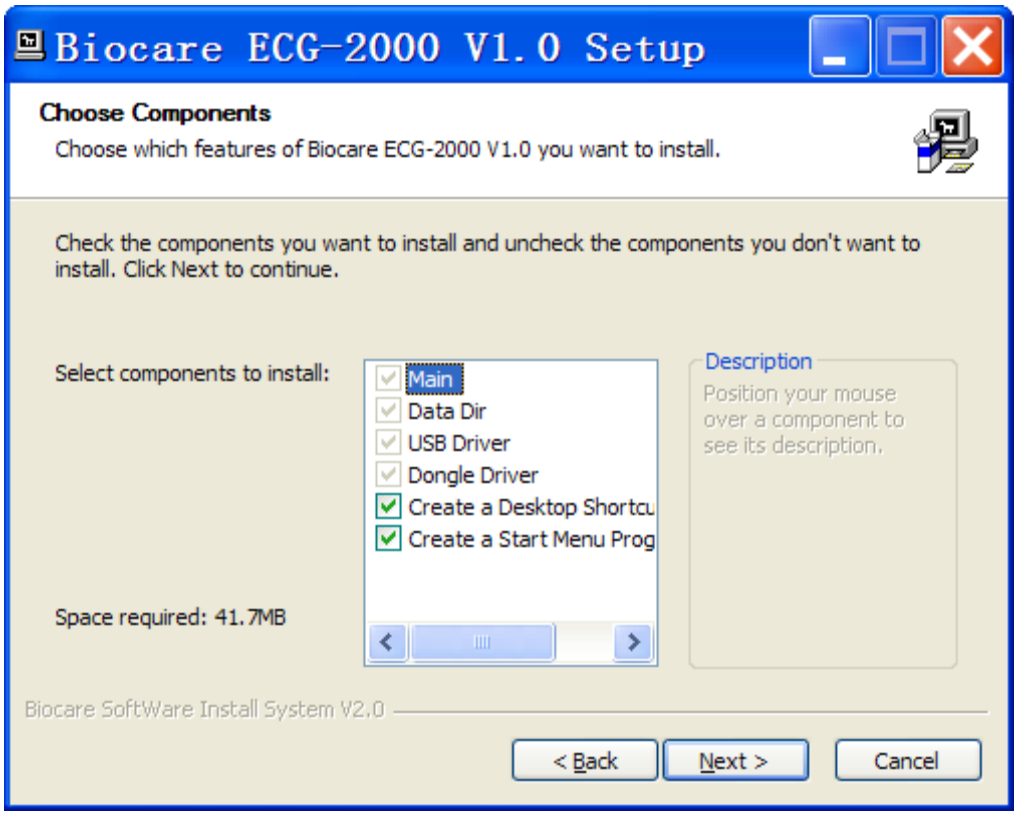

Fig. 2.1.2 Installation Step 2

c. Select the components to be installed, and click "Next", as shown below:

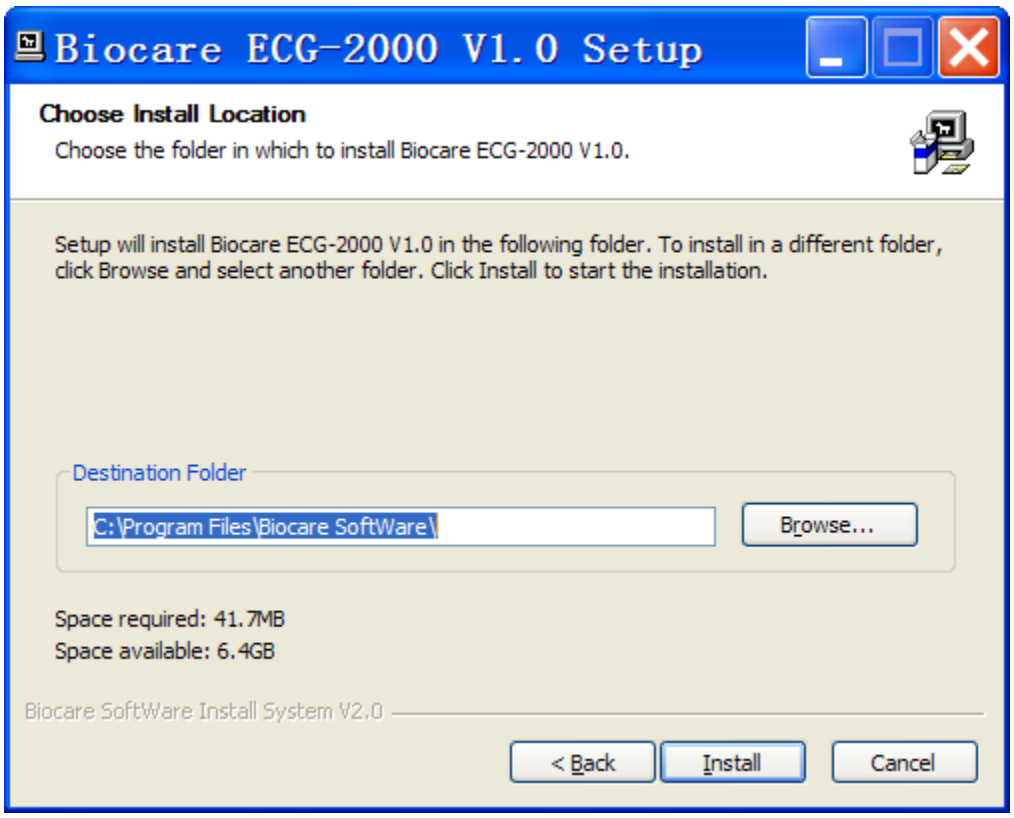

Fig. 2.1.3 Installation Step 3

d. Select the installation path, and click "Install" to install the Digital Electrocardiograph.

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3. Prompt box of driver installation will pop up during the installation process, as shown below. Click on the "Install" button to install.

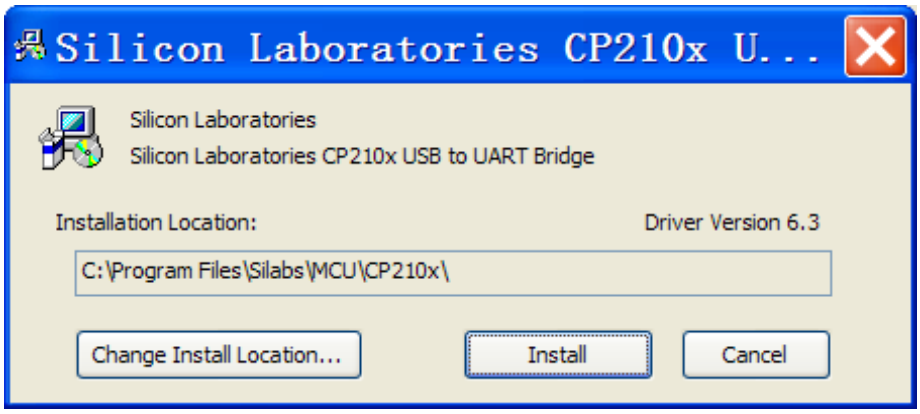

Figure 2.1.4 Driver Installation Prompt Box

4. Prompt box of dongle installation will pop up during the installation process, as shown below. Click on the "Install" button to install.

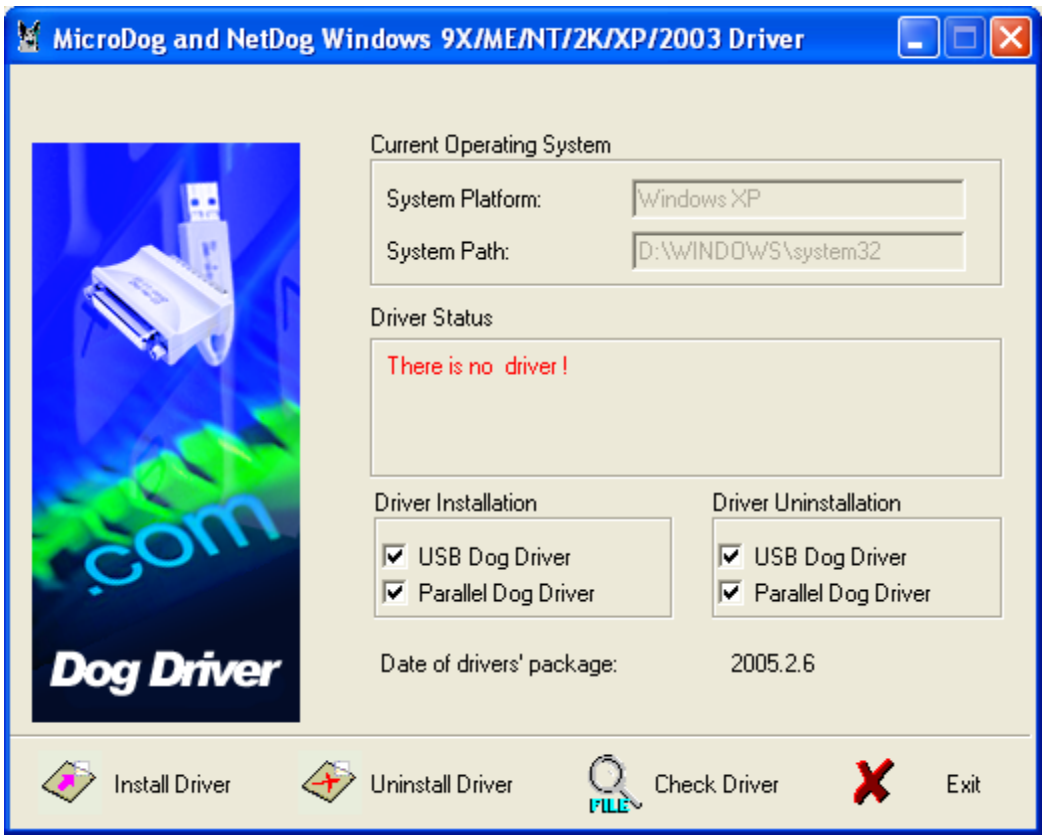

Figure 2.1.5 Dongle Installation Prompt Box

Wait for the installation to complete, and click “Exit” to finish, as shown below:

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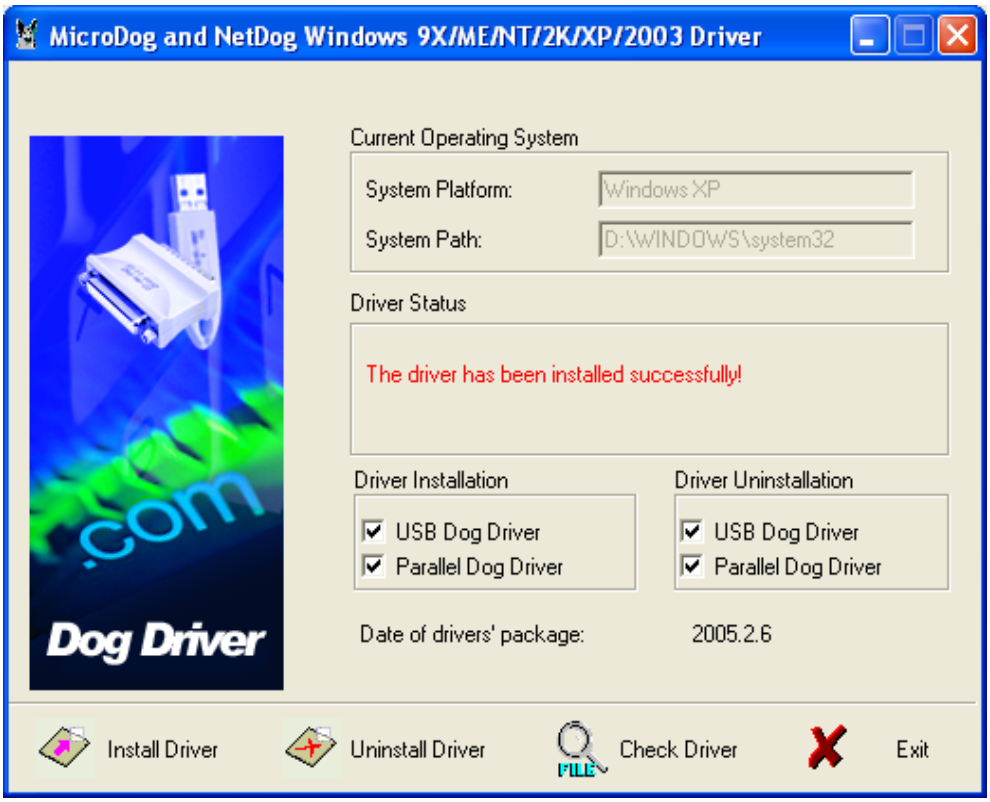

Figure 2.1.6 Successful Dongle Installation Prompt Box

5. Finally, click "Finish" to complete the installation.

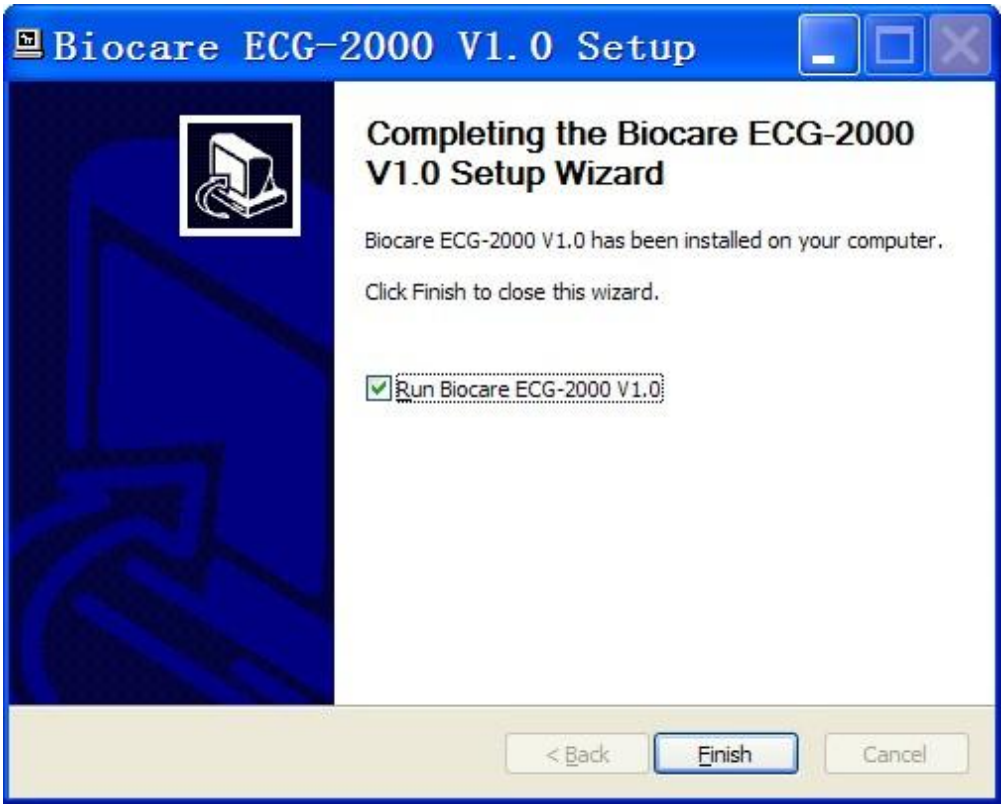

Fig. 2.1.7 Installation Step 4

6. After installation, connect the acquisition box to a USB port on the host, and the length of the USB cable should not exceed 1.5 m.

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2.2 Hardware connection

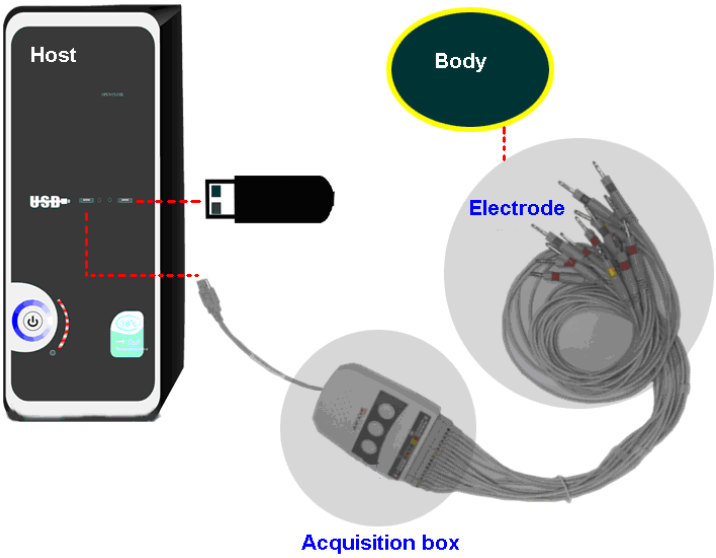

Fig. 2.2.1 System Connection Diagram

1) First, confirm that the flat end of the USB cable is connected to the PC system;
2) Ensure that the software dongle is connected to the computer's USB interface;
3) Connect chest lead and chest electrodes to the patient's chest, and connect the limb leads and limb electrodes to the patient's limbs. For the placement of chest electrodes and limb electrodes, please refer to **2.3 Electrode connection.**

2.3 Electrode connection

Correct installation of the electrodes is important for accurate ECG records. Please ensure proper electrode contact. The old and new electrodes or reusable electrodes and disposable electrodes cannot be used simultaneously. Using different types of electrodes together will seriously affect the ECG records. Do not contact the electrode or lead plug to the surface of other objects or conductors, such as metal bed. Replace all electrodes together.

2.3.1 Standard 12-lead electrode placement

1) **Connection of limb electrodes**

   Limb electrodes should be connected to the soft skin on the hands and feet. Clean the skin with alcohol before connecting the electrodes, and then coat a small amount of conductive paste on the skin after cleaning. Limbs electrodes connection (as shown below):

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R (RA) connected to the right hand;

L (LA) connected to the left hand;

N (RL) connected to the right leg;

F (LL) connected to the left leg.

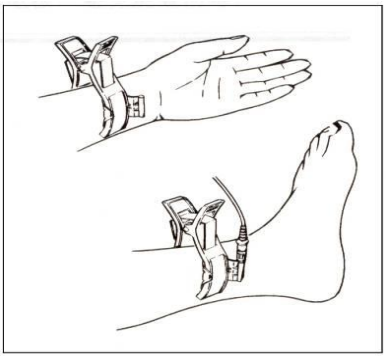

Fig. 2.3.1 Limb Electrode Connection Diagram (12-lead)

2) **Connection of chest electrodes**

Clean the chest skin with alcohol before connecting the electrodes, apply the conductive paste on the range of 25mm diameter and the edge of chest electrode blister bowl, press the suction ball of the chest electrodes, and adsorb the chest electrodes on location V1～V6. The connection of chest electrodes is shown below.

1: C1 (V1): the fourth intercostal of the right edge of the sternum;

2: C2 (V2): the fourth intercostal of the left edge of the sternum;

3: C3 (V3): line midpoint of C2 and C4;

4: C4 (V4): the intersection of the fifth flank gap of the left sternum and the clavicle midline;

5: C5 (V5): the same horizontal line of the left armpit frontline and C4;

6: C6 (V6): the same horizontal line of the left armpit midline and C4.

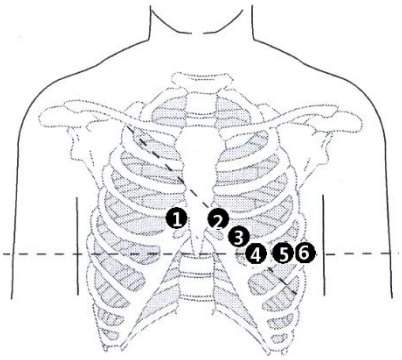

Fig. 2.3.2 Chest Electrode Installation (12-lead)

Note:

The conductive paste layers should be separated from each other, and the chest electrodes should not contact each other, to avoid short circuit. If no conductive paste is applied, for short ECG examination, clean the skins connected to each electrode with 75% alcohol, and then connect to respective electrodes immediately, so as to ensure that the electrode contact portion is moderately moist. Do not replace the conductive paste with saline to prevent corrosion of the electrodes.

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3) **Electrode and lead color table**

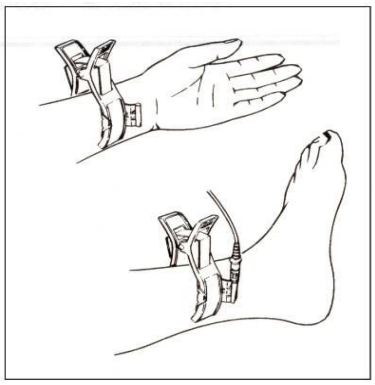
Table 2-1 Comparison of Electrode and Lead Wire Coding Marks and Colors (standard 12-lead)

System	European standards		American Standard	
	Symbol for electrode	Color code for electrode	Symbol for electrode	Color code for electrode
Limb electrodes	R	Red	RA	White
	L	Yellow	LA	Black
	N	Black	RL	Green
	F	Green	LL	Red
Chest electrodes	C	White	V	Brown
	C1	White / Red	V1	Brown / Red
	C2	White / Yellow	V2	Brown / Yellow
	C3	White / Green	V3	Brown / Green
	C4	White / Brown	V4	Brown / Blue
	C5	White /Black	V5	Brown / Orange
	C6	White / purple	V6	Brown / purple

2.3.2 Cardiac vector electrode placement

1） Connection of limb electrodes

Limb electrodes should be connected to the soft skin on the hands and feet. Clean the skin with alcohol before connecting the electrodes, and then coat a small amount of conductive paste on the skin after cleaning. Limbs electrodes connection (as shown below):



R (RA) connected to the right hand;
L (LA) connected to the left hand;
N (RL) connected to the right leg;
F (LL) connected to the left leg.

Fig. 2.3.3 Limb Electrode Connection Diagram (VCG)

2） Connection of chest and back electrodes

Clean the chest skin with alcohol before connecting the electrodes, apply the conductive paste on the range of 25mm diameter and the edge of chest electrode blister bowl, press the suction ball of the chest electrodes, and adsorb the chest electrodes on corresponding location. The connection of chest electrodes is shown below.

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1: C1 (V1): the intersection of the right armpit midline and the fifth intercostal;

2: C2 (V2): the horizontal intersection of the antemedial line and the fifth intercostal;

3: C3 (V3): the middle of V2 and V4;

4: C4 (V4): the intersection of the left armpit midline and the fifth intercostal;

5: C5 (V5): the horizontal intersection of the dorsum midline and the fifth intercostal;

6: C6 (V6):the right of neck

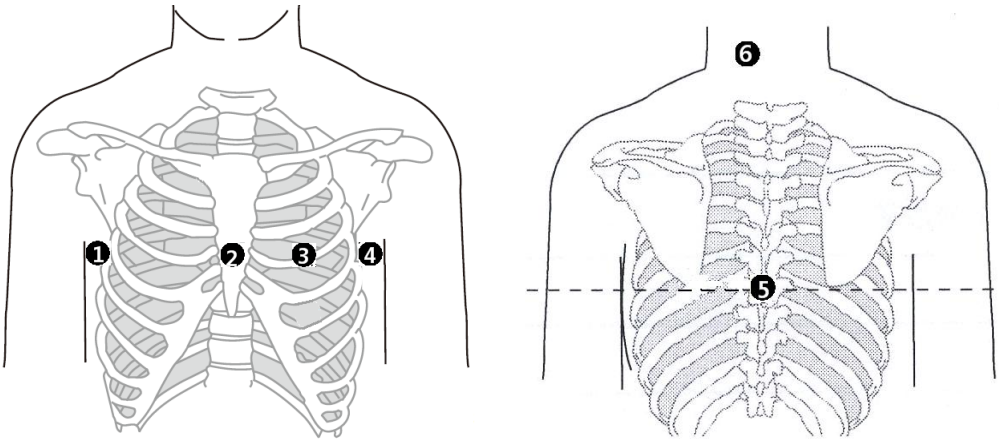

Fig .2.3.4 Chest Electrode Installation (VCG)

2) **Electrode and lead color table**

Table 2-2 Comparison of Electrode and Lead Wire Coding Marks and Colors (VCG)

System	European standards		American Standard	
	Symbol for electrode	Color code for electrode	Symbol for electrode	Color code for electrode
Limb electrodes	R	Red	RA	White
	L	Yellow	LA	Black
	N	Black	RL	Green
	F	Green	LL	Red
Chest electrodes	C	White	V	Brown
	C1	White / Red	V1	Brown / Red
	C2	White / Yellow	V2	Brown / Yellow
	C3	White / Green	V3	Brown / Green
	C4	White / Brown	V4	Brown / Blue
	C5	White /Black	V5	Brown / Orange
	C6	White / purple	V6	Brown / purple

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2.3.3 Ventricular late potential electrode placement

1) **Connection of limb electrodes**

Limb electrodes should be connected to the soft skin on the hands and feet. Clean the skin with alcohol before connecting the electrodes, and then coat a small amount of conductive paste on the skin after cleaning. Limbs electrodes connection (as shown below):

R (RA) connected to the right hand;

L (LA) connected to the left hand;

N (RL) connected to the right leg;

F (LL) connected to the left leg.

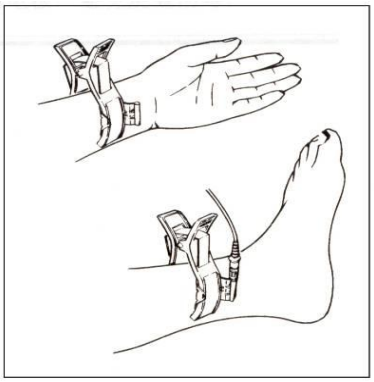

Fig. 2.3.5 Limb Electrode Connection Diagram (VLP)

2) **Connection of chest and back electrodes**

Clean the chest skin with alcohol before connecting the electrodes, apply the conductive paste on the range of 25mm diameter and the edge of chest electrode blister bowl, press the suction ball of the chest electrodes, and adsorb the chest electrodes on corresponding location. The connection of chest electrodes is shown below.

1: C1 (V1): the intersection of the left armpit midline and the fifth intercostal;

2: C2 (V2): the intersection of the right armpit midline and the fifth intercostal;

3: C3 (V3): the intersection of the left armpit frontline and the fifth intercostal;

4: C4 (V4): manubrium sterni;

5: C5 (V5): the forth intercostal space of the left edge of the sternum;

6: C6 (V6): the forth intercostal space of the left edge of the sternum, behind the heart.

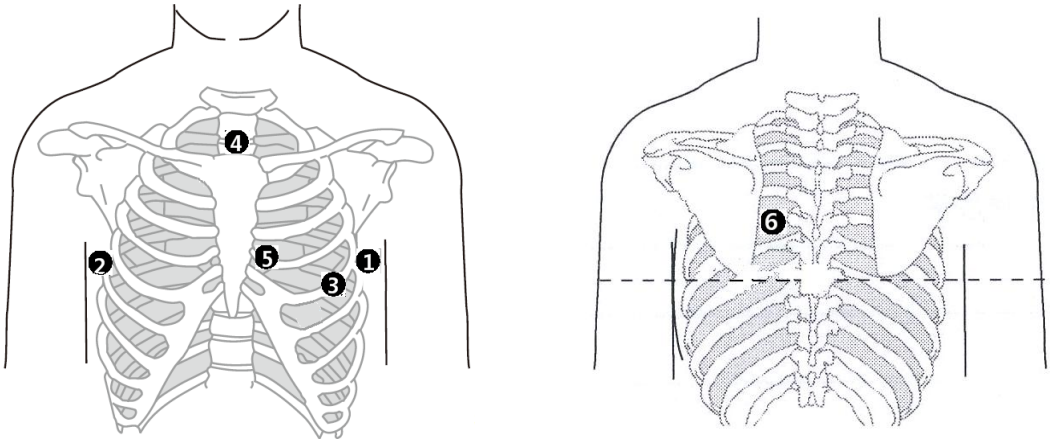

Fig. 2.3.6 Chest Electrode Installation (VLP)

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3) **Electrode and lead color table**

Table 2-3 Comparison of Electrode and Lead Wire Coding Marks and Colors (VLP)

System	European standards		American Standard	
	Symbol for electrode	Color code for electrode	Symbol for electrode	Color code for electrode
Limb electrodes	R	Red	RA	White
	L	Yellow	LA	Black
	N	Black	RL	Green
	F	Green	LL	Red
Chest electrodes	C	White	V	Brown
	C1	White / Red	V1	Brown / Red
	C2	White / Yellow	V2	Brown / Yellow
	C3	White / Green	V3	Brown / Green
	C4	White / Brown	V4	Brown / Blue
	C5	White /Black	V5	Brown / Orange
	C6	White / purple	V6	Brown / purple

2.3.4 Heart rate variability electrode placement

1) **Connection of limb electrodes**

Limb electrodes should be connected to the soft skin on the hands and feet. Clean the skin with alcohol before connecting the electrodes, and then coat a small amount of conductive paste on the skin after cleaning. Limbs electrodes connection (as shown below):

R (RA) connected to the right hand;

L (LA) connected to the left hand;

N (RL) connected to the right leg;

F (LL) connected to the left leg.

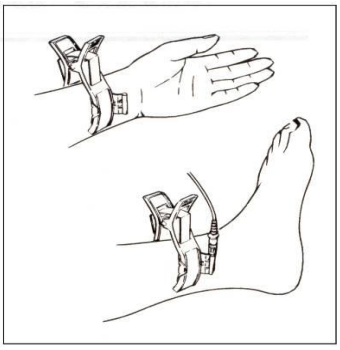

Fig. 2.3.7 Limb Electrode Connection Diagram (12-lead)

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2) **Electrode and lead color table**

Table 2-4 Comparison of Electrode and Lead Wire Coding Marks and Colors (standard 12-lead)

System	European standards		American Standard	
	Symbol for electrode	Color code for electrode	Symbol for electrode	Color code for electrode
Limb electrodes	R	Red	RA	White
	L	Yellow	LA	Black
	N	Black	RL	Green
	F	Green	LL	Red

2.4 Lead drop indication

This equipment can check the connection status of the lead at any time. If lead off is detected, the bottom of the interface displays “Lead Dropped”, as shown below:

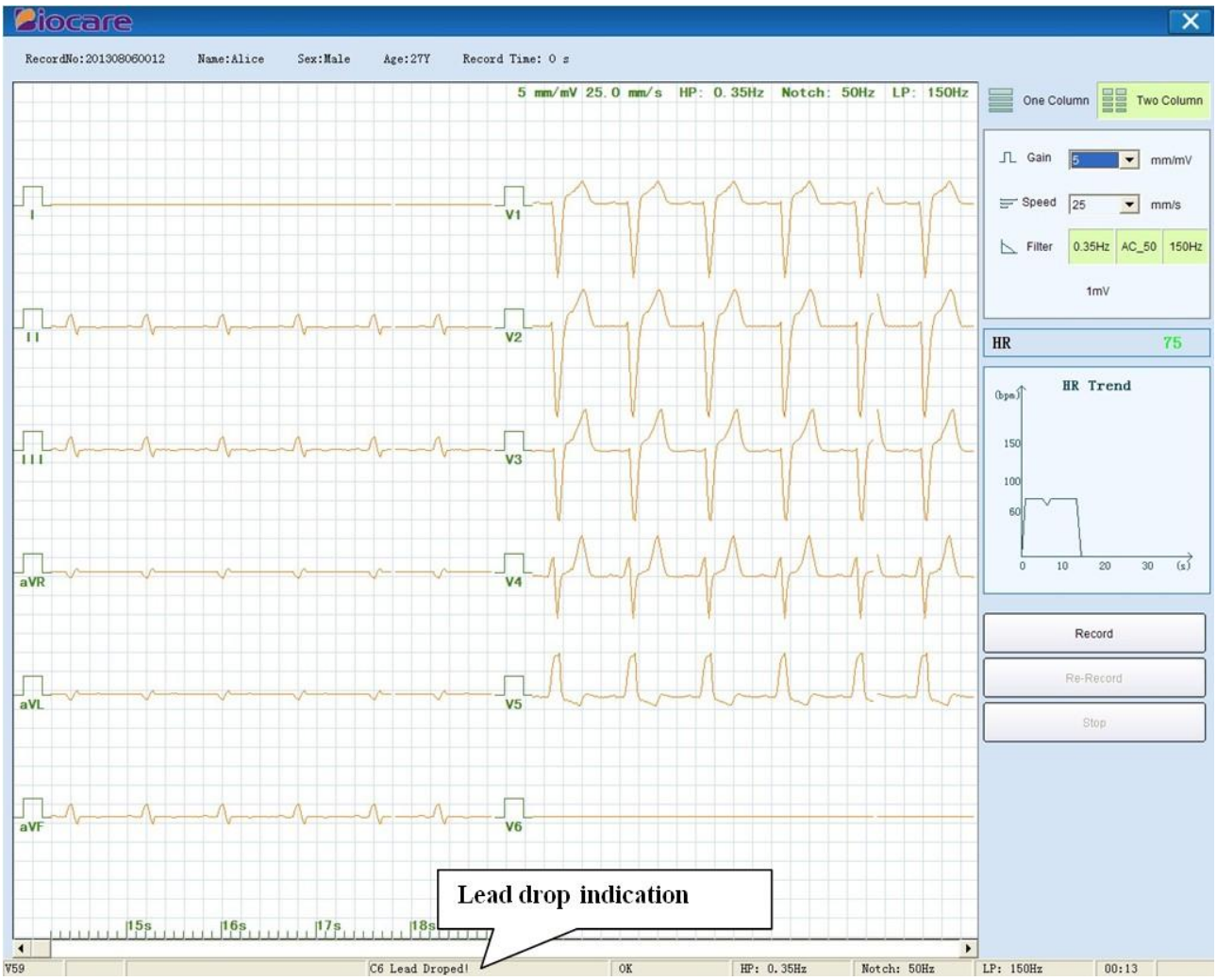

Fig. 2.4.1 Lead Drop Indication

When the lead is dropped, the lead waveform displayed as straight line. Please re-connect the electrodes or

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electrode leads according to the prompt information.

Note:

[* Lead Dropped]

When the cable is not reliably connected with the patient or equipment, the ECG signal cannot be transmitted correctly, and the symbol displays for reminding, in which "*" represents the current lead.

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Chapter 3 Common Operation Guide

This Chapter is about the common operation of the system, including the mouse concept in this Manual and common operation widgets. The introduction of the common operations of this chapter is limited to this system, aims to become familiar with the operation, and the widgets are not introduced in details. This chapter is intended for operators not familiar with computer operation, while those familiar with computer operation can skip this chapter.

3.1 Mouse operation glossary

Common mouse operations include click, double click, right-click, and drag.

1. Click: the most commonly used mouse operation. Click is to press the left mouse button once.
2. Double click: also a commonly used mouse operation; double click is to press the left mouse button twice continuously and quickly.
3. Right click: used for pop-up menu; right-click is to press the right mouse button once. In some complex widgets or special occasions, right-click will pop up a menu for the operation.
4. Drag: select an object, hold down the left mouse button, move the mouse and release the left button until the top of the target, and that is to complete a drag operation. Drag is a more complex operation.

3.2 Common widget operation

Common widgets include input boxes, drop down boxes, check boxes, buttons, tabs, etc.

1. Input box

The input box is the most commonly used input widget, which allows directly entry of numbers and characters, including words.

Commonly used input box:

Focus of widgets

Some commonly used widgets have focuses, such as input boxes, drop-down boxes, check boxes, buttons. These widgets will respond to the keyboard only when the focus is gotten. The focuses of these widgets will shift when Enter is pressed.

Focus shift usually has three ways: Under normal circumstances, if the system does not have a special control, the focus will shift to the widget after clicking on a widget; when the widget has gotten the focus, it will generally show a dashed box.

For input boxes, a blinking cursor displays on the input box after getting the focus. At this time, you can enter through the keyboard, or else, the input box won't respond to keyboard input.

2. Drop-down box

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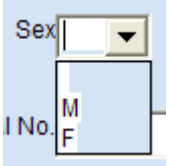
Drop-down box is a widget that allows selecting a value from the provided range and it is also one of the most commonly used widgets.

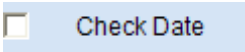


For operation, click the Down arrow to show a drop-down list, which has the available values. You can select the value by clicking on the appropriate line from the drop-down list.

The drop-down box is generally controlled by the mouse; however, after getting the focus, it also responds to keyboard operation, including space, up and down arrows, and Enter. Using the keyboard effectively can improve the input speed.

3. Check box

The check box is used for the option of yes or no. You can click the small box to the left of the check box to select or deselect the option. When the option is deselected, the small box is blank. As shown below:

Check box: 

Check box is generally operated by the mouse. After getting the focus, you can use the spacebar or click the left mouse button to select or deselect.

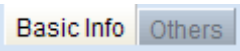
4. Button

Button is also one of the commonly used widgets. Generally, you can click on a button to execute the task. After getting the focus, you can press the spacebar or Enter key to activate the button.

Button is as shown:

5. Tab

Tab is a widget that displays and inputs through multiple pages. You can select to display a different page through the tab.



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Chapter 4 Software Functions

This chapter will explain software operation and functions in details according to the workflow.

4.1 Main interface of the system

Double-click on the

icon on desktop to enter the ECG-2000 system. The main interface of the system is shown below. You can select all the medical records, so that all ECG examinations will appear in the medical record list.

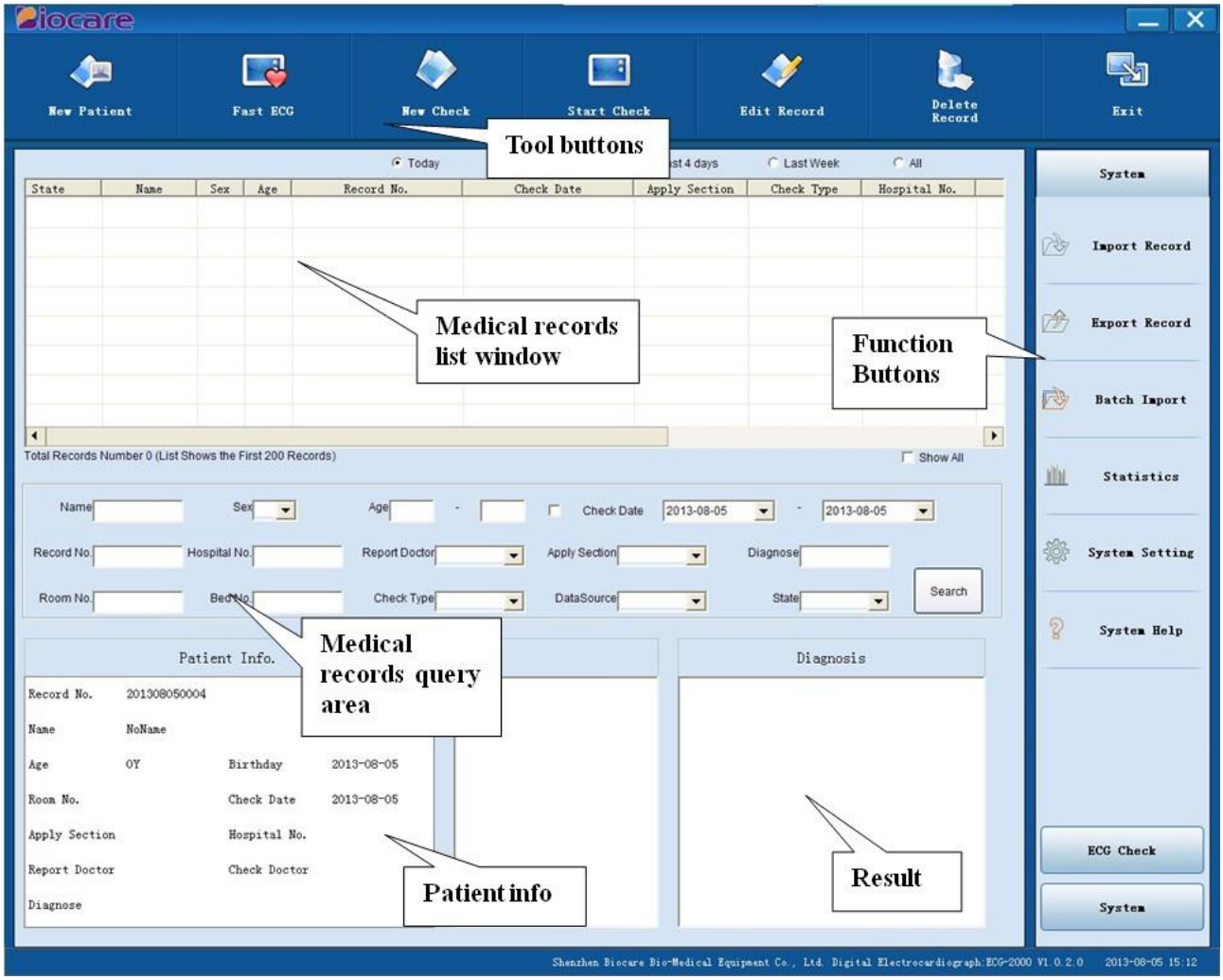

Fig. 4.1.1 Main Interface of the System

The buttons arranged horizontally in the top of the main interface are called tool buttons, which are used for operation of medical records.

The buttons arranged vertically in the right side of the main interface are called function buttons, which are used for ECG check and system control. The display includes “ECG Check” and “System”. The middle of the interface is medical records query area and medical records list window. The bottom is patient information and

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diagnostic conclusions. The areas will be introduced briefly below.

4.1.1 Tool button

- New Patient: Click the button to pop up the patient info window and create a new medical record.
- Fast ECG: acquire ECG first and then edit the medical records, applicable to emergency patients.
- New Check: Click the button to pop up the check selection box, and check up the patient again. After checking, a new record is created in the list.
- Start Check: start checking for the medical records without data; after checking, the medical records have data.
- Edit Record: Click the button to pop up the patient info window, and modify the medical record information.
- Delete Record: Select the medical record to be deleted, and the patient information of the medical record displays in the Patient Info window. Click the "Delete Record" button, and the system automatically pops up the prompt to confirm to delete the record:

You can click “Yes” to delete the records, or click "No" to exit.

- Exit: to exit the software.

4.1.2 ECG check button

After login the system, there are some functional buttons for electro cardio examination. Among them, it’s optional for VCG, VLP, HRV, HFECG, FCG, HRT and QT. It means if the user did not purchase the function, the function will be unavailable.

If the check type of the file is ECG12, it can be used in the function of ECG, HFECG, FCG, HRT and QT;

If the check type of the file is VCG, it can be used only in the function of VCG;

If the check type of the file is VLP, it can be used only in the function of VLP;

If the check type of the file is HRV, it can be used only in the function of HRV.

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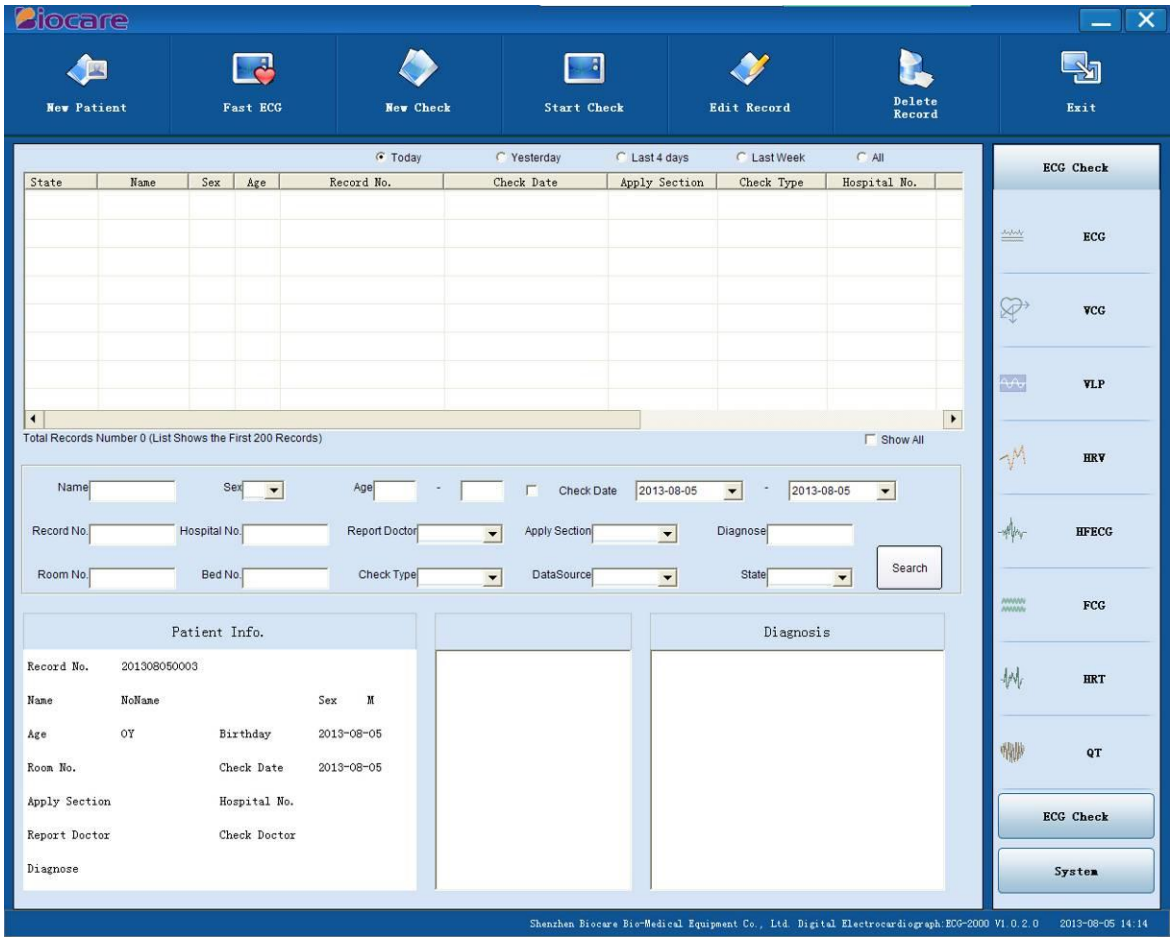

Fig. 4.1.2 Main Interface of the System

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4.1.3 System button

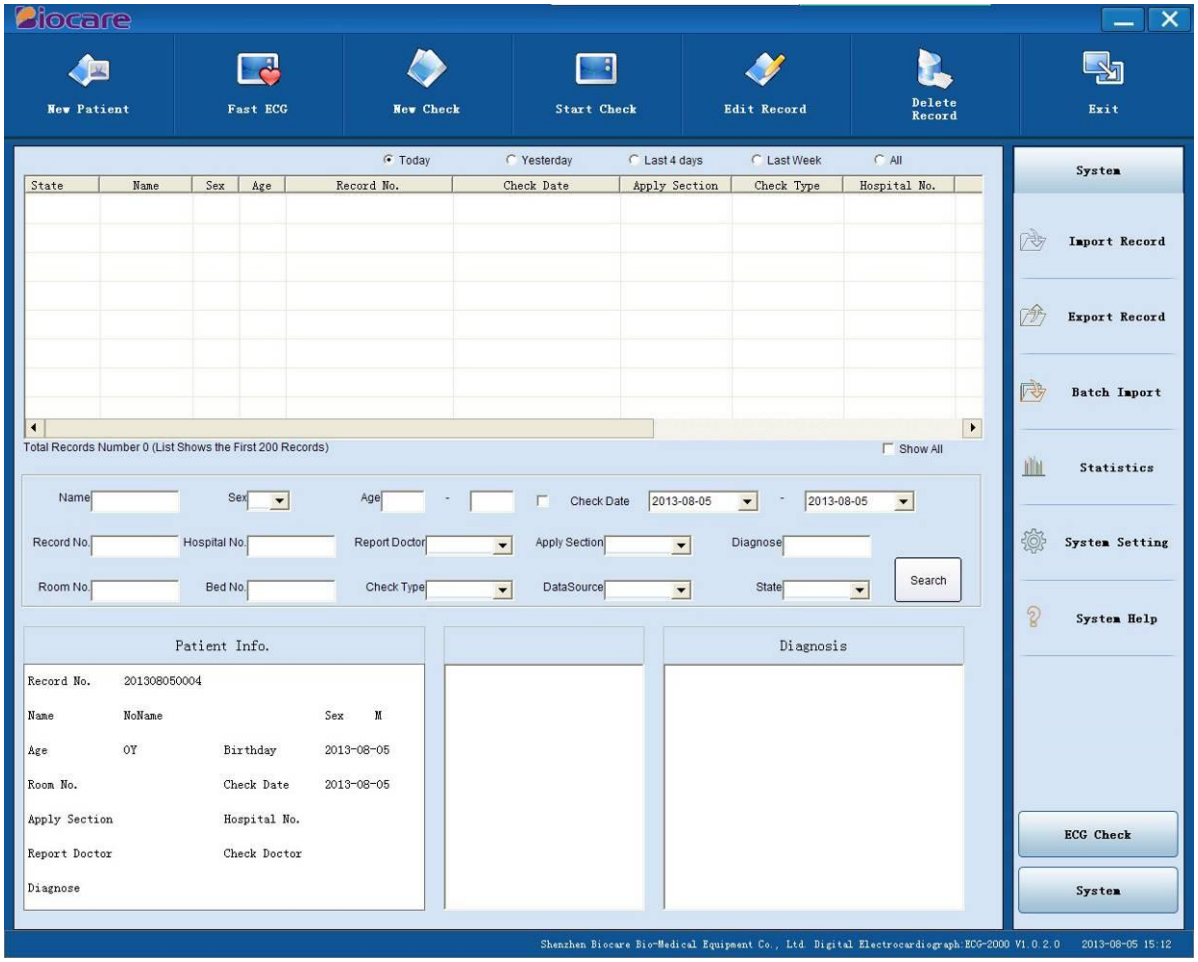

Fig. 4.1.3 Main Interface of Function Buttons

System settings have several options: Import Record, Export Record, Batch Import, Statistics, System Setting and System Help.

- Import/Export Record: to import and export the medical records; see Section 4.18.
- Batch Import: to import the medical records in batches.
- System Setting: Click the button to pop up the System Setting window; see Section 5.2 for specific operation.
- System Help: display the software information, as shown below.

Fig. 4.1.3 System Help Dialog

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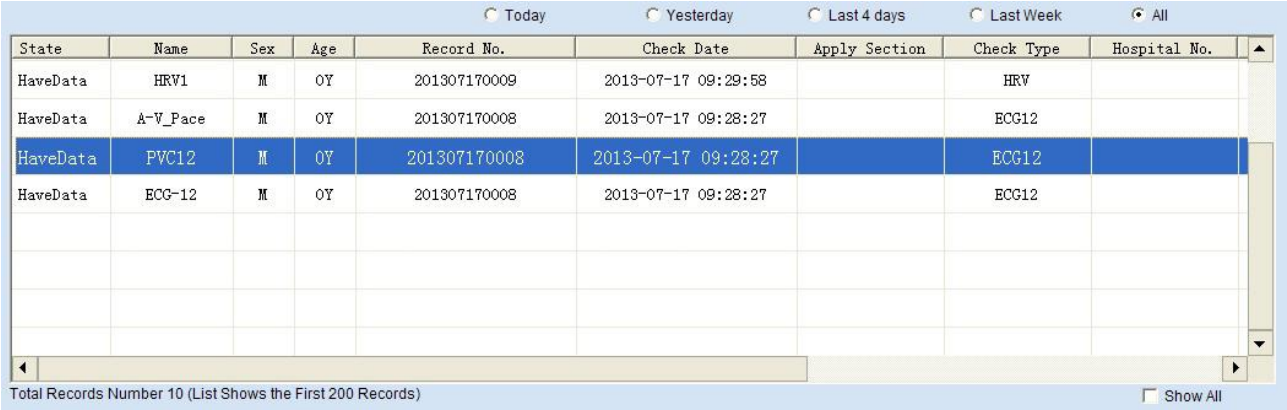
4.1.4 Medical records list

Medical records list: display the medical records sequentially by state, name, sex, age, or record number. You can place the cursor on the right side of Check Date column, hold the mouse and drag to the right to expand the column width.



State	Name	Sex	Age	Record No.	Check Date	Apply Section	Check Type	Hospital No.
HaveData	HRV1	M	0Y	201307170009	2013-07-17 09:29:58		HRV	
HaveData	A-V_Pace	M	0Y	201307170008	2013-07-17 09:28:27		ECG12	
HaveData	PVC12	M	0Y	201307170008	2013-07-17 09:28:27		ECG12	
HaveData	ECG-12	M	0Y	201307170008	2013-07-17 09:28:27		ECG12	

Fig. 4.1.4 Medical Records List

- Today: click the radio box in front to display the medical records of today in the list
- Yesterday: click the radio box in front to display the medical records of yesterday in the list
- Last 4 days: click the radio box in front to display the medical records of last 4 days in the list
- Last week: click the radio box in front to display the medical records of last week in the list
- All: click the radio box in front to display all the medical records in the list

Select a medical record in the list, and the patient info, and diagnostic conclusions will be displayed on the bottom of the screen.

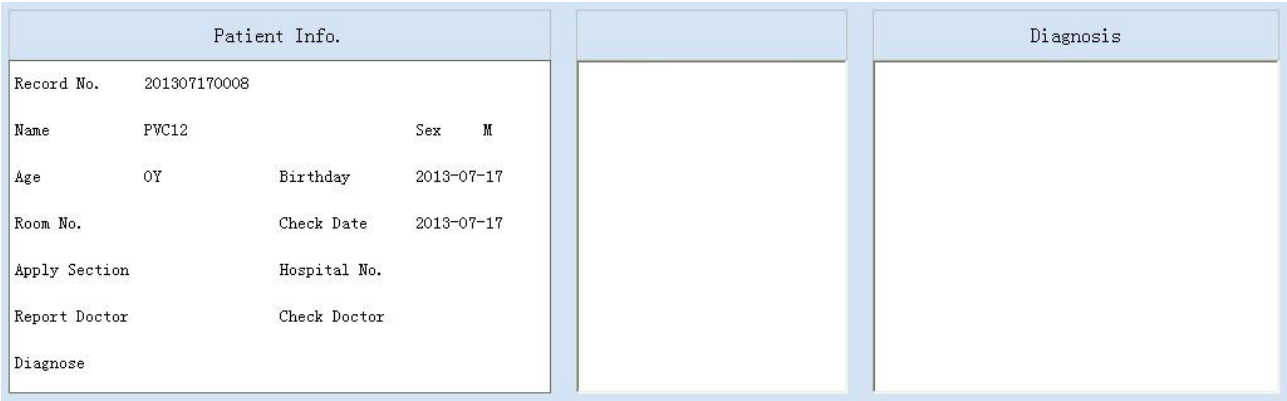


Fig. 4.1.5 Patient Info & Diagnosis

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4.2 System setting

Click the System Setting button in function button area to pop up the setting window as below:

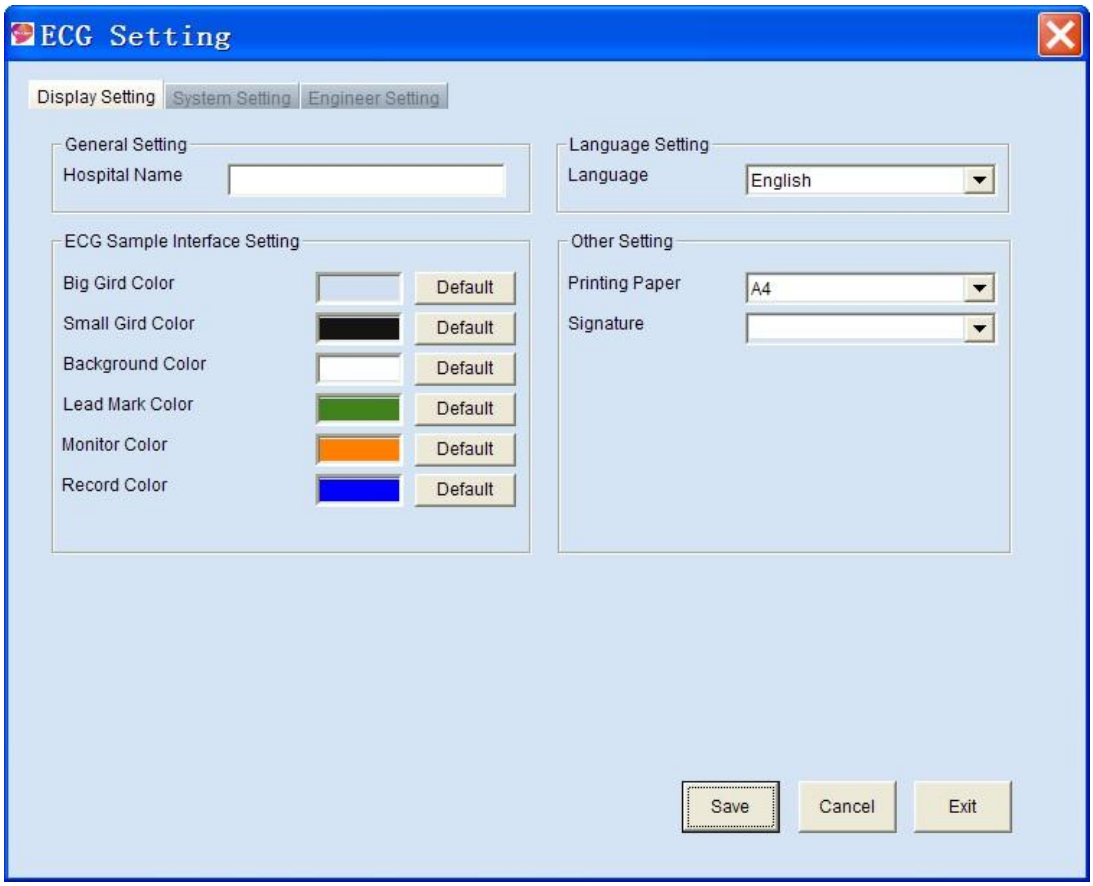

Fig. 4.2.1 System Setting Interface

4.2.1 Display setting

Allow setting the ECG waveform and background grid color of acquisition display.

Hospital name: enter a name of the hospital manually.

Language setting: to modify the display language of the software.

Printing paper: to modify the default paper type.

Signature: to set the signature of the doctor. This signature will be displayed in the position of doctor's signature of all reports. This check box can record 20 input data at most.

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4.2.2 System setting

You can set the default sample type and data path. This option had been configured by the engineer when the software was installed, and shall not be modified without permission.

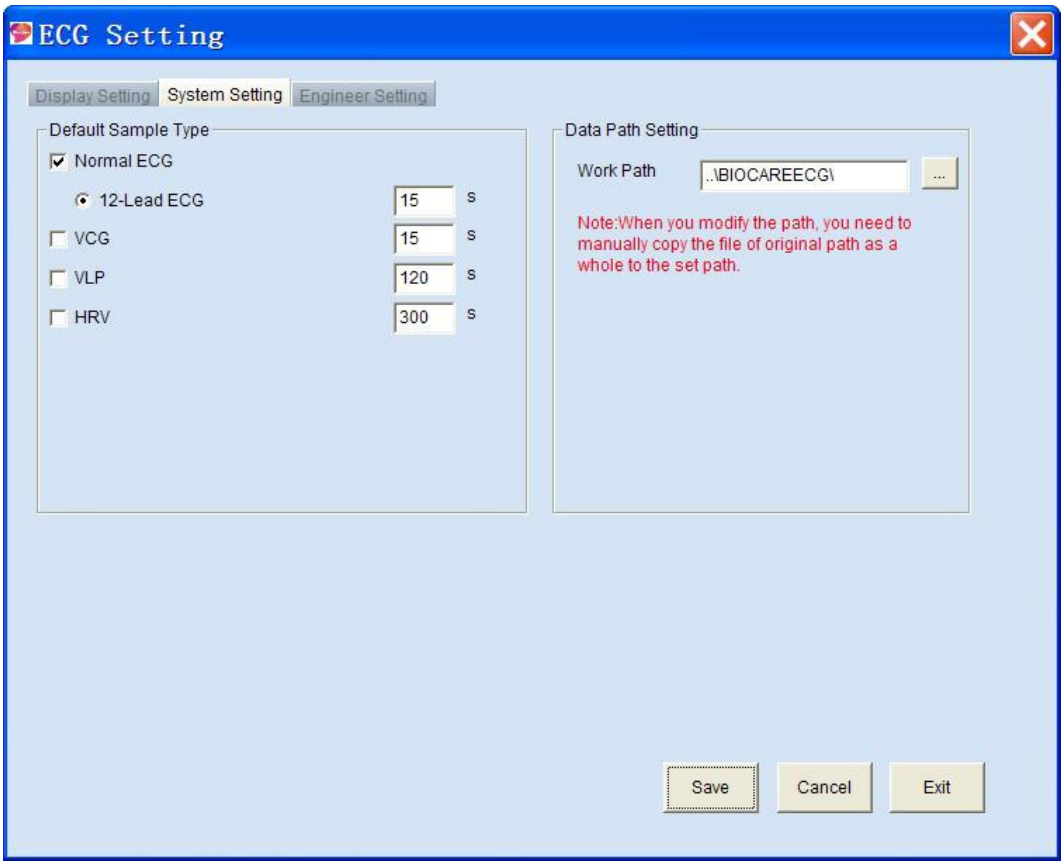

Fig. 4.2.2 System Setting Interface

Default Sample Type：Set default sample type and default sampling time.

Work path: to set the storage path of patient information and ECG data.

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4.3 New medical record

Click the "New Patient" button to pop up the patient info window: enter the patient information in the Patient Info window. When the cursor flashes in the input box, you can enter the content. Clinical diagnosis and remark accept up to 100 characters, while the sex, apply section, and apply doctor can be entered manually or selected from the drop-down box. User can also check pacemaker in this interface. **Note: Name and Age are required.** As shown in the figure, the seven check boxes in the red dotted line box can save 20 historical data at most after successfully saving data every time.

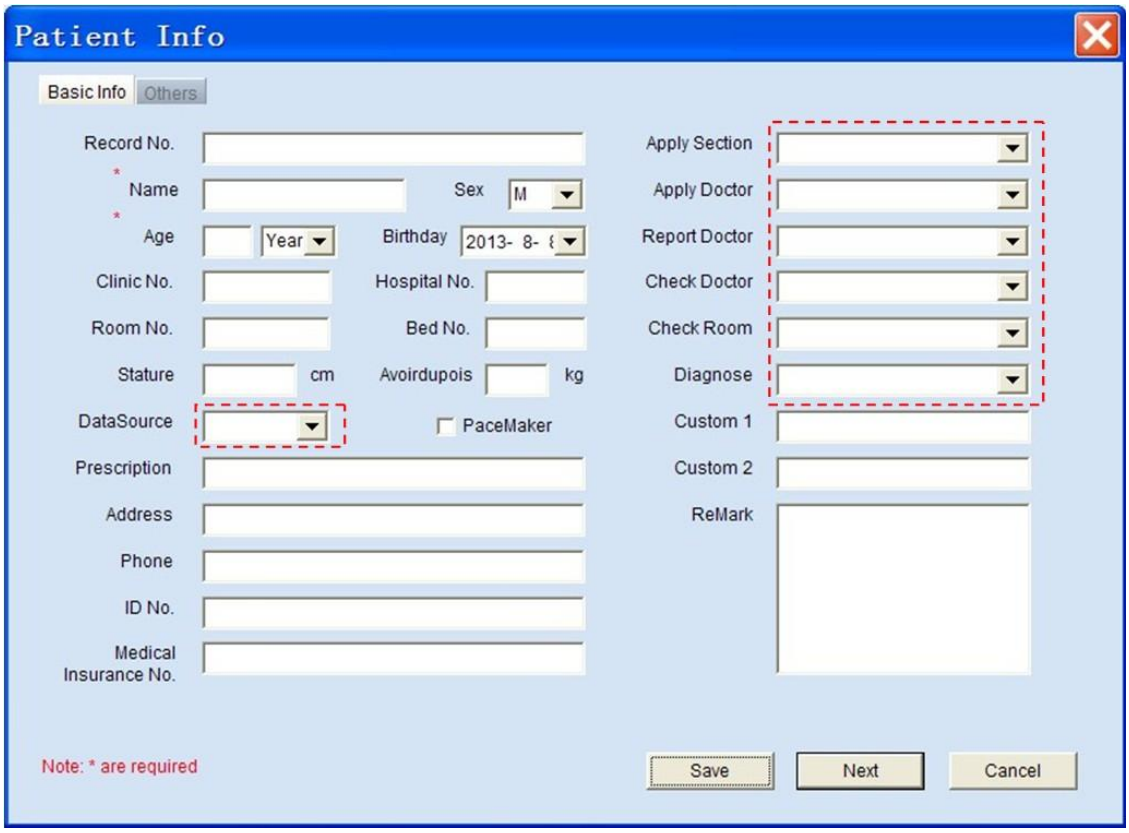

Fig. 4.3.1 Patient Info Input Interface

Click "Others" tab in the top to set more patient information (as shown below), and then click "Next" to enter the check selection window. If you do not need to set more patient information, click Save directly to save new medical record, or click "Next" to start checking.

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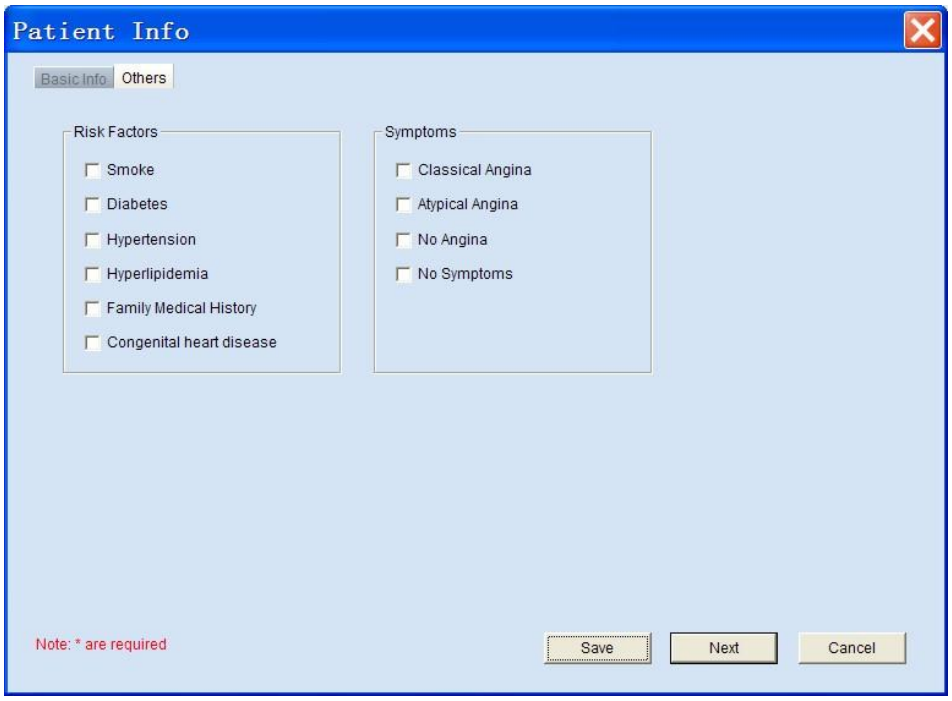

Fig. 4.3.2 Others Interface of Patient Info

4.4 Sampling

4.4.1 Sample options

Enter the Sample Options box as shown below, select the check items and sample time and then click “Next”.

Checking item: click the check box or radio box on the left of the item.

Sampling time: click the arrows on the right of the item, or move cursor to the input box and enter manually.

ECG signal sampling rate: 1000 Hz.

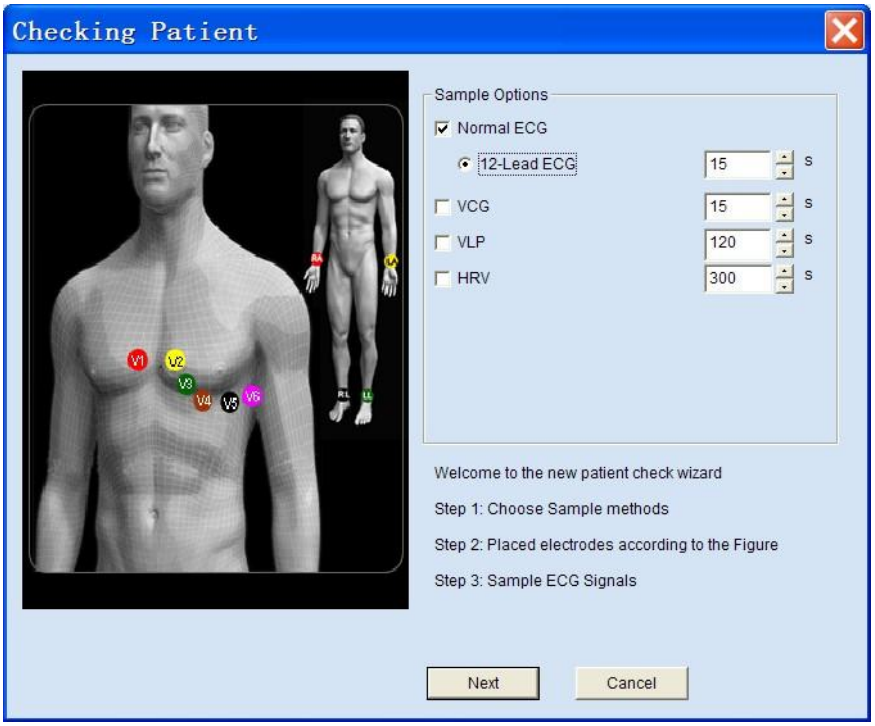

Fig. 4.4.1 Choosing Sample Methods

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Click “Next” to enter the sampling interface, take 12-lead ECG for example, the sample interface is as shown below:

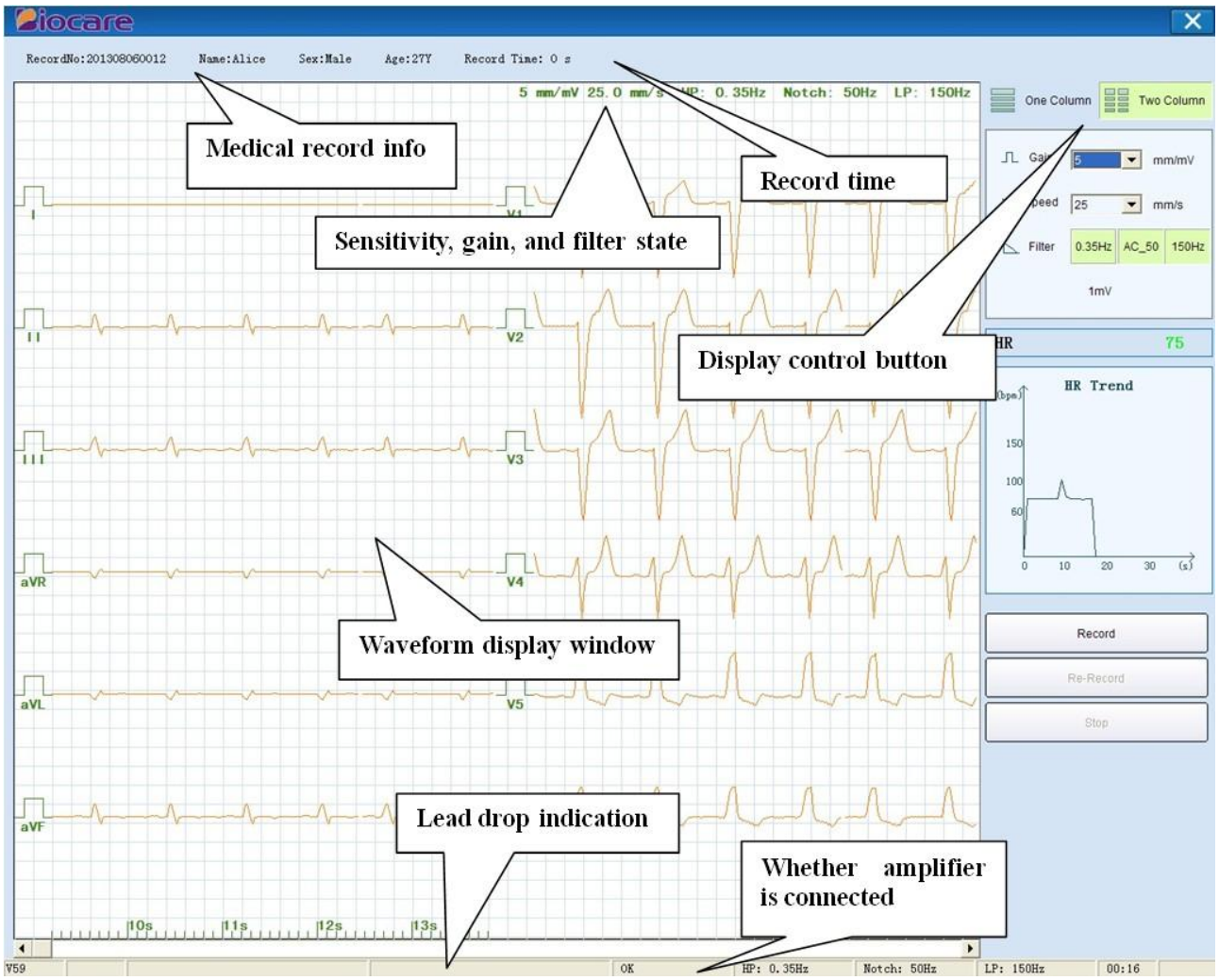

Fig. 4.4.2 12-lead Synchronous ECG Sample Interface

Enter the sample interface and start monitoring ECG waveform, of which the color is yellow at this time; check if all lead waveforms are normal, and adjust the placement of the lead wires or check the connection of ground wires if there is any interference lead. In this process, you can adjust the sensitivity , waveform speed and filter status .

When the monitoring is normal, click the Record button to start sampling the ECG waveform data; the times in the top of the window is started, and the waveform color changes to blue.

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Fig. 4.4.3 12-lead Synchronous ECG Sampling Interface

After the specified sampling time, it automatically exits the sample window and returns to the main interface.

After clicking the Stop button, you can playback the sampling waveform by dragging the scroll bar in the bottom.

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Fig. 4.4.4 Sampling Waveform Playback

Left click the Close button in the upper right corner directly, and the system automatically pops up the prompt box to ask the use to save the record or not.

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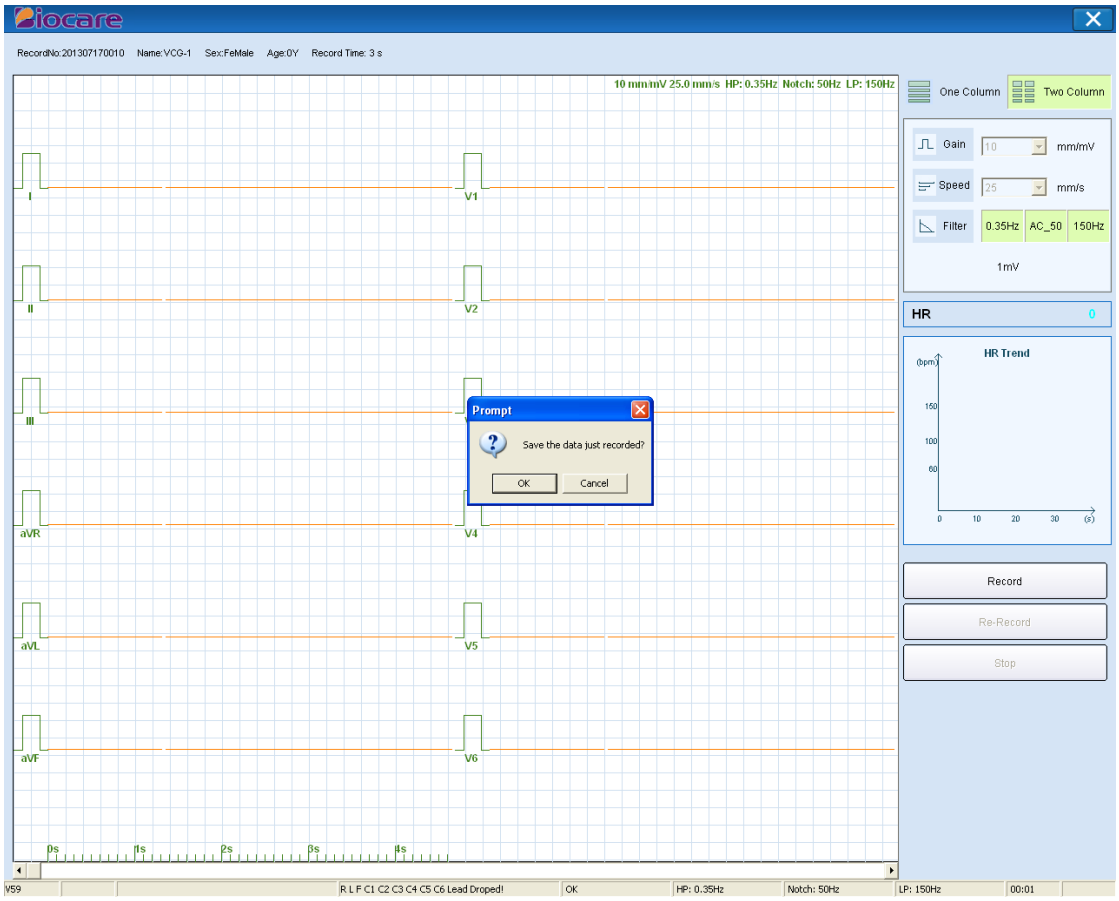

Fig. 4.4.5 Saving Prompt of 12-lead Synchronous ECG Sampling Records

4.4.2 Gain setting

Click the down arrow to show a drop-down list, and set the sensitivity to 5 mm/mV, 10 mm/mV or 20 mm/mV.

4.4.3 Speed setting

Click the down arrow to show a drop-down list, and set the waveform speed to 12.5 mm/s, 25 mm/s or 50 mm/s.

Note: before sampling, please make sure that the different ECG checks use the corresponding lead mode. For example, the conventional ECG uses Wilson lead, the VCG uses Frank lead, and the VLP uses orthogonal lead.

4.4.4 Filter setting

Click AC_50 to select notch filter, which has three options: not filter, 50 Hz (default) and 60 Hz.

Click 0.5 Hz to select high-pass filter, which has six options: 0.01 Hz, 0.02 Hz, 0.05 Hz, 0.35 Hz, 0.5 Hz (default) and 0.8 Hz.

Click 100 Hz to select low-pass filter, which has six options: 25 Hz, 35 Hz, 75 Hz, 100 Hz (default), 150 Hz and 250 Hz.

The filter state will be displayed in the upper right of the interface at the same time, as shown below:

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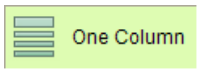
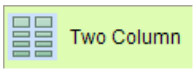
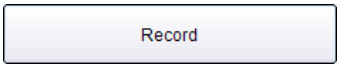
Fig. 4.4.6 Filter State Display

4.4.5 Other buttons and display



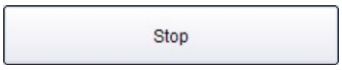
Display in full screen; 

display in two pages



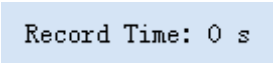
Record: to start recording the ECG waveform

Re-record: to re-record the ECG waveform, and automatically clear the previous record



Stop: to stop recording the ECG waveform

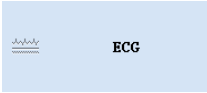
Exit the sample window



Display the recording time of ECG data

4.5 12-lead ECG waveform playback

4.5.1 12-lead playback interface

In the medical records list, double-click 12-lead ECG medical records or select 12-lead ECG medical records and click the 

button to enter the playback interface.

The playback window is as shown below:

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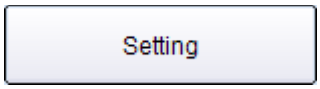
Fig. 4.5.1 12-lead Playback Interface



Click this button to enter the setting interface, as shown below:

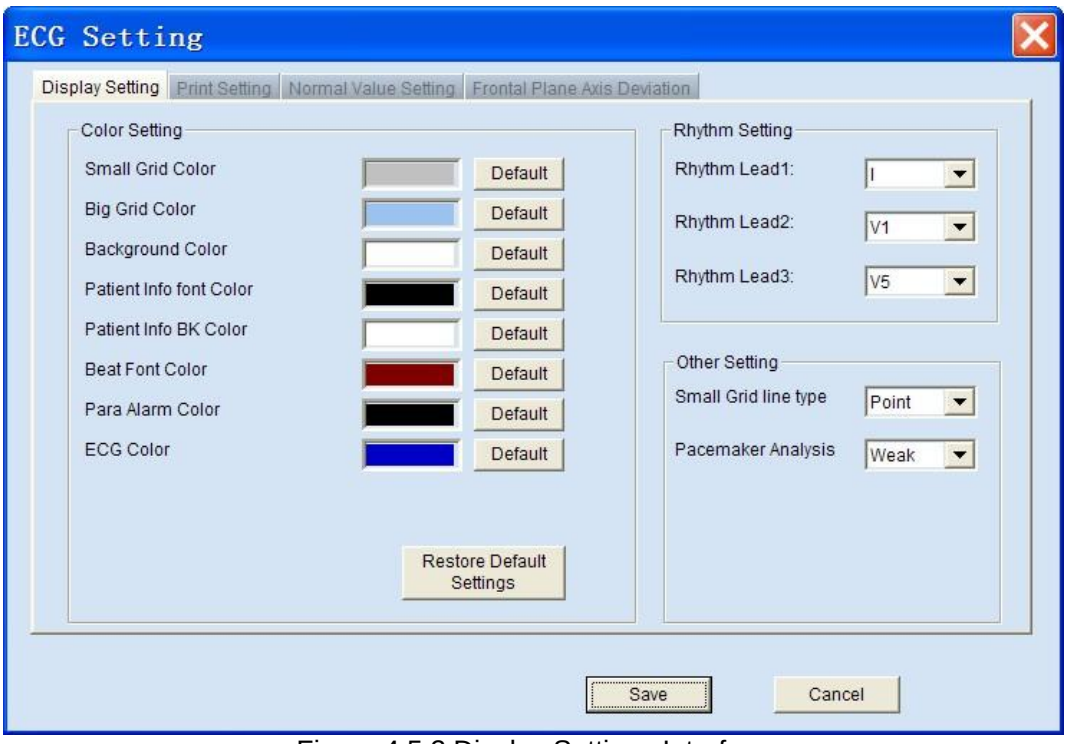


Figure 4.5.2 Display Settings Interface

Display setting: allow setting pacemaker (default to Weak), the background color, grid color, waveform color and

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display rhythm lead.

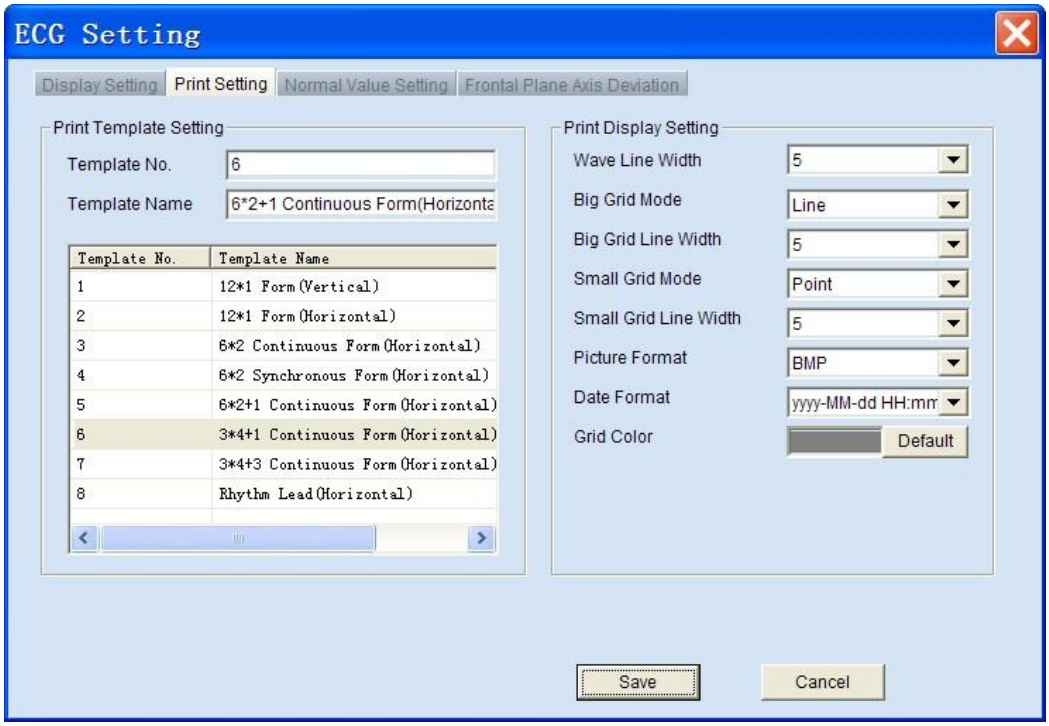

Figure 4.5.3 Print Settings Interface

Print setting: allow setting the print template (waveform arrangement and paper type), report date format, print grid mode, report type and color.

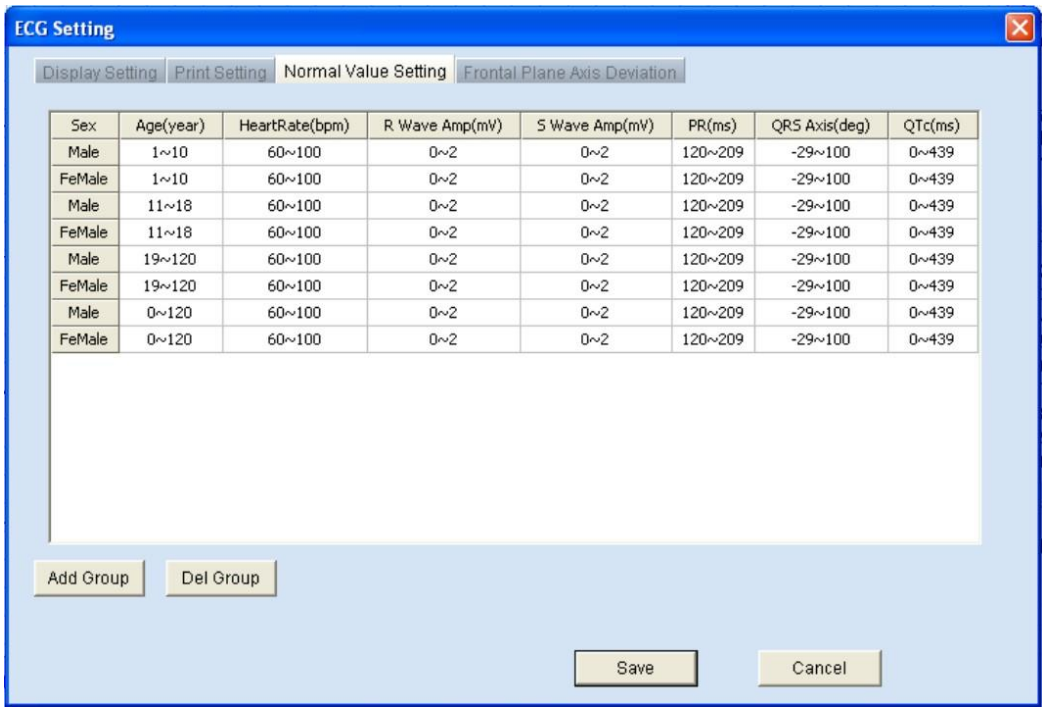

Fig. 4.5.4 Normal Value Setting Interface

Normal value setting: allow setting the normal values of the heart rate of different ages, R wave amplitude, S-wave amplitude, PR interval, QRS electrical axis, and QTc interval.

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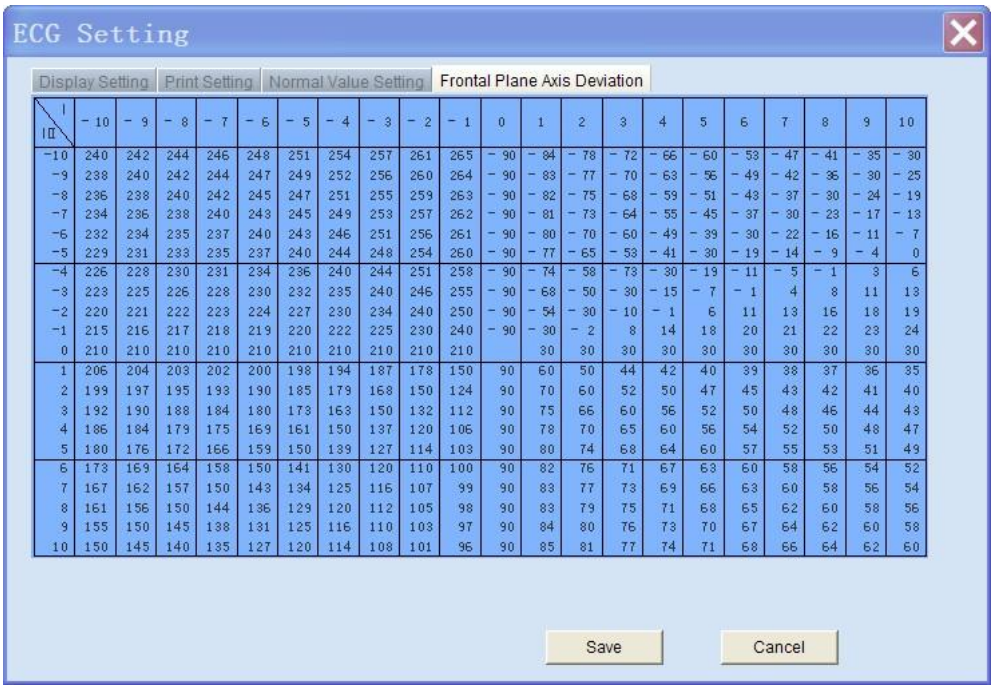

ECG Setting

Display Setting | Print Setting | Normal Value Setting | Frontal Plane Axis Deviation

II \ I	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1	0	1	2	3	4	5	6	7	8	9	10
-10	240	242	244	246	248	251	254	257	261	265	-90	-84	-78	-72	-66	-60	-53	-47	-41	-35	-30
-9	238	240	242	244	247	249	252	256	260	264	-90	-83	-77	-70	-63	-56	-49	-42	-36	-30	-25
-8	236	238	240	242	245	247	251	255	259	263	-90	-82	-75	-68	-59	-51	-43	-37	-30	-24	-19
-7	234	236	238	240	243	245	249	253	257	262	-90	-81	-73	-64	-55	-45	-37	-30	-23	-17	-13
-6	232	234	235	237	240	243	246	251	256	261	-90	-80	-70	-60	-49	-39	-30	-22	-16	-11	-7
-5	229	231	233	235	237	240	244	248	254	260	-90	-77	-65	-53	-41	-30	-19	-14	-9	-4	0
-4	226	228	230	231	234	236	240	244	251	258	-90	-74	-58	-73	-30	-19	-11	-5	-1	3	6
-3	223	225	226	228	230	232	235	240	246	255	-90	-68	-50	-30	-15	-7	-1	4	8	11	13
-2	220	221	222	223	224	227	230	234	240	250	-90	-54	-30	-10	-1	6	11	13	16	18	19
-1	215	216	217	218	219	220	222	225	230	240	-90	-30	-2	8	14	18	20	21	22	23	24
0	210	210	210	210	210	210	210	210	210	210		30	30	30	30	30	30	30	30	30	30
1	206	204	203	202	200	198	194	187	178	150	90	60	50	44	42	40	39	38	37	36	35
2	199	197	195	193	190	185	179	168	150	124	90	70	60	52	50	47	45	43	42	41	40
3	192	190	188	184	180	173	163	150	132	112	90	75	66	60	56	52	50	48	46	44	43
4	186	184	179	175	169	161	150	137	120	106	90	78	70	65	60	56	54	52	50	48	47
5	180	176	172	166	159	150	139	127	114	103	90	80	74	68	64	60	57	55	53	51	49
6	173	169	164	158	150	141	130	120	110	100	90	82	76	71	67	63	60	58	56	54	52
7	167	162	157	150	143	134	125	116	107	99	90	83	77	73	69	66	63	60	58	56	54
8	161	156	150	144	136	129	120	112	105	98	90	83	79	75	71	68	65	62	60	58	56
9	155	150	145	138	131	125	116	110	103	97	90	84	80	76	73	70	67	64	62	60	58
10	150	145	140	135	127	120	114	108	101	96	90	85	81	77	74	71	68	66	64	62	60

Save | Cancel

Fig. 4.5.5 Frontal Plane Axis Deviation Table

Frontal Plane Axis Deviation table: display the frontal plane ECG axis measuring table.

Full Screen Click this button to enter the full screen interface, as shown below. The full screen mode can display longer and clearer graphs; you can click the "Restore" button to return to the original playback interface.

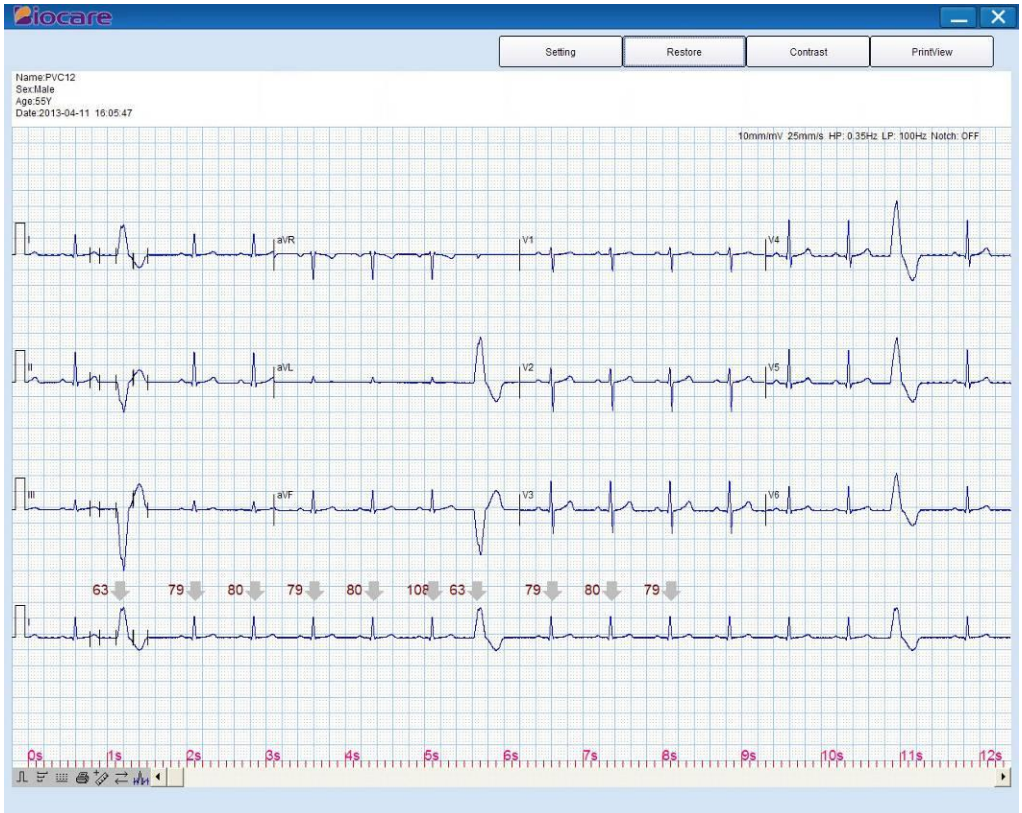

Fig. 4.5.6 Full Screen ECG Interface

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PrintView Click this button to enter the print preview interface and preview according to the template set in print setting.

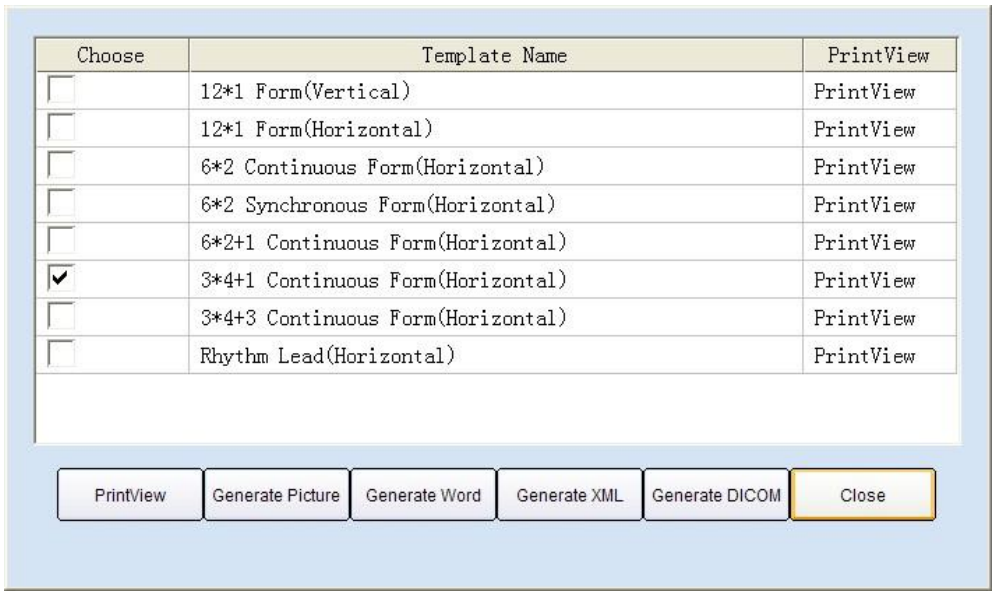

Fig. 4.5.7 Print Preview Setting Options

Generate Picture To generate a picture in JPG format or BMP format, and automatically save in the PIC directory under the data directory. The default path is C:\Program Files\Biocare SoftWare\BIOCAREECG\PIC\.

Generate Word To generate report in Word format and the file will be automatically saved in the Word directory under the data directory. The default path is C:\Program Files\Biocare SoftWare\BIOCAREECG\Word\.

Generate XML To generate XML, export data to XML format and automatically save in the XML directory under the data directory. The default path is C:\Program Files\Biocare SoftWare\BIOCAREECG\XML\.

Generate DICOM To generate DICOM file and the file will be saved in the DICOM directory under the data directory. The default path is C:\Program Files\Biocare SoftWare\BIOCAREECG\DICOM\.

Note: The format of the generated picture can be set in Settings - Print Setting - Graphic Report Type.

: Tool action bar:

: Sensitivity setting (see Section 4.5.3 for details);

: Waveform speed setting (see Section 4.5.3 for details);

: ECG display mode (see Section 4.5.2 for details);

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: Print preview (see Section 4.5.7 for details);

: Waveform (time difference, magnitude difference, discounted heart rate) measurements (see Section 4.5.4 for details);

: Lead switch (see Section 4.5.4 for details);

: Switch between composite heart beat and current heart beat.

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4.5.2 12-lead ECG display mode

Click the button on the lower left corner of the graph, and select the ECG display mode. Select 12 × 1 to enter the mode in playback interface, or select 6 × 2_S to display as follows: S represents the synchronous mode, the waveforms of the two leads start from the same time, and show time scale below the waveforms, corresponding to the time of the top waveforms; displaying only half the time indicates that the two waveforms have the same time.

Fig 4.5.8 12-lead Playback Interface in 6 × 2_S Mode

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Select 6 ×2_C to display as follows: C represents the continuous mode, i.e. the waveform time of the two leads of the same row in the interface is continuous, and show time scale below the waveforms, corresponding to the time of the top waveforms; the times of the two waveforms are connected, indicating that the later waveform displays following the former waveform.

Fig 4.5.9 12-lead Playback Interface in 6 × 2_C Mode

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Select 3 ×4_C +1 to display as follows: the graph displayed by the long leads in the same position is consistent with the graph displayed by above 12-lead.

Fig 4.5.10 12-lead Playback Interface in 3 × 4_C +1 Mode

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Select the 3 ×4_C +3 to display as follows:

Fig 4.5.11 12-lead Playback Interface in 3 × 4_C +3 Mode

4.5.3 Waveform speed and sensitivity

Click the button on the lower left corner of the graph, and select the ECG waveform speed.

You can choose ECG waveform displays in the waveform window at the speed of 5 mm/s, 6.25 mm/s, 10 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s.

Click the button on the lower left corner of the graph, and select the ECG sensitivity.

You can choose ECG waveform displays in the waveform window at the sensitivity of 1.25 mm/mV, 2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV.

10/5mm/mV, 20/10mm/mV Limb ECG waveform displays in the waveform window at the sensitivity of 10 mm/mV, 20 mm/mV, Chest ECG waveform displays in the waveform window at the sensitivity of 5 mm/mV, 10 mm/mV.

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4.5.4 Waveform measurement and lead interchange

Waveform measurement

Click on the button in the lower left corner of the graph. Move the cursor to the start of the waveform to be measured, press the left button to drag the mouse to the end position to be measured and release the mouse to measure; the measurement data window pops up, and displays the measurement data.

Fig. 4.5.12 Waveform Measurement Functions

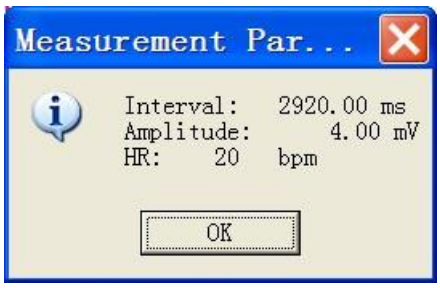

Fig. 4.5.13 Waveform Measurement Parameters

Lead interchange

Click the button in the lower left corner of the graph to pop up the lead interchange dialog, and then you can choose arm leads or chest leads. This function is mainly used by the users that connect the wrong lead during sampling; with this function, it doesn't need re-sampling ECG.

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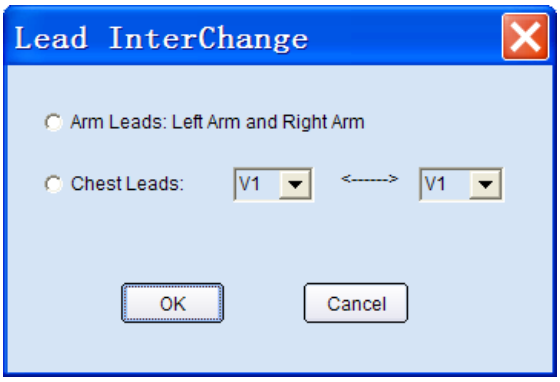

Fig. 4.5.14 Leads Interchange Setting Menu

4.5.5 Enlargement and fine tuning of representative heart beat

For analyzed data, double-click the corresponding lead with the left mouse button in the waveform display window to bring up the representative heart beat enlarging window and analyze the representative heart beat precisely, as shown below:

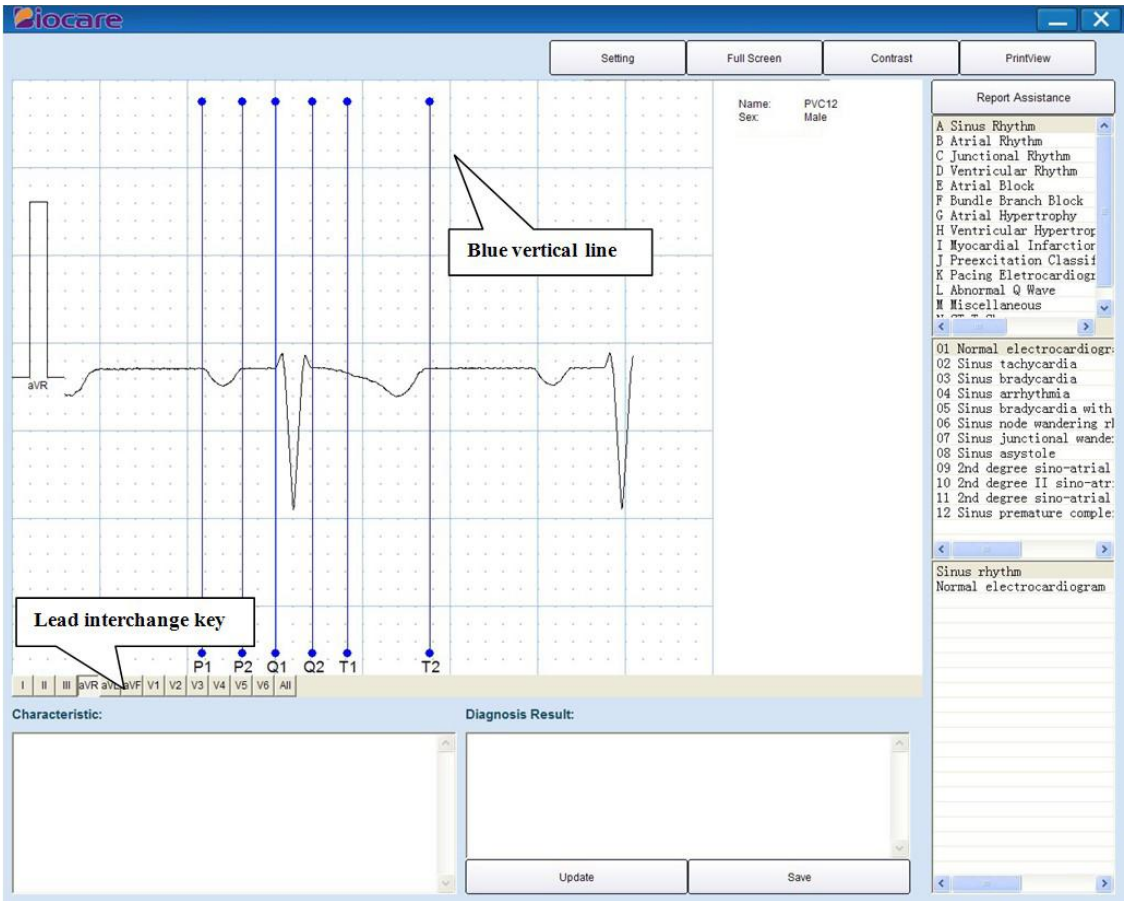

Fig. 4.5.15 Representative Heart Beat Enlargement and Fine-tuning Function

You can also select the Lead Interchange key below to switch the currently displayed lead, and drag the blue vertical line P1, P2, Q1, Q2, T1, and T2 to tune the current lead. Double-click the left mouse button to return to the waveform window.

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4.5.6 Diagnosis

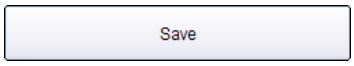
1. ECG characteristics

This window is mainly used to record the ECG characteristics. You can click on the window with the left mouse button and input the characteristics when the cursor flashes in the input window.

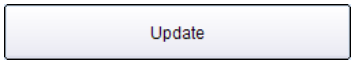
2. ECG conclusion

As shown in the following figure, the report assistant in the right side is displayed in three levels: the first level displays the symptom type; click a symptom type in the window of the first level and the symptom type of next level will be displayed in the window of second level; click a symptom type in the window of the second level and the symptom details will be displayed in the window of third level. Double-click a symptom in the third level window, and bring it into ECG diagnostic result. Doctors can modify and typeset the result, or enter the own diagnostic result.

Fig. 4.5.16 ECG Report Assistant Function



Save all the content in the interface.



Update the content of the library maintenance report assistant.

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4.5.7 Print

Click the PrintView button to enter the print preview interface, select the template to preview, and the report same as the template displays on the screen; then, you can click on Print to print the report. You can also click Generate Picture (the format of the generated picture can be set in Settings - Print Setting, and automatically saved in the PIC directory under data directory). The following example shows fast print of report in 3 ×4 +1 display mode:

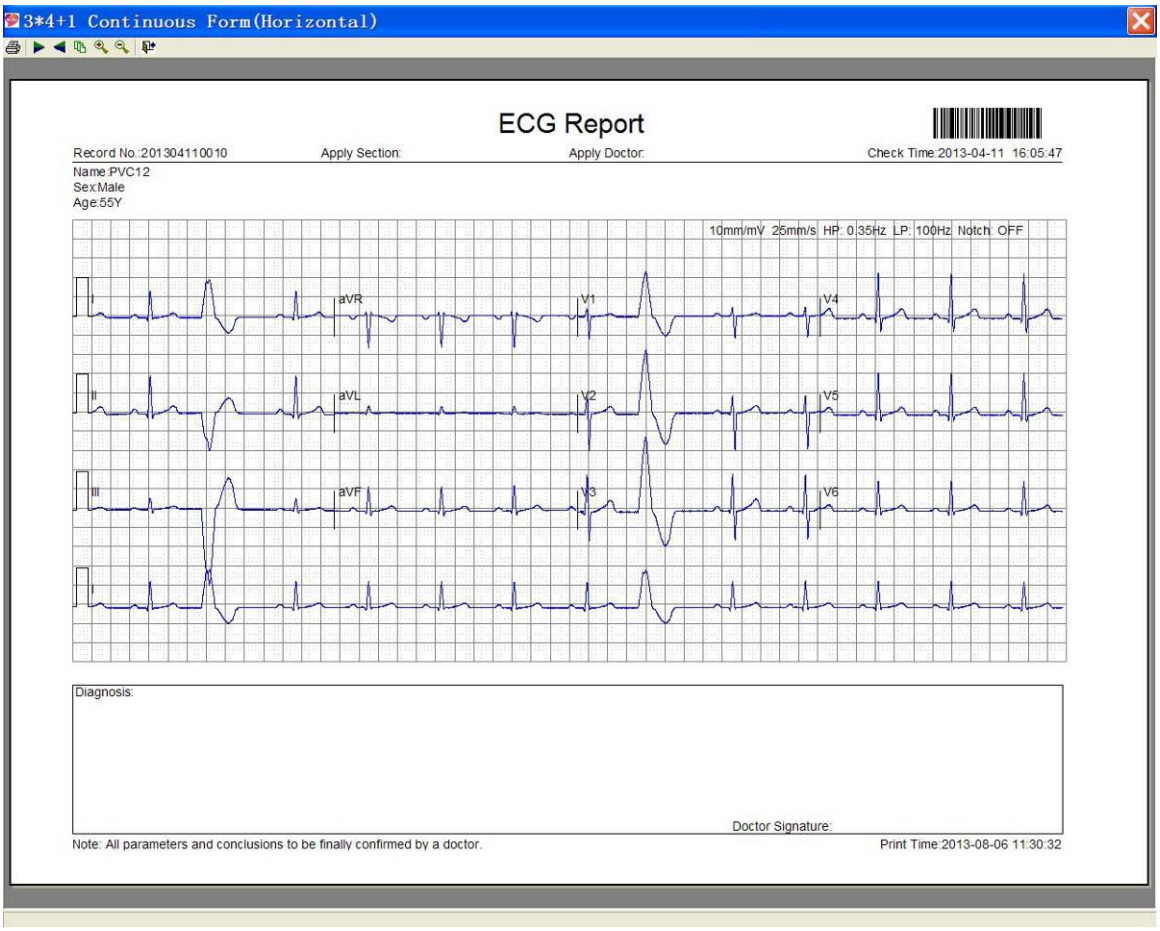

Fig. 4.5.17 12-lead ECG Waveform Playback Print Preview Legend

Click the button to enter the Print Preview interface as shown below, and click the button to print the report.

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4.5.8 ECG contrast

Click the Contrast button to enter the ECG contrast interface, and the medical records are displayed in the left side of the interface, as shown below:

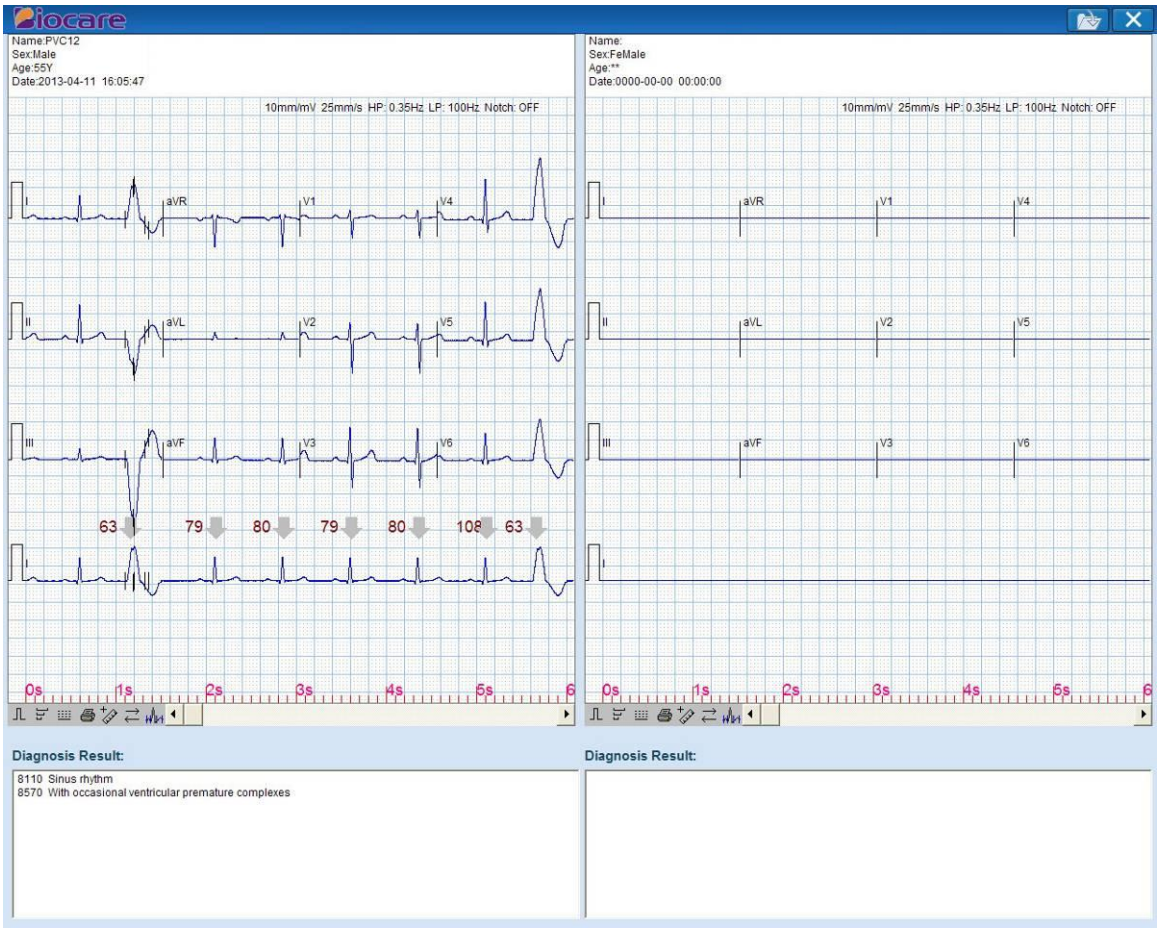

Fig. 4.5.18 ECG Contrast Interface

Note: The diagnostic results in this interface cannot be modified. Double-click a heartbeat to enter the heart beat enlarging interface for measurement, but the measurement results will not be saved.

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Click the button in the top right corner to open the medical records list, and medical records display by the same name when the list is opened.

Fig. 4.5.19 ECG Contrast & Checking Records Diagram

If you want to open other medical records, please enter the condition to be checked into the query area and select the check box; single condition query and multi-condition query are available. Example: To search the female patients from the check date 2012-1-18 to 2013-8-6 and aged between 0 and 60, enter as the figure below and click the Search button, and the results are as follows:

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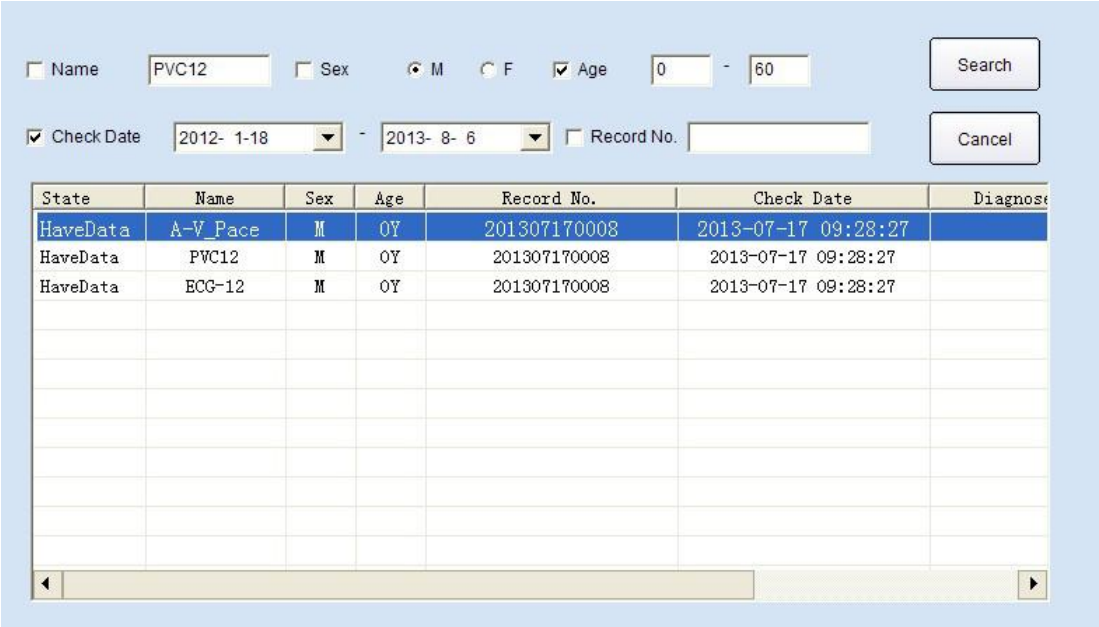

Fig. 4.5.20 ECG Contrast & Checking Results Diagram

As shown in the figure, the matching medical records will be displayed in the list, which sequentially displays the state of the medical record, name, sex, age, record number, etc.

Double-click a medical record in the list to import the ECG of selected medical record into the right side of the ECG contrast interface for comparison.

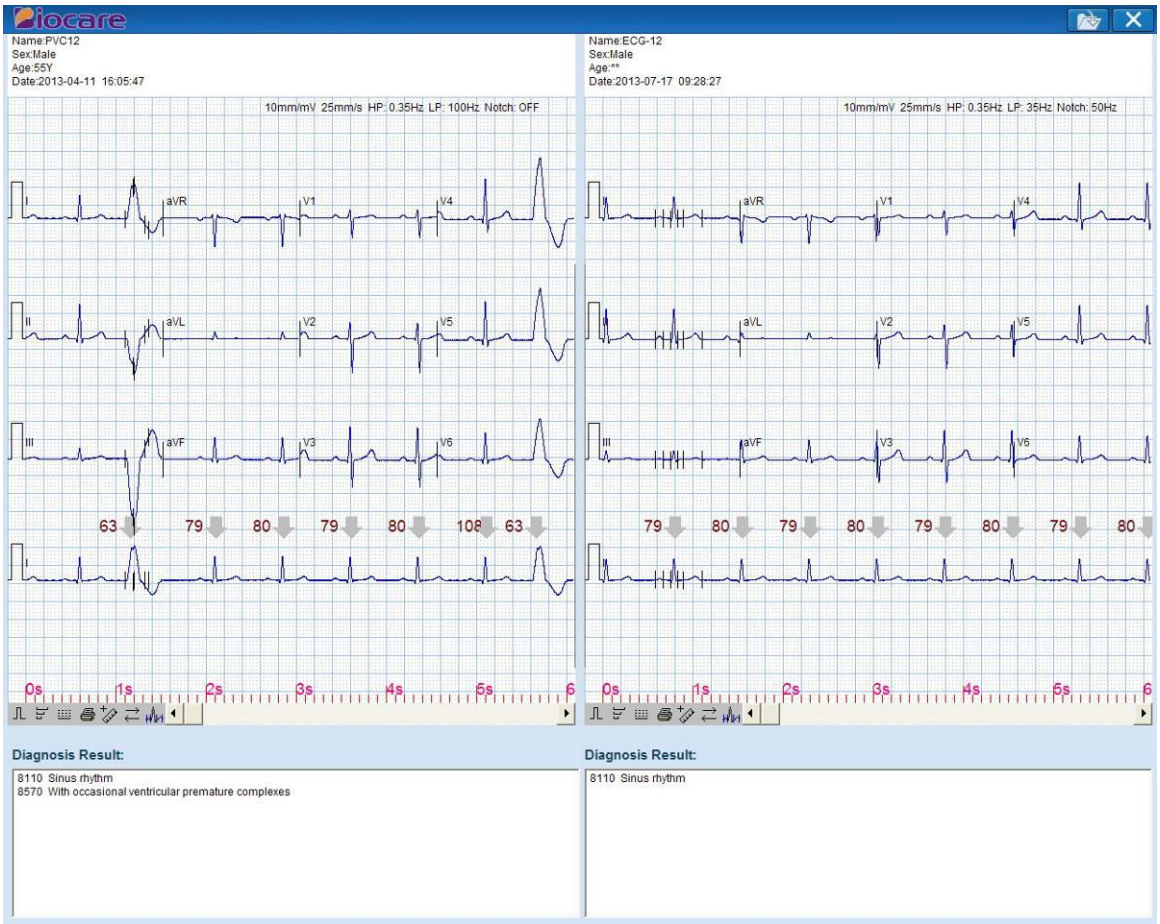

Fig. 4.5.21 ECG Comparison Chart

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4.6 Fast ECG

Click on the "Fast ECG" and the software directly starts the 12-lead sampling interface without filling out the patient information (see Section 4.4 Sampling). After sampling, the medical record list automatically generates a medical record called "NoName".

Note: Fast ECG can only sample 12-lead ECG.

4.7 New check

If you need to do ECG checks or other checks again to patients, select the patient in the medical record list, and click on "New Check" to repeat Section 4.4 Sampling. After sampling, the medical record list has one more record of the patient.

4.8 Editing medical records

Select a record to be modified in the medical record list, click "Edit" to modify the information, and then click "Save" to save the information and display in the patient info window. The records of fast ECG sample also can be modified in this step.

4.9 VCG playback

In the medical records list, double-click VCG medical records or select VCG medical records and click the

button to enter the playback interface.

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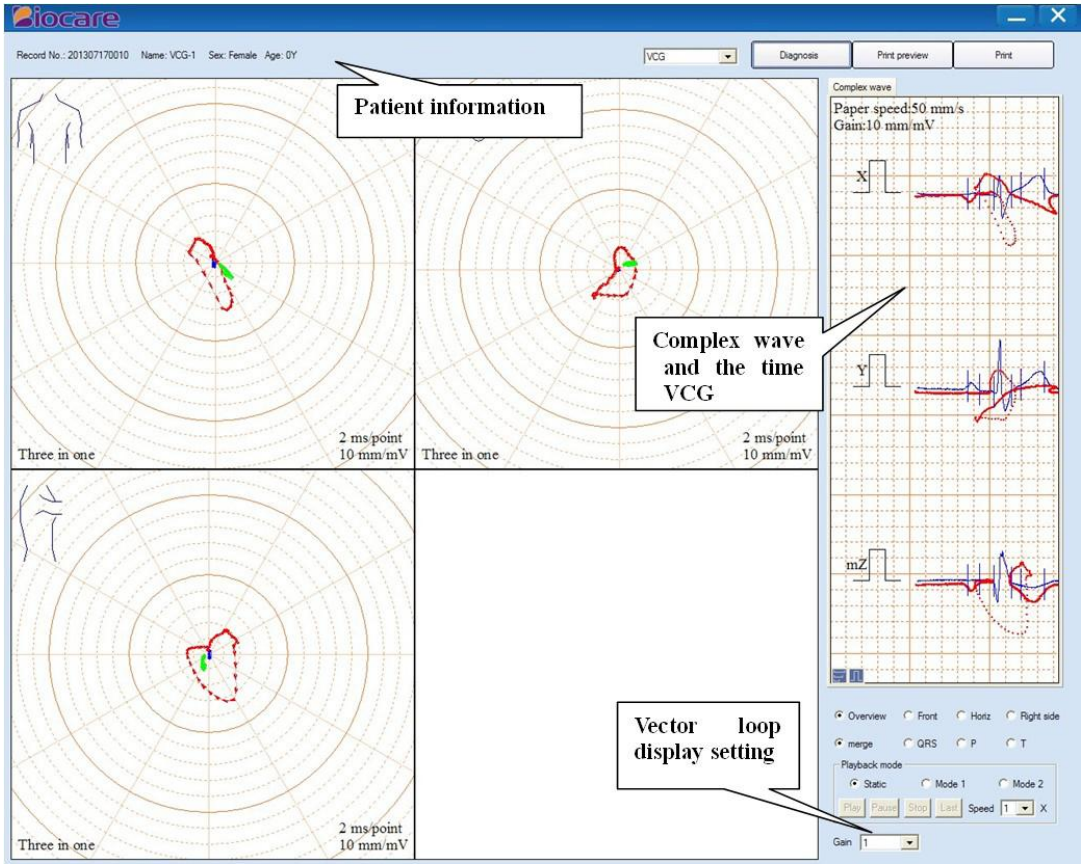
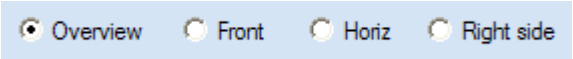
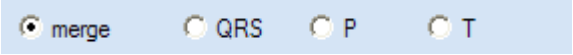


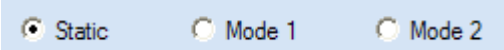
Fig. 4.9.1 VCG playback interface



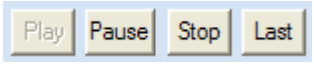
VCG is displayed in the loop in the form of Overview, Front, Horiz or Right side.



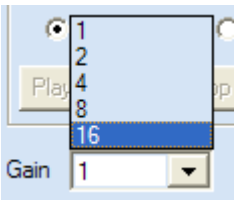
VCG is displayed in merged loop, QRS loop, P loop or T loop.



It is the playback mode of VCG. Static is to display the VCG motion track in the loop directly. Mode1 is to playback the VCG motion track in the loop dynamically. Mode 2 is that a red mark playback dynamically along the VCG motion track.



The control buttons of VCG motion track in the loop; it only can only be used in Mode 1 and Mode 2.



Gain represents the amplification factor for VCG displayed in the loop. There are five factors.

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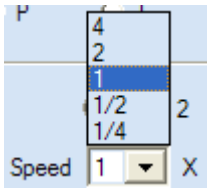
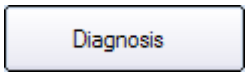
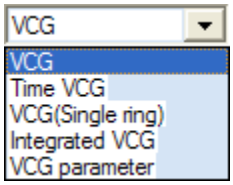


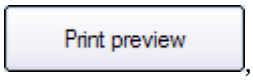
The speed control of the playback of VCG, there are five factors.



Click this button and enter into the diagnosis interface to input the diagnosis.



In the drop-down box, user can choose one of the five print templates, and then click



, user can enter into the print preview interface of VCG, as shown in the figure:

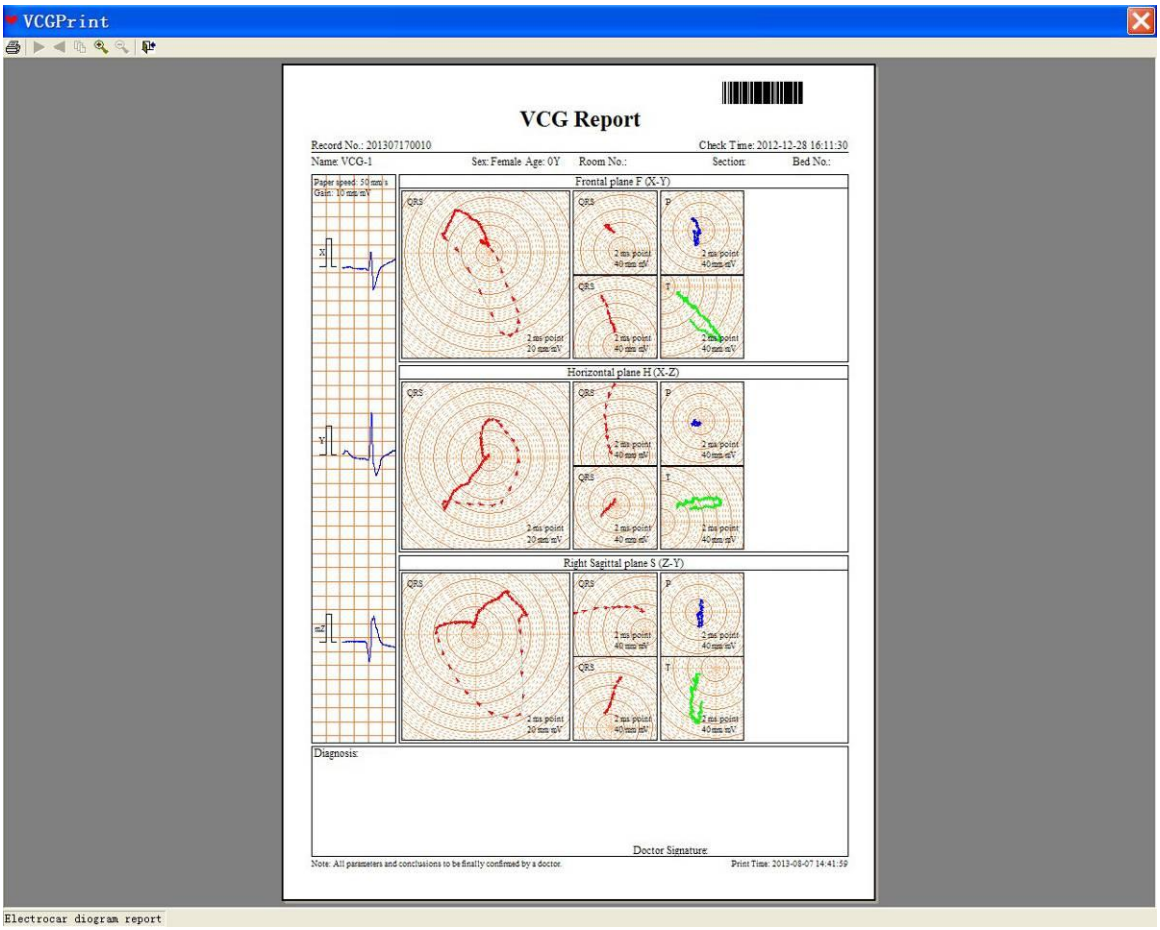
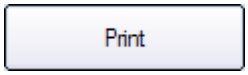


Fig. 4.9.2 Print preview legend of VCG playback



It is the print function of VCG.

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4.9.1 VCG wave playback

In the process of the playback of VCG wave, user can adjust Paper speed and Gain. User can adjust paper speed by , there are three kinds of speed, i.e. 12.5 mm/s, 25mm/s and 50mm/s. User can adjust gain by , there are three kinds of speed, i.e. 5 mm/mV, 10mm/ mV and 20mm/ mV.

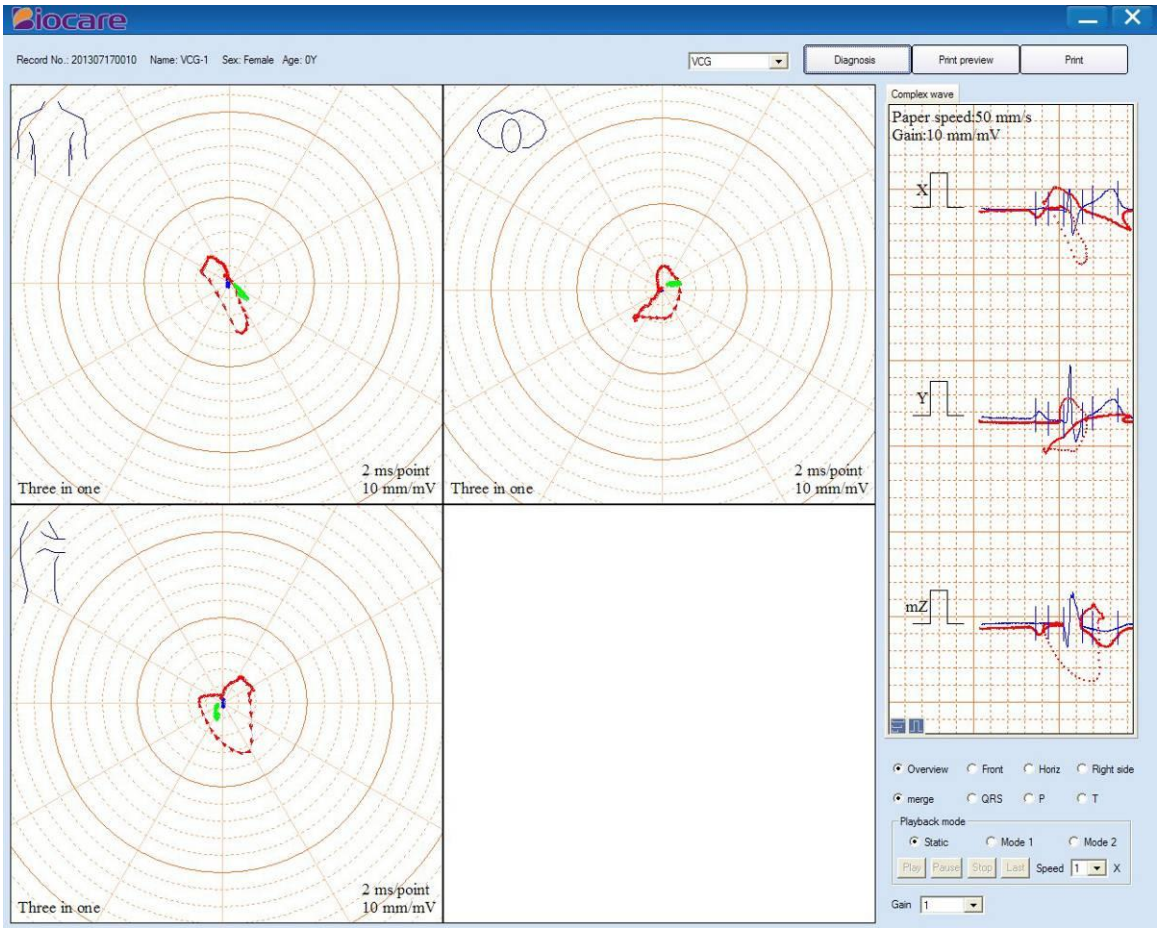
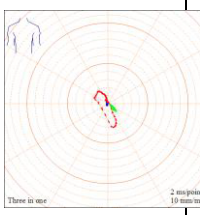
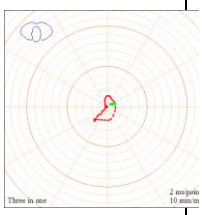
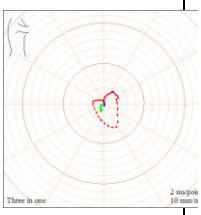
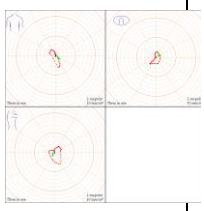


Fig. 4.9.3 VCG playback display

There are four kinds of display mode for VCG, as shown in the table:

Front(X-Y)	Horiz(X-Z)	Right side(Z-Y)	Overview
			

When it is displayed overview, double click certain graph, and it will be enlarged to the whole display interface. Double click again, it will restore to original state.

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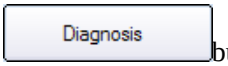
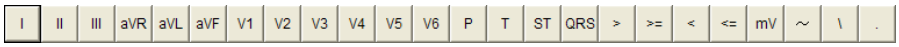
4.9.2 Diagnosis function

After wave playback, click 

button to enter into the diagnosis interface.

Features of ECG

This window record the features of ECG, left mouse button click the window. When the cursor flickers in the input window, user can input features in it. For convenient to input special character, special character buttons are designed. User can input special characters by clicking these buttons.



Results of ECG

As shown in the following figure, the report assistant in the right side is displayed in three levels: the first level displays the symptom type; click a symptom type in the window of the first level and the symptom type of next level will be displayed in the window of second level; click a symptom type in the window of the second level and the symptom details will be displayed in the window of third level. Double-click a symptom in the third level window, and bring it into ECG diagnostic result. Doctors can modify and typeset the result, or enter the own diagnostic result.

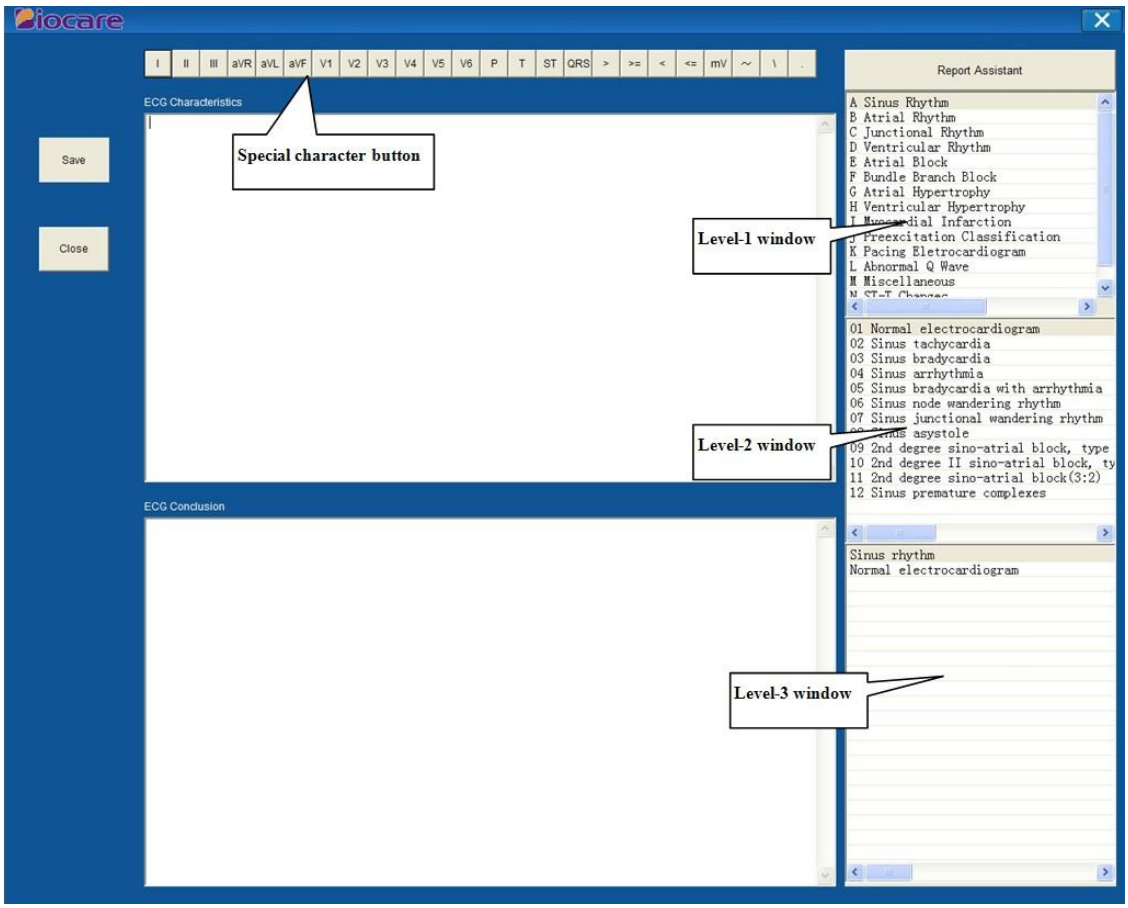


Fig. 4.9.4 Assistant function and display of VCG diagnosis

Save all the content in the interface.

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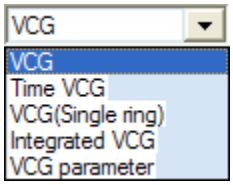
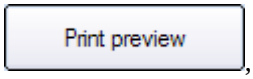
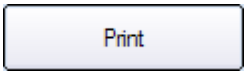
Close the interface.

4.9.2 VCG report print



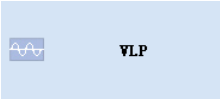
In the drop-down box, user can choose one of the five print templates, and then click 

, user can enter into the print preview interface of VCG.

After selecting a template, click 

button to print out VCG.

4.10 VLP playback

In the medical records list, double-click VLP medical records or select VLP medical records and click the 

button to enter the playback interface. Import the selected VLP data from medical records list.

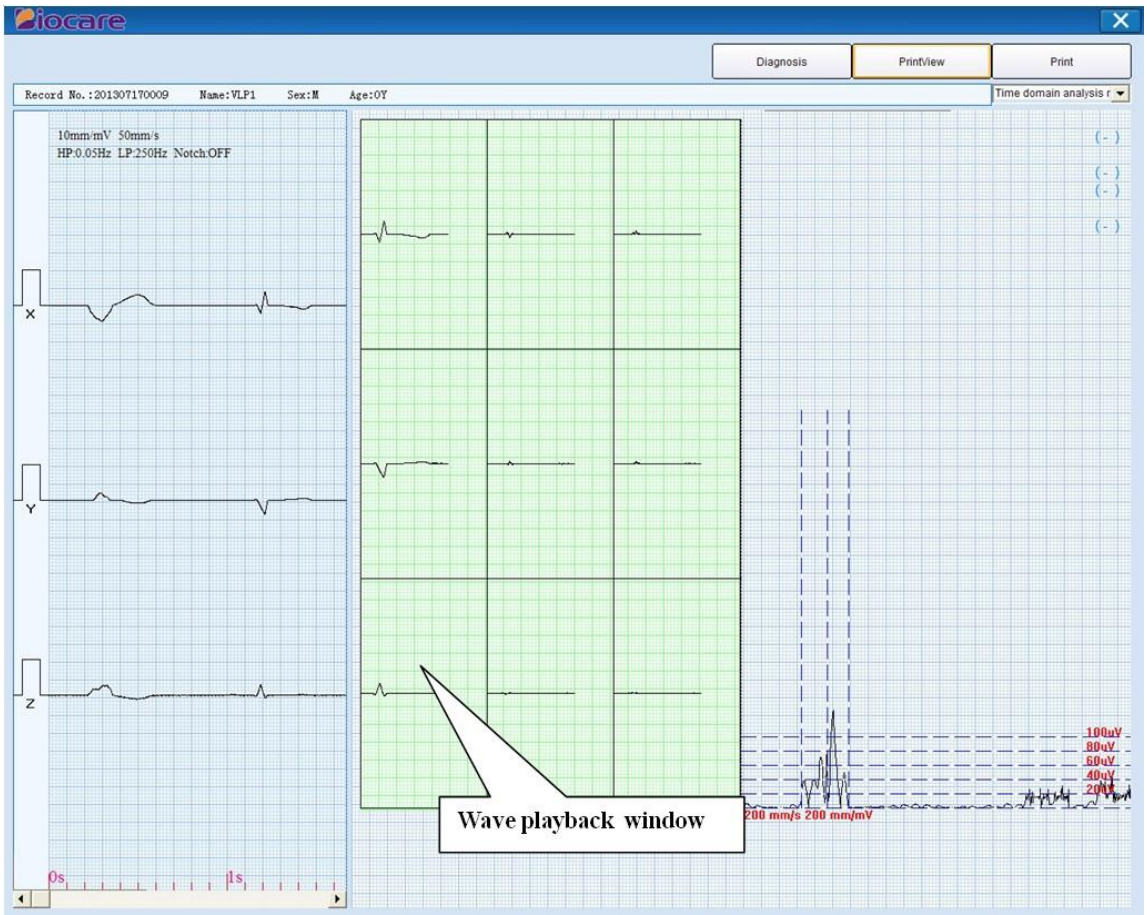


Fig. 4.10.1 Search Function Interface Display

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The output of report, click Diagnosis and enter the diagnosis window (as the same diagnosis window in the VCG), input or select report content. After that, choose print template and click PrintView button to preview the corresponding report content. Click Print button and start to print out the report. The diagnosis content are contained in the report.

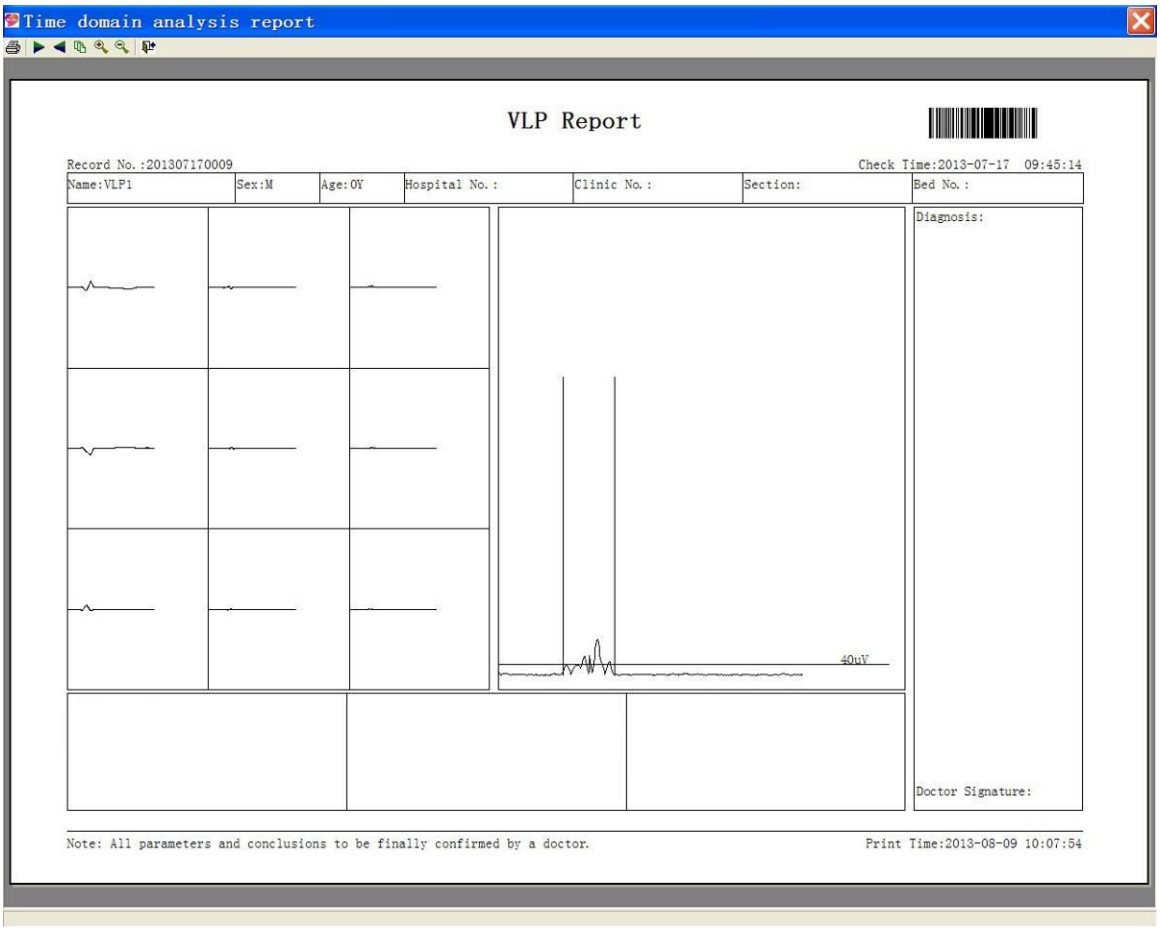

Fig. 4.10.2 Print preview legend of VLP playback

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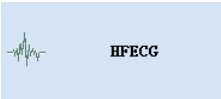
4.11 HFECG playback

Select an ECG medical record and click 

button. The HFECG window appears and the data of selected medical record will be imported, as shown in the figure:

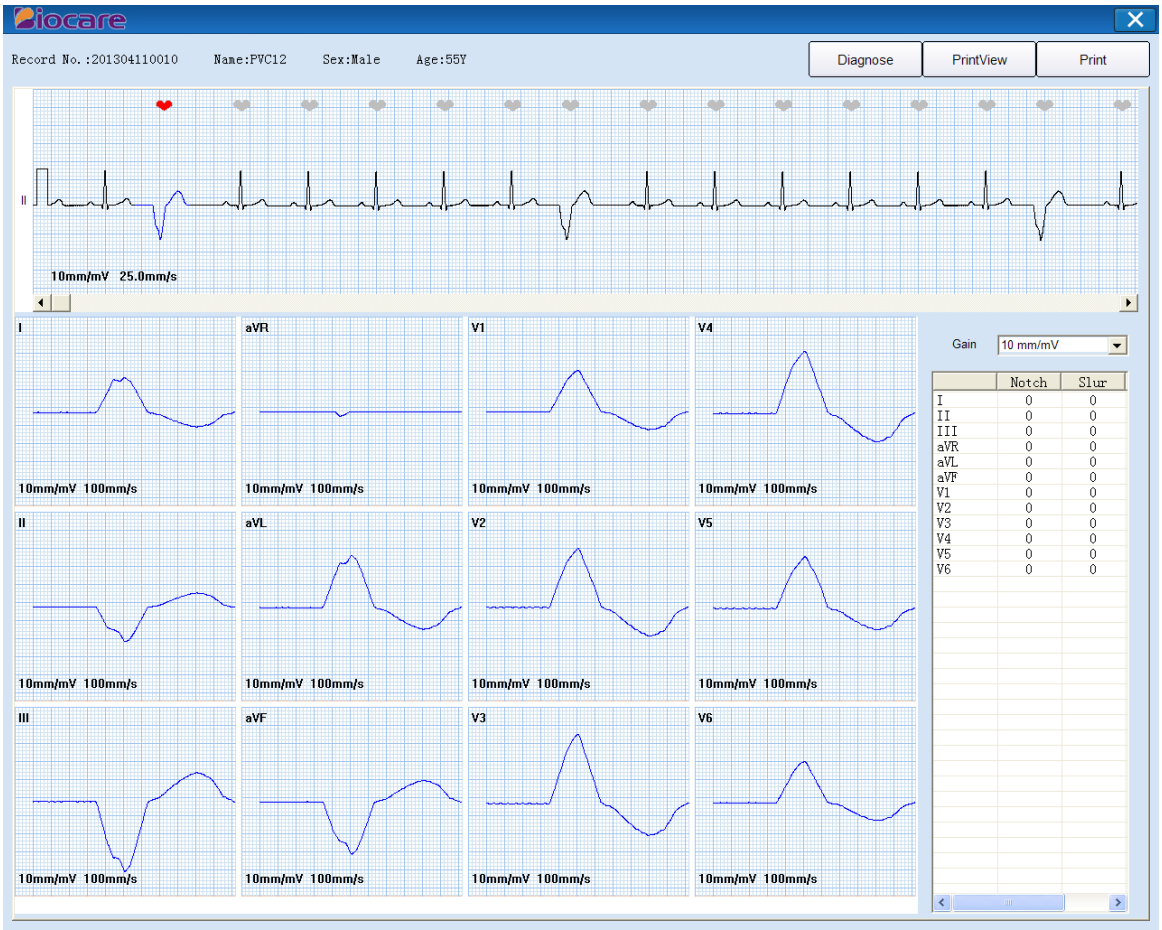


Fig. 4.11.1 HFECG window

The top of the window displays standard II lead, user can check all waves by dragging the cursor, or can select different heart beat. Represents the detective position of R wave, represents currently selected heart beat.

The bottom of the window displays corresponding QRS band of 12-lead of selected wave.

The right side of the window is Gain, which can be adjusted. The optional gain is 10mm/mV, 20mm/mV, 30 mm/mV, 40 mm/mV, 50 mm/mV and 60 mm/mV. The default is 10 mm/mV.

The table on the right displays detective high-frequency results of the selected heart beat, including notch and slur.

Note: This function is only available for 12-lead ECG.

The output of report, click Diagnosis and enter the diagnosis window (as the same diagnosis window in the VCG), input or select report content. After that, choose print template and click PrintView button to preview the report. Click Print button and start to print out the report. The diagnosis

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content are contained in the report.

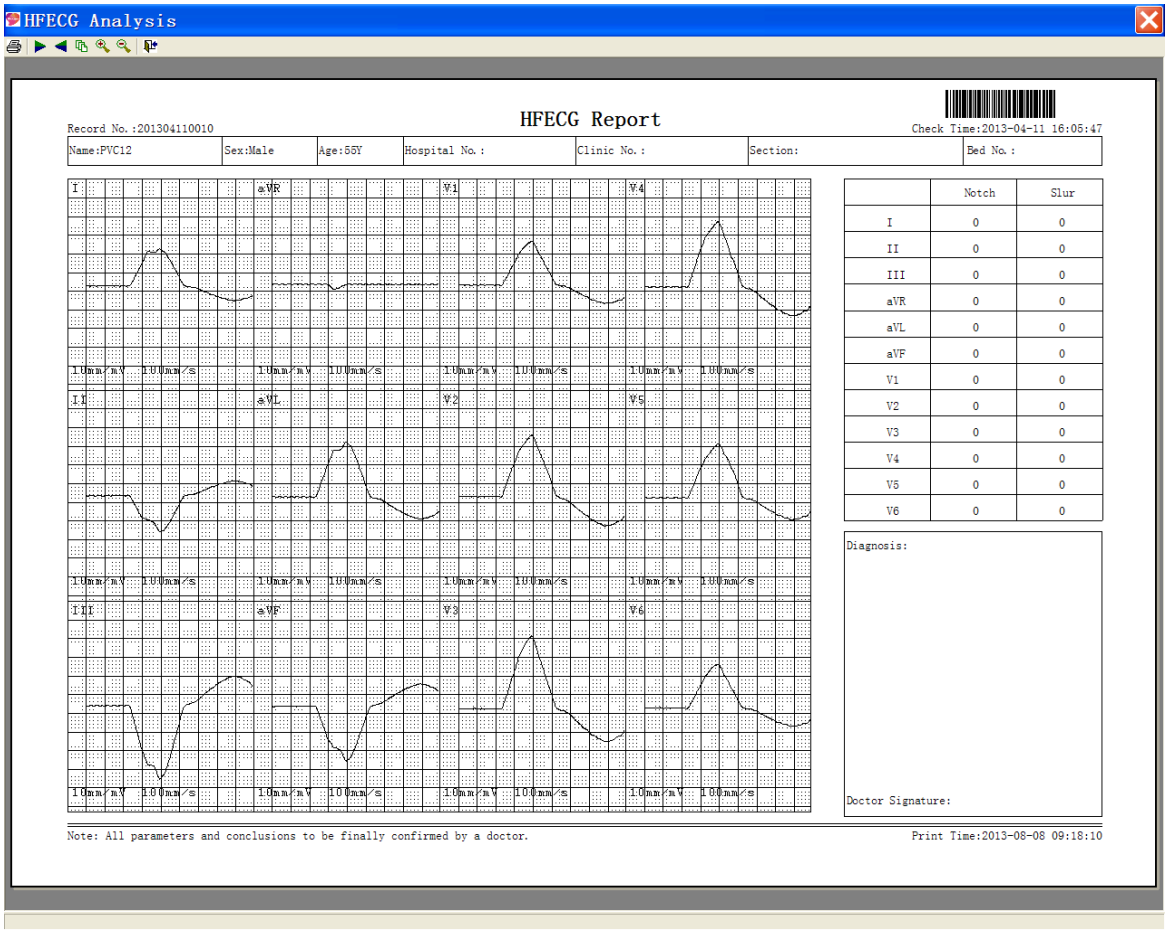

Fig. 4.11.2 Print preview legend of HFECG playback

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4.12 FCG playback

Select an ECG medical record and click

button. The FCG window appears and the data of selected medical record will be imported, as shown in the figure:

Fig. 4.12.1 FCG window

The window displays gyy Ⅱ lead self-power spectrum, gxx V5 lead self-power spectrum, RF coherent function, qxy phase shift function, vxy cross correlation function and PIH impulse response of ECG. Double click a certain graphic and it will be enlarged to full screen.

The option gain for Ⅱ and V5 lead self-power spectrum is 25mm/mV, 50mm/mV and 100 mm/mV. The default is 50mm/mV. In FCG window, click

and

, the corresponding Ⅱ and V5 lead self-power spectrum change accordingly. Click will increase the gain and click will decrease the gain. The data follows Y which is on the right top of self-power spectrum represents the gain value.

Note: This function is only available for 12-lead ECG.

The output of report, click Diagnosis and enter the diagnosis window (as the same diagnosis window in the VCG), input or select report content. After that, choose print template and click PrintView

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button to preview the report. Click Print button and start to print out the report. The diagnosis content are contained in the report.

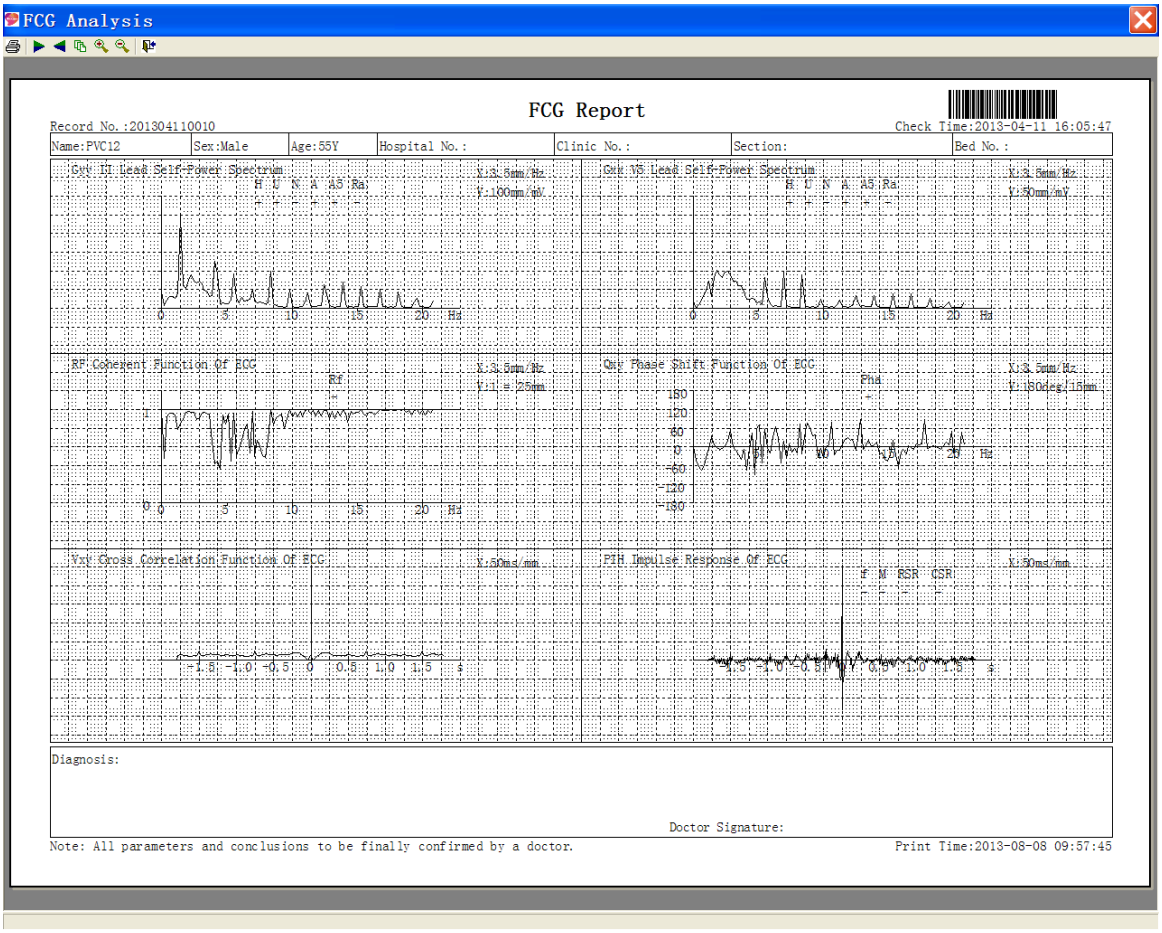

Fig. 4.12.2 Print preview legend of FCG playback

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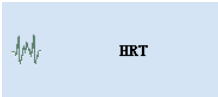
4.13 HRT playback

Select an ECG medical record and click 

button. The HRT window appears and the data of selected medical record will be imported, as shown in the figure:

Fig. 4.13.1 HRT window

Represents the position of detective R wave. represents the currently selected waveform. Select different waveform, the RR interval tendency chart result will change with it.

Through the preview block, User can preview the patient information, waveforms and HRT calculation result that to be printed. In HRT interface, click the PrintView button and enter the print preview interface, as shown in the figure:

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(1) Single mode:

Fig. 4.13.2 Print preview legend of HRT in single mode

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(2) Mean mode:

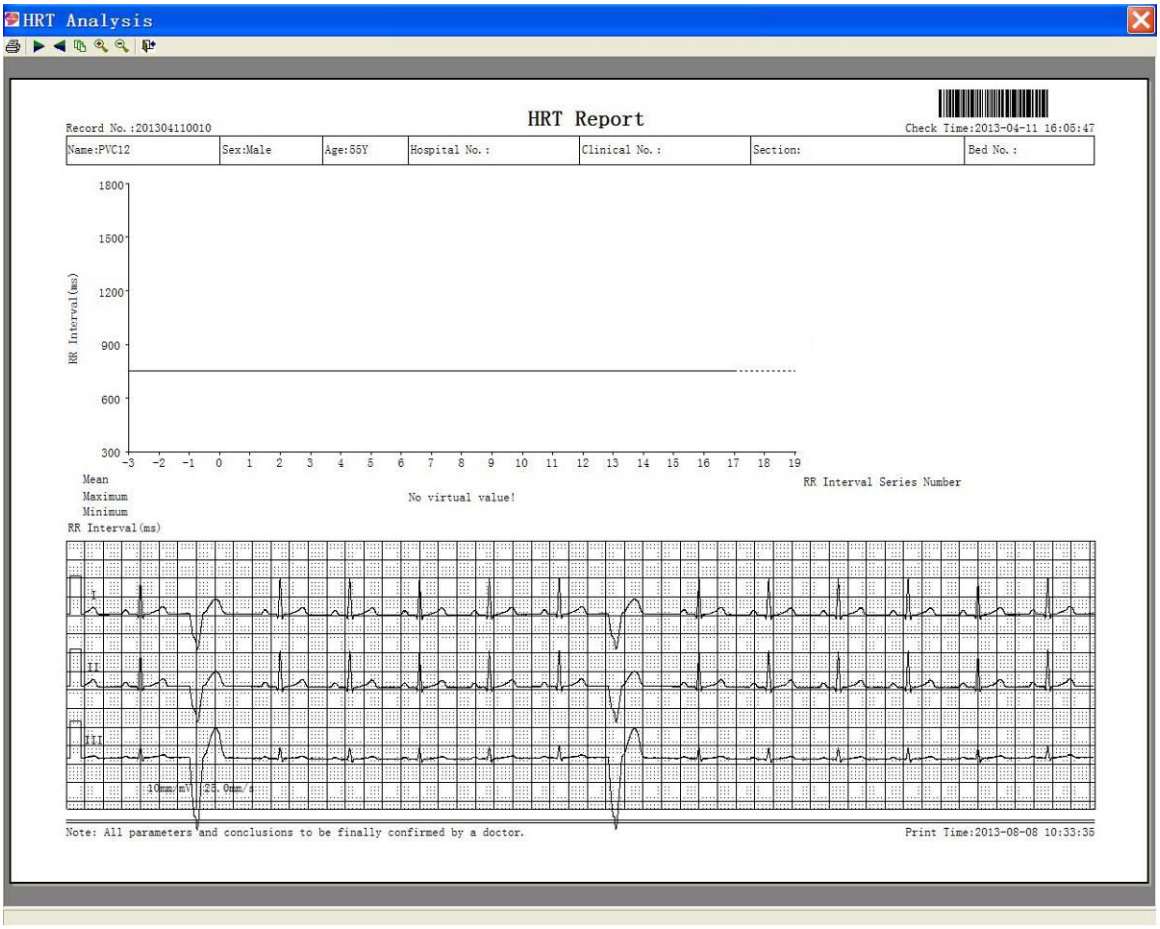

Fig. 4.13.3 Print preview legend of HRT in mean mode

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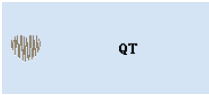
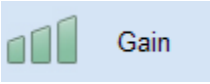
4.14 QT playback

Select an ECG medical record and click 

button. The QT window appears and the data of selected medical record will be imported, as shown in the figure:

Fig. 4.14.1 QT playback window

Set the paper speed, 12.5 mm/s, 25 mm/s or 50 mm/s. The default is 25 mm/s.



Set the gain, 5 mm/mV, 10 mm/mV or 20 mm/mV. The default is 10 mm/mV.

Measure parameters, as shown in the figure:

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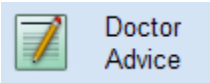
Fig. 4.14.2 Waveform measure function of QT playback



Open doctor advice dialogue. User can input advice in the edit box, as shown in the figure:

Fig. 4.14.3 Input dialogue of doctor advice

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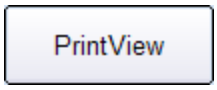

Start the print preview interface, as shown in the figure:

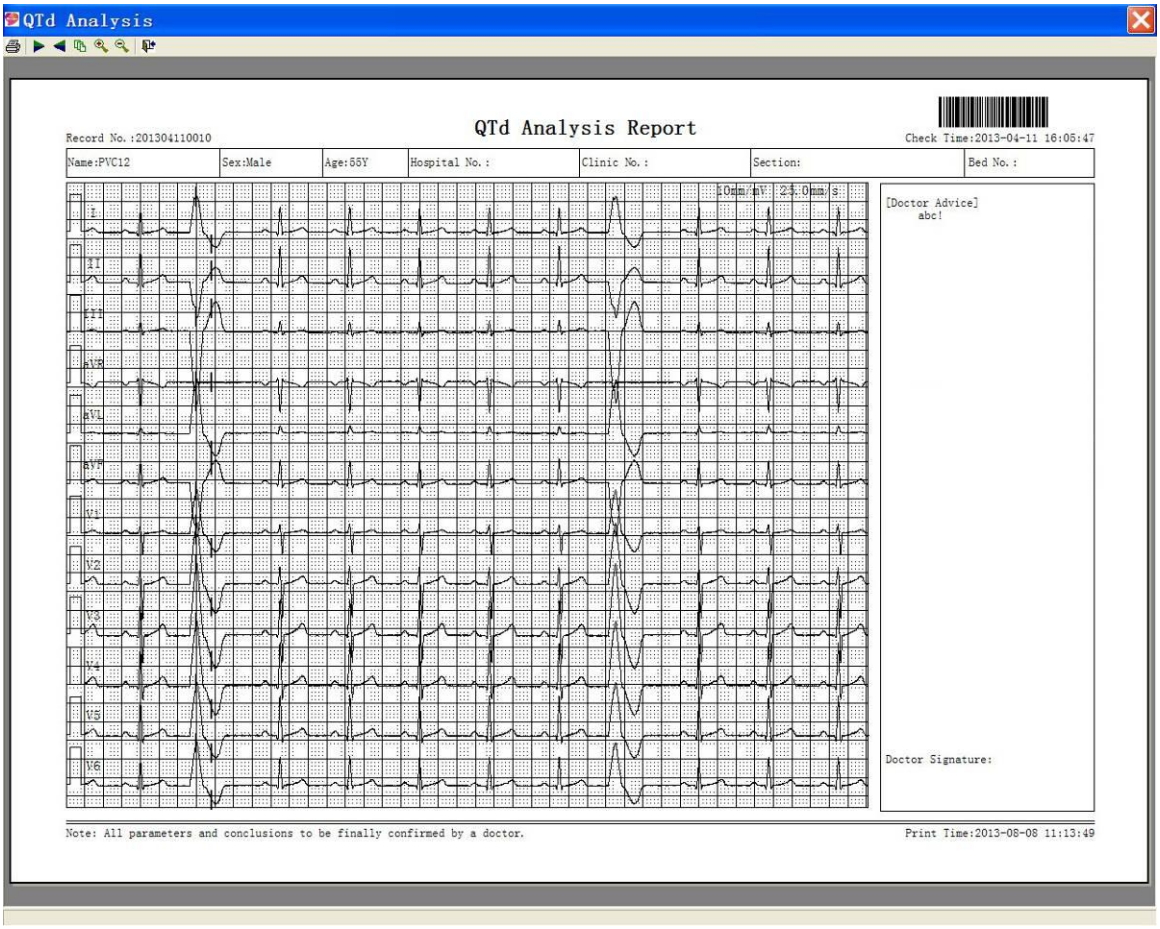

Fig. 4.14.4 The print preview legend of QT playback

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4.15 HRV playback

Double click a HRV medical or select it, and then click

button. The HRV playback window appears, as shown in the figure:

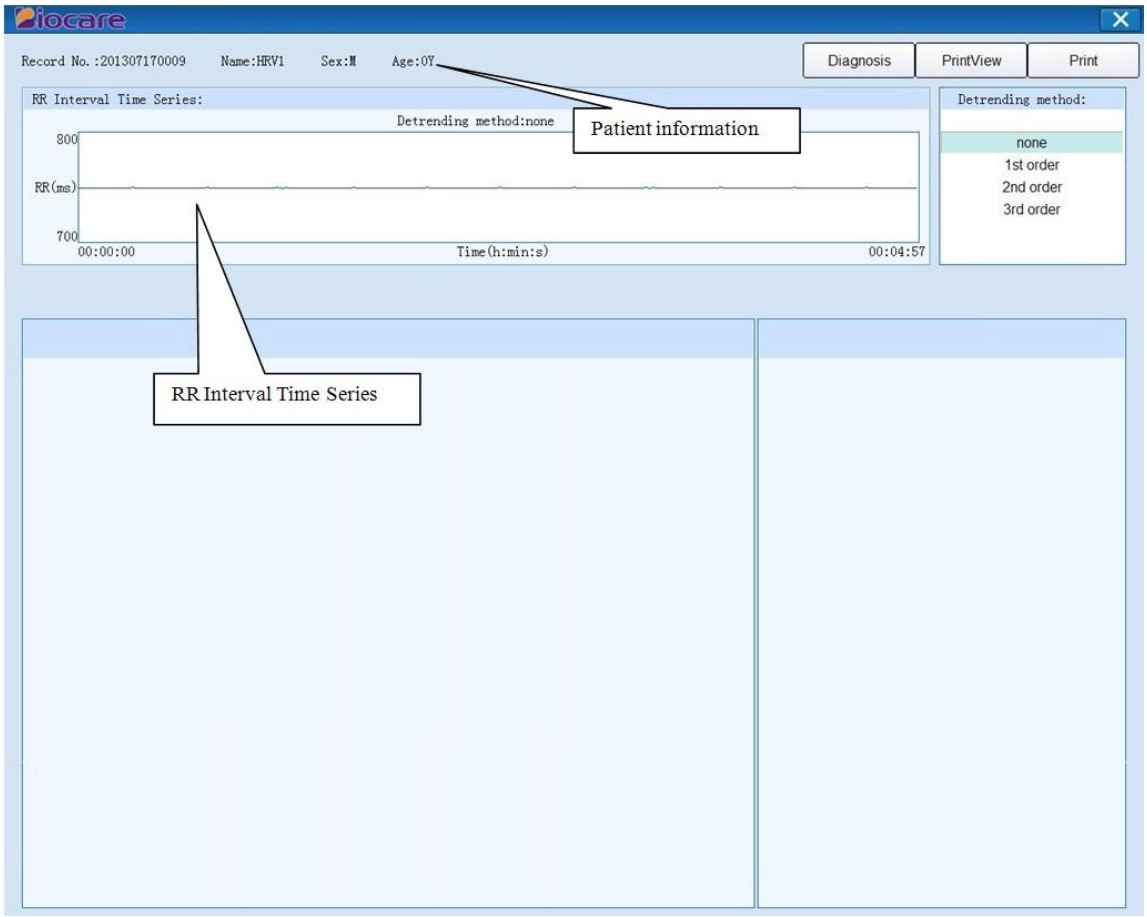

Fig. 4.15.1 HRV playback window

Start print preview interface, as shown in the figure:

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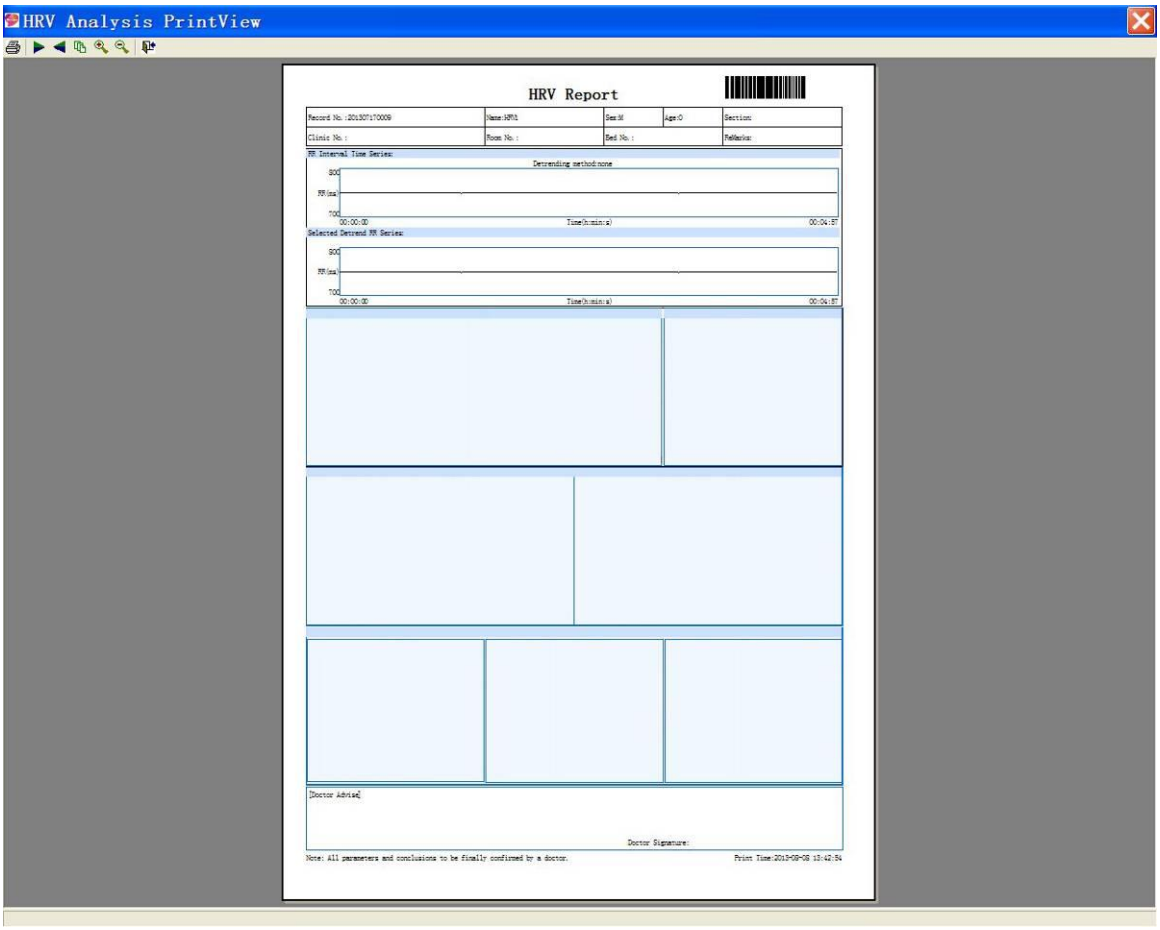

Fig. 4.15.2 The print preview legend of HRV playback

4.16 Search function

Multifunctional ECG Digital Electrocardiograph can achieve search by state, name, sex, age, record number, and date.

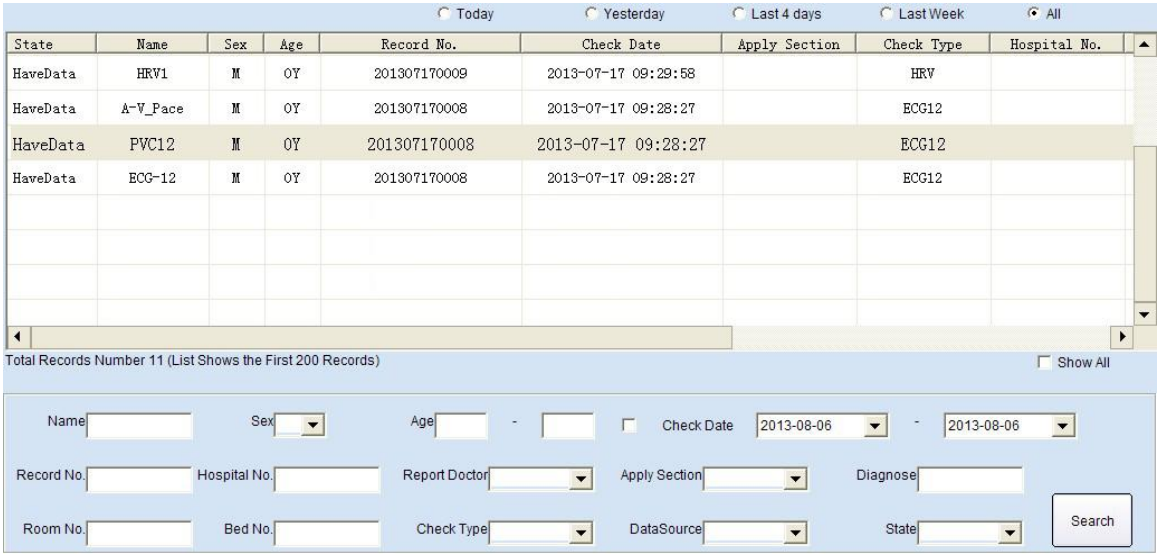

Fig. 4.16.1 Search Function Interface Display

The matching medical records will be displayed in the medical record list.

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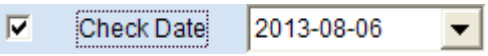
Select check date:

Method 1: Click the radio button in the top right of the medical records list, and then you can view the medical records of today, yesterday, four days, a week and all medical records.

Method 2: select the check box in the left of the check date, and fill in the date range. Click the year with the mouse 

, and enter the value manually when the year turns blue; enter the month and day in the same way. Or click the black arrow on the right of date to pop up the box below, and click the black arrows on both sides to select the year and month.

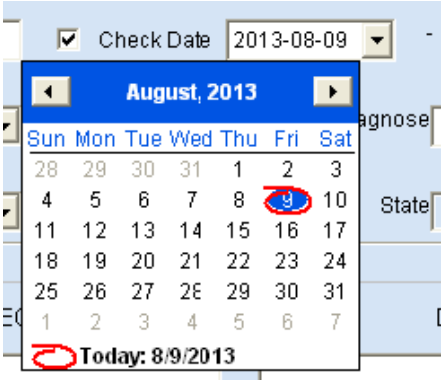


Fig. 4.16.2 Check Date Modification Dialog Box

Or click the black arrow on the right of the date, select month in the pop-up box, and click on the "Year" to pop up the black arrows and select the "Year".

Search by Name: manually enter the name in the name box, and click the Search button to search the results; support fuzzy query.

Search by sex: in the sex box, click the drop-down box to select the sex, and click the Search button to search the results.

Search by age: manually enter the number in the age box and click the Search button to search the results.

Search by record number: enter manually in the record number box, and click the Search button to search the results.

Search by hospital number: enter the hospital number manually, and click the Search button to search the results.

Search by report doctor: in the report doctor box, enter manually or click the drop-down box and select Search.

Search by apply section: in the apply section box, enter manually or click the drop-down box and select Search.

Search by diagnosis: enter manually in the diagnosis box, and click the Search button to search the results.

Search by room number: enter manually in the room number box, and click the Search button to search the results.

Search by bed number: enter the bed number manually, and click the Search button to search the results.

Search by check type: enter manually in the check type box, or click ECG, VCG, VLP or HRV in the drop-down box, and click the Search button to search the results.

Search by data source: enter manually in the data source box, and click the Search button to search the results.

Search by state: enter the state manually, and click the Search button to search the results.

Note: Report doctor box, apply section box and data source box can read data saved in new patient

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info, but cannot save data.

4.17 Statistics function

Click the

button in the function button area to enter the statistics interface, as shown below:

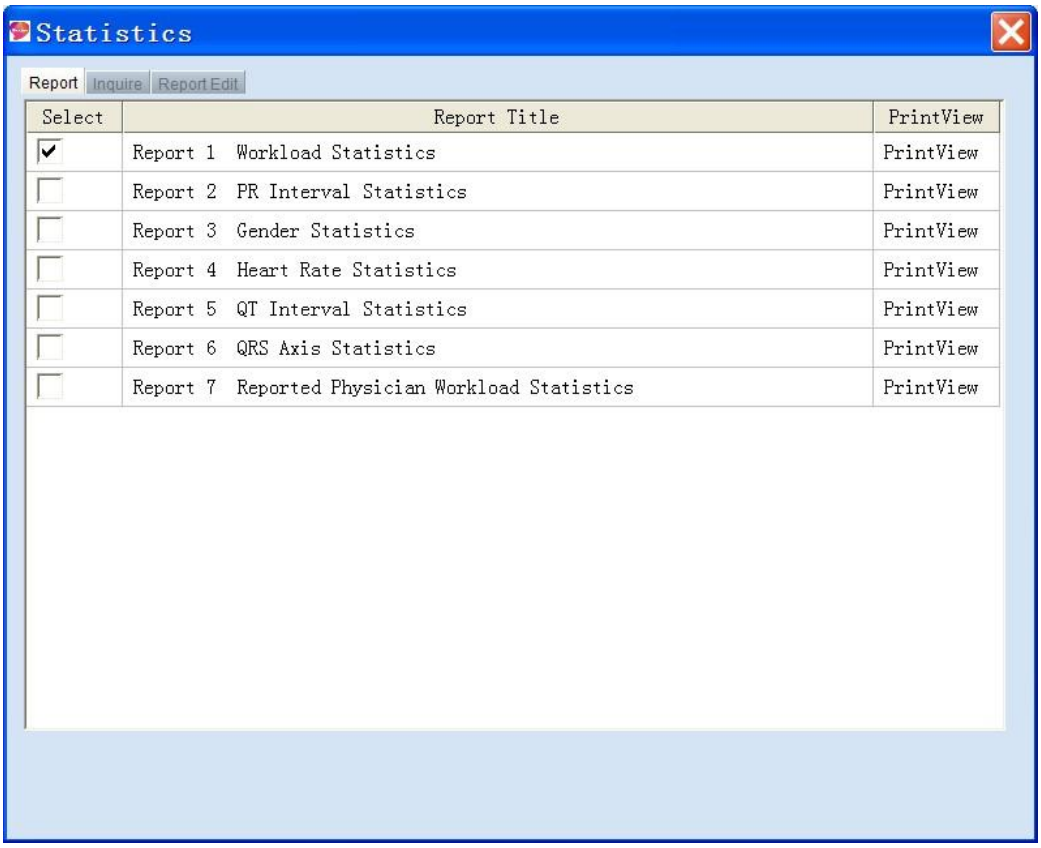

Fig. 4. 17.1 Statistics Function Reporting Interface

Seven report statistics are provided by default, which are workload statistics, PR interval statistics, gender statistics, heart rate statistics, QT interval statistics, QRS axis statistics, and reported physician workload statistics.

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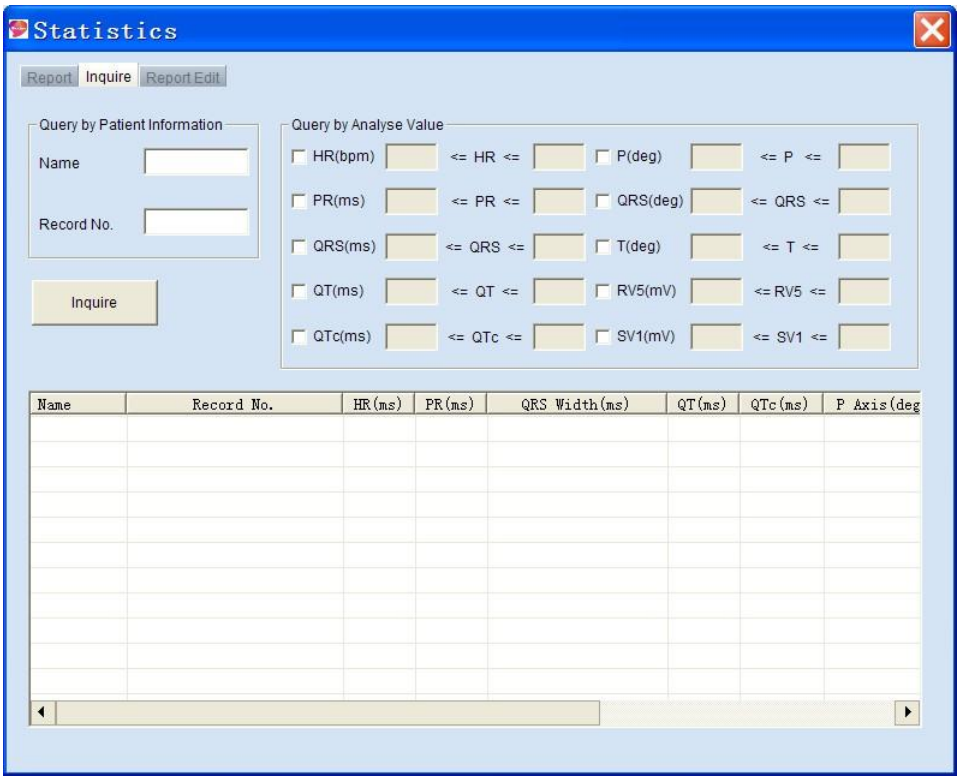

Fig. 4. 17.2 Statistics Function Inquiry Interface

The report editing interface allows adding, editing and deleting reports; only the administrator is allowed to enter the report editing interface, as shown below:

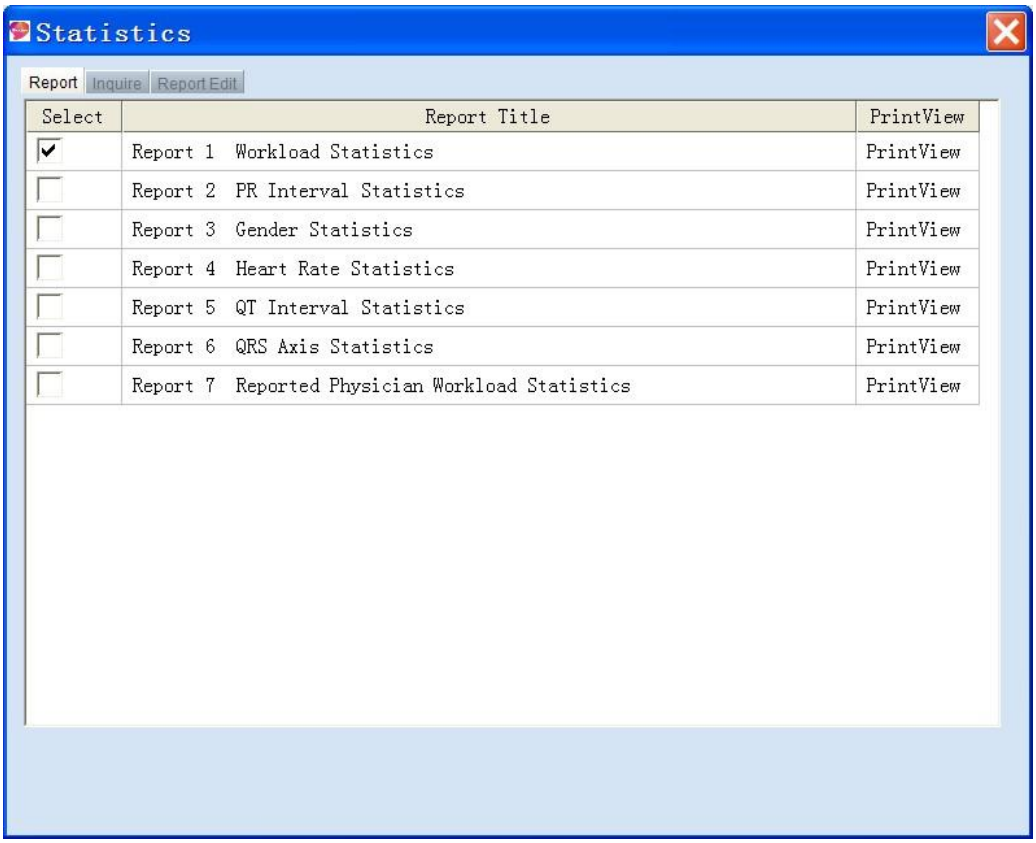

Fig. 4. 17.3 Report Editing Interface

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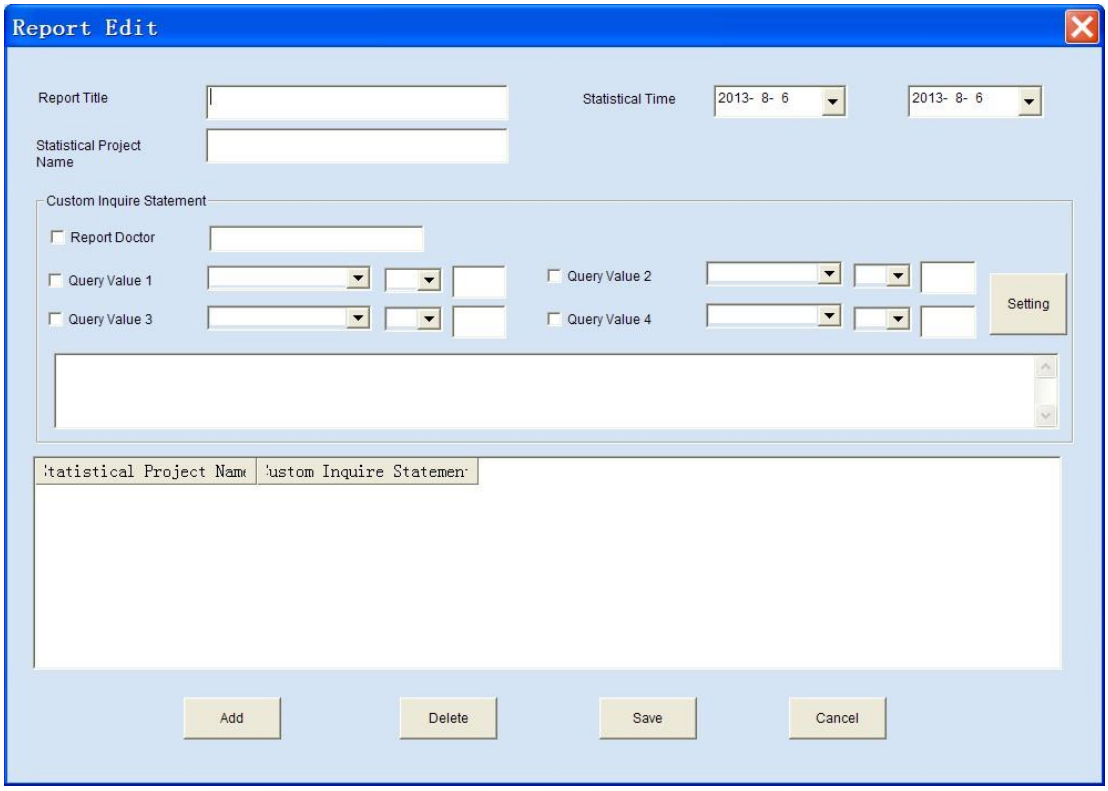

Fig. 4. 17.4 Report Editing Interface

4.18 Import and Export of medical records

4.18.1 Import of medical records

Medical record import allows importing the ECG files of ECG-1200/1210/1215/1216/1230/1260 into the system in the following steps: "System" - "Import Record - select ECG file.

Click "Import Record", as shown below:

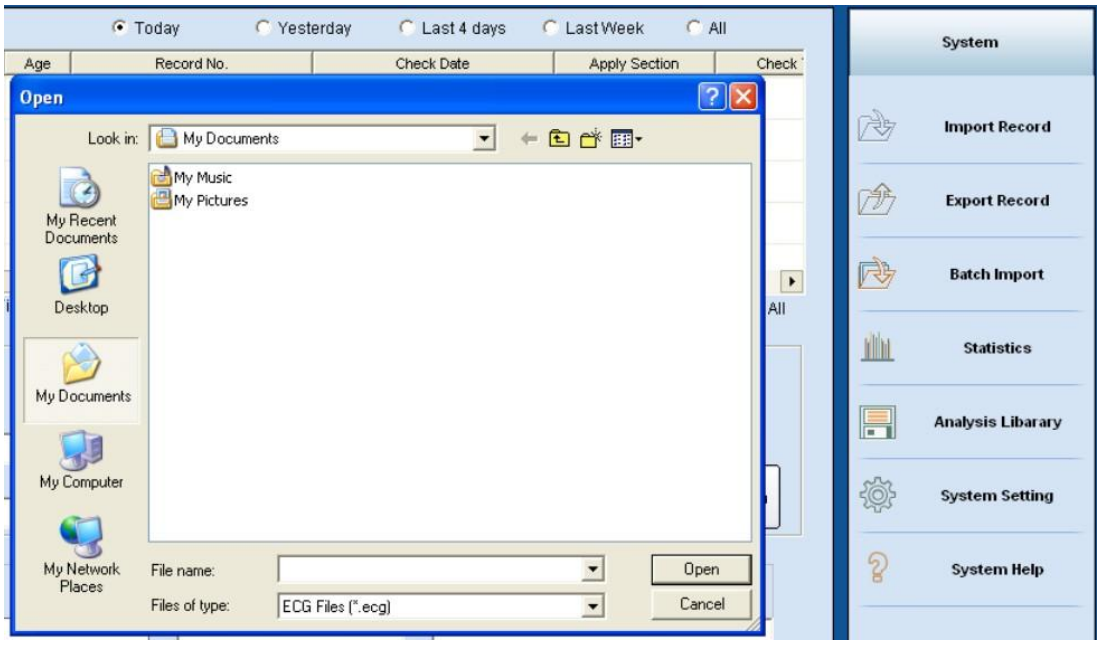

Fig. 4. 18.1 Import of Medical Records

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Select Import Record, double-click or click "Open", and the system suggests that whether the import is successful, as shown below.

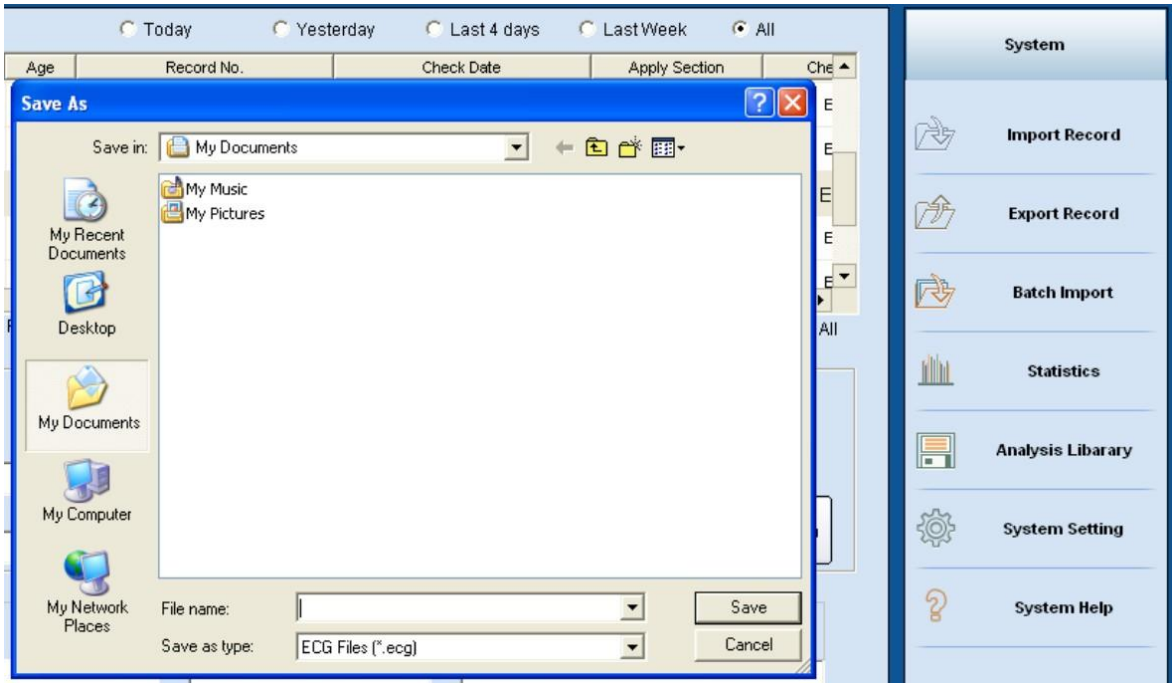
Fig. 4.18.2 Medical Record is Imported Successfully

4.18.2 Export of medical records

Medical record export allows exporting the ECG files from the system to a specified location. The step is: select the medical records to be exported in the list - "System" - "Export Record" - specify the storage location.

Note: Medical records of VCG, VLP and HRV cannot be exported.

Click "Export Record", and specify the path and file name, as shown below:



4.18.3 Export of Medical Records

Click "Save" and the system suggests that the operation is successful.

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Fig. 4.18.4 Medical Record is Exported Successfully

Try to export the medical record of VCG, VLP and HRV, and system prompts, as shown in the figure:

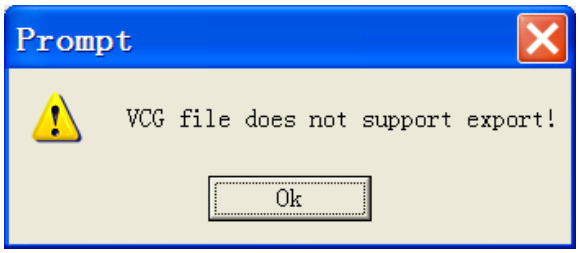

Fig. 4.18.5 Do not support export

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Chapter 5 Maintenance

1. It is prohibited to run this software with other applications simultaneously;
2. The PC should be used for this software specially, and it is prohibited to install games or other unrelated software to avoid interference;
3. The screen saver and power management function of PC must be disabled;
4. User manual should be used together with online help documentation of the software;
5. Before each measurement, the operator should check if the lead wires have physical impairment or crack; if yes, check the reliability of the lead wire.
6. The ECG-2000 system features data function of ECG check (ECG, VCG, VLP, HRV, HFECG, FCG, HRT and QT). The data (including reports) provided by this system are only used as the reference for medical staff to make diagnosis. The data can't be used as the diagnosis result, which should be determined by the medical staff.
7. When the sampling and monitoring are stopped, please close the sub-window of ECG-2000 software timely; if the system won't be used for a long time, disconnect the AC power of the computer, and turn off the main power switch.
8. After using the equipment, please cut off the power, and cover with a clean, soft cloth to prevent dust from entering and affecting the next use.
9. Keep moisture away from the equipment.
10. Use a clean, soft, damp cloth to clean the equipment and electrodes, and wipe the surface with cleaning solution; do not use strong cleaning agent, in order to avoid damage to the equipment.
11. Daily Check

    Perform a visual inspection of all equipment and accessory devices daily. If you notice any items that need repair, contact a qualified service engineer to make the repairs.

    ♦ Check the ECG acquisition box and cables for cracks or other damage.

    ♦Inspect all plugs, cords, cables, and connectors for fraying or other damage.

    ♦ Verify that all cords and connectors are securely seated.

    ♦ Inspect keys and controls for proper operation.
12. The ECG2000 Digital Electrocardiograph contains no user adjustable or serviceable parts. For repair or technical support, refer to the information below:

    Shenzhen Biocare Bio-Medical Equipment Co., Ltd.

    2/F West, 4th Block, Dayang Road South, Fuyong Sub-district, Bao'an District, 518103 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

    Tel: 86-755-27960888 Fax: 86-755-27960643

    Website: http://www.biocare.com.cn

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Chapter 6 Troubleshooting

6.1 USB driver installation error

Digital Electrocardiograph requires installing the software on the host first, and then connecting the acquisition box to the host. Run the

icon, and the following prompt of Silicon Laboratories CP210x USB to UART Bridge indicates that USB driver is not installed.

Solution:
Click Start —> Run —>Biocare software—>USB drivers —>CP210X to reinstall.

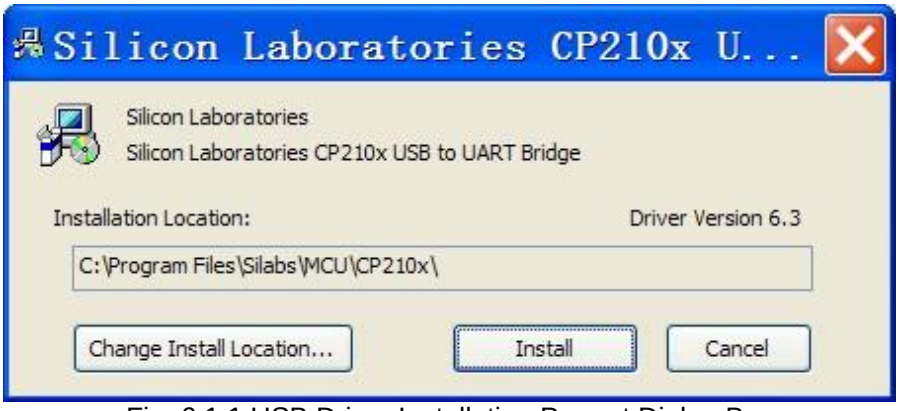

Fig. 6.1.1 USB Driver Installation Prompt Dialog Box

6.2 Error in Certain Lead Waveform

Solution:

Replace the lead wire.

6.3 Error in generating Word program

Solution:

1. Make sure the office 2000 or later is installed;
2. If multiple versions of Word are installed, please only keep the latest version;
3. To ensure the compatibility, it is best to install Office 2003.

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Appendix A Configuration List

A.1 Configuration list

The standard package should contain the following items:

Table A-1 ECG-2000 Configuration List

No.	Name	Part Number	Qty.	Unit
1	Acquisition box	60401006	1	Set
2	Lead Wires	02059027	1	Set
3	Limb electrode	60401008	4	PCS per set
4	Chest electrode	60401007	6	PCS per set
5	Installation CD	/	1	PCS
6	USB Dongle	/	1	PCS
7	User Manual	/	1	Copy
8	Certification	/	1	PCS
9	Warranty Card	/	1	PCS
10	Packing list	/	1	PCS
11	Verification certificate	/	1	PCS

Dimensions and weight:

Table A-2 Dimensions and weight

Length×width×height	335mm×255mm×94mm
Weight	1.3kg

A.2 Notice

1. Follow the prompt on the carton to unpack;
2. After unpacked, check the accessories and provided documentation with the packing list, and then check the devices;
3. If the items in the package can't meet the requirements or the equipment can't work normally, please contact our Sales Department or After-sales Department.
4. Please use the provided accessories, or else the performance and security will be affected. Please consult our After-sales Department before using other accessories;
5. To make sure that we can provide service for you in time, please fill in the Warranty Card (duplicate) and send to us.
6. The carton should be kept properly for periodic testing or maintenance of the equipment.

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Appendix B Technical Parameters

Table B-1 Technical Data Sheet

Defibrillation recovery time	＜ 10 s	
ECG signal sampling rate	1000 Hz	
DC power supple	5 V±5 % (by USB interface)	
Smallest signal detection	≤20 μV(10 Hz)	
Polarization resistance voltage	±500 mV	
Input impedance	>2.5 MΩ	
Input circuit current	≤0.1 μA	
Calibration voltage	1 mV±5 %	
Noise level	≤15 μVp-p	
Anti-jamming capability	CMRR	>89 dB
	Suppression of 10V interfering signal	The record amplitude should not exceed 10 mm
	50Hz interference suppression filter	≥20 dB
Normal sensitivity	10 mm/mV±2 %	
Time constant	≥3.2 s	
Amplitude frequency characteristics	At 10 Hz, (+0.4-3.0+0.4-3.0 $^{+0.4}_{-3.0}$ dB) in (0.05 Hz ~ 250 Hz); high frequency function requires higher frequency response, more than 250 Hz	
Sensitivity	1.25 mm/mV，2.5 mm/mV，5 mm/mV，10 mm/mV，20 mm/mV，10-5 mm/mV，20-10 mm/mV	
Waveform speed	5 mm/s，6.25 mm/s，10 mm/s， 12.5 mm/s，25 mm/s，50 mm/s	
Maximum trace deflection amplitude	≥25 mm	

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Appendix C EMC- Guidance and manufacture's declaration

C.1 Guidance and manufacture's declaration-electromagnetic emissions for all EQUIPMENT and SYSTEMS

1	**Guidance and manufacturer's declaration – electromagnetic emission**		
2	The Digital Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer or the user of Digital Electrocardiograph should assure that it is used in such an environment.		
3	Emissions test	Compliance	Electromagnetic environment - guidance
4	RF emissions EN 55011	Group 1	The Digital Electrocardiograph uses 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.
5	RF emissions EN 55011	Class B	The Digital Electrocardiograph is suitable for use in all establish ments, including domestic establishments and those directlyconn ected to the public low-voltage power supplynetwork that supplie s buildings used for domestic purposes.
6	Harmonic emissions EN 61000-3-2	N/A	
7	Voltage fluctuations / flicker emissions EN 61000-3-3	N/A	

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C.2 Guidance and manufacture's declaration-electromagnetic immunity for all EQUIPMENT and SYSTEMS.

Guidance and manufacture's declaration-electromagnetic immunity			
The Digital Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer of the user of the Digital Electrocardiograph should assure that it is used in such an environment			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic discharge(ESD) IEC61000-4-2	±6KV contact ±8KV air	±6KV contact ±8KV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC61000-4-4	±2KV for power supply lines ±1KV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1KV differential mode ±2KV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variation power supply input lines IEC61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	N/A	Main power quality should be that of a typical commercial or hospital environment. If the user of the Digital Electrocardiograph requires Continued operation during power mains interruptions, it is recommended that the Digital Electrocardiograph be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz)magnetic field IEC61000-4-8	3A/m	3A/m	Mains power quality should be that of a typical commercial or hospital environment.
NOTE: U_T is the A.C mains voltage prior to application of the test level			

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C.3 Guidance and manufacture's declaration-electromagnetic immunity for EQUIPMENT and SYSTEMS those are not LIFE-SUPPORTING

Guidance and manufacture's declaration-electromagnetic immunity			
The Digital Electrocardiograph is intended for use in the electromagnetic environment specified below. The customer of the user of the Digital Electrocardiograph should assure that it is used in such an environment			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Conducted RF IEC61000-4-6	$3V_{ms}$ 150KHz to 80MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the Digital Electrocardiograph, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=[\frac{3.5}{V_1}]\sqrt{P}$ $d=[\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d=[\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHzWhere 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, asdetermined by an electromagnetic site survey, range[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:
Radiated RF IEC61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	
NOTE1: At 80MHz and 800MHz, the higher frequency range applies. **NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.**			
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 Digital Electrocardiograph should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Digital Electrocardiograph. B. Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3V/m.			

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C.4 Recommended separation distance between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distance between portable and mobile RF communications equipment and the ECG-2000

The Digital Electrocardiograph is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Digital Electrocardiograph can help prevent electromagnetic Interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Digital Electrocardiograph 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)**		
	150 kHz to 80 MHz $d=[\frac{3.5}{V_1}]\sqrt{P}$	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	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance 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.

NOTE1: At 80MHz and 800MHz, the higher frequency range applies.

NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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Tab #17 Software Risk Analysis Report

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2. Risk Analysis

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Requirement Specification

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Detailed design specification of software/algorithm

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Unit Test Cases for ECG-2000 Collection Box Software

Company Name: Shenzhen Biocare Electronics Co., Ltd					Form Name: Unit Test

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[redacted]

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Tab #21 Software Development Environment Description

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Biocare 邦健	Confidentiality: Biocare Co. Ltd Development Documents	Doc No.: (b)(4) Version: (b) Pages: 8 pages

Project name: (b)(4)

Digital ECG Device

Document name:

Requirements specification of ECG management system

Scope: ECG-2000

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Item:

Digital ECG

Document name:

Software design specification of ECG management analysis system

Scope of application: ECG-2000

(b)(4)

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Functional Test Report

Product Name: Digital ECG Machine Product No. (b)(4) ECG-2000 Model: ECG-2000

(b)(4)

[redacted]

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TEST REPORT

For

Digital Electrocardiograph

According to IEC 60601-2-25

Model Number: ECG-2000

Report Number: (b)(4)

Test Laboratory :	(b)(4)
Site Location :	
Tel :	
Fax :	

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Biocompatibility Statement

The patient contact material, Tin Alloy and Acrylonitrile butadiene Styrene (ABS) of the electrodes of the Digital Electrocardiograph, ECG-2000, are identical to those of the Digital Electrocardiographs as they were approved in K133985, at January 22, 2015, in formulation, processing and sterilization and no other chemicals have been added (e.g., plasticizers, filers, color additives, cleaning agents, mold release agents, etc).

Hongbo Zhong

Authorized Signature
Hongbo Zhong
R&D Director
Shenzhen Biocare Bio-Medical Equipment Co., Ltd
July 27, 2015

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K152384/S001

MID-LINK
www.mid-link.net info@mid-link.net

Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120, China

FDA/CDRH/DCC
NOV 09 2015
RECEIVED

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66 G609
10903 New Hampshire Avenue
Silver Spring, MD 20993 0002

11/06/2015

RE: K152384 / Supplement 001
Premarket Notification Traditional Section 510(k) Submission
Shenzhen Biocare Bio-Medical Equipment Co., Ltd(***the Sponsor***)
Digital Electrocardiograph, ECG-2000(***the Device(s)***)

Dear Mr. Lacy,

This letter is our official response to the questions contained in your deficiencies letter dated 10/13/2015.

The CD-ROM provided with the submission is the eCopy of the submission; the eCopy is an exact duplicate of the paper copy.

(b)(4)

[redacted]

195

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[redacted]

If you have any question, please contact me vie email at info@mid-link.net or via fax at (240) 238-7587.

Thanks for your help.

Best Regards,

Fu, Lee 2015.11.06 14:46:36 +08'00'

Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

Enclosures

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Shanghai, 200120, China

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66 G609
10903 New Hampshire Avenue
Silver Spring, MD 20993 0002

11/06/2015

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TEST REPORT

For

Digital Electrocardiograph

According to IEC 60601-2-25

Model Number: ECG-2000

Report Number: (b)(4)

Test Laboratory :	(b)(4)
Site Location :	
Tel :	
Fax :	

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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For

Digital Electrocardiograph
According to IEC60601-1

Model Number: ECG-2000

Report Number: (b)(4)

Test Laboratory :	(b)(4)
Site Location :	
Tel :	
Fax :	

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TEST REPORT

EN 60601-1-2: 2007+AC: 2010

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

EN 60601-2-25: 1995+A1: 1999 Clause 36

Medical electrical equipment - Part 2 Clause 36: Particular requirements for the safety of electrocardiographs- Electromagnetic compatibility

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October 12, 2015</br></br> We have reviewed your submission K152384 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K152384 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at <a
href="http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf">http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf
for current information on the number of copies and the format (paper versus eCopy) you must submit.

Your response is due within 180 days from the date of this request, which is April 9, 2016. If a complete response is not received in CDRH's Document Control Center within 180 days, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

Should you have questions about this email, you may contact Frank Lacy, the lead reviewer assigned to your submission.

 *** This is a system-generated email notification ***

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

September 1, 2015</br></br>
Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K152384, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Frank Lacy.

 *** This is a system-generated email notification ***

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

December 18, 2015</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Luke Ralston.

 *** This is a system-generated email notification ***

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

Tab #7 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. Date of Preparation: 08/04/2016

2. Sponsor Identification

   Shenzhen Biocare Bio-Medical Equipment Co., Ltd.
   Room A735, Floor 7, Tower A,
   Shenzhen Famous Industrial Products Procurement & Exhibition Center,
   No. 168 Baoyuan Road, Baoan, Shenzhen, 518102, P.R. China

   Establishment Registration Number: 3008457078

   Contact Person: Mr. Hongbo Zhong
   Position: Director
   Tel: +86-755-36615333-8856
   Fax: +86-755-27960643
   Email: hb-zhong@tom.com

3. Designated Submission Correspondent

   Ms. Diana Hong (Primary Contact Person)
   Mr. Lee Fu (Alternative Contact Person)

   Mid-Link Consulting Co., Ltd
   P.O. Box 120-119, Shanghai, 200120, China

   Tel: +86-21-22815850,
   Fax: 240-238-7587
   Email: info@mid-link.net

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

4. Identification of Proposed Device

Trade Name: Digital Electrocardiograph
Model: ECG-2000
Proposed Device Common Name: Electrocardiograph

Regulatory Information:
Classification Name: Electrocardiograph
Classification: II;
Product Code: DPS;
Regulation Number: 21 CFR part 870.2340;
Review Panel: Cardiovascular;

Intended Use:

Digital Electrocardiograph is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

Device Description

Digital Electrocardiograph, ECG-2000, is intended to acquire ECG signals from adult patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease.

It consists of the acquisition box, optional accessories, installation CD, and USB dongle. The acquisition box is connected with ECG electrodes, and intends to acquire ECG signals from patient. The acquired ECG signal is filtered and amplified, then transferred to the working station. The acquisition box is powered by the working station via a USB line. The working station is a Personal Computer installed with ECG-2000 Software, it intends to receive the processed ECG signal from the acquisition box, and further display and record the signals. Optional accessories include lead wires, limb electrodes and chest electrodes, and general-purpose printer (with USB interface, support PCL language, such as HP1010, P2035, and P2055d series). The CD contains Digital Electrocardiograph installer and dongle installation program module.

5. Identification of Predicate Device(s)

Predicate Device 1
510(k) Number: K092010
Product Name: PC ECG
Manufacturer: Edan Instruments, Inc.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

Predicate device 2
510(k) Number: K133985
Product Name: Digital Electrocardiograph, ECG-2000
Manufacturer: Shenzhen Biocare Bio-Medical Equipment Co., Ltd.

6. Non-Clinical Test Conclusion

This submission is filed for extension of intended use, the device, including its hardware and software, has not been changed from the one cleared in the previous submission, K133985; therefore, only the following standard was tested to verify that the device can meet its additional intended use:

IEC 60601-2-25: 2011, Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device1	Predicate Device 2
Product Code	DPS	Same	Same
Regulation Number	21 CFR 870. 2340	Same	Same
Class	Class II	Same	Same
Intended Use	Digital Electrocardiograph is intended to acquire ECG signals from adult patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.	Same	Similar
Configuration	Chest Electrode and Limb Electrode	Same	Same
ECG Lead	Standard 12-lead	Same	Same
ECG Gain	1.25, 2.5, 5, 10, 20, 10-5, 20-10 (mm/mV)	Similar	Same
Sampling rate	1000Hz	Same	Same

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

Input circuit current	≤0.1 μA	Similar	Same
Noise level	<15μ Vp-p	Similar	Same
Electrical Safety	Comply with IEC 60601-1	Same	Same
EMC	Comply with IEC 60601-1-2	Same	Same
Patient-contact Material	Chest Electrode: Metal Limb Electrode: ABS	Same	Same

The proposed device provides more options for gains than those of the predicate device 1, therefore, this difference will not affect the safety and effectiveness;

The proposed device provides a wider range of bandwidth than that of the predicate device 1. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

The noise level and input circuit current of the proposed and predicate device 1 are different, however both the specifications comply with IEC 60601-1.

9. Substantially Equivalent (SE) Conclusion

The proposed device, Digital Electrocardiograph EG-2000, is determined to be Substantially Equivalent (SE) to the predicate devices, PC ECG (K092010) and Digital Electrocardiographs ECG-2000 (K133985), in respect of safety and effectiveness.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

K152384
Shenzhen Biocare Bio-medical Equipment Co., Ltd.
Digital Electrocardiograph

(b)(4) Deficiencies

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152384

Device Name
Digital Electrocardiograph, ECG-2000

Indications for Use *(Describe)*
Digital Electrocardiograph is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 18, 2015

Shenzhen Biocare Bio-medical Equipment Co., Ltd.
% Diana Hong
General Manager
Mid-link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 CHINA

Re: K152384
Trade/Device Name: Digital Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: November 6, 2015
Received: November 9, 2015

Dear Diana Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

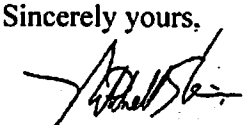
Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



forBram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 18, 2015

Shenzhen Biocare Bio-medical Equipment Co., Ltd.
% Diana Hong
General Manager
Mid-link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 CHINA

Re: K152384
Trade/Device Name: Digital Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: November 6, 2015
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Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sincerely yours,

forBram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152384

Device Name
Digital Electrocardiograph, ECG-2000

Indications for Use *(Describe)*
Digital Electrocardiograph is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Tab #7 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. Date of Preparation: 08/04/2016

2. Sponsor Identification

   Shenzhen Biocare Bio-Medical Equipment Co., Ltd.
   Room A735, Floor 7, Tower A,
   Shenzhen Famous Industrial Products Procurement & Exhibition Center,
   No. 168 Baoyuan Road, Baoan, Shenzhen, 518102, P.R. China

   Establishment Registration Number: 3008457078

   Contact Person: Mr. Hongbo Zhong
   Position: Director
   Tel: +86-755-36615333-8856
   Fax: +86-755-27960643
   Email: hb-zhong@tom.com

3. Designated Submission Correspondent

   Ms. Diana Hong (Primary Contact Person)
   Mr. Lee Fu (Alternative Contact Person)

   Mid-Link Consulting Co., Ltd
   P.O. Box 120-119, Shanghai, 200120, China

   Tel: +86-21-22815850,
   Fax: 240-238-7587
   Email: info@mid-link.net

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4. Identification of Proposed Device

Trade Name: Digital Electrocardiograph
Model: ECG-2000
Proposed Device Common Name: Electrocardiograph

Regulatory Information:
Classification Name: Electrocardiograph
Classification: II:
Product Code: DPS:
Regulation Number: 21 CFR part 870.2340:
Review Panel: Cardiovascular:

Intended Use:

Digital Electrocardiograph is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

Device Description

Digital Electrocardiograph, ECG-2000, is intended to acquire ECG signals from adult patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease.

It consists of the acquisition box, optional accessories, installation CD, and USB dongle. The acquisition box is connected with ECG electrodes, and intends to acquire ECG signals from patient. The acquired ECG signal is filtered and amplified, then transferred to the working station. The acquisition box is powered by the working station via a USB line. The working station is a Personal Computer installed with ECG-2000 Software, it intends to receive the processed ECG signal from the acquisition box, and further display and record the signals. Optional accessories include lead wires, limb electrodes and chest electrodes, and general-purpose printer (with USB interface, support PCL language, such as HP1010, P2035, and P2055d series). The CD contains Digital Electrocardiograph installer and dongle installation program module.

5. Identification of Predicate Device(s)

Predicate Device 1
510(k) Number: K092010
Product Name: PC ECG
Manufacturer: Edan Instruments, Inc.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Predicate device 2
510(k) Number: K133985
Product Name: Digital Electrocardiograph. ECG-2000
Manufacturer: Shenzhen Biocare Bio-Medical Equipment Co., Ltd.

6. Non-Clinical Test Conclusion

This submission is filed for extension of intended use, the device, including its hardware and software, has not been changed from the one cleared in the previous submission, K133985; therefore, only the following standard was tested to verify that the device can meet its additional intended use:

- IEC 60601-2-25: 2011, Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device1	Predicate Device 2
Product Code	DPS	Same	Same
Regulation Number	21 CFR 870. 2340	Same	Same
Class	Class II	Same	Same
Intended Use	Digital Electrocardiograph is intended to acquire ECG signals from adult patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.	Same	Similar
Configuration	Chest Electrode and Limb Electrode	Same	Same
ECG Lead	Standard 12-lead	Same	Same
ECG Gain	1.25. 2.5. 5. 10. 20, 10-5, 20-10 (mm/mV)	Similar	Same
Sampling rate	1000Hz	Same	Same

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

Input circuit current	≤0.1 μA	Similar	Same
Noise level	<15μ Vp-p	Similar	Same
Electrical Safety	Comply with IEC 60601-1	Same	Same
EMC	Comply with IEC 60601-1-2	Same	Same
Patient-contact Material	Chest Electrode: Metal Limb Electrode: ABS	Same	Same

The proposed device provides more options for gains than those of the predicate device 1, therefore, this difference will not affect the safety and effectiveness;

The proposed device provides a wider range of bandwidth than that of the predicate device 1. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

The noise level and input circuit current of the proposed and predicate device 1 are different, however both the specifications comply with IEC 60601-1.

9. Substantially Equivalent (SE) Conclusion

The proposed device, Digital Electrocardiograph EG-2000, is determined to be Substantially Equivalent (SE) to the predicate devices, PC ECG (K092010) and Digital Electrocardiographs ECG-2000 (K133985), in respect of safety and effectiveness.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

Tab #7 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. Date of Preparation: 08/04/2016

2. Sponsor Identification

   Shenzhen Biocare Bio-Medical Equipment Co., Ltd.
   Room A735, Floor 7, Tower A,
   Shenzhen Famous Industrial Products Procurement & Exhibition Center,
   No. 168 Baoyuan Road, Baoan, Shenzhen, 518102, P.R. China

   Establishment Registration Number: 3008457078

   Contact Person: Mr. Hongbo Zhong
   Position: Director
   Tel: +86-755-36615333-8856
   Fax: +86-755-27960643
   Email: hb-zhong@tom.com

3. Designated Submission Correspondent

   Ms. Diana Hong (Primary Contact Person)
   Mr. Lee Fu (Alternative Contact Person)

   Mid-Link Consulting Co., Ltd
   P.O. Box 120-119, Shanghai, 200120, China

   Tel: +86-21-22815850,
   Fax: 240-238-7587
   Email: info@mid-link.net

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

4. Identification of Proposed Device

Trade Name: Digital Electrocardiograph
Model: ECG-2000
Proposed Device Common Name: Electrocardiograph

Regulatory Information:
Classification Name: Electrocardiograph
Classification: II;
Product Code: DPS;
Regulation Number: 21 CFR part 870.2340;
Review Panel: Cardiovascular;

Intended Use:

Digital Electrocardiograph is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

Device Description

Digital Electrocardiograph, ECG-2000, is intended to acquire ECG signals from adult patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease.

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5. Identification of Predicate Device(s)

Predicate Device 1
510(k) Number: K092010
Product Name: PC ECG
Manufacturer: Edan Instruments, Inc.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

Predicate device 2
510(k) Number: K133985
Product Name: Digital Electrocardiograph. ECG-2000
Manufacturer: Shenzhen Biocare Bio-Medical Equipment Co., Ltd.

6. Non-Clinical Test Conclusion

This submission is filed for extension of intended use, the device, including its hardware and software. has not been changed from the one cleared in the previous submission, K133985; therefore, only the following standard was tested to verify that the device can meet its additional intended use:

IEC 60601-2-25: 2011. Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device1	Predicate Device 2
Product Code	DPS	Same	Same
Regulation Number	21 CFR 870. 2340	Same	Same
Class	Class II	Same	Same
Intended Use	Digital Electrocardiograph is intended to acquire ECG signals from adult patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.	Same	Similar
Configuration	Chest Electrode and Limb Electrode	Same	Same
ECG Lead	Standard 12-lead	Same	Same
ECG Gain	1.25. 2.5. 5. 10. 20. 10-5. 20-10 (mm/mV)	Similar	Same
Sampling rate	1000Hz	Same	Same

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Input circuit current	≤0.1 μA	Similar	Same
Noise level	<15μ Vp-p	Similar	Same
Electrical Safety	Comply with IEC 60601-1	Same	Same
EMC	Comply with IEC 60601-1-2	Same	Same
Patient-contact Material	Chest Electrode: Metal Limb Electrode: ABS	Same	Same

The proposed device provides more options for gains than those of the predicate device 1, therefore, this difference will not affect the safety and effectiveness;

The proposed device provides a wider range of bandwidth than that of the predicate device 1. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

The noise level and input circuit current of the proposed and predicate device 1 are different, however both the specifications comply with IEC 60601-1.

9. Substantially Equivalent (SE) Conclusion

The proposed device, Digital Electrocardiograph EG-2000, is determined to be Substantially Equivalent (SE) to the predicate devices, PC ECG (K092010) and Digital Electrocardiographs ECG-2000 (K133985), in respect of safety and effectiveness.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

K152384
Shenzhen Biocare Bio-medical Equipment Co., Ltd.
Digital Electrocardiograph

(b)(4) Deficiencies

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152384

Device Name
Digital Electrocardiograph, ECG-2000

Indications for Use *(Describe)*
Digital Electrocardiograph is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 18, 2015

Shenzhen Biocare Bio-medical Equipment Co., Ltd.
% Diana Hong
General Manager
Mid-link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 CHINA

Re: K152384
Trade/Device Name: Digital Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: November 6, 2015
Received: November 9, 2015

Dear Diana Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

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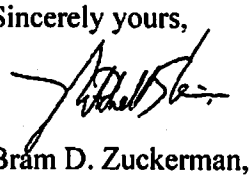
related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



forBram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K152384 Date Received by DCC: Aug 24, 2015

Lead Reviewer: Frank Lacy

Branch: CDDB Division: DCD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments?		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments?		
3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments?		
4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments?		

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5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		X
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

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Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

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Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*	X			
b) Statement contains all elements per 21 CFR 807.93			X	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			
6) Submission contains Class III Summary and Certification. *See recommended* content.			X	
7) Submission contains clinical data			X	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X			
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X			
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.	X			
B. Device Description				
10)				

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	X			
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.			X	
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.	X			
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.				
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding* documenting preamendment status *is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X			
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	X			
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)			X	
20)				
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	

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Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				
Submission states that the device and/or accessories are: (one of the below must be checked)				
provided sterile				
provided non-sterile but sterilized by the end user				
× non-sterile when used				
Information regarding the sterility status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
22) Assessment of the need for sterilization information				
a) Identification of device, and/or accessories, and/or components that are provided sterile.				
b) Identification of device, and/or accessories, and/or components that are end user sterilized.			×	
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.			×	
25)				
a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.			×	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			×	
c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			×	
F. Shelf Life				
26) Proposed shelf life/expiration date stated				
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.			×	

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X			
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				
Submission states that there: (one of the below must be checked)				
X are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	X			
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	X			
31) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X			
H. Software				
Submission states that the device: (one of the below must be checked)				
X does contain software/firmware.				
does not contain software/firmware.				
Information regarding whether the device contains software is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
32) Submission includes a statement of software level of concern and rationale for the software level of concern.	X			
33) All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submitter has provided an alternative approach with a rationale.	X			
I. EMC and Electrical Safety				

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Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
Submission states that the device: (one of the below must be checked)				
× does require EMC and Electrical Safety evaluation.				
does not require EMC and Electrical Safety evaluation.				
Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
34) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	×			
35) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	×			
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.	×			
37)				
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			×	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			×	

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed.				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
38) If literature is referenced in the submission, submission includes:			X	
39) For each completed nonclinical (i.e., animal) study conducted			X	
K. Performance Characteristics - In Vitro Diagnostic Devices Only (Also see 21 CFR 809.10(b)(12))				
Submission states that the device: (one of the below must be checked)				
	is an in vitro diagnostic device.			
X	is not an in vitro diagnostic device.			

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Decision: ◉ Accept ○ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	Frank Lacy -S 2015.09.01 07:00:19 -04'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
CDRH/ODE/DCD/CDDB
WO66 RM1236 HFZ-450
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6321

Premarket Notification [510(k)] Review

Date: October 7, 2015
To: FILE
From: Frank Lacy
Subject: Traditional 510(k)# K152384

Applicant: Shenzhen Biocare Bio-medical Equipment Co., Ltd.

Device Trade Name: Digital Electrocardiograph

Correspondent: Diana Hong

Correspondent Title: General Manager

Consultant Firm (if Applicable): Enter consultant name here, or erase this if there is none

Phone: 86 (212) 281-5850 **Email:** info@mid-link.net

FDA Received Date: August 24, 2015

Due Date: November 22, 2015

Reg #: 870.2340 **Reg Name:** Electrocardiograph

Class: II **Product Code(s):** DPS

Predicate Devices:

510(k) #	Pro Code	Device Trade Name	Owner
K092010	DPS	Pc Ecg, Model Se-1010	Edan Instruments, Inc.
K133985	DPS	Digital Electrocardiograph	Shenzhen Biocare Bio-medical Equipment Co., Ltd.

Review Summary

The subject device is an Electrocardiograph with the following Indications for Use: "Digital Electrocardiograph is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals." It is for Rx use.

Recommendation

I recommend that the Digital Electrocardiograph is/are in need of Additional Information (AINN)

Review Team

Lead Reviewer Frank Lacy (CDRH/ODE/DCD/CDDB)

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

I. Purpose and History

This is the first review of this file as it met the threshold for the Refuse to Accept policy in the original review.

The manufacturer wants to introduce a new Electrocardiographs into interstate commerce.

TPLC Information Recall Information Historyfalls

Predicate Recall Analysis

Predicate 510(k) Number: K092010	Yes	No	N/A
Recall Number: **Not part of pilot program**			X
Has the predicate been recalled for a design related issue? (if no, stop here)			X
Reason for Recall:			X

Predicate Recall Analysis

Predicate 510(k) Number: K133985	Yes	No	N/A
Recall Number: **Not part of pilot program**			X
Has the predicate been recalled for a design related issue? (if no, stop here)			X
Reason for Recall:			X

II. Device/System Description

Device Characteristics	Yes	No	Inadequate Or Marked
Is the intended use or fundamental technology new?	☐	☒	☐
Is the device life-supporting or life sustaining?	☐	☒	☐
Are there any direct or indirect patient contacting components?	☒	☐	☐
• Is the device or a component an implant?	☐	☒	☐
Does the device use software/firmware?	☒	☐	☐

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

Device Characteristics	Yes	No	Inadequate Or Marked
• Is the device a Mobile Medical App?	☐	☒	☐
Does the device or a component need sterilization (by manufacturer or user)?	☐	☒	☐
The device/system uses or is	a reusable multi-patient use device(s)		☐
Is the device a combination product?	N - Not a Part 3 Combination Product		☐
Is the device electrical (battery or wall powered)?	Yes, it is battery powered Only		☐

Check the attributes that are applicable to this submission.

	Nanotechnology	Reprocessed SUD	Companion Diagnostic
Yes	☐	☐	☐
No	☒	☒	☒
Unknown	☐	☐	☐

Device Description Table: Summary of important device characteristics

(b)(4)

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

(b)(4)

[redacted]

Reviewer Recommendation

The Device Description is acceptable.

III. Comparison of Indications for Use to Predicate Devices

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

Comparison of Indications for Use

Subject

510(k) #: K152384 Rx/OTC: Rx

Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/ Newborn
Yes	☐	☒	☐	☐	☐	☐	☐	☐
No	☐	☐	☐	☐	☐	☐	☐	☐
Unknown	☐	☐	☐	☐	☐	☐	☐	☐

Indications for Use: "Digital Electrocardiograph is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals."

Predicate(s)

510(k)#: K092010 Rx/OTC: Rx

Intended Population: Adults and Pediatrics

Indications for Use: Se-1010 pc is intended to acquire ecg signals from adult and pedatric patients through body surface ecg electrodes. Se 1010 pc ecg is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by se-1010 pc ecg can help users to analyze and diagnose heart disease. However the ecg with measurements and interpretive statements is offered to clinician on an advisory basis only

510(k)#: K133985 Rx/OTC: Rx

Intended Population: Adults

Indications for Use: Digital Electrocardiograph is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

Indications for Use Table: Compares the indications for use of the subject and predicate devices.

Reviewer Recommendation

The Comparison of the Indications for Use is acceptable.

IV. Comparison of Technology to Predicate Devices

Device & Predicate Device(s):	K152384	K092010	K133985
General Device Characteristics			

ITEM	Proposed Device	Predicate Device 1 K092010	Predicate Device 2 K133985	Remark
Product Code	DPS	DPS	DPS	SE
Regulation No.	870.2340	870.2340	870.2340	SE
Class	II	II	II	SE
Intended Use	Digital Electrocardiograph is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by	SE-1010 PC ECG is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. SE-1010 PC ECG is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by SE-1010 PC ECG	Digital Electrocardiograph is intended to acquire ECG signals from adult patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by	SE

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	doctors and/or trained healthcare professionals.	can help users to analyze and diagnose heart disease. However the ECG with measurements and interpretive statements is offered to clinician on an advisory basis only.	doctors and/or trained healthcare professionals.	
Intended Population	Adult and pediatric patients	Adult and pediatric patients	Adult patients	SE
Intended Environment	Healthcare facilities	Healthcare facilities	Healthcare facilities	SE
Configuration	Chest Electrode and Limb Electrode	Chest Electrode and Limb Electrode	Chest Electrode and Limb Electrode	SE
Contraindication	Not specified	Not specified	Not specified	SE
Programmable	No	No	No	SE
Components	• PC ECG software • ECG sampling box • Patient cable • Electrodes • USB Dongle (Sentinel) • USB cable	• PC ECG software • ECG sampling box • Patient cable • Electrodes • Sentinel • USB cable	• PC ECG software • ECG sampling box • Patient cable • Electrodes • USB Dongle (Sentinel) • USB cable	SE

(b)(4)

[redacted]

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

(b)(4)

[redacted]

Reviewer Recommendation
The Comparison of the Technology to Predicate Devices is acceptable.

V. Labeling

Labeling Review Needed?	Yes ☒	No ☐
Usability Consult Needed?	Yes ☐	No ☒

A General Labeling Requirements

General Labeling Requirements	Yes	No	Inadequate or Marked
Is the prescription statement (or "Rx only") included?	☒	☐	☐
The indications for use are consistent with the IFU page?	☒	☐	☐
Appropriate contraindications provided?	☒	☐	☐
Appropriate warnings provided?	☒	☐	☐
Instructions are in accordance with the guidance (if applicable)?	☒	☐	☐
Appropriate labeling inside device?	☐	☒	☐
Appropriate label/indicator outside device?	☒	☐	☐
Appropriate Manual labeling?	☒	☐	☐
What MRI safety information does the labeling contain?		Not Needed	☐

Labeling Table: A summary of the adequacy of several labeling requirements.

Reviewer Recommendation
The Labeling is acceptable.

VI. Cleaning, Sterilization, Shelf Life and/or Reuse

1. Sterilization
The proposed device is provided non-sterile, and not to be sterilized by the user prior to use.
2. Shelf Life
There is no shelf life of the proposed device, because it is provided non-sterile, and storage conditions could not affect device safety or effectiveness.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

Reviewer Recommendation
Cleaning, Sterilization, Shelf-Life and Reuse descriptions are acceptable.

VII. Biocompatibility

Biocompatibility Review Needed?	Yes ☐ No ☒
Biocompatibility Consult Needed?	Yes ☐ No ☒

1. Patient Contact Material(s)

The direct and indirect patient-contact component(s) along with the material(s) for the proposed devices are identified as follows:

Table 1 Patient Contact Material Identification

Components	Material	Contact Level	Contact Duration
Chest / Limb Metal Electrode	Copper Alloy	Surface	Limited (<24 hour)
Limb Electrode Clamp	ABS	Surface	Limited (<24 hour)

The patient contact materials of the proposed device as identified are identical to those of the legally marketed device, Digital Electrocardiograph, ECG-2000, as cleared in K123816.

Reviewer Recommendation
The Biocompatibility is acceptable.

VIII. Software/Firmware

Software Review Needed?	Yes ☒ No ☐
Software Consult Needed?	Yes ☐ No ☒

Software Documentation	Present	Absent	Inadequate
Software/Firmware Version: Ver. 1.0			
Level of Concern (LOC): Identified as Moderate			☐
Software/Firmware description: **Adequacy Comments:**	☒	☐	☐
Device Hazard Analysis: **Adequacy Comments:**	☒	☐	☐
Software Requirements Specifications: **Adequacy Comments:**	☒	☐	☐
Architecture Design Chart: N/A if Minor LOC **Adequacy Comments:**	☒	☐	☐

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

Software Documentation	Present	Absent	Inadequate
Software Design Specifications: N/A if Minor LOC **Adequacy Comments:**	☒	☐	☐
Traceability Analysis/Matrix: **Adequacy Comments:**	☒	☐	☐
SW Development Environment Descript.: N/A if Minor LOC **Adequacy Comments:**	☒	☐	☐
Verification & Validation Testing: **Adequacy Comments:**	☒	☐	☐
Revision level history: **Adequacy Comments:**	☒	☐	☐
Unresolved anomalies: N/A if Minor LOC **Adequacy Comments:**	☒	☐	☐
Software Table: Demonstrates the adequacy of the software documentation according to the Guidance Document.			

[The software/firmware was reviewed according to the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005.] [Since the device includes a Programmable Electrical Medical System, it was reviewed according to standard AAMI / ANSI ES 60601-1:2005/(R)2012 Cl. 14.]

Reviewer Recommendation
The Software is acceptable.

IX. EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

EMC Review Needed?	Yes ☐	No ☒
EMC Consult Needed?	Yes ☐	No ☒

Missing electrical safety and EMC reports.

Reviewer Recommendation
The EMC, EMT and Risk Analysis are **[not]** acceptable.

X. Performance Testing

A Bench Testing

The device is said to be in compliance with the bench tests provided as follows:

- IEC 60601-1:1988+ A1:1991+ A2:1995, Medical electrical equipment, Part 1: General requirements for safety;
- IEC 60601-1-2: 2007, Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests;
- IEC 60601-2-25:1993+A1:1999, Medical electrical equipment, Part 2-25: Particular requirements for the safety of electrocardiographs;

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

The patient cable of the proposed device complies with the mandatory performance standard (clause 56.3(c) of IEC 60601-1) as specified in Title 21, Code of Federal Regulations, part 898, Performance Standard for electrode Lead Wires and Patient Cables.

B Animal Testing

N/A

C Clinical Testing

N/A

Reviewer Recommendation

The Performance Testing [Verification & Validation] is acceptable.

XI. Kit Certification

N/A

XII. Manufacturing Information

N/A

XIII. References

N/A

XIV. SE Flowchart Questions

Substantial Equivalence Determination	Yes	No
Is the predicate device legally marketed?	☐	☐

XV. Original Deficiencies

(b)(4)

[redacted]

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

(b)(4)

[redacted]

XVI. Contact History

None

Digital Signature Concurrence Table	
Reviewer Sign-Off	Frank Lacy -A 2015.10.08 12:37:16 -04'00'

Shawn W. Forrest -S
2015.10.12 23:44:59
-04'00'

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
CDRH/ODE/DCD/CDDB
WO66 RM1311 HFZ-450
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6362

Premarket Notification 510(k) Review

Date: December 18, 2015

Reviewer: Luke Ralston

Subject: Traditional 510(k)# K152384/S001

Applicant: Shenzhen Biocare Bio-medical Equipment Co., Ltd.

Device Trade Name: Digital Electrocardiograph

Contact Name: Diana Hong

Contact Title: General Manager

Correspondent Firm: Mid-link Consulting Co., Ltd

Phone: 86 (212) 281-5850 **Email:** info@mid-link.net

Received Date: November 9, 2015

Due Date: December 20, 2015

Reg #: 870.2340 **Reg Name:** Electrocardiograph

Class: II **Product Code(s):** DPS

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K092010	DPS	Pc Ecg, Model Se-1010	Edan Instruments, Inc.
K133985	DPS	Digital Electrocardiograph	Shenzhen Biocare Bio-medical Equipment Co., Ltd.

Review Summary

The subject device is a Electrocardiograph with the following Indications for Use: "Digital Electrocardiograph is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals." It is for Rx use.

Recommendation

I recommend that the Digital Electrocardiograph is/are Substantially Equivalent (SESE)

Review Team

Lead Reviewer Luke Ralston (CDRH/ODE/DCD/CDDB)

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

I. Purpose and History

This Supplement has been submitted in response to deficiencies sent to the sponsor on 10/13/2015. The original file was reviewed by Frank Lacy and the file was transferred to me on 11/12/2015.

II. 510(k) Summary/Statement

510(k) Summary/Statement		
Was a 510(k) Summary or Statement provided?	Summary	Undo
The 510(k) Summary is complete.		

The content of the 510(k) Summary is adequate.

Reviewer Recommendation
The 510(k) Summary/Statement is acceptable.

III. Device/System Description

Device Characteristics		Inadequate Or Marked
Is the intended use or fundamental technology new?	No	☐
Is the device life-supporting or life sustaining?	No	☐
Are there any direct or indirect patient contacting components?	Yes	☐
• Is the device or a component an implant?	No	☐
Does the device use software/firmware?	Yes	☐
• Is the device, or does it contain, a Mobile Medical App?	No	☐
Does the device or a component need sterilization (by manufacturer or user)?	No	☐
The device/system uses or is...	a reusable multi-patient use device(s)	☐
The environment for use of the device/system includes...	Hospital	☐
Is the device a combination product?	N - Not a Part 3 Combination Product	☐
Is the device/system electrical (battery or wall powered)?	Yes, it is battery powered Only	☐

Check the attributes that are applicable to this submission.

	Nanotechnology	Reprocessed SUD	Companion Diagnostic	Medical Counter Measures
Yes	☐	☐	☐	☐
No	☒	☒	☒	☒
Unknown	☐	☐	☐	☐

Device Description Table: Summary of important device characteristics

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

(b)(4)

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

Third-party Components and Accessories:

Reviewer Recommendation
The Device Description is acceptable.

IV. Comparison of Indications for Use to Predicate Devices

Comparison of Indications for Use

Subject

510(k) #: K152384 Rx/OTC: Rx

Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/ Newborn
Yes	☐	☒	☐	☐	☐	☐	☐	☐
No	☐	☐	☐	☐	☐	☐	☐	☐
Unknown	☐	☐	☐	☐	☐	☐	☐	☐

Indications for Use: Digital Electrocardiograph is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

Predicate(s)

Submission#: K092010 Rx/OTC: Rx

Intended Population:

Indications for Use: Se-1010 pc is intended to acquire ecg signals from adult and pedatric patients through body surface ecg electrodes. Se 1010 pc ecg is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by se-1010 pc ecg can help users to analyze and diagnose heart disease. However the ecg with measurements and interpretive statements is offered to clinician on an advisory basis only

Submission#: K133985 Rx/OTC: Rx

Intended Population:

Indications for Use:

Indications for Use Table: Compares the indications for use of the subject and predicate devices.

Reviewer Recommendation
The Comparison of the Indications for Use is acceptable.

V. Comparison of Technology to Predicate Devices

Device & Predicate Device(s):	K152384	K092010	K133985
General Device Characteristics			

See original review memo.

Reviewer Recommendation
The Comparison of the Technology to Predicate Devices is acceptable.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

VI. Labeling

Labeling Review Needed?	Yes	Undo
Usability Consult Needed?	Undo	No

A General Labeling Requirements

General Labeling Requirements		Inadequate or Marked
Is the prescription statement (or "Rx only") included?	Yes	☐
The indications for use are consistent with the IFU page?	Yes	☐
Appropriate contraindications, warnings, precautions and adverse events provided?	Yes	☐
Instructions are in accordance with the guidance (if applicable)?	Yes	☐
Appropriate labeling inside device?	Inapplicable	☐
Appropriate label/indicator outside device?	Yes	☐
Appropriate Manual labeling?	Yes	☐
What MRI safety information does the labeling contain?	Not Evaluated and Not Needed	☐

Labeling Table: A summary of the adequacy of several labeling requirements.

Reviewer Recommendation
The Labeling is acceptable.

VII. Cleaning, Disinfection, Sterilization, Shelf-Life and Reuse

See original review memo.

Reviewer Recommendation
Cleaning, Sterilization, Shelf-Life and Reuse descriptions are acceptable.

VIII. Biocompatibility

Biocompatibility Review Needed?	Undo	No
Biocompatibility Consult Needed?	Undo	No

See original review memo.

Reviewer Recommendation
The Biocompatibility is acceptable.

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

IX. Software/Firmware

Software Review Needed?	Yes Undo
Software Consult Needed?	Undo No

See original review memo.

Reviewer Recommendation
The Software is acceptable.

X. EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

EMC Review Needed?	Yes Undo
EMC Consult Needed?	Yes No

EMC Information	Red = Inadequate or Unanswered	Yellow = Marked
Device/Accessory/Component 1:		
Device/Accessory/Component: PC ECG-2000		
Loss of function risks death/permanent injury?: No		
Summary of testing submitted?: Yes		
Specifications of the standard met/submitted?: Yes		
Device-specific pass/fail criteria submitted?: Yes		
Device-specific function testing provided?: Yes		
Performance test report provided?: Yes		
Standard's allowances that were used provided?: Inapplicable		
Description of deviations of specifications submitted?: Inapplicable		
Labeling compliant with standard?: Yes		
Changes required to pass EMC testing submitted?: Inapplicable		
EMC Table: This EMC table contains EMC information for the subject device.		

All test data was submitted in Supplement 001 as Tab 3 EMC Test Report.

Reviewer Recommendation
The EMC, EMT and Risk Analysis are acceptable.

XI. Performance Testing

A Bench Testing
See original review memo.

B Animal Testing

C Clinical Testing

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

Reviewer Recommendation

The Performance Testing [Verification & Validation] is acceptable.

XII. SE Flowchart Questions

Substantial Equivalence Determination	Yes	No
Is the predicate device legally marketed?	☒	☐
Do the devices have the same intended use?	☒	☐
Please explain how the intended use of the subject device is similar to or different from the predicate device: The intended use is identical to the predicate and the IFU has added pediatric patients to the intended patient population.		
Do the devices have the same technological characteristics?	☒	☐

XIII. Original Deficiencies

(b)(4)

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-5813; Released by CDRH on 4/3/2018

(b)(4)

[redacted]

XIV. Contact History

Digital Signature Concurrence Table	
Reviewer Sign-Off	Luke T. Ralston -S 2015.12.18 12:50:07 -05'00'
Senior Lead Reviewer Sign-Off	Bradley Q. Quinn -S 2015.12.18 13:14:51 -05'00'

Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118