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ECG ACQUISITION SYSTEM DMS 300-BTT02

Operator's manual

ATTENTION: The operators must carefully read and completely understand the present manual before using the product



EC

EF 33320 / 33321

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MTM Multitechmed GmbH Schwarzwaldstrasse 16 - 65597 Hunfelden-Dauborn - Germany Part number: 50207202 Release: July 5, 2013



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Preface

- Welcome to the DMS 300-BTT02 ECG Acquisition System. This system Include DMS 300-BTT02 ECG Acquisition Box and Resting 12-Lead ECG Software.
- In the following, we will introduce all the functions and uses of ECG Acquisition System specifically so that you can get familiar with it and grasp it quickly.
- ♦ FAQ are answered in this manual for you to solve all questions more easily.
- If you want to have a quick look at a certain function of ECG Acquisition System, please refer to the index page.
- The product bears the CE marking "CE 0197" indicating its conformity with the provision of the EC Directive 93/42/EEC concerning medical devices and fulfills the essential requirements of Annex V of this directive. It is class IIa (MDD) equipment.
- The product complies with the electromagnetic immunity requirements of standard IEC 60601-1-2/EN 60601-1-2 "Electromagnetic Compatibility- Medical Electrical Equipment".
- ♦ DM Systems (Beijing) Co., Limited quality management system complies with the standard EN ISO 13485.

Package List

A complete set of ECG Acquisition System should include the following items: (please check everything in the box on the first open and contact us if anything is missing.)

Part	Number
DMS 300-BTT02 ECG Acquisition Box	1
Patient Cable	1
Software CD (Resting 12-Lead ECG Software)	1
Security Key	1
Operator's Manual	1

Packing List (Standard)

How to contact us?

Thanks for purchasing and using our product, if you have any questions about the products, please contact us by the following address.

		EC REP
Company:	DM Systems (Beijing) Co., Limited	Mr. Rolf Herzog
Address:	Suite 1102, BeiKong Science	MTM Multitechmed GmbH
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Website:	www.dmsecg.com	

Safety and Effectiveness Considerations

The following safety and effectiveness issues are to be considered prior to the usage of the ECG Acquisition System.



- Safety protection type of this ECG Acquisition System is DEFIBRILLATION-PROOF TYPE CF APPLIED PART.
- The reliability of the ECG Acquisition System is dependent upon conformance with the operation instructions, as detailed in this manual.
- The ECG Acquisition System will not cause abnormal operation of a patient's cardiac pacemaker or other electronic stimulator.
- ♦ Only a physician should give final interpretation.

Warnings and Contraindications

- This equipment is not intended for use with high frequency surgical units. Disconnect the patient from the device before using the high frequency surgical unit.
 - Δ This equipment is not intended for use with electro surgery equipment.
 - Do not remove unit covers. The ECG Acquisition System does not contain any user serviceable components.
- The ECG Acquisition System is not suitable for intracardiac application.
- DO NOT immerse the device in any fluid, place fluids on top, or attempt to clean the unit with any liquid detergents. This may cause an electrical hazard. If accidental wetting occurs, please return to DMS.
- The patient cable should not be kneaded or bent. Or the cable will be broken. The connector of the patient cable should not get in touch with the earth line or other bare metal parts.
- /! The ECG Acquisition System is defibrillation-proof. Therefore it is not necessary to remove the ECG electrodes during defibrillation.
- During defibrillation, do not touch the patient, the electrodes or lead wires. If defibrillation be carried out during ECG sampling, this would cause a signal delay 10 seconds.
- △ The electrodes should be in accordance with the requirements of ANSI/AAMI EC12 and Directive 93/42/EEC.

 - (!) The used electrodes should be disposed of in accordance with the requirements of environment protection.
 - The equipment is used in accordance with the instructions given in this manual.
 - Keep the recorder and patient cable clean, especially the components that touch patients.

It is recommended that the ECG Acquisition System be calibrated annually by an authorized service center.

Please check the electrodes if main windows of the software indicate that the device is inoperable.

Equipment Symbols

The following symbols appear on the equipment.

Table Equipment Symbols		
Symbols	Meaning	
	Caution.	
4	DEFIBRILLATION-PROOF TYPE CF APPLIED PART.	
	Direct Current.	
X	Proper disposal of equipment.	
C € 0197	CE Mark. (according to MDD93/42/EEC)	
EC REP	Authorized Representative in the European Community.	
	Manufacturer.	
	Please read instructions carefully.	

EMC Declaration

The ECG Acquisition System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents; Portable and mobile RF communications equipment can affect the ECG Acquisition System. All cables and maximum length of cables, and other accessories with which the manufacturer of the ECG Acquisition System claims compliance with the requirements, Accessories that do not affect compliance with the requirements of these sub clauses need not be listed. Accessories and cables may be specified either generically or specifically.

Warning:

Transducers and cables sold by the manufacturer of the ECG Acquisition System as replacement parts for internal components need not be listed.

The use of accessories and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of The ECG Acquisition System as replacement parts for internal components, may result in increased emissions or decreased immunity of The ECG Acquisition System.

Guidance and manufacturer's declaration – electromagnetic emissions		
The ECG Acquisition System is intended for use in the electromagnetic environment		
specified below. The o	customer or the	user of the ECG Acquisition System should assure
that it is used in such a	an environment.	
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The ECG Acquisition System 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.
RF emissions CISPR 11	Class A	The ECG Acquisition System is suitable for use in all establishments other than domestic, and may
Harmonic emissions IEC 61000-3-2	Not applicable	be used in domestic establishments and those directly connected to the public low-voltage power
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
		Warning: This ECG Acquisition System is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the ECG Acquisition System or shielding the location.

Guidance and manufacturer's declaration – electromagnetic immunity The ECG Acquisition System is intended for use in the electromagnetic environment specified below. The customer or the user of the ECG Acquisition System should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 0,5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ECG Acquisition System requires continued operation during power mains interruptions, it is recommended that the ECG Acquisition System be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Power frequency magnetic fields should be t levels characteristic of a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The ECG Acquisition System is intended for use in the electromagnetic environment			
specified below. The customer or the user of the ECG Acquisition System should assure			
that it is used in such an electromagnetic environment.			
IMMUNITY test	IEC 60601	Compliance	Electromagnetic environment –
	test level	level	guidance
Conducted RF	Not applicable	N/A	Portable and mobile RF
IEC 61000-4-6			communications equipment should
			be used no closer to any part of the

	Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	ECG Acquisition System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
				Recommended separation distance
				$d = \left[\frac{3.5}{3}\right]\sqrt{P}$ 80 MHz to 800 MHz
				$d = \left[\frac{7}{3}\right]\sqrt{P}$ 800 MHz to 2.5 GHz
				where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
				Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b
				Interference may occur in the vicinity of equipment marked with the following symbol:
				$((\bullet))$
			the higher freque	
	NOTE TAL OUMITZ and OUMITZ, the higher frequency range applies.			
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			
	considered. If the measured field strength in the location in which the ECG Acquisition			
	System is used exceeds the applicable RF compliance level above, the ECG Acquisition			
	System should be observed to verify normal operation. If abnormal performance is			
	observed, additional measures may be necessary, such as re-orienting or relocating the			
	ECG Acquisition System.			
	^o Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between

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

Rated maximum output power	Separation distance according to frequency of transmitter		
of transmitter W	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = \left[\frac{3.5}{V1}\right]\sqrt{P}$	$d = \left[\frac{3.5}{3}\right]\sqrt{P}$	$d = \left\lfloor \frac{1}{3} \right\rfloor \sqrt{P}$
0.01	N/A	0.117	0.233
0.1	N/A	0.369	0.738
1	N/A	1.167	2.333
10	N/A	3.689	7.379
100	N/A	11.667	23.333

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

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Chapter 1. Equipment Overview

1.1 Intended Use

- The ECG Acquisition System is capable of sampling, recording patient's resting ECG. This system is applicable to the heart disease for the medical treatment institution.
- The ECG Acquisition System is intended for use under the direct supervision of a licensed health care practitioner.
- The device is to be used on an adult population, typically symptomatic.

1.2 Specifications

Voltage:	DC 5.0V, 200mA (USB Interface).
Sample rate:	10240Hz.
Sample resolution:	16 bit.
Lead:	12-lead standard ECG.
Input circuit current:	≤0.1µA.
Input impedance:	≥5 MΩ.
Noise electric level:	≤15µV _{p-p} .
Standard sensitivity:	10mm/mV, ±5%.
Anti-polarization voltage:	if add $\pm 300 \text{mV}$ DC polarization voltage, the change
	of sensitivity is not more than ±5%.
CMRR:	≥89 dB.
Frequency response:	$0.5 \text{ -150 Hz} \ (\text{+0.4 dB}, \text{-3.0 dB})$.
Lower frequency feature:	time constant is not less than 3.2s.
50Hz filter:	≥20dB.
Equipment safety type:	Defibrillation-proof Type CF Applied Part.
Working environment:	Temperature: 5- 40℃,
	Relative humidity: 30 - 80%,
	Atmospheric pressure: 860 - 1060hPa.
Storage and Transport environment	:: Temperature: -40 - 50℃,
	Relative humidity: ≤93%,
	Atmospheric pressure: 500 - 1060hPa.
Dimensions:	Approximately 120 × 85 × 28 mm
Weight:	Approximately 190g
Data Connector:	USB

1.3 Hardware Connection

Model:	DMS 300-BTT02
Patient Cable Model:	IEC10/L-15P-M
Electrode Model:	01-3633





Connect to computer USB port

Patient cable port



Connect to patient cable

Chapter 2. Software System

2.1 System Requirements

CPU:	Pentium PIII or Celeron 800 or above
Memory:	at least 512M
Hard disk:	above 30G
VGA Card:	at least 4M memory
CD-ROM:	CD-ROM or DVD
Operation System:	Windows XP/Vista/7
Resolution:	1024x768 pixels

You can change these settings in Windows XP/Vista/7 in display property. If you have

other questions in changing settings, please refer to Windows XP/Vista/7 help.

/! The computer should meet the requirements of EN60950-1.

The printer should meet the requirements of EN60950-1.

The computer should be placed outside the PATIENT ENVIRONMENT.

2.2 Software Installation

USB security key driver installation:

- 1. Put the "DMS Software Installation CD" into CD-ROM.
- 2. Double click "Sentinel Protection Installer", The Installation process starts.
- 3. Follow the prompt step by step until the installation finishes.

Resting 12-Lead ECG Software Installation:

- 1. Put the "DMS Software Installation CD" into CD-ROM.
- 2. Double click "Resting 12-Lead ECG software", The Installation process starts.
- 3. Follow the prompt step by step until the installation finishes.

2.3 Before You Begin

Before start Resting 12-Lead ECG, please check the following things:

- ♦ Check if the ECG acquisition Box has been correctly connected.
- ♦ Check if the ground line has been properly connected.
- ♦ Check if the USB security key has been plugged into the computer USB port.
- ♦ Check if the patient cable has been properly hookup on patient.
- Check if the windows system settings are correct. (Refer to "System requirements" for detailed information.)

2.4 Software Functions

This software functions include:

- ♦ New Patient
- ♦ Report
- \diamond Tools
- ♦ Exit
- ♦ 12 Lead Resting ECG with auto interpretation (ECG)
- \diamond QTd (QTD)
- ♦ Frequency Cardiogram (FCG)
- ♦ High Frequency ECG (HFECG)
- $\Leftrightarrow \text{ Hour ECG (Hour)}$
- ♦ Signal Averaged ECG, also called Ventricular Late Potential, VLP (SAECG)
- \diamond Vector ECG (VCG)
- \diamond Timed Vector ECG (TVCG)

2.4.1 New Patient

2.4.1.1 Standard ECG Collecting

Click "New Patient" icon and then "Standard ECG Collecting" on the main screen and you will see the following picture. You have two different options which are "12-lead Simultaneous ECG", and "3-lead Simultaneous VCG". "12-lead Simultaneous ECG" use standard 12 leads hookups. "3-lead Simultaneous VCG" uses Frank X, Y, Z hookups. User can select to perform all of these functions or any one of them. The program will guide you to do the tests step by step.

New Patient	
	Welcome to our new patient wizard! The Wizard will guide you to do following things.
AAS	😑 Select sample style you want
1 123	\varTheta Fill out essential information.
1 2 2	Attach lead-wires to the patient.
Cal to 1	\varTheta Sample the patient's ECG data.
	😑 Finish data sampling and start to analyze.
The second	Sample Style
1	✓ 12-lead Simultaneous ECG 90 second
*Up	3-lead Simultaneous VCG 360 second
	Click Next to continue.
	< Back Next > Cancel Help

12-lead simultaneous ECG: You can change the sampling time according to your needs. But if you want to sample data for FCG (Frequency ECG), it is strongly recommended sampling 90 seconds.

3-lead Simultaneous VCG: If you want to sample data for Vector ECG, SAECG (Signal Averaged ECG) and TVCG (Time Vector ECG), you need to apply Frank X, Y, Z hookups, If you want to test SAECG, the sampling time should not be less than 240 seconds.

User can select to perform all of these functions or any one of them.

If user select "12-lead Simultaneous ECG", when sampling finishes, the ECG, FCG, HFECG, QTD, button will be lighted up.

If user selects "3-lead Simultaneous VCG", SAECG, VCG and TVCG will be lighted up.

2.4.1.2 Quick ECG Collecting

If you want to sample only 12-lead Simultaneous ECG data, you have a very quick method.

Click "Quick ECG" icon on the main screen, Fill in some necessary information.

2.4.1.3 Multi-Hour ECG Monitoring

If you want to sample multi hour 12-lead Simultaneous ECG data, you click Multi-Hour ECG Monitoring.

2.4.1.4 Simple Stress Test

If you want to sample simple stress test 12-lead Simultaneous ECG data, you click Simple Stress Test.

2.4.1.5 Stress Test

If you want to enter Stress Test software, you click Stress Test.

2.4.2 Report





Click on the icon of "Report" on the main screen. Make a checkmark in the report you want to print out. The grey color items are inactive and can not be selected. It is because that functions are not performed and there is no suitable data. Click "Print All" if you want to print the entire reports.

Click "Send E-mail" button. The selected reports can be sent to other doctors by e-mail via Microsoft Outlook.GDT is only used for Germany customers. You can create the ASCII file (ASCIIECG.txt) by clicking "Save ASCIIECG" button. You can view the ASCIIECG.TXT file by entering the patient data directory and opening the patient file.

2.4.3 Tools

Click "Tools" button on the main screen to display the following interface:

System Settings Leads Placement	
Make Cardio Card Import data from PDA(CF/SD Card) Import data from PDA(Synchronous Connected) Import Cardio Prefect SCP File	
Output ECG Data Output VCG Data	

System Settings: You can set the software system; include General Information, Interface Setting, Signal Processing, Report and Password Setting, System Manager.

Leads Placement: Careful skin preparation is the key to get an interference-free ECG.

Make Cardio Card: It allows to a make a patient ECG card just like the ID card. Print the 12

lead ECG strips, fold in half and print it out. Then seal it with plastic seal machine.

Import data from PDA (CF/SD Card): Import patient ECG data by CF/SD Card.

Import data from PDA (Synchronous Connected): Connect PDA to import patient ECG data.

Import Cardio Prefect SCP files: Choose the path to import SCP file.

Output ECG data: Output current patient ECG data.

Output VCG data: Output current patient VCG data.

2.4.4 Exit

Exit the software program.

2.4.5 ECG



ECG Review: Click "ECG" icon on the main screen with left mouse button, to enter into the 12-lead simultaneous ECG. The hart rate and RR interval are displayed on top of each beat with unit of BPM (Beat Per Minute) and ms (millisecond). The red marker indicates the active beat which can be edited by user.

Complex: Click Complex tab, you can see 12 leads complex beat in one screen Use mouse left click to select which beat you want to adjust, use tab key to change the active Cursor, left and right key to move the position.

Complex Big: Click complex big tab show you a single channel complex beat.

Page Scan: Click Page Scan tab you can see a 90 seconds ECG data.

Interpretation: Click Interpretation tab you can review the ECG parameter, and change the conclusion, print report.

2.4.6 QTD



Click "QTD" icon with left mouse button to enter into QT dispersion screen.

2.4.7 FCG



Click "FCG" icon with left mouse button to enter into Frequency Cardiogram.

FCG include CAD Locating Diagnosis, Two Leads Compare, Limb Lead Power Precordial Lead Power and Index Table.

2.4.8 HFECG



Click "HFECG" icon with left mouse button to enter into high frequency ECG screen. HFECG is to detect high frequency components of QRS such as notches, slurs and beadings.



2.4.9 Hour

Click "Hour" icon with left mouse button to enter into Hour ECG screen. Hour ECG include HRV and Trend, PageScan.

2.4.10 SAECG



The SAECG is also called Ventricular Late Potential (VLP). The SAECG screen display consists of two parts. The top display is the R-R Interval graph. Each vertical line represents the heart rate of one beat. The longer the line the slower the heart rate is. Moving the cursor bar with a mouse click or with the arrow keys to the desired location, and using "Reject" button to reject the R-R interval can delete individual R-R intervals.

The large data display is one minute of ECG data. Each horizontal sweep represents 12 seconds of ECG data. Placing the mouse cursor on the desired location and clicking can eliminate undesired ECG beats. Reversing this process will cause rejected beats to be accepted. It is desirable to remove beats with artifact from the SAECG Late Potential file. You can access minutes 1 by pointing and clicking the mouse on the Page 1 tab, or you can change the minutes by pressing the PGUP and PGDN keys on the keyboard.

2.4.11 VCG



Click "VCG" icon with left mouse button to enter into Vector ECG screen.

2.4.12 TVCG



Click "TVCG" icon with left mouse button to enter into Timed Vector ECG screen.

Appendix

Appendix A: Recommended Basic Procedure of Using Resting 12-lead ECG Software

When it is the first time to use RESTING 12-LEAD ECG software, it is recommended to do according to following steps which will help you easily perform a new patient test.

- 1. Select "USB Device" if you are using DMS 300-BTT02 ECG Acquisition System.
- 2. Click on "System Settings" on the main screen. Click "Report and Password Setting" and type in the corresponding passwords for all the 7 functions. The password is in an envelope together with the products. After you input the entire passwords, you can see all the ten function modules are turning into active.
- 3. Make some system settings. Enter general hospital information; the information will be displayed on the heading of final reports.

Click "Signal Processing". Make a checkmark in the box before "Enable Main filter", "Enable ADS" and "Enable Beep". Select filter from 50Hz and 60Hz.

Click "Report and Password Setting" Select the print mode, color, Orientation. Select the report format of the printout from the Landscape (3*4+2), Landscape (12) and Landscape (3*4+1) with table. Make a checkmark if you want the data table be printed out. Click "General Information". Set the Raw Data Directory. Click the question sign to select the directory. Select Language you want to use.

- 4. Start a new patient test. Click "New Patient" icon on the main screen. Select the preferable items from 12-lead Simultaneous ECG, 3-lead Simultaneous VCG and set the sampling time for each item.Click "Next". You will be asked to type in some patient information. Pay attention in the "Type" field, select the correct ECG sampling device you are using. Follow the wizard to finish ECG sampling.
- 5. After ECG sampling finishes, you need to set the ECG components.
- 6. Now you can perform all the functions by click on the corresponding icons on the main screen. For example, clicking on the "ECG" icon on the main screen allows user to perform 12-lead simultaneous ECG. Click on "FCG" icon, you can perform the Frequency ECG. Please refer to the related chapter for the different functions. You may see some of the function modules are grey and inactive. It is because you did not sample data for that function. For example, if you only sample data for 12-lead simultaneous ECG, the SAECG, VCG and TVCG icons will be grey color and inactive.

Appendix B: Maintenance and Cleaning

To keep your ECG Acquisition System in good working condition, please observe the following:

Cleaning components

- 1. The external housing of the ECG Acquisition Box should be cleaned and disinfected as required and at least semi-annually.
- 2. Remove the Data Input Line before cleaning.
- 3. Clean external surfaces with a damp cloth moistened with mild soap solution; wipe dry with a clean cloth.

Maintenance of the patient cable

- 1. The patient cable should be cleaned regularly. Use cotton cloth to wipe the dirt. Do not use the detergent with the content of alcohol, or the cable will become rigidified and easy to break.
- 2. The patient cable should be checked if it has physical break each time when starting a new patient test.
- 3. Do not submerse, autoclave, or steam clean the patient cable.
- 4. The patient cable should be disinfected by 2% glutaraldehyde solution(such as Cidex).

Maintenance of ECG Acquisition Box

- 1. Keep the ECG Acquisition Box clean.
- 2. The devices should not work in humid environment.
- 3. Do not use acetone, ether, Freon, petroleum derivatives, or other solvents to clean the devices.

4. Do not let soap or water flow into the devices or come into contact with patient connector pins.

5. The Box should be disinfected by 2% glutaraldehyde solution(such as Cidex).

Disposal of Waste Materials

1. The used electrodes should be disposed of in accordance with the requirements of environment protection.

Discarding of the Equipment

- 1. Discard the ECG Acquisition Box, patient cable, and accessories according to local laws.
- 2. Please follow the state's recycling laws or your facility's recycling policy to ensure proper disposal of the ECG Acquisition System patient cable and accessories.

Appendix C: Trouble Shooting

1. When I start the RESTING 12-LEAD ECG software, it pop up "Security key not found". How to solve the problem?

A: First check if the security key that plugged into the computer USB port is loose. Then check if the security key driver has been installed and worked.

2. Why the sampling ECG is just line or artifacts?

A: First, check if the ECG lead wire is loose from the ECG acquisition System. Second, check if the earth line worked. Third, check if the correct sampling device is selected.

3. The printer does not work even after several minutes after I click the print button in the software.

A: Check the printer cable connected to the computer. Reinstall the printer driver.

4. The printer cable is good, but the printer does not work at all.

A: Maybe there are too many programs are running at the same time. Close these programs and restart windows. If the printer still does not work, contact with your dealer or DMS for consultation.

5. In case of the program abnormally exit, will the patient data will be lost?

A: The patient data will not be lost. Restart computer and RESTING 12-LEAD ECG software and you can check the data

6. How can I do if the printer speed is too slow?

A: Go to printer properties. Click "Advance" tab. Click "Print Processor" button. Select "Raw" in the default data type.

- 7. Why the heart rate of the sampled ECG is two times of the actual heart rate?A: Please check if the T wave is too high in the heart rate channel. Change to other lead with lower T wave for heart rate calculation.
- 8. Why the sampled ECG is too tiny?

A: Different person has different ECG waves. You may increase ECG gain in the software.

9. Why all of the function modules are grey color and inactive when I start RESTING 12-LEAD ECG software?

A: If it is the first time to use the software, all of the function modules are grey color and inactive including FCG, HFECG, QTD, PMECG, SAECG, VCG, TVCG and Hour ECG, Each function has a unique password. You must enter these passwords before start to use the corresponding function. Go to "System Settings" on the main screen. Click "Report and Password setting" and enter the passwords. Please contact with your distributor or DMS for the passwords.

- 10. What is the meaning of "Custom Item1" on the report? How to delete this information?A: User may enter the customized information in the four "Custom Item" fields and this information will appear on the heading of the report. User can edit this in "System Settings/Patient Info Custom Item".
- 11. On the far right of the QTD report, there are some data highlighted with black rectangle and some with white rectangle. What does this mean?

A: The data highlighted with black rectangle is the maximum value of the QT/QTM. The data highlighted with the white rectangle is the minimum value of the QT/QTM.

Appendix D: Warranty Liabilities

- 1. This product is warranted to be free from manufacturing and material defects for a period for 12 months or period specified in contract. (The warranty does not include disposable spare parts.)
- 2. This warranty is voided if the product is damaged by accident, abnormal handling or misuse.
- 3. The repair service provided after warranty period is subject to appropriate charge.
- 4. Resale of this product must be done by qualified party. To modify or assemble with this product, a manufacture license is required. DMS takes no legal responsibility for any operations like resale, modification or assembling of this product.

Thank you!

Thank you for your support. We hope you can pleasantly use our products and we will welcome your suggestions. Please return the product registration card to be a legal user of our product. We will promptly provide you information about product upgrading at the proper time.

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