

Technical data file (confidential)
ECG equipment iMAC120, Zoncare

<p>Radio frequency radiation 61000-4-3</p>	<p>3V/m 80MHz 2.5GHz</p>	<p>~ 3 V/m</p>	<p>The recommended isolation distance is calculated as:</p> <p>80 MHz to 800 MHz: $d = 1.2 \sqrt{P}$</p> <p>800MHz to 2.5GHz: $d = 2.3 \sqrt{P}$</p> <p>P is the transmitter's rated maximum output rated power, in watts, provided by the transmitter manufacturer;</p> <p>d is the recommended isolation distance in meters.</p> <p>The field strength of the RF transmitter obtained by electromagnetic field measurement must be less than the compliance level in each frequency range.</p> <p>Interference may occur near devices marked</p> <div style="text-align: center;">  </div> <p>with the following symbols:</p>
<p>Note 1: At 80MHz and 800MHz frequencies, the formula for the higher frequency band is used.</p> <p>Note 2: The above guidelines may not be applicable in all situations. Electromagnetic wave propagation is affected by absorption and reflection from buildings, objects and the human body.</p> <p>Note 3: This equipment is intended to receive RF electromagnetic energy and is exempt from basic performance requirements in the occupied frequency band (2395.825MHz-2487.645MHz), but remains safe.</p>			

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For fixed-type airports, such as wireless (cellular/cordless) telephones and terrestrial mobile radio base stations, amateur radio, AM (amplitude modulation) and FM (frequency modulation) radio broadcasts, and television broadcasts, the field strength is theoretically can not be accurately predicted. In order to assess the electromagnetic environment of a stationary RF transmitter, an electromagnetic field survey should be considered. If the measured field strength of the location where the ECG is located is higher than the RF compliance level of the above application, the ECG should be observed to verify that it is functioning properly. Additional measures may be necessary if abnormal performance is observed, such as reorienting the ECG machine and repositioning it.

Recommended isolation distance between portable and mobile RF communications equipment and ECG machines

The electrocardiograph is expected to be used in an electromagnetic environment where radio frequency radiation disturbance is controlled. Depending on the maximum rated output power of the communication device, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile RF communication device (device machine) and the ECG machine as recommended below.

Maximum rated output power of the transmitter (W)	Isolated distance for different frequency transmitters (m)		
	150 kHz ~ 80 MHz $d = 1.2 \sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2 \sqrt{P}$	800 MHz ~ 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30

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ECG equipment iMAC120, Zoncare

100	12.00	12.00	23.00
<p>For the rated maximum output power of the transmitter not listed above, the recommended isolation distance d, in meters (m), can be determined using the formula in the corresponding transmitter frequency column, where P is provided by the transmitter manufacturer. Transmitter maximum output rated power in watts (W).</p> <p>Note 1: Formulas for higher frequency ranges are used at frequencies of 80 MHz and 800 MHz.</p> <p>Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.</p>			

Appendix III Environmental Statement

Names and Contents of Hazardous and Noxious Substances:

Name	Hazardous and Noxious Substances or Elements					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (CrVI)	PBB	PBDE
Built-in PCB	○	○	○	○	○	○
plug-in board	○	○	○	○	○	○
Metal parts	○	○	○	○	○	○
Shell	○	○	○	○	○	○
Display part	○	○	○	○	○	○
Package	○	○	○	○	○	○
Accessories	○	○	○	○	○	○
○: It indicates that contents of hazardous substances in the all homogeneous materials of the part are below the limits specified in SJ/T 11363-2006 standard.						
 CAUTION		The product and its spare parts should be disposed of in accordance with the local laws and regulations, and shall not be discarded as useless together with household waste.				

I.4 Appearance Parameters

Size	(L × W × H) 285mm×360mm×94mm
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Weight	about 3.7 kg
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I.5 Environmental Conditions

Operation

Ambient Temperature	+ 5°C ~ + 40°C
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Ambient Humidity	20%~85%(no condensation)
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Atmospheric Pressure	570hPa~1060hPa
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Shipment and Storage

Ambient Temperature	-20°C ~ +55°C
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Ambient Humidity	10%~95%
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Atmospheric Pressure	500hPa~1060hPa
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I.6 Adherence to Standards

EN ISO 13485:2016	Medical devices-quality management system-Requirements for regulatory purpose;
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EN ISO 14971:2012	Medical devices-Application of risk management to medical devices
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EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
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ISO10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
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ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
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ISO 10993-10:2010	Biological evaluation of medical devices-Part 10:Tests for irritation and skin sensitization
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EN 1041:2008	Information supplied by the manufacturer of medical devices
IEC 60601-1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-2-25: 2011	Medical Electrical Equipment - Part 2-25: Particular Requirements For The Basic Safety And Essential Performance of Electrocardiographs;
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance -Collateral standard: Electromagnetic compatibility-Requirements and tests;
EN 62304:2006/AC:2008	Medical device software - Software life-cycle processes
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN 60601-1-6:2015	Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability

Appendix II Electromagnetic (EMC)

Electromagnetic compatibility (EMC) is defined as the ability of a product, device, or system to function properly in its electromagnetic environment without posing unacceptable electromagnetic disturbances to anything in the environment.

Anti-electromagnetic interference is the ability of a product, device, or system to function properly in the presence of electromagnetic interference (EMI).

It is designed and manufactured in accordance with existing electromagnetic compatibility standards and related requirements. Use in the presence of an electromagnetic field may cause performance degradation such as output anomalies. If this happens frequently, it is recommended to check the environment in which the ECG is used to determine possible sources of disturbance. These harassments may come from other electrical equipment used in the same room or in a nearby room, or from portable and mobile RF communications equipment such as cell phones, walkie-talkies, or from nearby radios, televisions, or microwave transmission equipment. If electromagnetic interference (EMI) interferes with the ECG, it may be necessary to move the ECG to another location or take appropriate electromagnetic interference suppression measures.

This product complies with the requirements of the EMC standard IEC 60601-1-2.

Warning

- ◆ *It will not be used for the lead wire and power cord of the electrocardiograph for the electrocardiograph, which may result in an increase in the emission of the electrocardiograph or a decrease in the immunity.*
- ◆ *The electrocardiograph should not be used close to or stacked with other equipment. If it must be used close to or stacked, it should be observed that it will function properly in the configuration in which it is used.*

Note

- ◆ Medical equipment has special precautions for EMC and needs to be installed and used according to the EMC information provided in the

documentation provided with the ECG.

- ◆ This section includes information on electromagnetic radiation and immunity to electromagnetic systems. Ensure that the operation of the electrocardiograph meets the conditions specified in the reference information. Operating an electrocardiograph in an environment that does not meet these conditions may degrade the performance of the system.
 - ◆ To ensure electromagnetic compatibility when installing and using an electrocardiograph, follow the information and warnings contained in this and other sections.
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Description

- ◆ If you operate and use an electrocardiograph in the electromagnetic environment described in “Anti-Electromagnetic Interference” below, it will work safely and provide the following basic properties:
 - 1 button works normally;
 - 2 The host continuously collects signals and displays the waveform and measured value results on the display.
-

Electromagnetic radiation		
The electrocardiograph is expected to be used in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in this electromagnetic environment.		
Launch Test	Compliance	Electromagnetic Environment - Guide
Radio frequency emission CISPR 1	Group 1	The ECG uses RF energy only for its internal functions. Therefore, its RF emissions are low and there is little chance of interference with nearby electronic equipment.

Radio frequency emission CISPR 11	Class A	The electrocardiograph is suitable for use in all facilities that are not directly connected to the home and to the public low voltage power supply network of the home.
Harmonic emission IEC61000-3-2	Not applicable	
Voltage fluctuation/ flicker emission IEC61000-3-3	Not applicable	

Approved accessories that meet electromagnetic standards

Accessories for electrocardiographs may affect their amount of radiation. The accessories listed in this section have been tested in accordance with international standards when used in electrocardiographs to confirm compliance with radiation standards. Please use only the attachments listed in this section.

When connecting the accessories to the ECG machine, the user should ensure the electromagnetic compatibility of the ECG machine. Unless otherwise stated, use only EMC-compliant equipment.

No.	Name	Cable length (m)	Shielding or Not
1	power cord	1.6	NO
2	Patient cable	< 3	NO

Anti-electromagnetic interference

The electrocardiograph is designed for use in the electromagnetic environment specified herein. The user or user of the electrocardiograph should ensure that it is used in such an environment.

Electromagnetic Immunity Guidelines and Statements			
The electrocardiograph is expected to be used in a defined electromagnetic environment and the purchaser or user should ensure that it is used in such an electromagnetic environment.			
Anti-interference test	IEC60601Test level	Compliance level	Electromagnetic environment- guide
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV Contact discharge ±8 kV Air discharge	±6 kV Contact discharge ±8 kV Air discharge	The floor must be wood, concrete or tile. If the floor is covered with synthetic material, the relative humidity is at least 30%.
Electrical fast transient (EFT)/burst IEC 61000-4-4	±2kV power cord ±1 kV I/O cables (Length >3m).	±2kV power cord ±1 kV input/output cables (>3m)	The network power supply should have the quality used in a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	The network power supply should have the quality used in a typical commercial or

			hospital environment.
Voltage dip, short interruption and voltage change on the power input line IEC 61000-4-11	<p>< 5% UT (drop > 95 % UT) 0.5cycle</p> <p>40%UT (drop 60%UT) 5cycle</p> <p>70%UT (drop 30%UT) 25cycle</p> <p>< 5% UT (drop > 95 % UT) 5sec</p>	<p>< 5% UT (drop > 95 % UT) 0.5cycle</p> <p>40%UT (drop 60%UT) 5cycle</p> <p>70%UT (drop 30%UT) 25cycle</p> <p>< 5% UT (drop > 95 % UT) 5sec</p>	<p>The network power supply should have the quality used in a typical commercial or hospital environment.</p> <p>If the user of the ECG machine needs to run continuously during a power outage, it is recommended that the ECG machine be powered by an uninterruptible power supply or battery.</p>
Power frequency magnetic field (50/60Hz) EC 61000-4-8	3 A/m	3 A/m	The power frequency magnetic field should have a power frequency magnetic field level characteristic typical of a typical commercial or hospital environment.
Note 1: UT is the A.C. mains voltage prior to application of the test level.			

Electromagnetic interference

Electromagnetic interference can occur on the electrocardiograph in a variety of ways. These disturbances depend on the immunity of the device. In the presence of interference, be careful when continuing to use the ECG machine.

Electromagnetic Immunity Guidelines and Statements

The electrocardiograph is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in such an electromagnetic environment.

Immunity test	IEC60601 Test level	Compliance level	Electromagnetic environment - guide
Radio frequency conduction 61000-4-6	3 Vrms 150k ~ 80MHz	3Vrms	<p>Portable and mobile RF communications equipment should not be used closer to any part of the electrocardiograph, including cables, than the recommended isolation distance. This distance is calculated by a formula corresponding to the transmitter frequency.</p> <p>The recommended isolation distance is calculated as:</p> $d = 1.2 \sqrt{P}$

<p>Radio frequency radiation 61000-4-3</p>	<p>3V/m 80MHz 2.5GHz</p>	<p>~ 3 V/m</p>	<p>The recommended isolation distance is calculated as:</p> <p>80 MHz to 800 MHz: $d = 1.2\sqrt{P}$</p> <p>800MHz to 2.5GHz: $d = 2.3\sqrt{P}$</p> <p>P is the transmitter's rated maximum output power, in watts, provided by the transmitter manufacturer;</p> <p>d is the recommended isolation distance in meters.</p> <p>The field strength of the RF transmitter obtained by electromagnetic field measurement must be less than the compliance level in each frequency range.</p> <p>Interference may occur near devices marked</p> <div style="text-align: center;">  </div> <p>with the following symbols:</p>
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Note 1: At 80MHz and 800MHz frequencies, the formula for the higher frequency band is used.

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10	3.80	3.80	7.30

100	12.00	12.00	23.00
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For the rated maximum output power of the transmitter not listed above, the recommended isolation distance d , in meters (m), can be determined using the formula in the corresponding transmitter frequency column, where P is provided by the transmitter manufacturer. Transmitter maximum output rated power in watts (W).

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plug-in board	○	○	○	○	○	○
Metal parts	○	○	○	○	○	○
Shell	○	○	○	○	○	○
Display part	○	○	○	○	○	○
Package	○	○	○	○	○	○
Accessories	○	○	○	○	○	○
○: It indicates that contents of hazardous substances in the all homogeneous materials of the part are below the limits specified in SJ/T 11363-2006 standard.						
 CAUTION		The product and its spare parts should be disposed of in accordance with the local laws and regulations, and shall not be discarded as useless together with household waste.				

ECG report

Reporting time : 2021-06-03 11:15:20

Confirm and sign:

ID : 36212120090 HR : 80 bpm
Name : Jonas Jonaitis PR : 162 ms
Gender : M QRS : 84 ms
Age : 59 Years QT/QTc : 356/391 ms
Dept : 92 kg P/QRS/T : 51/31/48 °
Bed No : 180 cm RV5/SV1 : 0.964/0.461 mv
RV5+SV1 : 1.425 mv

Interpretations :
Sinus rhythm
Normal ECG



ECG report

ID : 36212120090
 Name : Jonas Jonaitis
 Gender : M
 Age : 59 Years
 Dept : 92 kg
 Bed No : 180 cm

Reporting time : 2021-06-03 11:15:21
 Confirm and sign:

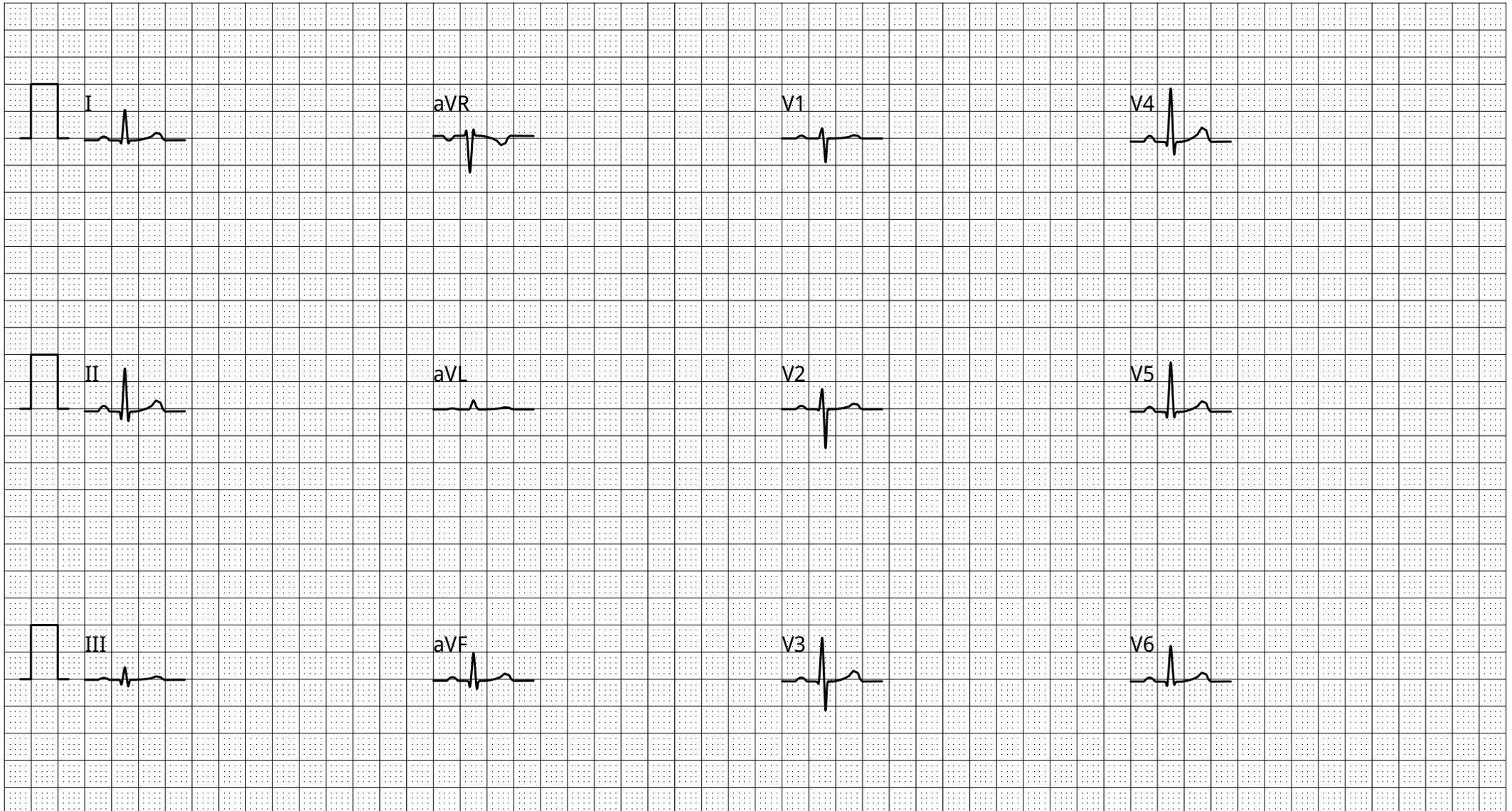
	I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
P Ons	264	264	264	264	264	264	264	264	264	264	264	264
P Dur	94	94	94	94	94	94	94	94	94	94	94	94
QRS Ons	426	426	426	426	430	426	440	442	428	426	426	426
QRS Dur	60	82	80	78	70	82	68	68	82	84	84	68
Q Dur	16	18	21	0	0	19	0	0	12	15	17	17
R Dur	43	40	34	17	70	38	33	32	39	42	44	50
S Dur	0	23	24	41	0	24	34	35	29	25	22	0
ST Dur	174	128	128	152	172	150	166	156	122	126	144	162
T Ons	660	636	634	656	672	658	674	666	632	636	654	656
T Dur	122	146	148	126	110	124	94	116	150	146	128	126
QRS IntD	36	36	37	62	34	37	22	20	34	39	39	39
Q Amp	-49	-143	-94	0	0	-118	0	0	-35	-73	-103	-80
R Amp	582	834	250	96	166	542	184	381	847	1042	964	687
S Amp	0	-173	-130	-707	0	-151	-461	-768	-571	-236	-86	0
ST Amp	7	14	6	-10	0	11	0	3	9	10	13	7
QRS Area	694	804	109	-747	295	458	-223	-280	526	1085	1103	802
P Area	173	251	77	-211	49	166	108	135	172	291	228	182
T Area	649	951	297	-794	182	630	201	408	882	1215	929	747
P Morph	1	1	1	-1	1	1	1	1	1	1	1	1
T Morph	1	1	1	-1	1	1	1	1	1	1	1	1
STM Amp	3	5	2	-4	0	4	0	1	1	2	4	3
ST60 Amp	7	9	1	-8	3	5	0	3	8	10	9	7
STTMidAmp	2	5	3	-3	0	4	0	3	2	1	4	0

Examination time: 2021-06-03 11:10:02

ECG report

ID : 36212120090
Name : Jonas Jonaitis
Gender : M
Age : 59 Years
Dept : 92 kg
Bed No : 180 cm

Reporting time : 2021-06-03 11:15:22
Confirm and sign:

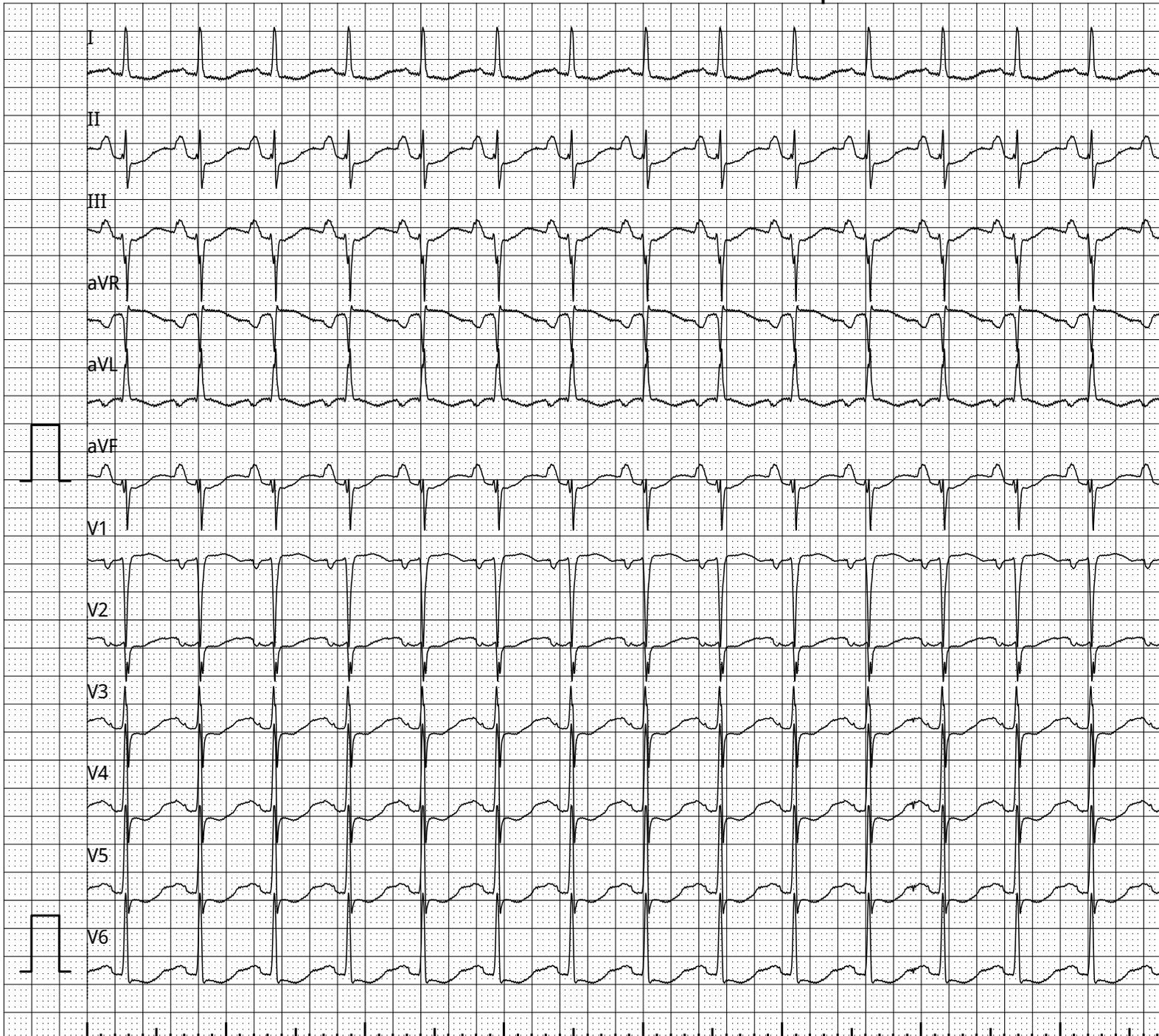


25mm/s 10mm/mv

Examination time: 2021-06-03 11:10:02

ECG report

Reporting time: 2021-06-03 11:15:25



ID : 36212120090
Name : Jonas Jonaitis
Gender : M
Age : 59 Years
Dept : 92 kg
Bed No : 180 cm
HR : 113 bpm
PR : 154 ms
QRS : 80 ms
QT/QTc : 290/383 ms
P/QRS/T : 79/-37/109 °
RV5/SV1 : 1.609/1.515 mv
RV5+SV1 : 3.124 mv

Interpretations :
Sinus tachycardia with sinus arrhythmia
Possible right atrial abnormality
Possible left anterior fascicular block
Left ventricular hypertrophy
Widespread ST-T abnormality ~ may be due to the hypertrophy and/or ischemia
Abnormal ECG

Confirm and sign:

ECG report

Reporting time: 2021-06-03 11:15:27

	I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
P Ons	280	280	280	280	280	280	280	280	280	280	280	280
P Dur	106	106	106	106	106	106	106	106	106	106	106	106
QRS Ons	444	434	434	436	436	434	434	444	438	440	440	440
QRS Dur	52	78	76	62	72	76	74	66	74	74	74	46
Q Dur	0	0	0	45	11	0	0	0	0	0	0	0
R Dur	52	40	14	16	60	15	11	13	43	43	44	46
S Dur	0	37	61	0	0	15	62	52	30	30	29	0
ST Dur	150	126	138	148	140	116	140	128	118	120	128	148
T Ons	646	638	648	646	648	626	648	638	630	634	642	634
T Dur	72	82	76	74	76	98	52	70	90	86	78	86
QRS IntD	22	34	10	51	41	32	6	10	24	26	26	28
Q Amp	0	0	0	-633	-28	0	0	0	0	0	0	0
R Amp	790	481	62	181	904	64	28	34	713	1528	1609	1414
S Amp	0	-542	-1117	0	0	-160	-1515	-635	-658	-553	-367	0
ST Amp	-56	-87	-31	71	-18	-59	51	-43	-122	-145	-133	-97
QRS Area	1029	-235	-1240	-385	1128	-736	-1826	-842	158	1280	1480	1456
P Area	1	476	475	-238	-236	474	-266	-434	-347	-158	19	94
T Area	-645	99	963	262	-779	448	749	85	-489	-1159	-1219	-1042
P Morph	1	1	1	-1	-1	1	-1	1	1	1	1	1
T Morph	-1	1	1	2	-1	1	1	1	-2	-1	-1	-1
STM Amp	-46	-83	-36	64	-5	-59	73	-28	-91	-129	-126	-105
ST60 Amj	-66	-55	10	60	-38	-22	75	-27	-98	-143	-140	-118
STTMidAr	-50	-84	-32	64	-1	-62	74	-27	-91	-128	-125	-104

ID : 36212120090
 Name : Jonas Jonaitis
 Gender : M
 Age : 59 Years
 Dept : 92 kg
 Bed No : 180 cm

Confirm and sign:

Examination time: 2021-06-03 11:08:26

ECG report

Reporting time: 2021-06-03 11:15:27

ID : 36212120090

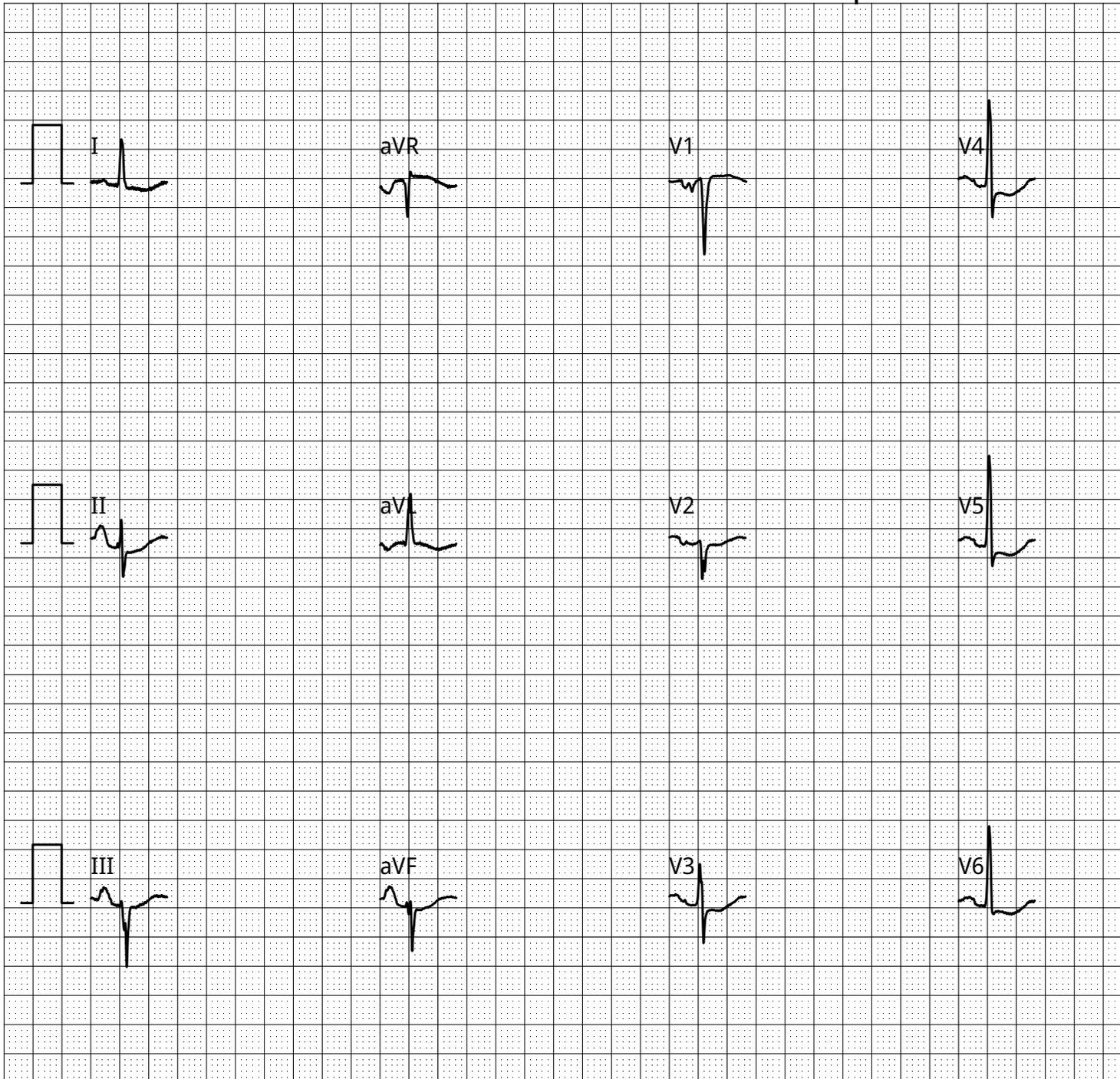
Name : Jonas Jonaitis

Gender : M

Age : 59 Years

Dept : 92 kg

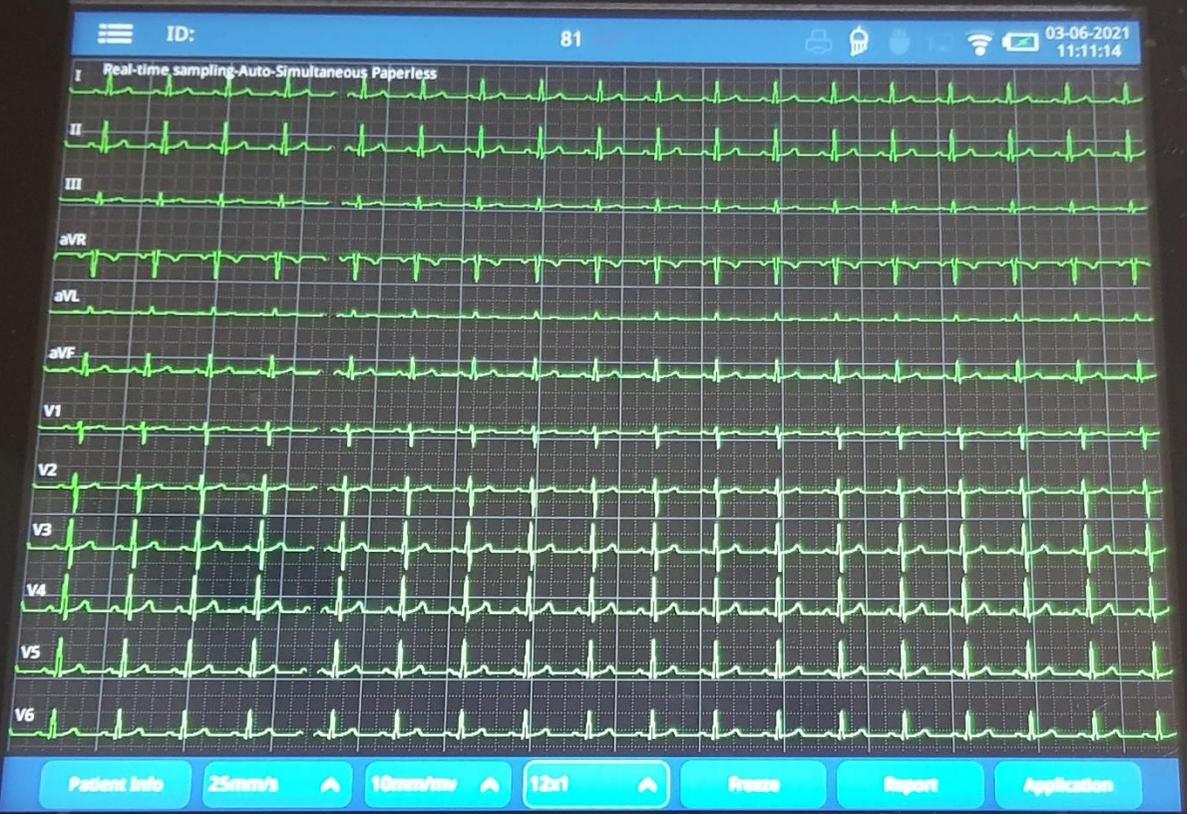
Bed No : 180 cm



25mm/s 10mm/mv

Examination time: 2021-06-03 11:08:26

Confirm and sign:



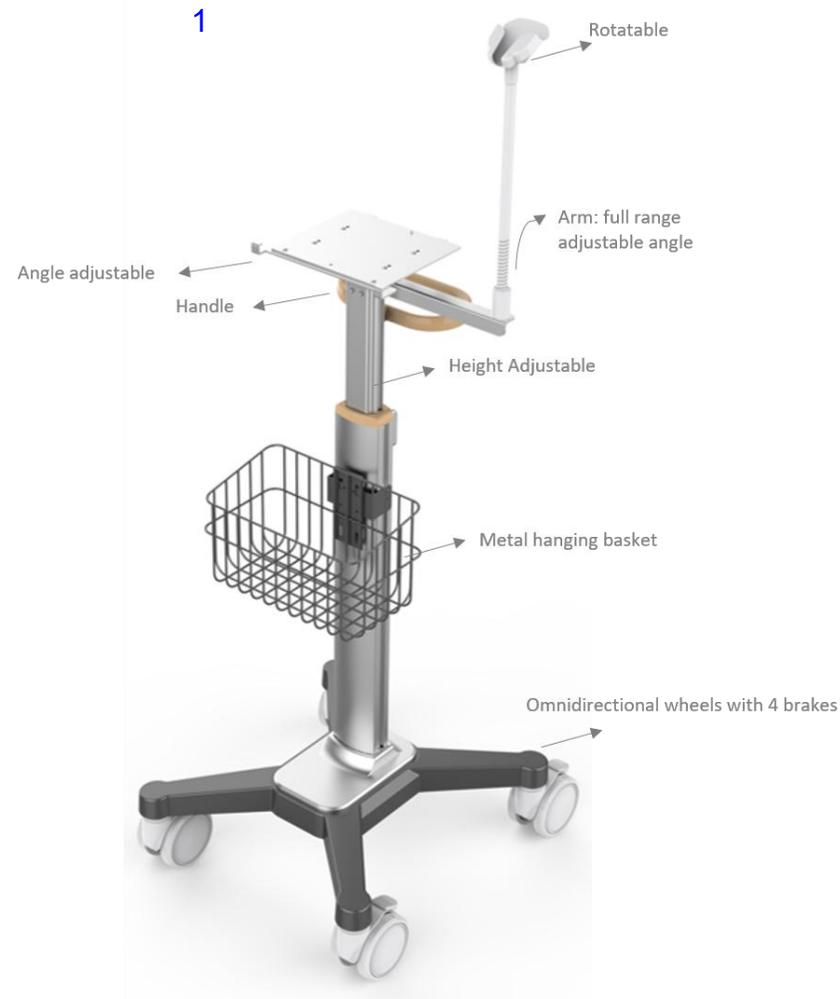
F1 F2 F3 F4 F5 F6 F7

o/o Mode Save ID ECG

iMAC 300/ iMAC 120/ iMAC 12 trolley characteristics and material

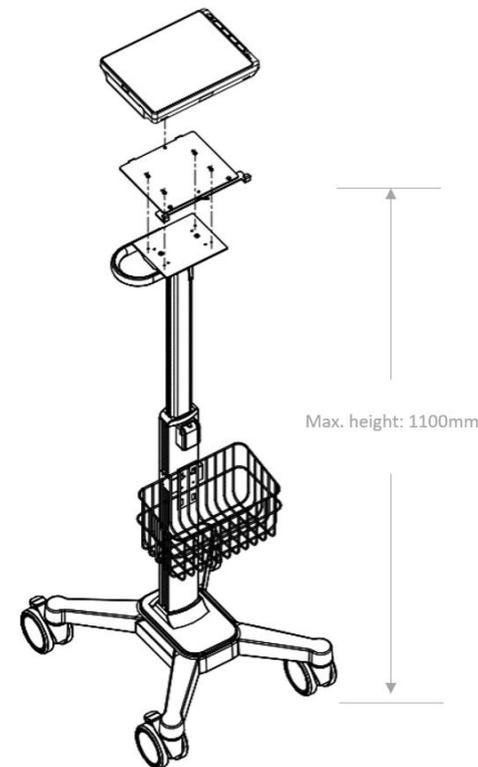
Code No.: 3902800106

Full View



Height Range: 90cm - 110cm

Size



Package size: 750 * 502 * 235 (mm)

G.W.: approx. 7.1 kg

N.W.: approx. 5.6 kg

Material



DECLARATION OF CONFORMITY

Manufacturer: *Wuhan Zoncare Bio-Medical Electronics Co., Ltd.*

380, High-tech 2nd road, Eastlake High-tech Development Zone, Wuhan, Hubei (430206), China.

Product: *Trolley (Medical use)*

UMDNS (Name/Code): *Carts, Instrument/10641*

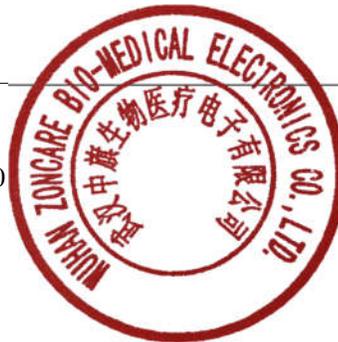
Classification: *Class I, Rule 1 according to Annex IX of the MDD.*

**WE HEREWITH DECLARE THAT the ECG Trolley(for models iMAC 300)
conform to the safety, reliability and product design criteria referenced in
regulations MDD 93/42/EEC and conform with EN 60601-1, 3rd edition.**

Place, Date of Issue: WUHAN, Dec 10, 2020

Signature: 蔡海学 (Paul Tsai)

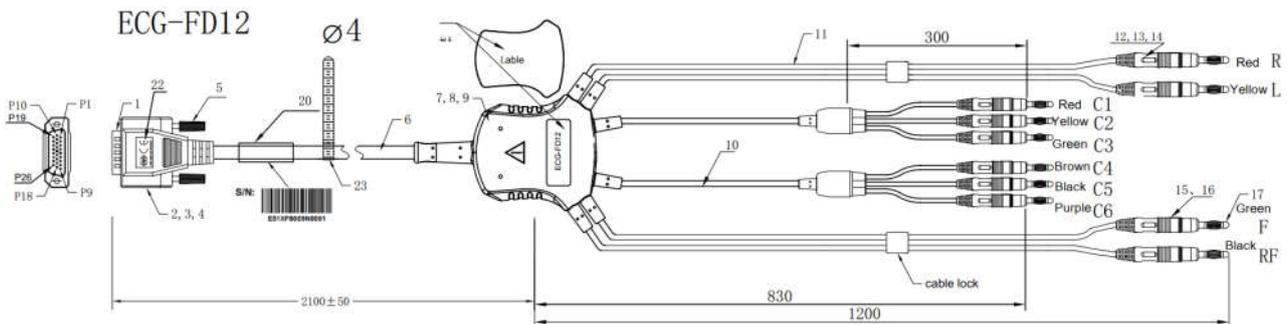
Position: Sales Director



ECG Cable Specifications



1. Model : ECG-FD12
2. Code : 3902800031
3. Material and specifications :

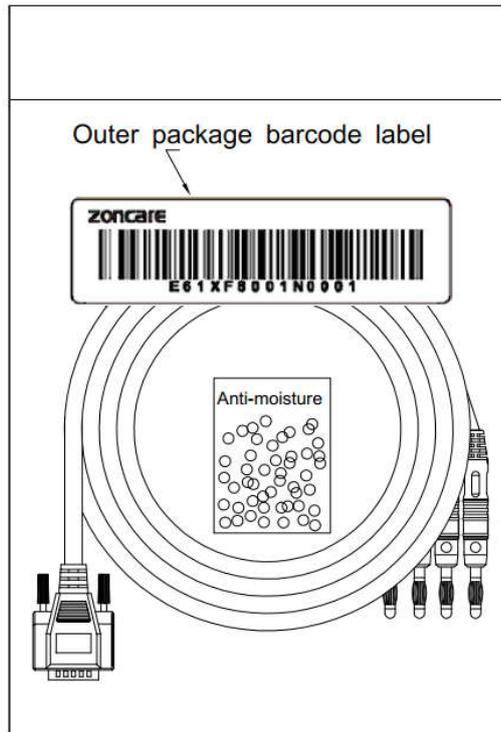


1	Plug		DB 26P
2	PVC	20g	55P gray-white color PVC
3	Gum	10g	LD-PE natural color
4	Copper foil	1PCS	W30*L60mm
5	Screws	2PCS	Lock bolt
6	Wire	2210mm	∅6.5
7	Printed board	1SET	PCB Board
8	Gum	50g	
9	Gum	100g	
10	Wire	2*500mm	∅3.2
11	Wire	2*650mm	∅3.2
12	Internal mold	5g	PP natural color
13	PVC	4-10g	55P White PVC
14	Resistance	10PCS	Anti-defibrillation resistance
15	PVC	6-10g	55P White PVC
16	Color label set	5g	85P, 10 characters
17	Pins	10PCS	∅4, H62 nickel plating
18	Clip chain	1PCS	W190*L220*0.1mm

19	Chip	1PCS	DS2431
20	product label	1PCS	Transparent PVC
21	Identification label	1PCS	PVC cold gray 3C
22	CE label	1PCS	
23	Magic cable tie	1PCS	1.5 × 15 Gray

4. Packing

Package Method



Limb electrodes, 4 units



Chest electrodes, 6 units



Confirm Patient Info Previous

Input List Settings

ID: 20210330131447

Name: **Age setting** ✕

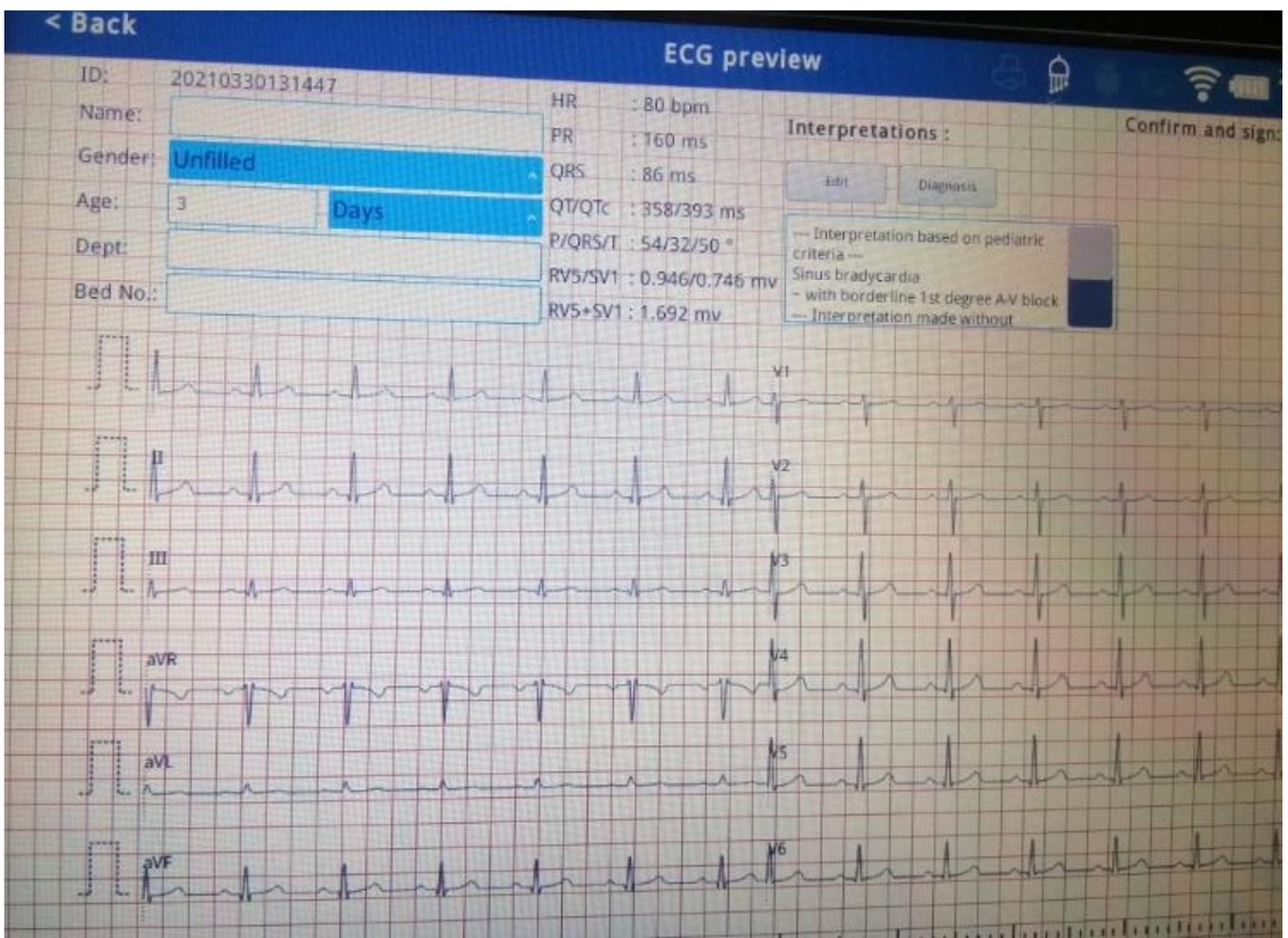
Gender: 3 Days

Dept: Birth date: Year: Months: D:

Race: Unknown

Medicine: 0 Undefined

PREV DIAG: 0 Undefined



Neonatal ECG cable and disposable electrodes



EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
12351-2018-CE-RGC-NA-PS Rev. 2.0

Project No.:
PRJC-217612-2010-PRC-CHN

Valid Until:
27 May 2024

This is to certify that the quality system of:

Wuhan Zoncare Bio-medical Electronics Co., Ltd.

#380, High-tech 2nd Road, Eastlake high-tech district, Wuhan, Hubei, P. R. China.

For design, production and final product inspection/testing of:

DIGITAL MULTI-CHANNEL ELECTROCARDIOGRAPH

Has been assessed with respect to:

THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 06 January 2021

For:
DNV GL PRESAFE AS
Notified Body No.: 2460

Sholeh Gheissar

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html



Certificate No.:
12351-2018-CE-RGC-NA-PS Rev. 2.0

Project No.:
PRJC-217612-2010-PRC-CHN

Valid Until:
27 May 2024

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2018-04-20
1.0	Extension in scope	2020-06-17
2.0	Recertification	2021-01-06

Products covered by this Certificate:

Product Description	Product Name	Class
Digital Multi-Channel Electrocardiograph	iMAC 120, iMAC 120pro	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Wuhan Zoncare Bio-medical Electronics Co., Ltd.	#380, High-tech 2nd Road, Eastlake high-tech district, Wuhan, Hubei, P. R. China.

EU Representative

Well kang Limited , The Black Church, St. Mary's Place , Dublin 7, Ireland

Certificate No.:
12351-2018-CE-RGC-NA-PS Rev. 2.0

Project No.:
PRJC-217612-2010-PRC-CHN

Valid Until:
27 May 2024

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

1. Declaration of Conformity

Declaration of Conformity

For the following products:

Digital Multi-channel Electrocardiograph

(Product Name)

iMAC 120, iMAC 120A, iMAC 120B, iMAC 120pro

(Model Designation)

is hereinafter confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC As amended by 2007/47/EC)

EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008, ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010, IEC 60601-1:2005/A1:2012, EN 60601-1-2:2015, IEC 60601-2-25:2011, EN 62304:2006/A1:2015, EN 62366-1:2015, EN 60601-1-6:2010/A1:2015.

Conformity Assessment Route:

Annex II excluding section 4 of Medical Device Directive

Notified Body:

DNV GL Presafe AS (NB No. 2460)

Veritasveien 3, 1363 Høvik, Norway

The following representative in Europe is responsible for making this declaration:

Company Name: Well kang Limited

Company Address: The Black Church, St. Mary's Place, Dublin 7, Ireland

The following manufacturer is responsible for making this declaration:

Company Name: Wuhan Zoncare Bio-medical Electronics Co., Ltd.

Company Address: #380, High-tech 2nd road, Eastlake high-tech district, Wuhan, Hubei, P. R. China

Qi Wang

General Manager

(Legal Signature)

(Position/title)



(Date)



Notified Body Confirmation Letter Reference: C684165

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Wuhan Zoncare Bio-medical Electronics Co., Ltd.

#380, High-tech 2nd Road, Eastlake high-tech district, Wuhan, Hubei, P.R. China.

SRN Number: CN-MF-000010439

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

Place and date:
Høvik, 2024/04/17



For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

André Fernandes
Management Representative

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device name: Digital Multi-channel Electrocardiograph iMAC 12, iMAC 12pro Basic UDI-DI: 695691348214MQ	Class IIa	NA	Certificate number: 12350-2018-CE-RGC-NA-PS Rev. 2.0 NB name: DNV Product Assurance AS, NB number: 2460
Device name: Digital Multi-channel Electrocardiograph iMAC 120, iMAC 120pro Basic UDI-DI: 695691348214MQ	Class IIa	NA	Certificate number: 12351-2018-CE-RGC-NA-PS Rev. 2.0 NB name: DNV Product Assurance AS, NB number: 2460
Device name: Digital Multi-channel Electrocardiograph iMAC 300, iMAC 300pro Basic UDI-DI: 695691348214MQ	Class IIa	NA	Certificate number: 12349-2018-CE-RGC-NA-PS Rev. 2.0 NB name: DNV Product Assurance AS, NB number: 2460

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device name: Digital Multi-channel Electrocardiograph iMAC 1800, iMAC 1800pro Basic UDI-DI: 695691348217MW	Class IIa	NA	Certificate number: 9861-2017-CE-RGC-NA-PS Rev. 3.0 NB name: DNV Product Assurance AS, NB number: 2460

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/04/17	C684165	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.

Statement on iMAC ECG Noise Reduction

To whom it may concern,

We, Wuhan Zoncare Bio-medical Electronics Co., Ltd., manufacturer of ECG Machine, Ultrasound Machine, Patient Monitor makes the statement regarding our iMAC 120, iMAC 12, iMAC 300 ECG machines as below:

In the case that some specific tenders require the indication of ECG noise reduction function/technology, while it's not included in our technical specifications such as datasheet, user manual, etc., we hereby state that the iMAC ECGs obtained two patents for inventions relating to noise filtering/removal:

- ◆ Apparatus and method for filtering out industrial frequency noise(Patent No. ZL 2017 1 0082475.3).
- ◆ An ECG signal filtering method for removing ringing(Patent No. ZL 2018 1 1443998.7).

The original patent certificate are attached.

This parameter is for reference and Zoncare holds the final right of explanation.



Date: July. 26th 2023

Statement on some parameters of iMAC120

To whom it may concern,

We, Wuhan Zoncare Bio-medical Electronics Co., Ltd., manufacturer of ECG Machine, Ultrasound Machine, Patient Monitor makes the statement regarding our iMAC 120 ECG machine as below.

1, Printer speed when recording the rhythm of calm $\leq 6,25$ mm/s

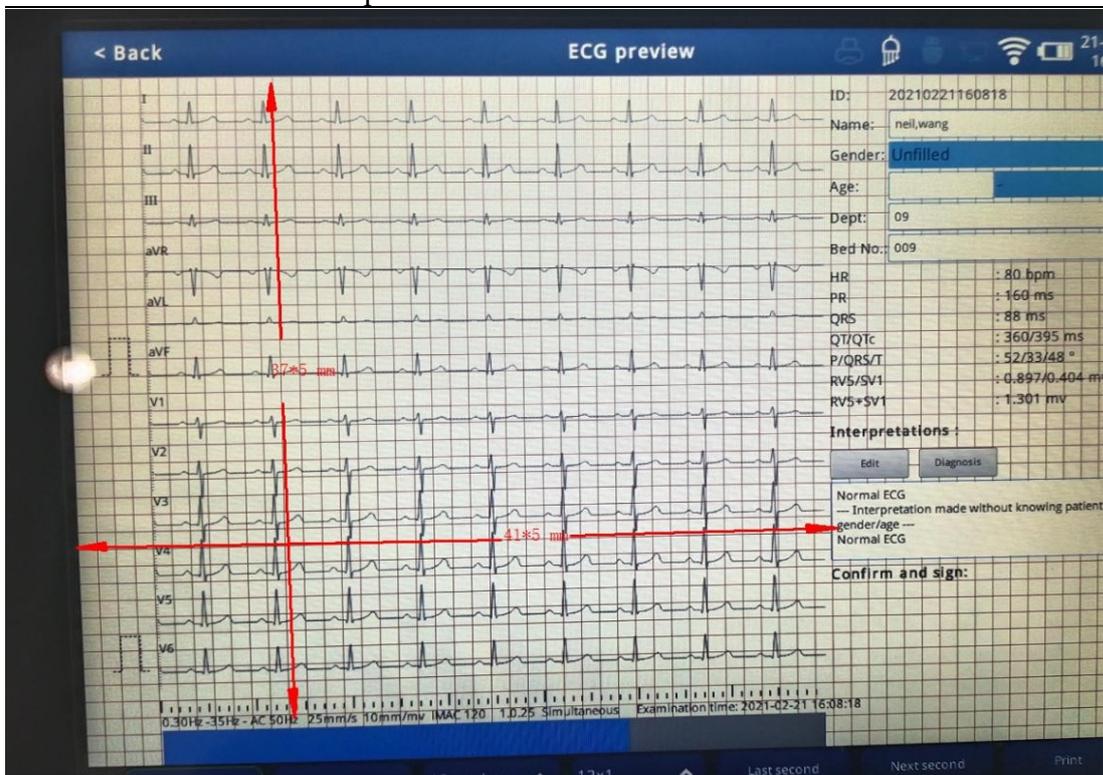
Yes, support in all Manual/Auto/Rhythm Modes.

2, Changes the sensitivity of the cardiograph printer to recording the rhythm of rest 2.5/5 mm/mV

Yes, support in all Manual/Auto/Rhythm Modes.

3, The cardiograph display must be able to view the electrocardiogram At least 110 x 190 mm on a screen width

Yes, the ECG review area for iMAC 120 is 205x140 mm based on the layout of 12x1. As show in the below picture.

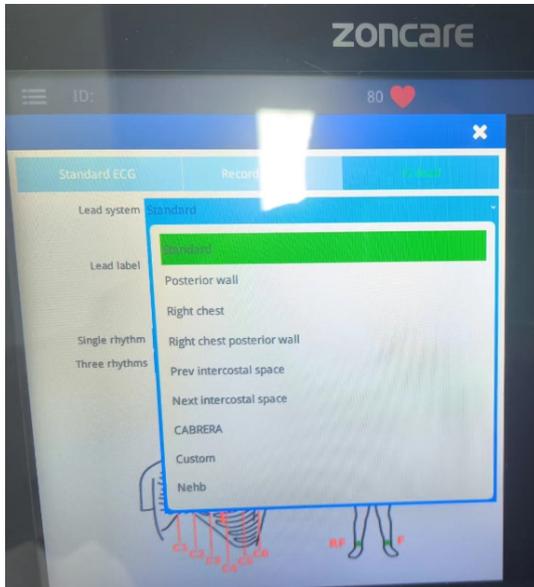


4, The possibility for the user to choose from the following derivations:

- Standard
- Posterior wall
- Right chest(which includes C4r)
- Right chest posterior wall(which includes C4r)
- Prev intercostal space
- Next intercostal space

- CABRERA
- Custom
- Nehb

The machine interface as below:



5, In our data sheet, frequency response indicated starting from 0.01, which is the High-Pass Filter frequency. But it is possible to set frequency to “0”, when High-Pass Filter is turned off. Therefore, the total minimum frequency is “0” .

This parameter is for reference and Zoncare holds the final right of explanation.



Date: 2024-7-1



Wuhan Zoncare Bio-medical Electronics Co., Ltd.

Add: 380, High-tech 2nd road, Eastlake High-tech Development Zone, Wuhan, Hubei (430206), China.

Tel: 86-27-87770581 Email: info@zoncare.com

Fax: 86-27-87770203 Website: www.zoncare.com

Service Certificate

We, Wuhan Zoncare Bio-medical Electronics Co., Ltd., located at the following address: #380, High-tech 2nd road, Eastlake high-tech development zone, Wuhan, Hubei, P. R. China hereby certify that, Dr. Raimondas Binkys of **Litfarma, Jeruzales 45., Vilnius Lithuania**, has passed the training courses and is authorized for installation, training of the personnel for work with the equipment and to perform warranty and after warranty service, repair, maintenance for the following models:

Digital Electrocardiograph:

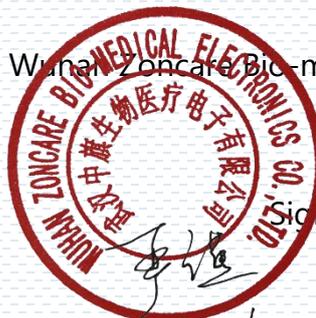
iMAC 300, iMAC 12, iMAC 120, iMAC 1200

Wuhan Zoncare Bio-medical Electronics Co., Ltd.

Jan 3rd, 2022

Signature: 严谨 Johnny Yan

Title: Area Sales Director



Johnny Yan

ZONCARE

Wuhan Zoncare Bio-medical Electronics Co., Ltd.

Add: 380, High-tech 2nd road, Eastlake High-tech district, Wuhan, Hubei (430206), China.

Tel: 86-27-87770581 Email: info@zoncare.com

Fax: 86-27-87770203 Website: www.zoncare.com

Letter of Authorization

We, **Wuhan Zoncare Bio-medical Electronics Co., Ltd.**, located at the following address: *#380, High-tech 2nd road, Eastlake high-tech district, Wuhan, Hubei, P. R. China* hereby authorize company

UAB "LITFARMA", *Jeruzales 45, Vilnius, Lithuania*, as our distributor to promote, register, make delivery, installation, training of the personnel for work with the equipment and to perform warranty and after warranty service for the following models:

Digital Electrocardiograph:

iMAC 300, iMAC 12, iMAC 120

This Authorization letter is valid until Dec 31st, 2025 from the date of issuance.



Wuhan Zoncare Bio-medical Electronics Co., Ltd.

December 6, 2024

Signature: 严谨 Johnny Yan

Title: Senior Area Manager