Technical File

Product: Automated External Defibrillator

Model: HR-501

Document: RD-TF-111 (Rev. 14)

Manufacturer;	EC Representative;
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Revision History

Rev	Date	Description	Prepared	Reviewed	Approved by *PRESIDENT*
2.00	07/07/2016	Correction according to 1st review.	Jae-hoon Hong	Jae-hoon Hong	Beom-ki Kim
3.00	18/10/2016	Correction according to 2nd review.	Jae-hoon Hong	Jae-hoon Hong	Beom-ki Kim
4.00	15/03/2017	Change of Notified Body.	Jae-hoon Hong	Jae-hoon Hong	Beom-ki Kim
5.00	08/09/2017	Correction according to initial audit	Hwang-kyu Lee	Hwang-kyu Lee	Beom-ki Kim
6.00	15/May/2018	Company name change	Hwang-kyu LEE	Hwang-kyu LEE	Beom-ki KIM
7.00	30/Sep./2019	.Update of obsolete standards .Add of 8.3 Justification for packaging/transport .Add of 9.3.1 Justification for IFU	Chuelwon Lee	OH Kwon	Beom-ki KIM
8.00	24/Sep./2020	Add of 1.1.1.2.1 EU representative review. Update of 1.1.2.2 classification of Pad, 3.2.1 accessory information, 8.3 market experience, 9.1 label of main body	Seonggeun Park	OH Kwon	Beom-ki KIM
9.00	20/Oct./2020	Changed address of European Representative	Seonggeun Park	OH Kwon	Beom-ki KIM
10.00	21/Apr./2021	Change of capacitor supplier in section 3.2.2	Seonggeun Park	OH Kwon	Beom-ki KIM
11.00	01/Oct./2021	Change of battery model name in section 3.0 and section 3.2	Seonggeun Park	OH Kwon	Beom-ki KIM
12.00	02/Feb./2022	Update of market experience in section 8.3	Seonggeun Park	OH Kwon	Beom-ki KIM
13.00	10/May./2023	Update of market experience in section and Customer feedback include complain 8.3	Gichan Ahn	Jonghwan Jang	Beom-ki KIM
14.00	20/May./2024	Partial revision to comply with regulation MDR 2017/745	Gichan Ahn	Jonghwan Jang	Beom-ki KIM

Part A: Technical File 4

1.0 Instruction 4
1.1 Regulatory Information 4
1.2 Brief description of the product....6

2.0 Technical File Summary Information 9
2.1 Comprehensive description 9
2.2 In case of a Change Notification 9
2.3 Summary description of manufacturing process 10

Part B: Annexes 11

1.0 Essential Requirements Checklist 11

2.0 Risk Analysis 12
2.1 General information 12
2.2 Usability engineering file 13

3.0 Drawings, Design, - Product - Specifications 14
3.1 Comprehensive description of the product....14
3.2 Components and materials 16
3.3 Blueprints 22

4.0 Electromechanical safety, Electromagnetic compatibility and performance Tests 32
4.1 Electromechanical safety tests....32
4.2 Electromagnetic compatibility tests 32
4.3 Performance tests 32

5.0 Biological Tests 34
5.1 Biocompatibility Tests 34

6.0 Software 35

7.0 Clinical Data 36

8.0 Package Qualification 37
8.1 Inner package 37
8.2 Carton package (shipping)....37

9.0 Labels - Instructions for use....41
9.1 labels on the product 41
9.2 Carton box (shipping) : 240 x 140 mm 43
9.3 Instructions for use 43

10.0 Manufacturing....44
10.1 Flow chart....44
10.2 QS Certificate from MFDS and a Notified Body for the manufacturing plant....45

11.0 Conclusion 46

12.0 EC Declaration of Conformity 47

Part A: Technical File

1.0 Instruction

This Technical File consists of technical documentation relating to products of Automated External Defibrillator, Heart Guardian HR-501 Series. It meets the requirements of the Medical Device Regulation 2017/745 and is requested to bear the CE Mark to enable them to move freely within the European Community and to be put into service in accordance with its intended purpose.

1.1 Regulatory Information

1.1.1 Name, postal address of;

1.1.1.1 Manufacture

a) Name: RADIANQBIO Co., Ltd.
b) Postal address: #1609~1611, HALLA-SIGMA VALLEY, 53, Gasan digital 2-ro, Geumcheon-gu, Seoul, Korea
c) Contact person: Mr. Jonghwan Jang / QMR
d) Telephone: +82-2-852-1122
e) Facsimile: +82-2-6343-6430
f) SRN: KR-MF-000013678

1.1.1.2 European Representative

a) Name: S.B. PHARMA GMBH
b) Postal address: Bunsenstr. 14 53121 Bonn, Germany
c) Telephone: +49 (0) 228 52266916
d) Facsimile: +49 (0) 228 52266918
e) SRN:KR-MF-000005392

Refer to the attachment #13-1, European Authorized Representative Agreement.

1.1.1.2.1 EU representative review

A. The qualification of EC representative agreement was reviewed by the CV information of EU representative. This information also includes the work experiences, educations and skills of Sina Seifi who signed the EC representative agreement.
   (1) MDD knowledge
   EUR had the educational training about European Medical Devices Directive Requirements
      a) The European CE Marking Approach to Regulated Products
      b) The structure of the Medical Devices Directive 93/42/EEC
      c) The classification and conformity assessment routes
      d) The steps in CE marking

   (2) Vigilance system operation
      a) The post-market surveillance obligations are complied with in accordance with the requirement of the MDR
      b) The conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released

   (3) Authority communication
      a) The role in detail of European Authorized Representative is defined in Article 15 of the new EU MDR (2017/745), or old MDD 93/42/EEC as amended by 2007/47/EC.
      b) The technical documentation and the EU declaration of conformity are drawn up and kept up to date reporting obligations are fulfilled
      Refer to the attachment #13-2, EC Rep. Qualification Review

B. According to the agreement between RADIANQBIO Co., Ltd. and S.B. PHARMA GMBH, EUR has duties for vigilance system operation in section 2.4 and for authority communication in section 2.2.
Refer to the attachment #13-1, European Authorized Representative Agreement

1.1.2 Product and accessory classification, rule according to MDR, Annex VIII and according to ISO 10993-1 Annex A

1.1.2.1 Classification of Automated External Defibrillator, rule according to MDR, Annex VIII

Class III, according to the Rule 22 (Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators)

1.1.2.2 Categorization according to ISO 10993-1 Annex A

For the Electric Pads,

a) Categorization by nature of body contact
Surface-contacting devices in contact with skin

b) Categorization by duration of contact
Limited exposure (A) – devices whose cumulative single, multiple or repeated use or contact is up to 24 h.

c) Evaluation tests for consideration
- Cytotoxicity
- Sensitization
- Skin irritation

1.1.3 Conformity Assessment Route that has been chosen

Annex IX of Regulation MDR 2017/745

1.1.4 CND-code

C020400 - Defibrillator, automated, external

1.1.5 MDA/DMN, MDT and MDS code

MDA 0305 /MDT 2010 /MDT2011

1.1.6 Basic UDI-DI

880943432AED0016N

1.1.7 Product History

a) Approvals
Product-License No. 14-1338 and Manufacturer Registered No. 4626 by MFDS (Ministry of Food and Drug Safety)

Refer to the attachment #A03, Free Sales Certificate and Certificate of Manufacturer

b) Market release
The following products were released on the Korea market in 2014.

No.	Model/Type	Regulatory Category	Approved for sale in
1.	Heart Guardian HR-501	MD*	Korea

*MD=Medical Device

1.2 Brief description of the product

HR-501, a portable electric device operated by battery power, is an easy-to-use Semi-Automated External Defibrillator. The AED automatically analysis patient's ECG and identifies and advise electric shock if it is necessary. Nearly every procedure for AED operation is guided through voice message and beep sound, as well as the visual guidance with picture description with LED. Heart Guardian, HR-501 is manufactured based on CPR guideline of AHA revised in 2015.
A proprietary ECG analysis algorithm automatically determines whether a victim has a shockable or non-shockable rhythm and advises a shock when appropriate.
If a shock is required, the Heart Guardian HR-501 will automatically charge to the appropriate energy level and prompt the user to press the illuminated shock button. This enables the delivery of therapeutic energy to the patient.
An escalating, truncated exponential biphasic waveform pulse is delivered to the patient via two disposable defibrillator electrodes. This waveform is known as BTE (Biphasic Truncated Exponential). A 50 Joule (Child) or, 150 Joule (Adult) escalating energy sequence is used in accordance with current AHA resuscitation guidelines.
After initial analysis and shock delivery (if appropriate), the Heart Guardian HR-501 will advise that CPR (cardiopulmonary resuscitation) may be commenced via a number of voice prompts such as "Conduct chest compressions 30 times" and "Conduct CPR" in addition to emitting an audible metronome.
The defibrillator records the patient's electrocardiogram (ECG) and the patient's ICG (Impedance Cardiogram). The ECG can be viewed using HR-501 software.
The Pad is a combined battery and electrode unit which is single use. The electrodes used with the Heart Guardian HR-501 are two non-sterile, single-use, self-adhesive, conductive gelled defibrillation electrodes. The Pad can be used with both children and adults.
The Heart Guardian HR-501 incorporates the following features:
- Controls for Power ON/OFF and Shock
- Automated charging at escalating energies of 50J, 150J
- Automated self-tests and LED status indicator
- Combined, disposable battery and electrodes (Pad)
- Electrode placement guidance voice prompts and LED/icon indicators
- CPR voice prompts and metronome
- Pediatric function for victims between the ages of 1 and 8 years at non-escalating energy of 50J
- Integral event data recording

1.2.1 Common/Generic name

Automated External Defibrillator

1.2.2 Trade/Proprietary name

Heart Guardian HR-501

1.2.3 Intended use/indications for use

The Heart Guardian HR-501 is a device that automatically analyzes the heart rhythm in victims of cardiac arrest, and delivers an electrical shock to the heart to restore its normal rhythm. It is indicated for use on victims of cardiac arrest who are exhibiting the following signs:

- Unconscious
- Not breathing
- Without circulation

The Heart Guardian HR-501 is intended for use by personnel who have been trained in its operation. Users should have received training in basic life support / AED, advanced life support or a physician-authorized emergency medical response training program.
The Heart Guardian HR-501 is indicated for use with electric pads (on patients greater than 8 years old or over 25 kg when used with the adult mode and/or on children between 1 and 8 years of age or up to 25 kg when used with the kid mode).

Refer to the attachment #08-1. Operating Manual (Rev.2.4.2)

1.2.4 Side effect and contraindications

Do not use the Heart Guardian HR-501 when the patient:
1. is conscious; or
2. is breathing; or
3. has a detectable pulse or other signs of circulation.

Refer to the attachment #08-1. Operating Manual (Rev. 2.4.2)

1.2.5 Accessories for the product, integral parts of package

a) Portable AED case (1EA)
b) Battery (1EA)
c) Pads (1EA)
d) Operating manual & Quick guide (1EA)

1.2.6 Applied standards

European Norms and Standards and other Documents supporting Technical Files;
Medical Device Ragulation 2017/745
Waste Electrical and Electronic Equipment Directive 2012/19/EU
.EN ISO 20417:2021, Information to be supplied by the manufacturer
.EN ISO 10993-1:2020, Biological evaluation of medical devices
– Part 1: Evaluation and testing
.EN ISO 10993-5:2009, Biological evaluation of medical devices
– Part 5: Tests for in vitro cytotoxicity
.EN ISO 10993-10:2023, Biological evaluation of medical devices
– Part 10: Tests for irritation and skin sensitization
.EN ISO 13485:2016/A11:2021, Medical devices - Quality management systems
- Requirements for regulatory purpose
.EN ISO 14971:2019/A11:2021, Medical devices - Application of risk management to medical devices (ISO 14971:2019)
.ISO 15223-1:2021, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
.EN 60601-1:2006/A2:2021, Medical electrical equipment
– Part 1: General requirements for safety and essential performance
.EN 60601-1-2:2015/A1:2021, Medical electrical equipment – Part 1: General requirements for safety – Collateral standard: Electromagnetic compatibility - Requirements and tests
.EN 60601-1-6:2010/A2:2021, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
.EN 60601-1-12:2015/A1:2020, Medical electrical equipment – Part 1-12: General requirements for basic
safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment
.IEC 60068-2-31:2008/A1:2019; Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens, Free fall tests is conducted by this standard.
.IEC 60529: 1992/A2:2013; Degrees of protection provided by enclosures (IP Code)
.IEC 60068-2:64:2008/A1:2019, Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance
.IEC 60068-2-27:2009, Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock
.EN 60601-2-4:2011/A1:2019, Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators
.EN 62304:2006/A1:2015, Medical device software – Software life-cycle processes
.IEC 62366-1:2015/A1:2020, Medical devices – Application of usability engineering to medical devices
.IEC 60086-4:2019, Primary batteries – Part 4: Safety of lithium batteries
.MEDDEV 2.1/1, Definitions of “medical devices”, “accessory” and “manufacturer”
.MEDDEV 2.2/1 rev.1,EMC requirements
.MEDDEV 2.4/1 rev.9, Classification of medical devices
.MEDDEV 2.5/10, Guideline for Authorised Representatives

.MEDDEV 2.7/1 rev.4, Clinical evaluation: Guide for manufacturers and notified bodies
.MEDDEV 2.12/1 rev.8, Guidelines on a Medical Devices Vigilance System
.MEDDEV 2.12/2 rev.2, Guidelines on post market clinical follow-up studies

2.0 Technical File Summary Information

2.1 Comprehensive description

The Heart Guardian HR-501 is a small, lightweight portable battery operated Automated External Defibrillator (AED) designed to treat victims of a cardiac arrest. The Heart Guardian HR-501 incorporates a simple user interface of voice and text/icon prompts to guide the user in the use of the device. The Heart Guardian HR-501 also incorporates an audible metronome to guide the user as to the correct rate at which chest compressions should be administered in accordance with current AHA resuscitation guidelines.
A proprietary ECG analysis algorithm automatically determines whether a victim has a shockable or non-shockable rhythm and advises a shock when appropriate.
If a shock is required, the Heart Guardian HR-501 will automatically charge to the appropriate energy level and prompt the user to press the illuminated shock button. This enables the delivery of therapeutic energy to the patient.
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The defibrillator records the patient's electrocardiogram (ECG) and the patient's ICG (Impedance Cardiogram). The ECG can be viewed using HR-501 software.
The Pad is a combined battery and electrode unit which is single use. The electrodes used with the Heart Guardian HR-501 are two non-sterile, single-use, self-adhesive, conductive gelled defibrillation electrodes. The Pad is available in three versions: an adult version, a pediatric version, and an adult version meeting FAA temperature, shock and flammability requirements for use on commercial aircraft.
The Heart Guardian HR-501 incorporates the following features:
- Controls for Power ON/OFF and Shock
- Automated charging at escalating energies of 50J, 150J
- Automated self-tests and LED status indicator
- Combined, disposable battery and electrodes (Pad)
- Electrode placement guidance voice prompts and LED/icon indicators
- CPR voice prompts and metronome
- Pediatric function for victims between the ages of 1 and 8 years at non-escalating energy of 50J
- Integral event data recording

2.2 In case of a Change Notification

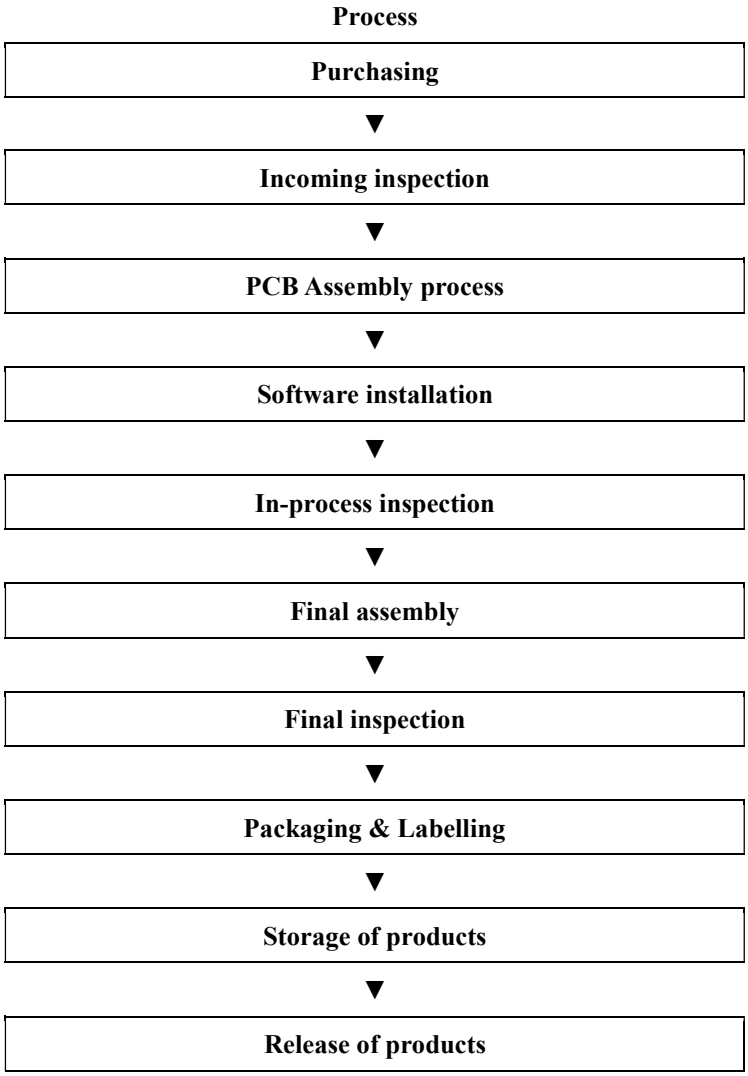
A QMR shall notify to the authorized Notified Body (NB) about significant changes related product and/or system as follows;

a) Product-related changes
   - Change of representative and/or the company name
   - Addition of new product
   - Change of intended use/purpose and/or labeling
   - Change of performance data
   - Change of safety-related functions
   - Change of materials
   - Change of product specifications

b) System-related changes
   - Change of representative name and/or the company name
   - Change of address
   - Addition of new product family
   - Change of QMR
   - Change of Production Technology (ex. Sterilization process and etc.)
   - Change of product design and production (ex. OEM and etc.)
   - Change of quality manual, post-market surveillance
   - Change of European Representative

2.3 Summary description of manufacturing process

The production and inspection is followed by our documented procedures based on our quality systems – KGMP and EN ISO 13485.



Part B: Annexes

1.0 Essential Requirements Checklist

The Essential Requirements Checklist was prepared according to Annex I of MDD 93/42/EEC as amended by 2007/47/EC.

Refer to the attachment #05-1, Essential Requirements Checklist (No. ERC-111, Rev.5)

2.0 Risk Analysis

2.1 General information

This analysis is based on the assessment conducted and documented in report in accordance with EN ISO 14971:2019.
The assessment of product quality states that there are no critical quality issues or reported defects that would cause patient or user to be put at risk. Control of design, materials and production processes is based on preventive action to achieve product quality and minimize risk.
In general the risk analysis for the Heart Guardian HR-501 made by RADIANQBIO Co., Ltd. was carried out in accordance with the requirement of medical device directive 93/42/EEC as amended by 2007/47/EC and the standard of EN ISO 14971:2019 and the solutions adopted by RADIANQBIO Co., Ltd. for the design and construction of the devices are conform to the essential requirements, taking account of the current acknowledged state of the art.
In selecting the most appropriate solutions, the following principle has been applied in the following order;

- eliminate or reduce risks as far as possible (inherently safe design and construction)
- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated.
- inform users of the residual risks due to any shortcomings of the protection measures adopted.

Refer to the attachment #07-1, Risk Management Plan (No. RD-RMP-111, Rev 4) and Risk management Report (No. RD-RMR-111, Rev 5)

2.2 Usability engineering file

This usability according EN 62366:2008 in relation to the accompanying documents (labelling, IFU) and use scenario of the medical device.

An essential requirement for a medical device is usability, which has the following primary requirement:

- To reduce, as much as possible, the risk of user error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety).
- To consider the technical knowledge, experience, education and training and, where applicable, the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

Refer to the attachment #09-2, Usability Engineering File (No. UEF-111, Rev 3)

3.0 Drawings, Design, - Product - Specifications

3.1 Comprehensive description of the product

The Heart Guardian HR-501 is a small, lightweight portable battery operated Automated External Defibrillator (AED) designed to treat victims of a cardiac arrest. The Heart Guardian HR-501 incorporates a simple user interface of voice and text/icon prompts to guide the user in the use of the device. The Heart Guardian HR-501 also incorporates an audible metronome to guide the user as to the correct rate at which chest compressions should be administered in accordance with current AHA resuscitation guidelines.
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The Heart Guardian HR-501 incorporates the following features:
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- Automated charging at escalating energies of 50J, 150J
- Automated self-tests and LED status indicator
- Combined, disposable battery and electrodes (Pad)
- Electrode placement guidance voice prompts and LED/icon indicators
- CPR voice prompts and metronome
- Pediatric function for victims between the ages of 1 and 8 years at non-escalating energy of 50J
- Integral event data recording

Specifications:

Product Type	Semi-automated External Defibrillator
Auto/Manual Diagnosis	Automatic diagnosis (battery power, circuit power, button operation checks)
ECG complete analysis	FFT ECG Analysis
Step by Step Audio Guidance	Voice record (English)
Compatible Adult/Child	Adult/child mode switch (default)
Charge Method	Hi-Cap charge
Output Range	150J±10% (Adult) / 50J±10% (Child)
Data Storage	108 times of ECG log can be recorded
Control Button	Power, Analysis, Shock, Adult/child mode switch
Product Size (mm)	223.3(W) x 311.6(L) x 84.5(H)mm
Product Weight (kg)	2.15kg
Product Color	Red
Number of shock	At least 200 times (New battery)
Life time	5 years from date of manufacture
Portable AED case (HR-B1)	235(W) x 330(H) x 95(T)mm, 370g
AED Pads (P-303)	98.00mm(H) x 145.00mm(W) 1,765(cable length), 120g, Single time use only. Life time: Single use only, 2 years for unpacked/sealed product since the manufacturing date
Battery (BT-303 R)	LiMnO2 (12V DC 4.2A), Non-Rechargeable 60(H) x 175(W) x 25(T)mm, 285g Life time: 4 years for standby mode
Operating Manual	210(H) x 140(W)mm, Paper
Basic Components	AED portable case, AED pads(P-303), Battery(BT-303 R), User Manual

3.2 Components and materials

3.2.1 Appearance and Structure

a) Main body

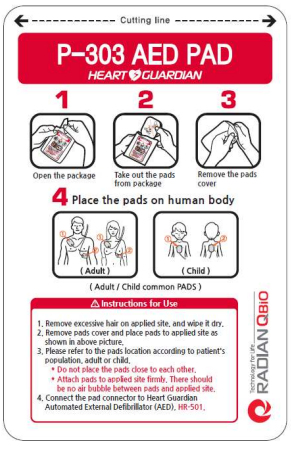
Ⓐ	Power Button	Used to turn on or off the product
Ⓑ	Summarized Instruction	Simple Instruction for CPR and AED use
Ⓒ	Status indication light	LED light informs about product status to user by blinking to various color
Ⓓ	Handle	For carrying AED safely
Ⓔ	Cover	Prevents external substances exposure to AED
Ⓕ	Battery	Provides electrics to AED
Ⓖ	AED Pad Connector	Connect the AED pads prior to attaching the pads to patient
Ⓗ	Shock Button	Press the button when guidance indicates to deliver charged electric shock to patient
Ⓘ	Adult/Child Mode Switch	Select Adult/Child mode, default is Adult mode
Ⓙ	Procedure Guidance LED	LED light informs CPR and AED operating procedure to user
Ⓚ	Bluetooth Port	Communication port for maintains of AED
Ⓛ	Battery Slot	Mount the battery correctly to this slot
Ⓜ	Speaker	Speaker for Audio guidance

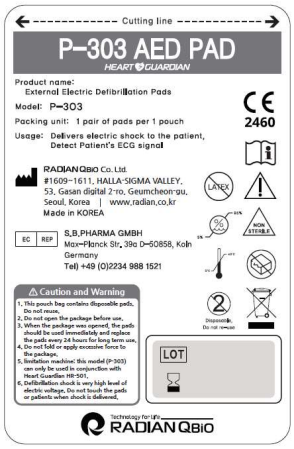
b) Portable AED case

Product Type	Specification
Portable AED case (HR-B1)	Size: 235(W) x 330(H) x 95(T)mm, Weight: 370g Material: FEBURIC Color: Red

c) Pads

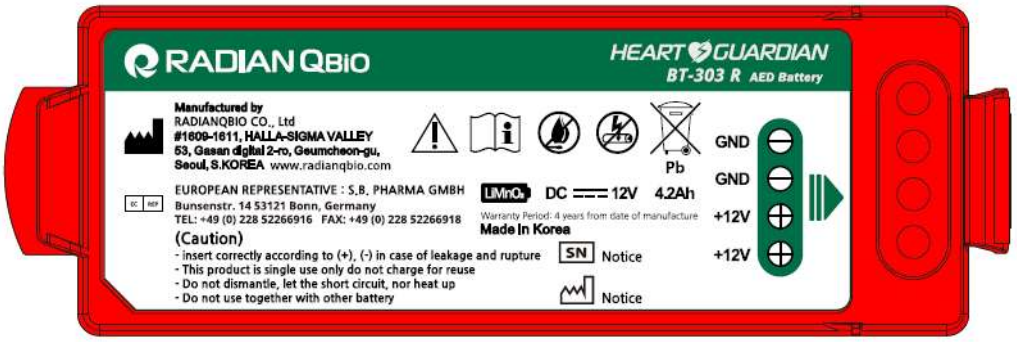
Product Type	Specification
AED Pads (P-303)	Size: 98.00mm(H) x 145.00mm(W) 1,765mm(cable length) Weight: 120g Material: Polyolefin foam Life-time: 2 years for unpacked/sealed product since the manufacturing date Adults/Kids compatible Single time use only.





d) Battery

Product Type	Specification
Battery (BT-303 R)	60(H) x 175(W) x 25(T)mm, 285g LiMnO2 (12V DC 4.2A) Life-time: 4 years for standby mode Non-Rechargeable

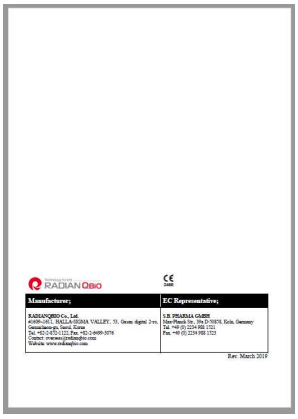


e) Operating Manual & Quick guide

Product Type	Specification
Operating Manual	210(H) x 140(W)mm, Paper
Quick guide	177(H) x 330(W)mm, Paper

<Front of operating manual>

<Back of operating manual>



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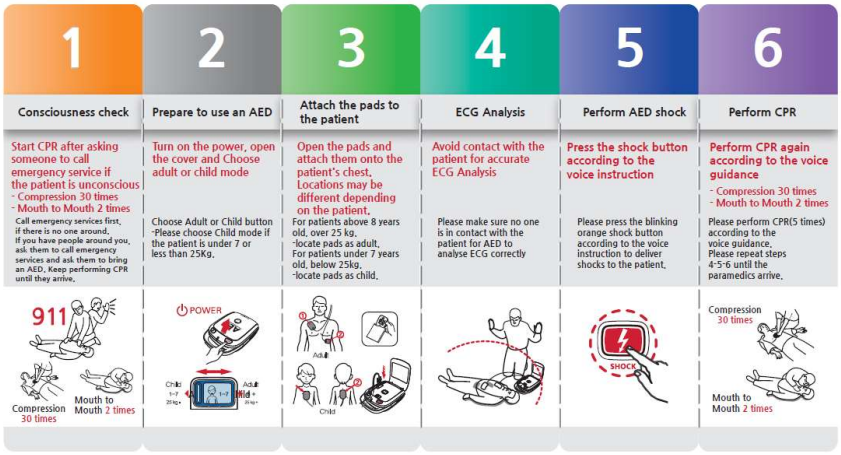


3.2.2 Materials

No.	Component	Component Control No. or Raw Material or Standard	Q'ty (EA)	Suppliers
1.	Outside plastic enclosure	Min. 2.0mm V-1	1	SAMSUNG SDI
2.	Insulators for Quick-connect tabs	Tab Width: 6.35mm; Tab Thickness: 0.81mm	6	MOLEX INC AEPD
3.	Lithium battery pack	4S3P; Non-rechargeable cell; rated 12.0Vdc; 4650mAh	1	Mplus Electronics Co., Ltd.
4.	Capacitor (Energy storage device)	2300 Vdc; 100uF	1	Sungho electronics Co., Ltd.
5.	PCB	FR-4	1	Various
6.	Relay	12 Vdc; 250 Vac; 2 pole 8A; 85 °C;	1	SCHRACK
7.	Internal Wire	VW-1; 22AWG; 10 kV; 150 °C	1	YOUNG CHANG SILICONE CO LTD
8.	Transformer T1	Class A	1	SANG YONG ELECTRONICS CO.
9.	Defibrillator Electrodes Wire	VW-1; 18AWG; 300 V; 80 °C	1	SHINHWA ELECTRIC WIRE CO., LTD
10.	Defibrillator Electrodes	Adult / Pediatric use Non-reusable Electrodes	1	HUREV CO., LTD
11.	Main processor	ARM CORTEX-M4 , 32BIT , 168MHz , 1MB FLASH , 192+4KB RAM , LQFP	1	STMicroelectronics
12	Memory	56-PIN TSOP , 512MB , NOR FLASH	1	MICRON
13	Bluetooth Module	BLUETOOTH V2.0 + EDR , CLASS2 , V2.0.6	1	SENA

Refer to the attachment #07-4. Datasheet

3.2.3 Mechanical part list(Enclosure)

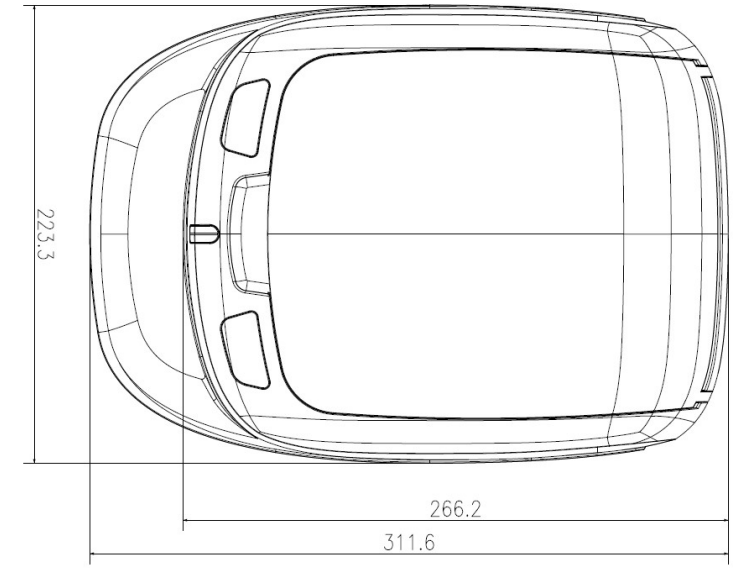
No.	Component	Component Specification	Q'ty (EA)	Suppliers
1.	Upper case	Color:RED , ABS(V-0)	1	Sae Han Precision Co.
2.	Lower case	Color:RED , ABS(V-0)	1	Sae Han Precision Co.
3.	Handle	Color:GRAY , TPU, Hardness 80°	1	Sae Han Precision Co.
4.	Door	SILICONE, Hardness 60°	1	Sae Han Precision Co.
5.	Partition	Color:RED , ABS(V-0)	1	Sae Han Precision Co.
6.	Power LED Window	Color: TRANSPARENCY , PC(V-2)	1	Sae Han Precision Co.
7.	RF Window	Color: TRANSPARENCY , PC(V-2)	1	Sae Han Precision Co.
8.	Select Switch	Color:BLUE , ABS(V-0)	1	Sae Han Precision Co.
9.	Switch Bracket	Color:BLUE , ABS(V-0)	1	Sae Han Precision Co.
10.	Power Button	SILICONE, Hardness 60°	1	Chalgomu Keyboard Co.
11.	I Button	SILICONE, Hardness 60°	1	Chalgomu Keyboard Co.
12.	Shock Button	SILICONE, Hardness 60°	1	Chalgomu Keyboard Co.
13.	Bumpon	Color:BLACK, SILICONE, Hardness 80°, Φ19x4t	1	Dong Jin Silicone Co.
14.	Buffer Plate	SUS304, 2t	1	Sungsan precision Co., Ltd
15.	Battery Lower-S	Color:RED , ABS(V-0)	1	Sae Han Precision Co.
16.	Battery Upper-S	Color:RED , ABS(V-0)	1	Sae Han Precision Co.
17.	PAD Con-Up	Color:BLUE , ABS(V-0)	1	Sae Han Precision Co.
18	PAD Con-Down	Color:BLUE , ABS(V-0)	1	Sae Han Precision Co.

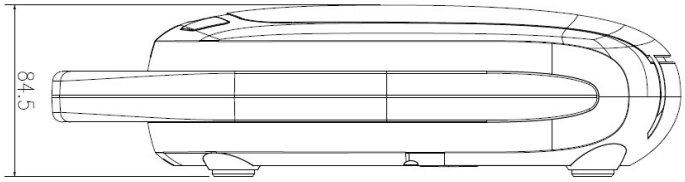
3.2.4 Mechanical drawings

Refer to the attachment #08-2. Mechanical part Drawings

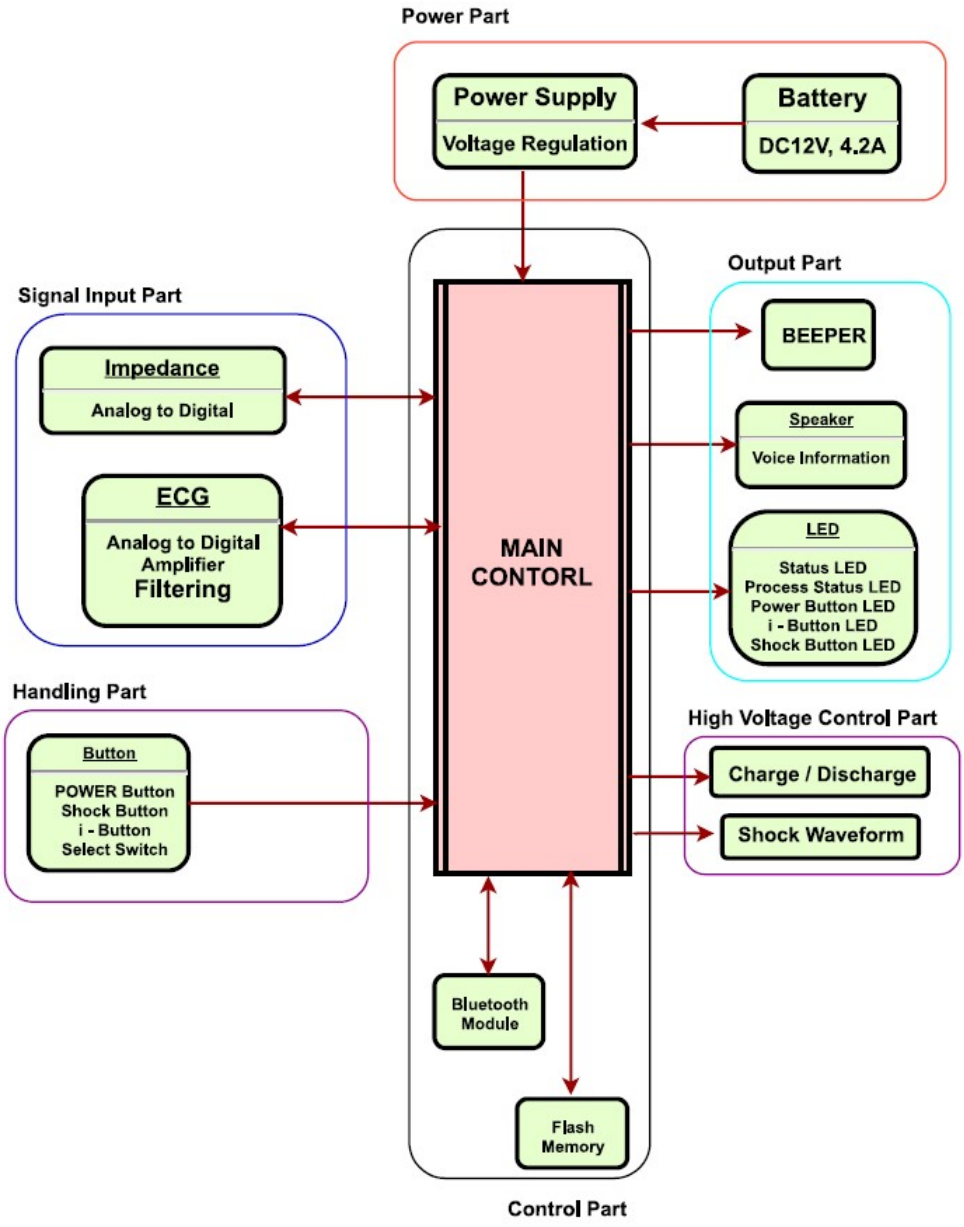
3.3 Blueprints

3.3.1 Dimension (mm)



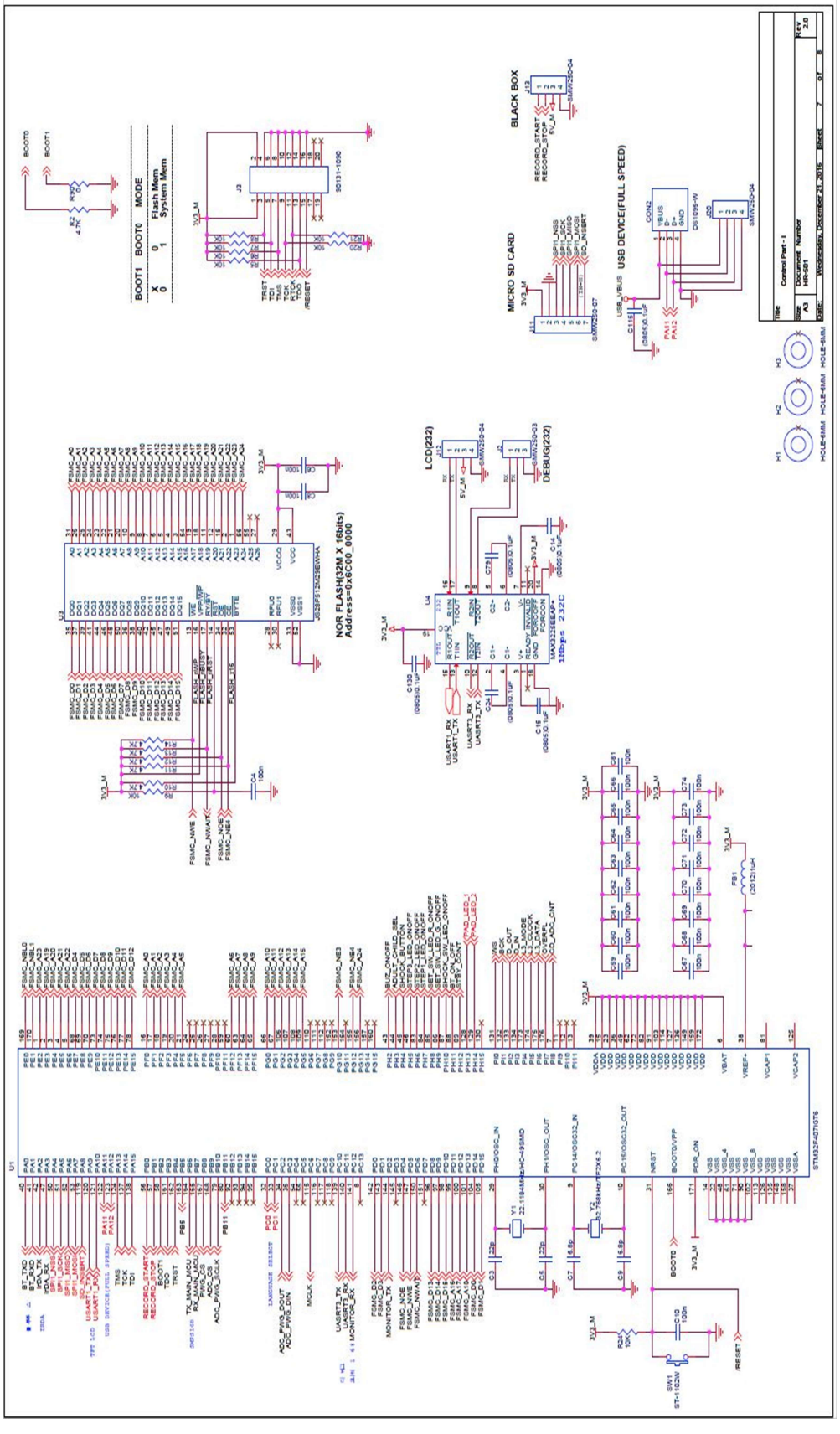


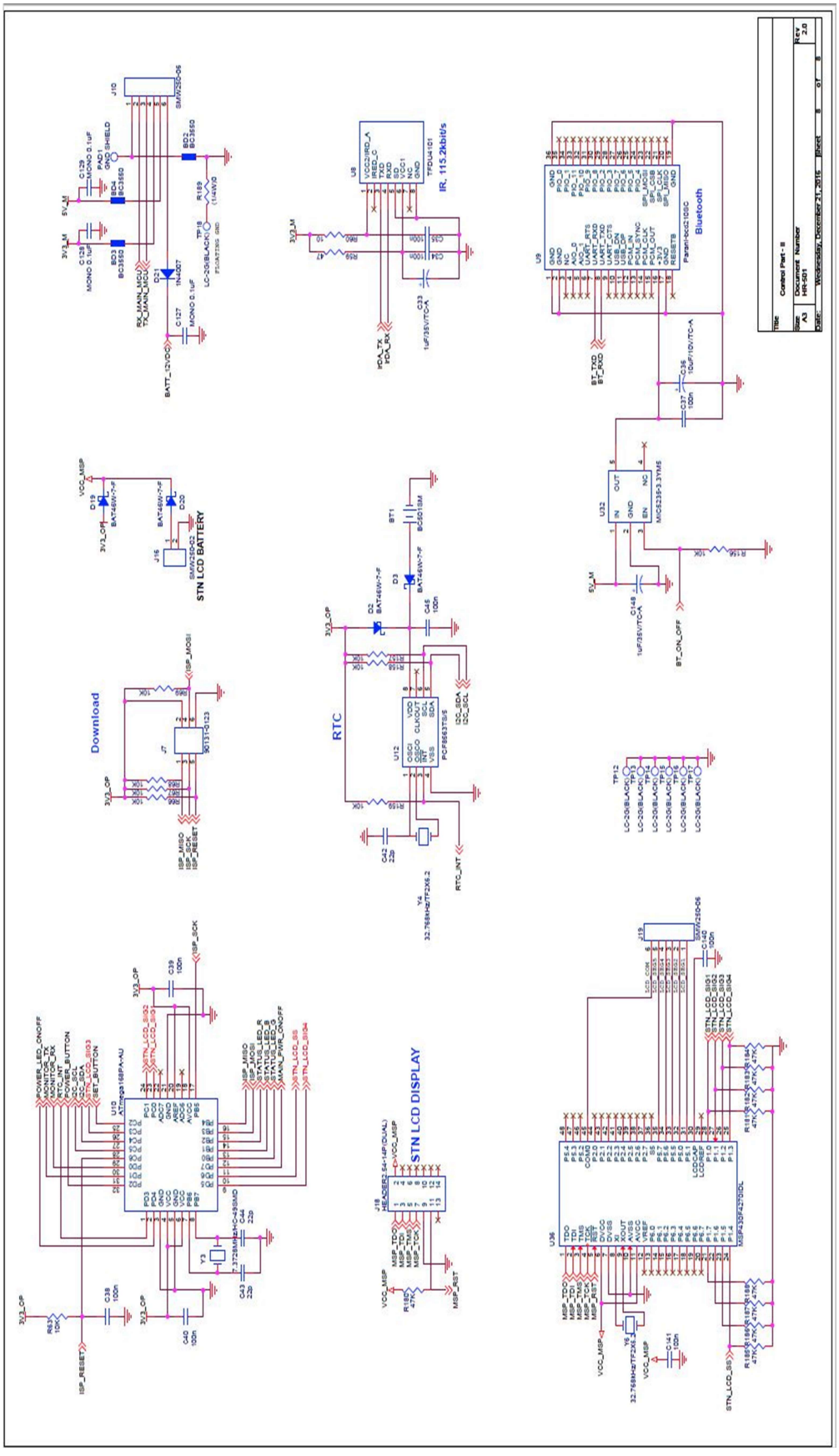
3.3.2 System Block diagram



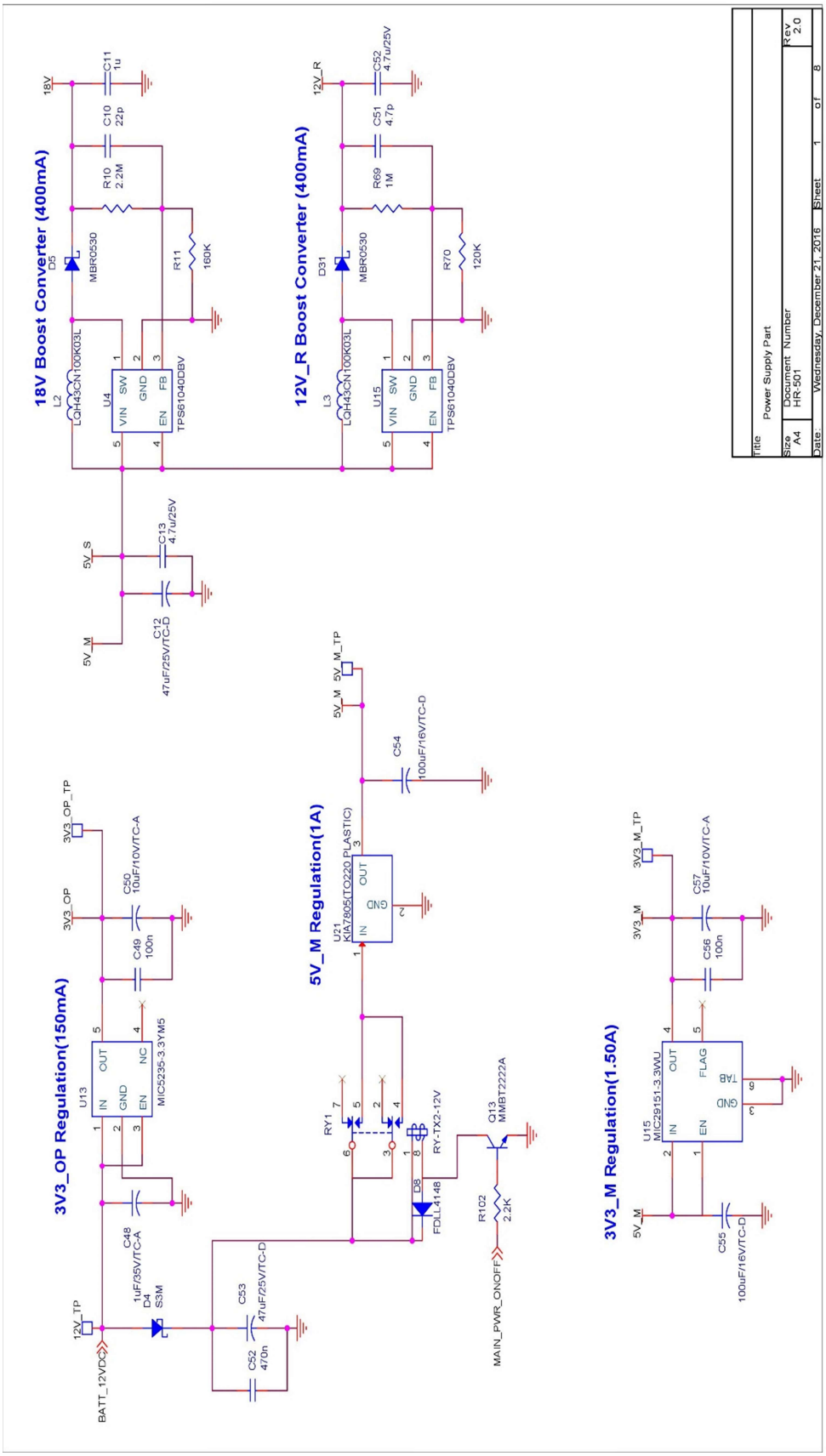
3.3.3 Circuit diagram

a) Control part

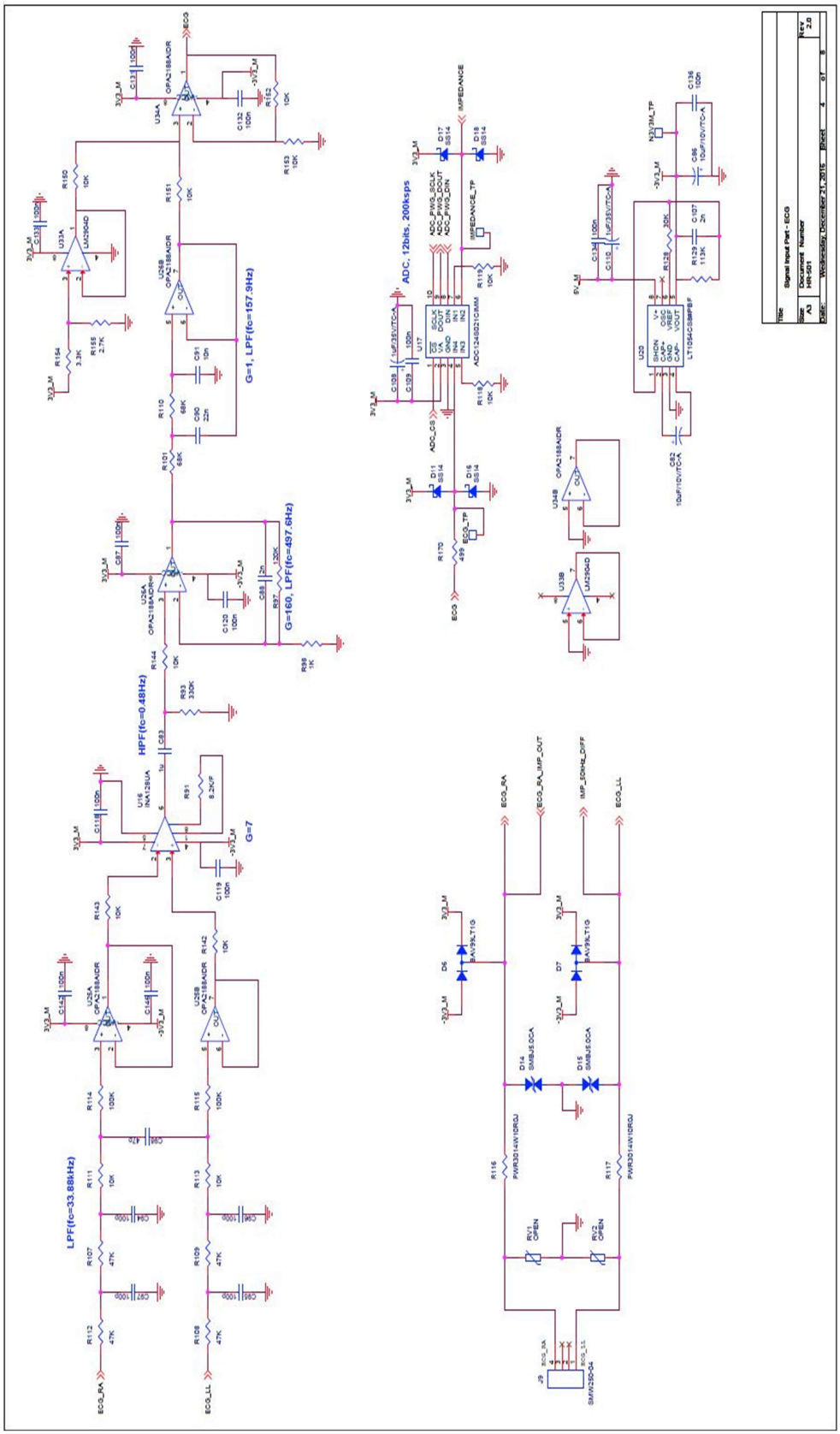


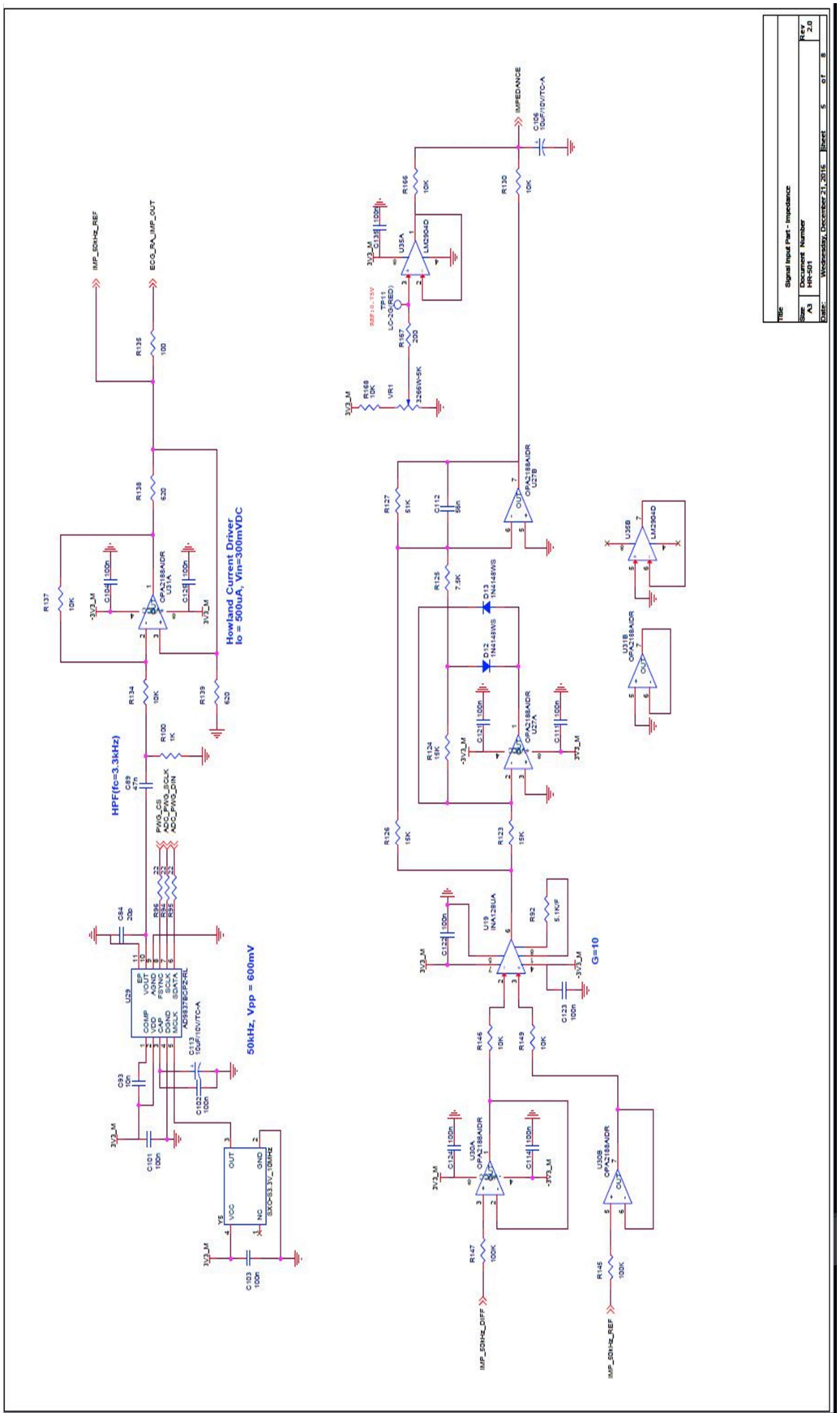

Bluetooth
STN LCD BATTERY
Download
RTC
STN LCD DISPLAY
IR, 115.2kbit/s

b) Power Part

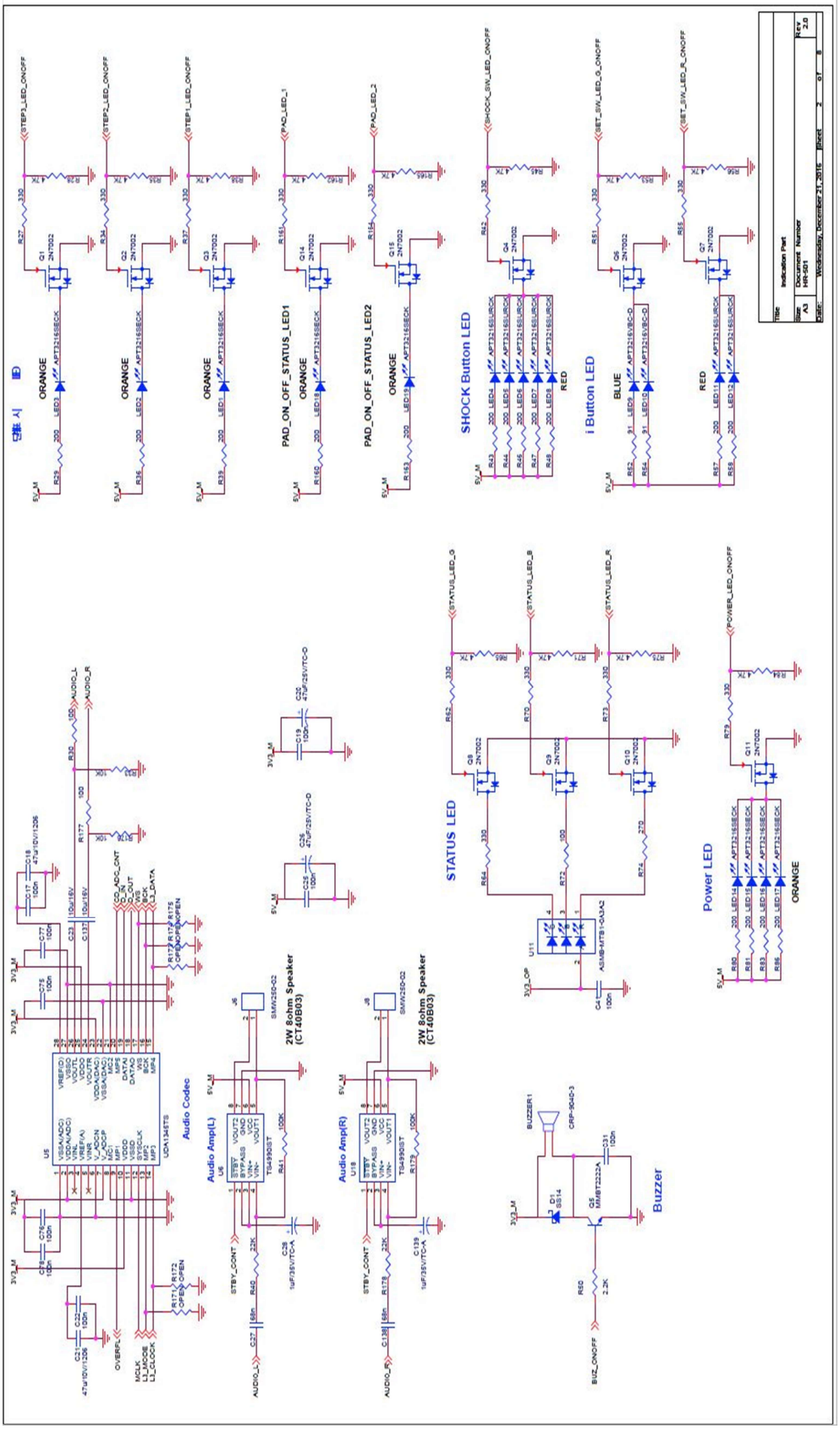

18V Boost Converter (400mA)
12V_R Boost Converter (400mA)
3V3_OP Regulation(150mA)
5V_M Regulation(1A)
3V3_M Regulation(1.50A)
Title Power Supply Part
Size A4
Document Number HR-501
Rev 2.0
Date: Wednesday, December 21, 2016
Sheet 1 of 8

c) Signal Input Part

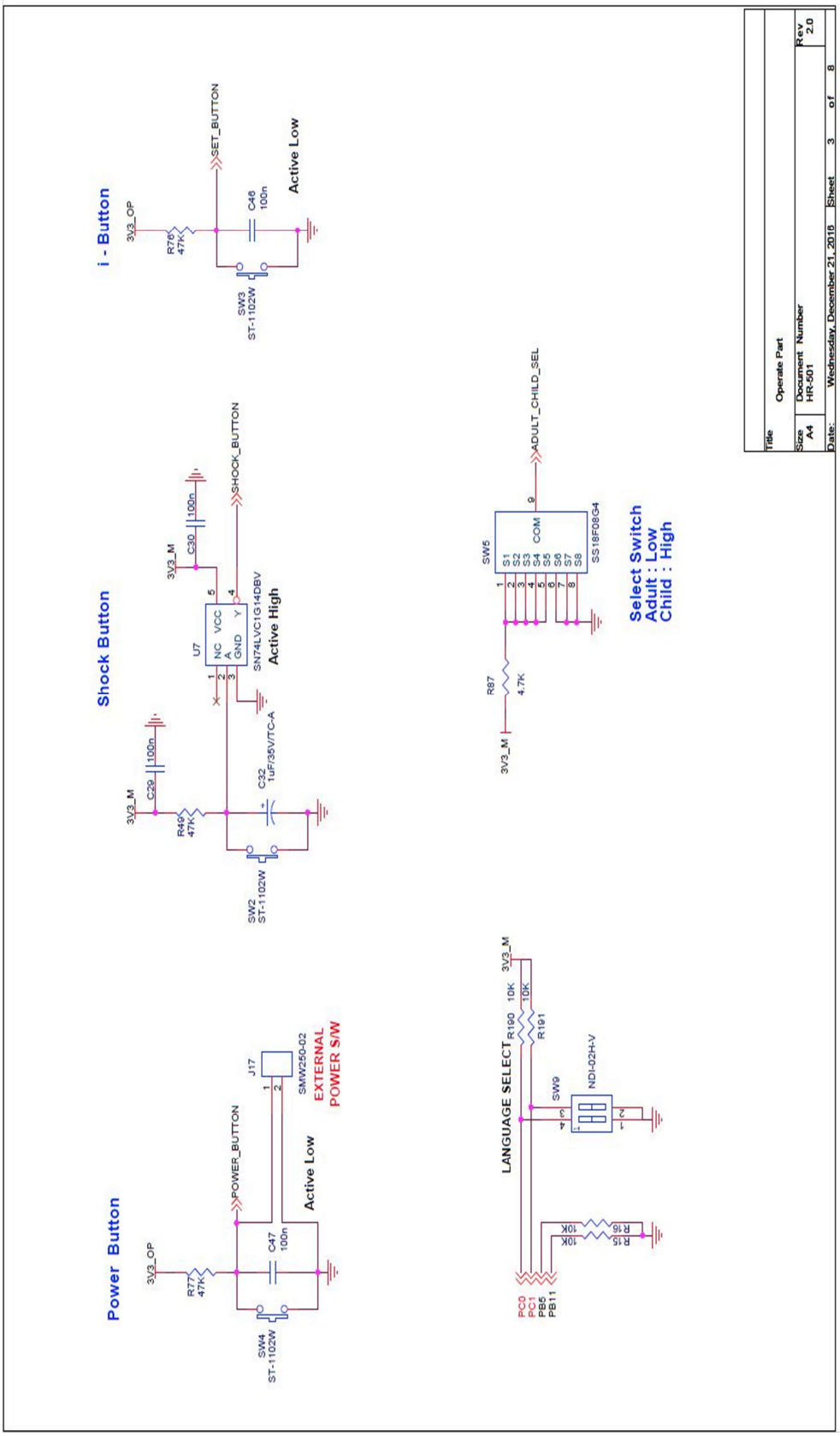



IMPEDANCE
IMP_50KHZ_REF
ECG_RA_IMP_OUT
IMP_50KHZ_DIFF
Howland Current Driver
Io = 500uA, Vin=300mVDC
HPF(fc=3.3kHz)
50kHz, Vpp = 600mV
G=10

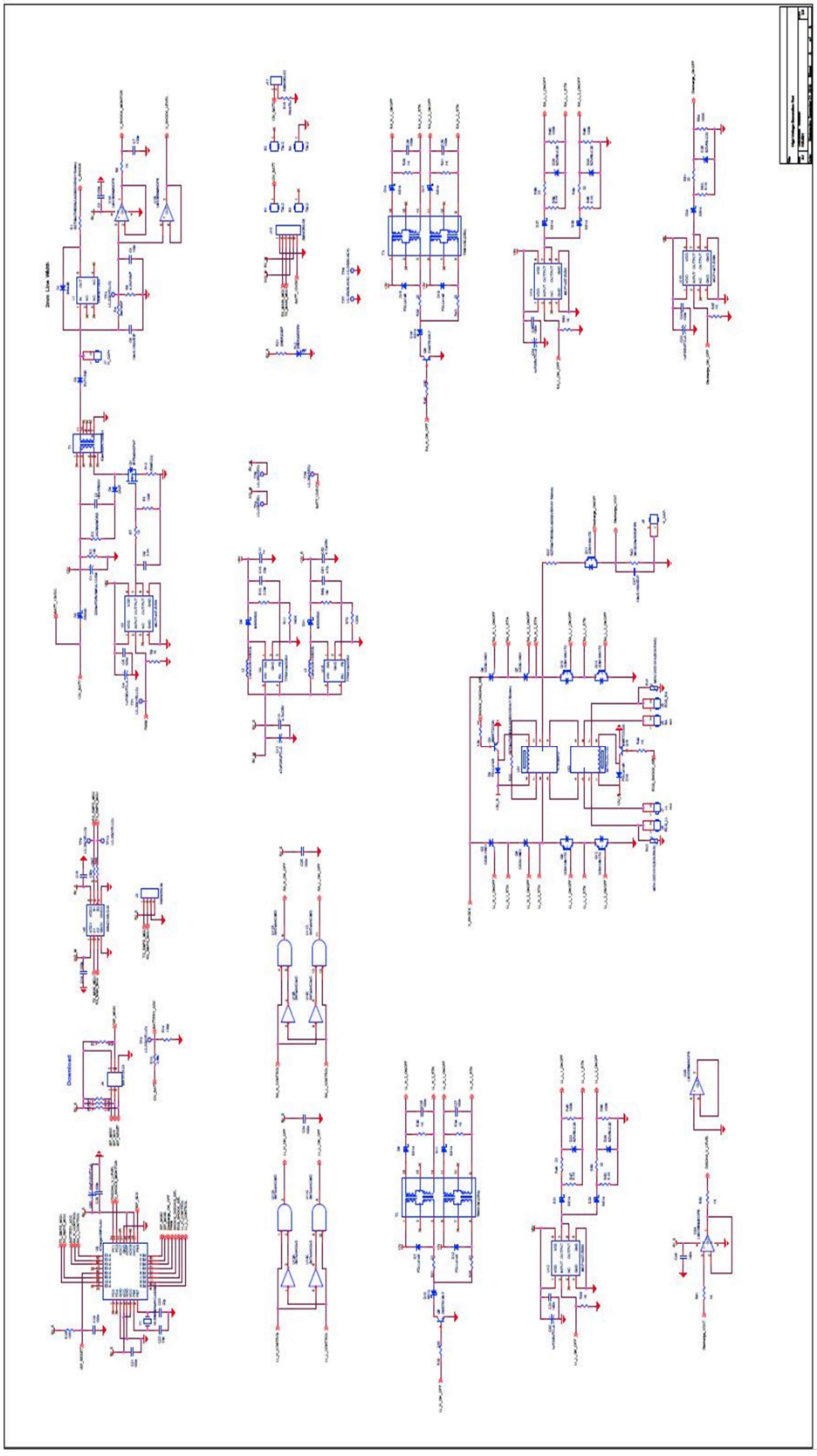
d) Output Part



e) Handling Part



f) High Voltage Control Part



4.0 Electromechanical safety, Electromagnetic compatibility and performance Tests

4.1 Electromechanical safety tests

4.1.1 Qualification of test laboratory

Standard Bank Co., Ltd.

4.1.2 Applied standards

- EN 60601-1:2006/A1:2013, Medical electrical equipment - Part 1: General requirements for safety and essential performance
- EN 60601-1-11:2010, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- EN 60601-2-4:2011, Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators

4.1.3 Test date (Issue)

27/11/2015

4.1.4 Test results (reports)

MDWD-STB15-0028(S)-A

Refer to the attachment #B5. Safety and Essential Performance Test Report of EN 60601-1:2006/A1:2013 [No. MDWD-STB15-0283(S)-A)], EN 60601-1-11:2010 [No. MDWD-STB15-0028(S)-A-C11], EN 60601-2-4:2011 [No. MDWD-STB15-0028(S)-A-P04]

4.2 Electromagnetic compatibility tests

4.2.1 Qualification of test laboratory

KTC (Korea Testing Certification), KES Co., Ltd.

4.2.2 Applied standards

- EN 60601-1-2:2015, Medical electrical equipment - Part 1: General requirements for safety – Collateral standard: Electromagnetic compatibility - Requirements and tests

4.2.3 Test date (Issue)

17/10/2016, 06/03/2019

4.2.4 Test results (reports)

DoC. No: CE2015-00007(R2), DoC. No: KES-E1-19T0133

Refer to the attachment #B06-1, EMC Test Report [No. CE2015-00007(R2)]
#B06-2, EMC Test Report [No. KES-E1-19T0133]

4.3 Performance tests

4.3.1 Qualification of test laboratory

QC Office of RADIANQBIO Co., Ltd.

4.3.2 Applied standards

- Performance regulation of manufacture approval (MFDS)

4.3.3 Test date

09/12/2015

4.3.4 Test results (reports)

15/12/2015, SN: DIR2115N0113, Final Inspection Sheet

Refer to the attachment #B7. Finished Products Inspection Report

4.4 Water proof Tests

4.4.1 Qualification of test laboratory

KESCO Safety Test Center

4.4.2 Applied standards

- IEC 60529 Ed. 2.2: 2013 / IP54 (CATEGORY 2)

4.4.3 Test date(Issue)

24/03/2015

4.4.4 Test results (reports)

STC-B15-070

#06.1b06-4-2, HR-501 IEC 60529(water proof),IP54 (STC-B15-070)TEST REPORT 150324

5.0 Biological Tests

5.1 Biocompatibility Tests

5.1.1 Qualification of test laboratory

HUREV Co., Ltd.

5.1.2 Test date

05/03/2019

5.1.3 Test sample

RADIAN Defibrillation Pads (Model name: P-303)

5.1.4 Standard/norm

- EN ISO 10993-1:2009/AC:2010, Biological evaluation of medical devices – Part 1: Evaluation and testing
- EN ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

5.1.5 Test result

Doc. No. HRT0014-LOR-02

5.1.6 Reference

1) hydrogel
   Cytotoxicity : JS98YW
   Irritation : MG57WS
   Sensitization : VJ37DG
2) PE foam adhesive
   Cytotoxicity : 95T 18588 00
   Cytotoxicity : Study No. 8790
   Cytotoxicity : Study No. 8797

Refer to the attachment #06-7. Certificate of Compliance with ISO 10993 Biological Evaluation of Medical Device (Rev 1) (incl. Test Report)

6.0 Software

This software validation is conducted and documented in report.

This software validation is performed on Heart Guardian HR-501, we design and manufactured for the purpose of eliminating the software caused risk of this device. This software validation was planned at the beginning stage of device firmware design. It is implemented that referred to EN 62304:2006/AC:2008, Medical device software - Software life-cycle processes.

Refer to the attachment #09-4. Software Validation Report (No. RD-SVR-111, Rev 4)

7.0 Clinical Data

This report is based on the documents of the Clinical document, Comparison Chart of Predicate Device, Customer's complaints and Clinical Investigation Result.

- Clinical document
- Comparison Chart of Predicate Device
- Customer's complaints

The assessment of clinical evaluation states that are no side effect or significant accident that would cause patient.

Conclusion

Based on the above evaluation it is considered that there are no side effects or significant accident. The safety and performance of the ELPIS has been proved by its market experience and clinical investigation as well as market experiences of same and similar devices and scientific literature.

Refer to the attachment #11-1. Clinical Evaluation Report (No. CER-111, Rev 4)

8.0 Package Qualification

Packaging method	Primarily packaging	Carton packaging (1 method)	Carton packaging (2 method)
Material	Paper	Paper	Paper
Unit (set)	1 set	2 sets	4 sets
Weight (kg)	3.7	8.3	16.4
Size (cm)	38 × 33 × 13	40 × 35 × 28	40 × 35 × 54

8.1 Inner package

8.2 Carton package (shipping)

▲ 2 sets ▲ 4 sets

8.3 Justification for packaging/transport

HR-501 does not have any complain for lastest 3 years in packaging and transporting. Therefore, HR-501 will be not have any complain. We attached the records of market experience and customer feedback for HR-501.

8.3.1 Market experience of HR-501 in latest 3 years released:

Quantity Year	Total manufactured (EA) (A + B)	Distributed to				
		A.Domestic (EA)	B.Overseas (EA)	C. Quantity (EA)	D.Country	E.Region
2023	5,797	1,897	3,900 (Asia:2,716, Europe:886, South America:123 Afirica:130 Oceania:45)	570	AE	Asia
				1,372	IN	Asia
				360	ID	Asia
				192	TH	Asia
				88	HK	Asia
				60	QA	Asia
				50	RU	Asia
				549	IT	Europe
				62	GR	Europe
				32	UA	Europe
				80	NO	Europe
				75	IE	Europe
				40	FR	Europe
				32	PT	Europe
				46	UY	South America
				75	AR	South America
				93	MA	Africa
				30	TZ	Africa
				30	NZ	Oceania
				15	AU	Oceania
				49	Etc.	
2022	8723	3980	4743 (Asia:2196, Europe:2209, South America:212 Afirica:74 Oceania:53)	1050	AE	Asia
				532	IN	Asia
				100	TH	Asia
				96	HK	Asia
				225	QA	Asia
				193	Etc.	Asia
				805	IT	Europe
				265	GR	Europe
				192	UA	Europe
				202	NO	Europe
				201	IE	Europe
				157	FR	Europe
				212	PT	Europe

				175	Etc.	Europe
				76	CL	South America
				96	UY	South America
				40	AR	South America
				51	MA	Africa
				17	TZ	Africa
				6	ZA	Africa
				50	NZ	Oceania
				3	AU	Oceania
2021	6640	2811	3,829 (Asia:1499, Europe:2061, South America:186 Africa:58 Oceania:25)	645	AE	Asia
				320	ID	Asia
				231	IN	Asia
				60	TH	Asia
				68	HK	Asia
				175	Etc.	Asia
				174	ES	Europe
				946	IT	Europe
				150	IE	Europe
				77	FR	Europe
				150	NO	Europe
				273	GR	Europe
				64	PT	Europe
				138	UA	Europe
				89	Etc.	Europe
				152	CL	South America
				34	UY	South America
				45	MA	Africa
				13	ZA	Africa
				24	NZ	Oceania
				1	AU	Oceania

*B. Overseas (EA) is the sum of each quantity in C. Quantity (EA)

8.3.2 Customer feedback include complain (Latest 3years)

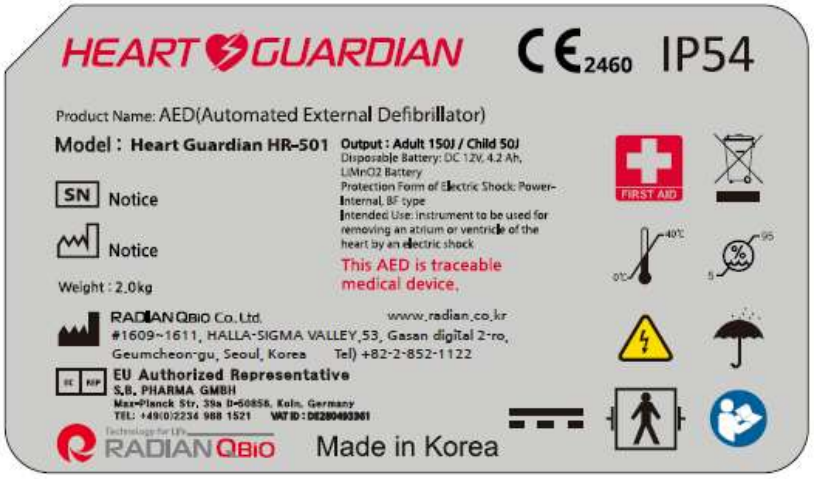
Year	Safety	Performance	Malfunction/ repair	Labeling	Packing	Incident
2021	0	0	1	0	0	0
2022	0	0	3	0	0	0
2023	0	0	0	0	0	0
Total	0	0	4	0	0	0

- 2021-11-23(Korea): Repair; The case was damaged due to a fall during transport. The product works normally. Damaged parts such as door, upper case, lower case were replaced with new ones.
- 2022-02-10(Korea): Repair; A sudden error code occurred, so we replaced the Y01 part and it works normally.
- 2022-04-07(Korea): Repair; A temporary communication failure occurred, so it operated normally after downloading the component S/W.
- 2022-05-18(Korea): Repair; Due to poor communication, the firmware upgrade and damaged injection were repaired and operated normally.

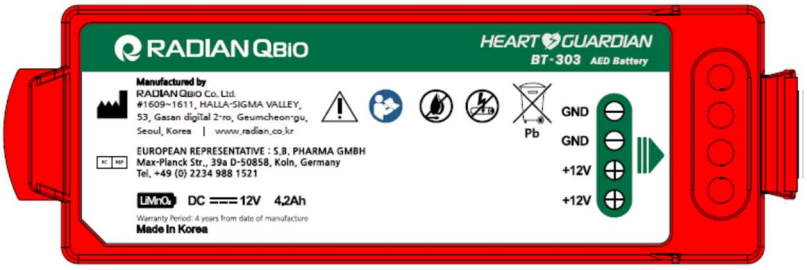
9.0 Labels - Instructions for use

9.1 labels on the product

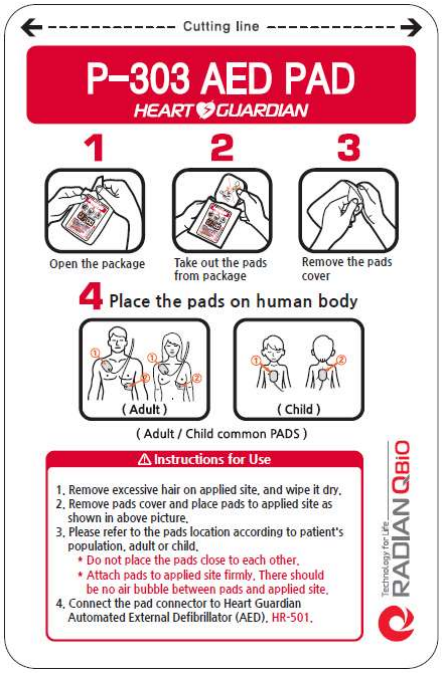
a) Main body: 119 x 69mm

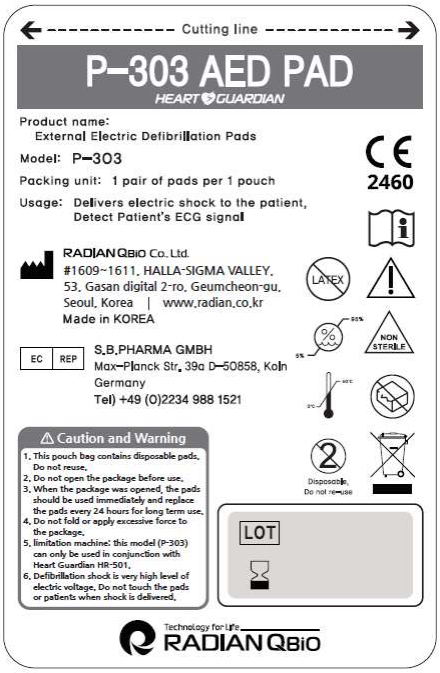


b) Battery: 134 x 50mm

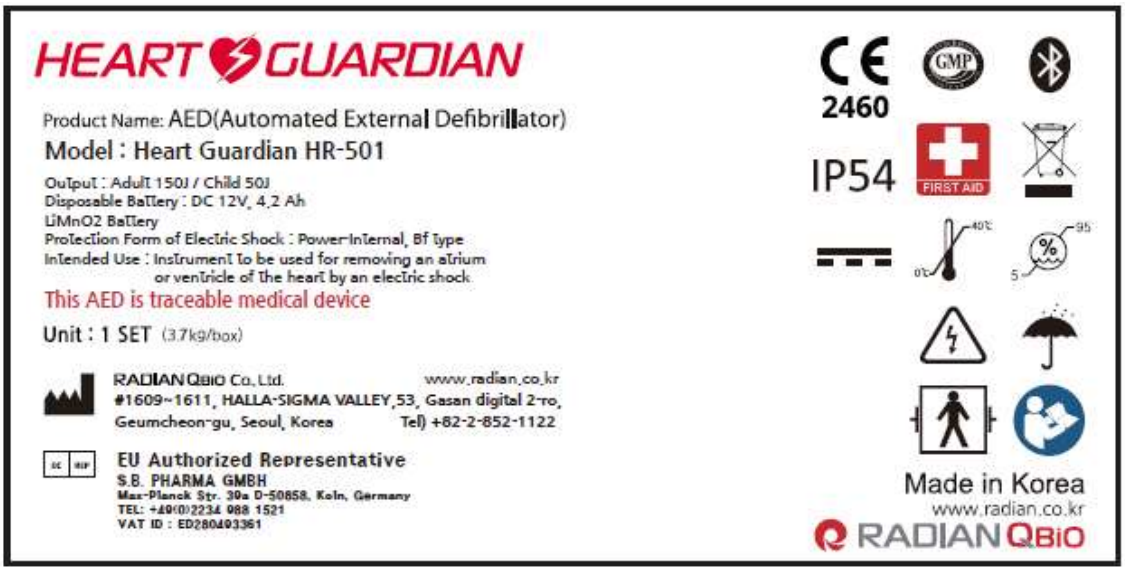


c) Pads: 170 x 250mm





9.2 Carton box (shipping) : 240 x 140 mm



9.3 Instructions for use

9.3.1 Justification for IFU

Currently we offer IFU written by English, French, Greek, Italy, Nederland, Slovenia, Spanish, and Thai language. We will provide additional IFU after checking the sales trend and additional requirements of customers.

Refer to the attachment #08-1. Operating Manual (Rev. 2.4.2)

10.0 Manufacturing

Description of the manufacturing process

10.1 Flow chart

Process	Reference document
Purchasing	Purchasing procedure (RDQP-706)
▼	
Incoming inspection	Inspection and test procedure (RDQP-805), Device master files (DMF-111), and Incoming inspection standards (xxx) a) Test items: appearance, performance, and/or operating b) Test method (according to KS Q ISO 2859-1) - Single sampling plans for normal inspection - Special inspection levels (S-2) - AQL 2.5
▼	
PCB Assembly	Production realization procedure (RDQP-701), working instructions (WS-111) a) Process control: assembly conditions b) Process method: The PCB assembly is assembled by SMD.
▼	
Firmware	Production realization procedure (RDQP-701), working instructions (WS-111) a) Process control: software download b) Process method: The software download is assembled by firmware guide.
▼	
In-process inspection	Inspection and test procedure (RDQP-805), Device master files (DMF-111), and Process inspection standards (xxx) a) Test items: appearance, program downloading, PCB setting, output and operating. b) Test method (total inspection)
▼	
Final assembly	Production realization procedure (RDQP-701), working instructions (WS-111) a) Process control: assembly conditions b) Process method: The final assembly is assembled by hand.
▼	
Final inspection	Inspection and test procedure (RDQP-805), Device master files (DMF-111), and Final inspection standards (xxx) a) Test items: Appearance, labelling, pads connect, display, output control range, Internal discharge circuit, Charging time, Bluetooth, operating, Heartbeat rhythm analysis, Current leakage, Protective earthing. b) Test method (total inspection)
▼	
Packaging & Labelling	Production realization procedure (RDQP-701), working instructions (WS-111) a) Process control: components and labeling b) Process method: Components are packed in a box by hand.
▼	
Storage of products	Handling, storage, packaging, Material and products control procedure (RDQP-710)
▼	
Release of products	Handling, storage, packaging, Material and products control procedure (RDQP-710)

10.2 QS Certificate from MFDS and a Notified Body for the manufacturing plant

The production and inspection is followed by our documented procedures based on our quality management systems – GMP

Refer to the attachment #09-5, Certificate of GMP

11.0 Conclusion

The Heart Guardian HR-501 Series of RADIANQBIO Co., Ltd. adheres to requirements of Regulation MDR 2017/745.

The assessment of product quality states that there are no critical quality issues or reported defects that would cause user to be put at risk. Control of design, materials and production processes is based on preventive action to achieve product quality and minimize risk.

Based on the risk analysis evaluation it is considered that any risks associated with the use of these products are minimal and acceptable when weighed against the benefits to the users. Also, it is considered that there no side effect or significant accident. The safety and performance of the Heart Guardian HR-501 has been proved by its market experience as well as market experience of same and similar devices.

12.0 EC Declaration of Conformity

Refer to the attachment #00-1. EC Declaration of Conformity (No. DOC-111)
Refer to the attachment #00-2, Declaration of Conformity (No. RDROHSDOC-111)

Rule 22 Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators