VIVEST

Declaration of Conformity Relating to Directive 2011/65/EU

We ViVest Medical Technology Co., Ltd.

Address: Unit 205, 206, 207, B1 Building, SIP BioBay No.218, Xinghu Street, Suzhou Industrial Park, Suzhou Area, Suzhou Free Trade Pilot Zone 215123 Jiangsu, China

Declare our compliance with the requirements of Directive 2011/65/EU and its subsequent amendment (EU)2015/863,on the restriction of the use of certain hazardous substances in electrical and electronic equipment (hereinafter called, "RoHS-Directive").

The RoHS-Directive defines threshold values to avoid hazardous substances,in electrical and electronic equipment as follows (maximum concentration values tolerated by weight in homogeneous materials):

- Lead (0.1%)
- Mercury (0.1%)
- Cadmium (0.01%)
- Hexavalent chromium (0.1%)
- Polybrominated biphenyls (PBB) (0.1%)
- Polybrominated diphenyl ethers (PBDE) (0.1%)
- Bis(2-ethylhexyl)phthalate (DEHP) (0.1%)
- Butylbenzyl phthalate (BBP) (0.1%)
- Dibutyl phthalate (DBP) (0.1%)
- Dlisobutyl phthalate (DIBP) (0.1%)

We confirm that the products supplied by ViVest Medical Technology Co., Ltd that fall within the scope of the RoHS Directive meet the requirements of the RoHS Directive.

Product name: Automated External Defibrillator

Product model: PowerBeat X1 & PowerBeat X3

Any additional requirements would have to be specified in separate agreements.This declaration is based on our current knowledge and experience.We take neither liability nor warranty for factors beyond our knowledge and control.

Responsible for making this declaration is the:

☑ Manufacturer ☐ Authorised representative established within the EU

Person responsible for making this declaration

Print name/Title: Lia Li Manager of Rgulatory Affairs

Suzhou	2024-06-18	Lia Li.
(Place)	(Date)	(Signature)

X1 and X3 Product Technical Specifications

Safety Specification

Safety classification	Internally powered ME equipment
Protection against electric shock	Defibrillation-Proof Type BF Applied Part.
Protection against harmful ingress of water or particulate matter	IP55
Operational mode	Continuous operation
ME equipment type	Portable

Physical Specification

Size (including handle)	232±1mm(H)*209±1mm(W)*59±0.5mm(D)
Weight (including battery)	Approx. 1.5kg
Drop	Free to fall from a height of 1.5 m on a hard surface
Service life	10 years (test condition: ambient temperature of 25°C)

Environmental Specification

Operation temperature	-10 to 50°C (After entering environment of - 20°C from room temperature, it can work for at least 60 minutes)
Storage temperature	5 to 50°C
Short term storage/ transportation temperature	-40 to 70°C (<7 days)
Relative humidity	5 to 95% no condensation
Air pressure	59.4 to 106kPa (-382 meters to +4283 meters)

Display Specification

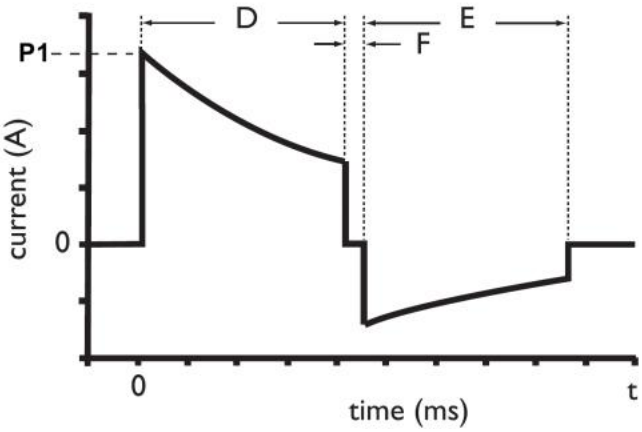
Size	105.5mm (H) *65.3mm (W)
Resolution	800×480

Battery Specification

Battery type	$LiMnO_2$ battery, 12V/3000mAh
The number of maximum energy discharge times	New battery can charge and discharge at least 200 times in rated energy of 150J at 20±2°C environment.
Battery standby life	5 years
Battery service life	5.5 years
Low battery condition	The device can deliver at least 30 shocks after the low battery indication is first displayed.

Charging time (In the environment of 20±2°C)			
Battery Status	From initial power on to charge done	From initial rhythm analysis to charge done	From second rhythm analysis to charge done
New battery	≤17s	≤11s	≤7s
New battery after 6 times of maximum energy discharge	≤17s	≤11s	≤7s
New battery after 15 times of maximum energy discharge	≤17s	≤11s	≤7s

Defibrillation Specification

Waveform	Truncated biphasic exponential waveform 
Energy level	For adults: 150J; For children: 50J
Output control	Manual
Patient impedance range	20 to 180Ω

Adult defibrillation:

Load impedance (Ω)	Phase 1 pulse width D(ms) ±15%	Phase 2 pulse width E(ms) ±15%	Time interval between Phase 1 and Phase 2 F(ms) ±15%	Peak current P1 (A) ±15%	Energy output (J) ±15%
25	2.8	2.8	0.5	61.0	128
50	4.5	4.5	0.5	33.5	150
75	6.3	5	0.5	23.4	155
100	8	5.3	0.5	18.0	157
125	9.7	6.4	0.5	14.5	158
150	11.5	7.7	0.5	12.0	160
175	12	8	0.5	10.5	158

Child defibrillation:

Load impedance (Ω)	Phase 1 pulse width D(ms) ±15%	Phase 2 pulse width E(ms) ±15%	Time interval between Phase 1 and Phase 2 F(ms) ±15%	Peak current P1 (A) ±15%	Energy output (J) ±15%
25	2.8	2.8	0.5	36.0	43.4
50	4.5	4.5	0.5	19.6	50.0
75	6.3	5.0	0.5	13.5	52.0
100	8.0	5.3	0.5	10.3	52.2
125	9.0	6.0	0.5	8.4	52.3
150	9.0	6.0	0.5	7.0	50.0
175	9.0	6.0	0.5	6.0	49.0

ECG Analysis System

Function	Automatically identifies the patient's heart rhythm and provides shock advice to the operator.
Pacemaker detection	Identify and erase the pacing signal before analyzing heart rhythm.
Artifacts detection	If an interfering signal that affects the accuracy of the heart rhythm analysis is detected, the device will delay performing the analysis and give a prompt.
Analysis decision time	≤7s
Analysis accuracy	Comply with IEC60601-2-4 requirements

Cardiac arrest threshold	<0.2mV

Performance of heart rhythm recognition detector

Rhythms	Sample Size	Performance Goal of IEC60601-2-4	Observed Performance
Shockable		Sensitivity	
VF	726	>90%	100%
VT	368	>75%	99.7%
Nonshockable		Specificity	
	3350	>99%	99.7%

Classification of heart rhythm recognition detector

Rhythms	VF and VT	All other rhythms
Shockable	True positive	False positive
	99.7%	0.3%
Nonshockable	False negative	True negative
	0.3%	99.7%