Pulsiocare

Technical data sheet

This document is intended to provide information to an international audience outside of the US.

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General information

Legal Manufacturer	Pulsion Medical Systems SE
Device name	Pulsiocare
Country of origin	Poland
Type of device	Advanced Hemodynamic Monitoring system
Intended use	Pulsiocare is used for monitoring of blood pressure, cardiopulmonary, circulatory and organ function variables
Classification in accordance with Regulation EU 2017/745 on medical devices, Annex VIII, Rule 10	Class IIb
Notified body certification	TÜV Süd (CE 0123)

General technical data

Dimensions (W x D x H)	350 x 206 x 253 mm
Weight	4.7 kg
Operating system	Yocto Linux
Visual alarm system	360-degree LED alarm light
Mounting options	VESA interface Integrated mounting plate for universal, wall and bedrail mounting

User interface

Screen type	TFT-LCD Touchscreen
Screen size	13.3-inch
Touch screen	Projective capacitive touch
Viewing area	294 x 165 mm
Resolution	1080 x 1920 (Full HD)

Electrical data

Power consumption	Max. 140 W
Mains voltage	90 – 240 VAC
Frequency	50/60 Hz
Battery type	Lithium-ion battery (rechargeable)
Battery backup time	min 1 hour (factory new battery, fully charged)
Battery standards	IEC 62133-2:2017; UN 38.3
IP code according to IEC 60529	IP32 • Protected against solid objects >2.5 mm • Protected against dripping water when tilted up to 15 degrees from the normal position (0°)

Operating conditions

Operating temperature	10 °C – 40 °C
Relative humidity	15 – 90% (non-condensing)
Atmospheric pressure	700 hPa – 1060 hPa / up to 3000 m altitude

Transport & Storage conditions

Storage temperature	10 °C – 40 °C
Storage relative humidity	Up to 95%
Storage atmospheric pressure	470 hPa – 1060 hPa
Transport temperature	-25 °C – 60 °C
Transport relative humidity	Up to 95%
Transport atmospheric pressure	470 hPa – 1060 hPa

Interfaces & Data handling

External device interface	2 x USB-A, USB-C, LAN*, 2 x AUX, Mini display port*
Patient Data Management System	USB-A ports for PDMS connection via USB to RS232 converter
Export files	Log files, screenshots and event list can be saved and exported to a USB memory stick
Screenshots	Up to 40 screenshots can be stored

*Not functional for release version 1.0

Standards

Electrical safety, Environmental management, Risk management, Usability, Software lifecycle management, Biocompatibility

IEC 60601-1:2020; IEC 60601-1-2:2020; IEC 60601-1-6:2010 + A1:2013 + A2:2020; IEC 60601-1-8:2006 + AMD1:2012 + AMD2:2020; IEC 60601-1-9:2007 + A1:2013 + A2:2020; IEC 60601-2-34:2011; IEC 62311:2019; IEC 80601-2-49:2018; ISO 80601-2-56:2017 + A1:2018; IEC 62304:2016 + Cor1:2008 + A1:2015; ISO 10993-1: 2018; IEC 81001-5-1:2021; IEC 62366-1:2015/A1:2020; EN ISO 14971:2019 + A11:2021; ISO 14001:2015; EN ISO 13485:2016 + AC:2018 + A11:2021

Displayed parameters

Parameter	Unit	PICCO	ProAQT	Measuring range
AP_{dia}	mmHg	x	x	20 – 200
AP_{sys}	mmHg	x	x	30 – 300
CFI	1/min	x		1 – 15
CI_{cal}/CI_{Trend}	l/min/m²	x	x	0.1 – 15
CO	l/min	x	x	0.25 – 25
CPI	W/m²	x	x	0.01 – 9.99
CPO	W	x	x	0.01 – 9.99
CVP	mmHg	x	x	-10 – 50
dP_{mx}	mmHg/s	x	x	200 – 5000
EA_{dyn}	-	x	x	0 – 10
ELWI	ml/kg	x		0 – 50
EVLW	ml	x		10 – 5000
GEDI	ml/m²	x		80 – 2400
GEDV	ml	x		40 – 4800
GEF	%	x		1 – 99
ITBI	ml/m²	x		25 – 3000
ITBV	ml	x		50 – 6000
MAP	mmHg	x	x	-50 – 300
PPV	%	x	x	0 – 50
PR	1/min	x	x	30 – 240
PVPI	-	x		0.1 – 9.9
SV	ml/min	x	x	1 – 250
SVI	ml/m²	x	x	1 – 125
SVR	ml/m²	x	x	25 – 3000
SVRI	dyn*s*cm^{-5}*m²	x	x	1 – 30000
SVV	%	x	x	0 – 50
T_b	°C	x		28 – 45
T_{inj}	°C	x		0 – 30

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