Neo*ICU* / Neo*IW* - Technical specifications

Essential performance of the medical device		Measures, adjusts and maintains the function-specific pressure values in the mattress system, specified in the software for each program.
Permissible weight of the patient		0-6 kg
Basic UDI-DI (GMN)		Neo*ICU*: 6429810591NEID4 Neo*IW*: 6429810591NEWDY
REF code of the controller		NEIxyz (Neo*ICU*) / NEWxyz (Neo*IW*), where x=language (F=Finnish, S=Swedish, E=English, D=German, R=French, P=Spanish, J=Japanese, N=Dutch, O=Norwegian, T=Danish, G=Portuguese), y=voltage range (E=230 V, S=120 V), z=hanger type
Controller dimensions (W x L x H)		26 x 26 x 11.5 cm
Mattress dimensions (W x L x H)		35 x 65 x 4 cm (Neo*ICU*), 48 x 66 x 4 cm (Neo*ICU* Giraffe), 47 x 74 x 4 cm (Neo*IW*)
Weight (controller/mattress)		5 kg/2 kg (depending on cell dimensions)
Controller decibel level		26,41 dB LAeq (24-hour operating time, 1 m)
Flammability (mattress)		EN 597-1:2015; EN 597-2:2015; IMO 2010 FTP Code, Annex 1, Part 9
Operating voltage		230V 50HZ (voltage range E) **or** 120V 50/60HZ (voltage range S)
Nominal input power		max. 35W
Battery type		Lithium-ion, 7.26V, capacity 2,650mAh, manufacturer: Celltech Oy / Varta Storage GmbH
Non-rechargeable battery type		CR2032, lithium-ion, 3.0V, capacity 230mAh, manufacturer: Varta Microbattery GmbH
Fuses		F1 & F2 – T 2.5A/250V 5X20 mm; F3 – T5A/250V 5X20 mm; F4 – T 2.0A/250V 5X20 mm; pump/motor fuse – T 1.6A/250V; main fuse: (voltage range E) – T315mA/250V 5X20 mm, breaking capacity (BC) 35A or (voltage range S) – T500mA/250V 5X20 mm, breaking capacity (BC) 35A
Separating device		Power cable – EU/UK/AU (voltage range E): C13, 1 mm², 10A/250 VAC; 50 Hz or US (voltage range S): C13, SJT 3x16 AWG, 13 A / 125 VAC; 50/60 Hz
Electromagnetic compatibility		See Appendix 1: Carital Controllers - Guidance and Manufacturer's Declarations – EMC
	**Applied part** **Applied part type**	Mattress (cover and cells) BF
IP22	**IP class**	IP22 (protected against particles with a diameter of 12.5mm or greater and from water falling vertically or at an angle not exceeding 15°)
	**Protection class**	II, insulated
	**Operating environment temperature range**	+10°C – +35°C
	**Operating environment air humidity**	15% – 90%
	**Operating environment atmospheric pressure**	700 hPa – 1,060 hPa

CE	MD	Class 1 medical device under the EU Medical Device Regulation 2017/745 (MDR) (Rule 1 - Non-invasive devices / Rule 13 - All other active devices).
	Design standards	IEC 60601-1:2005 & IEC 60601-1:2005/AMD1:2012 except for clause 11.7 IEC 60601-2:2014 IEC 60601-1-6:2010 & IEC 60601-1-6:2010/AMD1:2013 IEC 60601-1-11:2015 IEC 62304:2006 & IEC 62304:2006/AMD1:2015 IEC 62366:2007 & IEC 62366:2007/AMD1:2014 EN ISO 13485:2016 EN ISO 14971:2019 EN ISO 10993-1:2018 EN ISO 15223-1:2016 EN ISO 3758:2012 EN 597-1:2015 & EN 597-2:2015 EN 12182:2012