FOR LIFE | UNDERSTANDING MOVEMENT & PERFORMANCE

Manual - Valiant 2
Pediatric

Pediatric

Lode BV
Zernikepark 16
NL 9747 AN
Groningen
The Netherlands
t: +31 50 571 28 11
f: +31 50 571 67 46
@: ask@lode.nl

CE
0344

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1 - Intended Use

This device is intended to be used as a stress test device in a medical environment. The main goal of the use of the devices is to create reproducible stress tests. With cycling ergometers typically workload (watt) is imposed. With treadmills typically speed (km/h) and inclination (% grade) are imposed. This product is designed both for manual operation and for control by external ECG-, pulmonary equipment. Most likely this device will be used in conjunction with another medical device to obtain other important physiological data, allowing a physician to evaluate a test subjects physical status.
The product may also be used for rehabilitation or active aging therapy.
As such the intended use of the device solely cannot be defined specifically.

The device has to be operated under the supervision of well-trained medical specialists in the field of use.
The ultimate judgment whether a test subject should undertake a stress test with the device must be made by the responsible medical specialist, based on the limitations of each individual, the medical history and all other applicable circumstances. Neither the manufacturer nor its distributors assume any responsibility for the final use of its equipment.

2 - Precautions

⚠ Read this manual before using the device and follow it carefully.

⚠ The operator should instruct the test subject prior to performing an exercise protocol. If, at any time during exercise, the test subject feels faint, dizzy, or experiences pain, stop the test and he or she should be consulted by the physician.

⚠ Care should be taken in mounting or dismounting the ergometer. Be aware of feet when replacing the ergometer.

⚠ The operator should not touch accessible parts and the patient simultaneously.

⚠ The test subject should always wear the belt of the lanyard safety belt.

⚠ Replacement of the power supply cord should be installed by authorised service personnel, instructions for correct connection and anchoring must be ensured, securing that the requirements of clause 8.11.3 of IEC 60601 1:2005 are met.

⚠ Set up and operate the device on a solid level surface.

⚠ The test subject should not wear loose or dangling clothing while using the device.

⚠ Service of this device is restricted to factory trained personnel only.

⚠ Do not jump onto the rotating belt. Do not jump off the rotating belt (not even to the front). Do not stop moving on the running belt. Do not turn around on the running belt. Do not move sideways or backwards. Do not make movement that could get you out of balance.

⚠ The test subject shall wear clothes when using the harness or the lanyard belt to prevent skin irritation.

⚠ Replacement of parts can only be done by the manufacturer or designated service personnel.

⚠ Read all warnings posted on the device.

⚠ Inspect the device for worn or loose components prior to use. Tighten / replace any loose or worn components prior to use.

⚠ Do not place any loose parts or objects on the device before and during use.

⚠ The equipment has a safety earth (ground) connection and must be connected to a (grounded) wall socket with protective earth to avoid the risk of electric shock. The functional earth connection is for potential equalisation only.

⚠ The operator must keep away from the footrail while lowering.

⚠ The test subject should wear proper sports or running shoes (no spikes).

⚠ If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

⚠ Cleaning and user maintenance shall not be made by children without supervision.

⚠ Children being supervised are not to play with the appliance.

⚠ Children shall not play with the appliance.

⚠ Heart rate monitoring systems may be inaccurate. Over exercise may result in serious injury or death. If the test person feels faint stop exercising immediately.

⚠ Keep away from the rollers.

⚠ No modification of this equipment is allowed.

⚠ Not suitable for use in the presence of flammable anaesthetics.

⚠ The appliance is not to be used by persons (including children) with reduced physical, sensory or mental capabilities, or lack of experience and knowledge.

⚠ The test subject should wear proper sports clothing. The operator should check possible entrapment of clothing, fingers or feet, before the start of an exercise test.

⚠ This appliance can be used by children aged from 8 years and above and persons with reduced physical, sensory or mental capabilities or lack of experience and knowledge if they have been given supervision or instruction concerning use of the appliance in a safe way and understand the hazards involved.

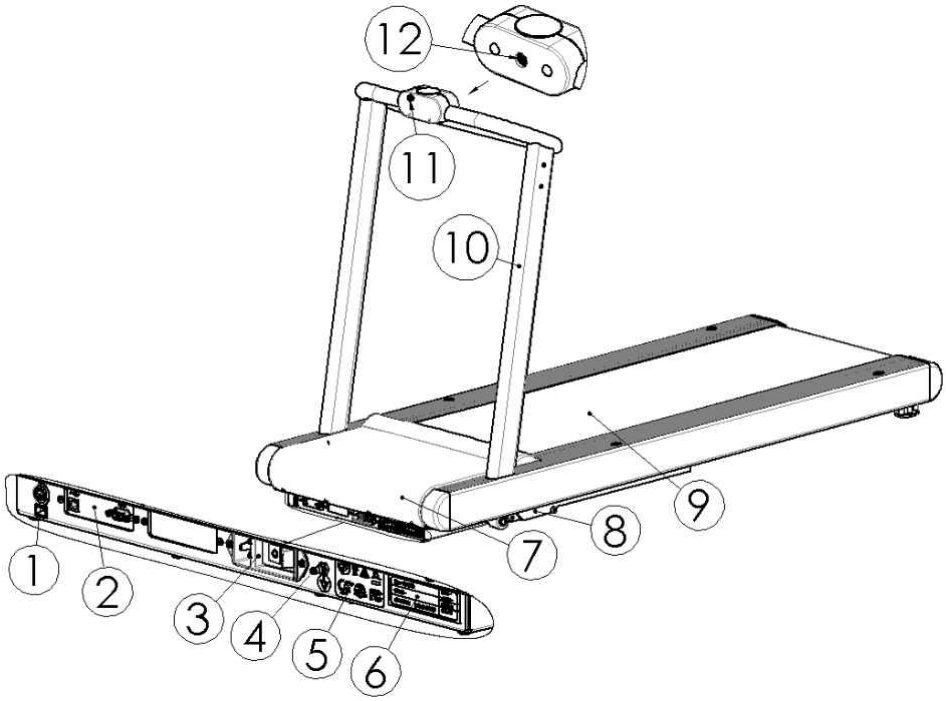
⚠ This device should only be sold by, or under the supervision of authorized persons.

⚠ Your device may be executed with heart rate measurement, blood pressure measurement, and / or SpO2 (blood saturation) measurement. These measurements may be inaccurate, depending on use circumstances. These measurements are indicative and cannot be used for diagnostic purposes.

3 - Contra Indication

The device is to be operated by classified personnel only. As stated in the intended use, the device is intended to be used in a medical environment. During the intended use the test subject will deliver energy. Application of the wrong dosis of energy could lead to permanent damage of the test subject health. Only use this device under supervision of a medical physician.

4 - Definition of parts



1. Service Connector
2. Communication Interface Module (CIM)
3. On/Off switch
4. Equipotential bonding plug
5. Safety symbols tag
6. Serial number tag
7. Motor compartment for height adjustment and drive
8. Height adjustment (optional)
9. Walking surface (APPLIED PART)
10. Front bar
11. Connector for external emergency stop
12. Magnetic contact for safety belt

5 - Validity

This manual covers all Valiant 2 Pediatric versions starting with the following serial number:

938904 Valiant Pediatric: S/N 20140001

Date of issue: June 14

6 - Install your treadmill

1. While unpacking the Lode treadmill ergometer, leave the transport straps on both ends in place.
2. Place the treadmill in the location where it will be used.
3. Remove Both transport straps and remaining packaging materials.
4. The power supply cord should be installed by authorised service personnel and instructions for correct connection and anchoring must be ensured, securing that the requirements of clause 8.11.3 of IEC 60601-1:2005 are met.
5. Remove all objects from the walking surface.
6. Switch on the unit with the on/off button and wait until the self-test is carried out. The product is ready for use after you have heard a series of “beeps”.

7 - Maintenance

7.1 - Emergency stop installation

When your treadmill is delivered with an emergency stop, please note the following:

The plug of the emergency stop button needs to be placed in the back connector of the console on the front handrail.

Some emergency stop buttons have a connector for another emergency stop. You can place the spare dummy there in case you have one button.

Also make sure that the magnet of the emergency lanyard is connected to the console.Otherwise the treadmill will not operate.

Maintenance should be carried out on a regular and planned basis. We recommend to check the unit annually. This may be done by your local dealer. It is also recommended that a record of the service history is kept for all activities relating to service and maintenance.

Maintenance and all repairs should only be carried out by an authorized agency. The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.
The check up and/or technical maintenance must be carried out conform the procedure described in the service manual of the unit.
Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.

Lode will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist authorized service personnel to repair those parts of the ergometer that are designated by Lode as repairable by authorized service personnel.

8 - Troubleshooting

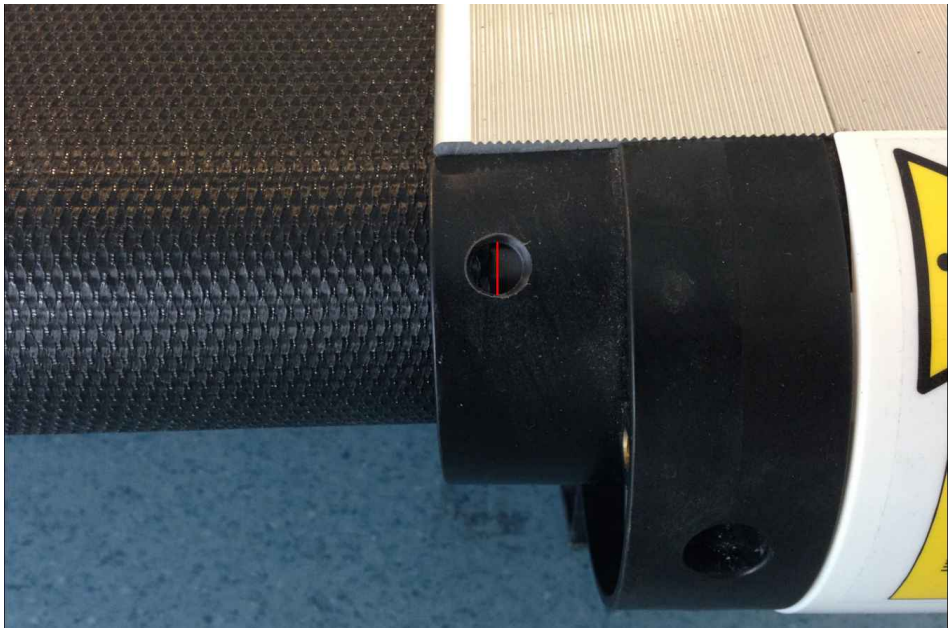
For a complete overview of possible error message and the solutions belonging to these messages, please consult the service manual of the ergometer.

8.1 - Belt alignment

Place the allen key on the left bolt while standing behind the treadmill as shown on the picture.

Adjusting the belt tension is very easy with the key on the left side. Turning the key clockwise will make the belt move to the right side of the treadmill. Turning the key counterclockwise will make the belt go left.

The red marked area shows where you can check the belt alignment. The goal is to align the belt edge exactly in the center of the hole.



Now start the treadmill with a speed of 2 km/h. Make corrections with the allen tool to the belt alignment so the edge of the belt stays in the middle of the hole.

When the belt is properly aligned you may repeat the above procedure on higher speeds. But be cautious; higher speeds will have a faster implementation of the belt alignment when turning the allen key. Always start with the 2km/h so you can timely intervene is the belt goes to one side quickly.

To finalize the alignment procedure set the treadmill to maximum speed for 2 minutes and check the alignment of the belt.

Note: NEVER use any lubricants on the walking belt. The belt is self greasing using a wax layer that will dispose on the deck on high friction points and on higher speeds. The belt does not need to be re-waxed and runs the complete lifetime of aproximately 10.000km. Incorrect tension, alignment and/or use can decrease the lifetime of the belt.

9 - Cleaning

The belt can be cleaned with a sponge, with little lukewarm water. Allow the belt to dry thoroughly after cleaning before re-using the treadmill.

Before cleaning and other maintenance of any part of the device, first switch off the device and disconnect it from the mains. The surfaces can be cleaned with a damp cloth and a liquid (non-abrasive) cleaning product.

General Cleaning
Wipe the device surface down with a cloth moistened with soap water or a disinfectant. The cloth should not be dripping wet; do not allow liquids to enter the device

Cleaning the Saddle
Clean the saddle with a soft and dry or moist cloth. Disinfectants used should not contain any alcohol.

Cleaning the Upholstery (e.g. couch ergometer)
Wipe the upholstery down with a soft cloth moistened with soap water. The cloth should only be moist and not dripping wet. If the cleaning agents and disinfectants used are caustic or contain alcohol, they may damage and/or discolor the upholstery.

If you are not certain about the discolouring effect of a cleaning agent, you may try a little on a part of the product that is not visible during normal use.

Lode cannot advise a specific cleaning agent, since local recipes may differ.

10 - Control with an External Device

If your device is fitted with a communication card you can connect to many external devices.

1. Connect the device with the supplied cable to the external device. You can control the device with e.g. an exercise ECG device or Metabolic Card.
2. Download the interfacing instructions from the internet at www.lode.nl after you have registered your device.
3. If your device has a control unit, select “Terminal”- mode to allow external commands. When the device does not have a control unit the terminal mode is automatically selected. (See for detailed instructions the user manual of your external device).

11 - Control with the Lode Ergometry Manager (LEM)

1. If your device has an RS232 or USB port, connect it directly to the PC LEM is installed on. If your device has a RJ45 connector plug it with an UTP cable to the special interface connector that was delivered with your device and to a USB port in your PC.
2. Start Lode Ergometry Manager on your PC
3. If your device has a control unit, select “Terminal”- mode to allow external command. If your device does not have a control unit the terminal mode is automatically selected. (See for detailed instructions the user manual of LEM).

Trapping zone. Warning: do not jump onto the rotating belt. Do not jump off the rotating belt (not even to the front). Do not stop moving on the running belt. Do not turn around on the running belt. Do not move sideways or backwards. Do not make movement that could get you out of balance. Keep away from rollers. The operator must keep away from the footrail while lowering.

12 - List of symbols used


External Control Connector


Emergency Stop


Network (Proprietary Lode)


Class I MEDICAL EQUIPMENT Type B Electrical Safety IEC 60601-1


Safety notes


Potential Equalization Conductor


RS232

USB

Read manufacturer's guide, advises and instructions and manual

On-off Switch

The equipment has a safety earth (ground) connection and must be connected to an earthed (grounded) wall socket.

Tested and certified to U.S. and Canadian National Standards by a NRTL, viz TÜV Rheinland. Compliance for U.S. and Canadian markets.

FCC 18 RF ISM tested

Symbol for collection, treatment, recycling and disposal of waste electrical and electronic equipment (WEEE) as set out in Directive 2002/96/EC of 27 January 2003 of the European Parliament and of the Council on waste electrical an electronic equipment are necessary to reduce the waste management problems linked to the heavy metals concerned and the flame retardants concerned

The Lode equipment is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the Lode equipment is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR11	Group 1	The equipmentr uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The equipment is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / Flicker emissionsIEC 61000-3-3	Complies	
Harmonic Emissions IEC 61000-3-2	Not applicable	Equipment for professional use with a total rated power greater than 1 kW and is excluded from this requirement

The Lode equipment is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the Lode equipment is used in such an environment.			
Immunity Test	**IEC 60601-Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN 61000-4-4	Not Applicable	Not Applicable	Conducted only on ports interfacing with cables whose total length, according to the manufacturer's functional specification, may exceed 3 meters
Surge EN 61000-4-5	Not Applicable	Not Applicable	Conducted only on ports interfacing with cables whose total length, according to the manufacturer's functional specification, may exceed 3 meters
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	Not applicable	Not applicable	Equipment for professional use with a total rated power greater than 1 kW and is excluded from this requirement
Power frequency (50/60	3 A/m	3 A/m	Power frequency magnetic

Hz) magnetic field EN 61000-4-8			fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
NOTE: *Ut* is the AC mains voltage prior to application of the test level.			

The Lode equipment is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the Lode equipment is used in such an environment.

Immunity Test	**IEC 60601-Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Lode equipment including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** d= 1,2 √ P
Conducted RF 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	
Radiated RF 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	d= 1,2 √ P 80 MHz to 800 MHz d= 2,3 √ P 800 MHz to 2,5 GHz where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and **d** is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a , should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 

13 - Electromagnetic Compatibility (EMC)

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection
from structures, objects, and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment.
b. Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communication Equipment and the Lode equipmentr

TheLode equipment is intended for use in the electromagnetic environment on which radiated RF disturbances are controlled. The customer or the user of theLode equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Lode equipment as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output Power Transmitter in Watts W	Separation Distance in Meters (m) according to frequency of Transmitter		
	150 kHz to 80 MHz d= 1,2 √ P	80 MHz to 800 MHz d= 1,2 √ P	800 MHz to 2,5 GHz d= 2,3 √ P
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,7	3,7	7,37
100	11,7	11,7	23,3

For transmitters rated at a maximum output power not listed above, the recommended separation distance [d] in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE:
These guidelines may not apply in all instances. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

14 - Specification remarks

The specification in this manual is of the basic version of the product at the time of the publication of this manual. The specification of all actual versions can be found on the Lode website. www.lode.nl

Changes to specifications can be made without prior notice.

Mentioned speed at the specifications in this manual is the standard speed supplied on the treadmill. When optional speed upgrade or speed downgrade is installed on the treadmill, the actual speed of your treadmill may differ from the speed mentioned at the specifications.

15 - Accessories

Colour display 3.5" - single display

Partnumber: 945810

Clear feedback

Colour display 3.5" - single display

Control Unit with 7" touch screen for treadmill

Partnumber: 945814

Multifunctionality

Control Unit with Touchscreen

Programmable Control Unit with 7" touch screen for ...

Partnumber: 945815

Programmable

Programmable Control Unit

Colour Display 3.5" - 2nd screen

Partnumber: 945819

Multifunctionality

Colour Display 3.5"

SpO2 for control unit with touch panel (treadmill)

Partnumber: 945822

Oxygen saturation

SpO2 for control unit with touch panel

Blood Pressure Measurement with ECG trigger for ...

Partnumber: 945824

with ECG trigger

Blood Pressure Measurement with ECG trigger

Heart rate for treadmills

Partnumber: 945820

Heart rate in beats per minute

Heart rate for treadmills

Emergency Stop Button

Partnumber: 945804

Ultimate safety

Emergency Stop Button

Adjustable Acceleration & Deceleration for Valiant 2

Partnumber: 945846

Flexibility in exercising

Acceleration & Deceleration

Reverse Walking for Valiant 2

Partnumber: 938842

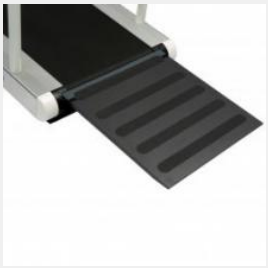
Simple switching between forward and

Switch direction of belt up to 5 km/h

Entrance plate

Partnumber: 938809

Even easier entrance to the treadmill



Entrance plate

Handrails, Side - Fixed (yellow), for Valiant 2 ...

Partnumber: 938800

Extra support for the test subject

Handrails, Side - Fixed, for Valiant 2 pediatric

Handrails, Side - Adjustable for Valiant 2 Pediatric (...

Partnumber: 938802

Making your treadmill suitable for children

Adjustable pediatric side handrails

Handrail, front singlesided - Pediatric - Valiant 2

Partnumber: 938816

Obstacle free observation of the test

Singlesided Front Handlebar - Pediatric

Ambient sensor pack

Partnumber: 945826

Check environmental conditions during test

Ambient sensor pack for treadmills

Universal treadmill Arm Support

Partnumber: 945805

Comfort for both test subject and test

Universal treadmill Arm Support

Bottle holder

Partnumber: 401200

Convenient beverage storage

Bottle holder

Extension for emergency lanyard

Partnumber: 945931

Original Accessory

Extension for emergency lanyard

Speed upgrade from 0.1-12 to 0.5-20 km/h for Valiant 2

Partnumber: 945841

Higher speeds

Speed 0.5 – 20 km/h for Valiant 2

Network Module

Partnumber: 945851

Easy networking with LEM and LCRM

Network Module

USB to Serial converter

Partnumber: 226012

Easy connection

USB to Serial converter

RS232 cable

Partnumber: 930911

Easy connection

RS232 cable

16 - Specifications

Workload		
Maximum speed	12 km/h	7.5 mph
Minimum operational speed	0.1 km/h	0.1 mph
Positive elevation	25 %	
Elevation adjustment steps	0.5 %	
Accuracy		
Speed accuracy	5 %	
Accuracy inclination	0,5 %	
Comfort		
Allowed user weight	225 kg	496 lbs
Connectivity		
USB connector	✓	
RS232 in connector	✓	
Dimensions		
Screen resolution	800 x 400 pixels	
Walking surface length	127 cm	50 inch
Walking surface width	50 cm	19.7 inch
Step up height	17 cm	6.7 inch
Product length (cm)	192 cm	75.6 inch
Product width (cm)	76 cm	29.9 inch
Product height	130 cm	51.2 inch
Power requirements		
Power cord length	250 cm	98.4 inch
Power cord IEC 60320 C19 with CEE 7/7 plug	✓	
Power cord NEMA	✗	
Maximum rated power input	2500 VA	
115 V AC 50/60 Hz (2 phases)	✓	
230 V AC 50/60 Hz	✓	
Maximum motor power	1.8 kW	
Standards & Safety		
IEC 60601-1:2005	✓	
ISO 13485:2016 compliant	✓	
ISO 9001:2015 compliant	✓	
Standard emergency lanyard	✓	

Certification	
CE class Im according to MDD93/42/EEC	✓
CE class of product with optional SpO2	IIa
CE class of product with optional BPM	IIa
CB according to IECEE CB	✓
Environmental conditions	
Maximum operational temperature	40 °C
Minimum operational temperature	14 °C
Maximum operational air pressure	106 kPa
Minimum operational air pressure	70 kPa
Maximum operational non-condensing humidity	90 %
Minimum operational non-condensing humidity	30 %
Maximum storage & transport temperature	70 °C
Minimum storage & transport temperature	-25 °C
Maximum storage & transport air pressure	106 kPa
Minimum air pressure storage & transport	50 kPa
Max. humidity storage & transport	95 %
Min. humidity storage & transport	10 %

Order info

Partnumber	938904