M967900 - Manual Angio single set

Cardio Pulmonary

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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.

If the device is used as arm ergometer (with hand curbles) it can be combined with various products (e.g. wall mounts, automatic stand, etc.) to facilitate the stress tests. The device in those situations can be used for (cardiac) rehabilitation or cardio pulmonary exercise testing with patients who can't use their legs (f.i. wheelchair users).

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.

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

⚠ 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.

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

⚠ 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.

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

⚠ Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ The operator should clean the device (handgrips, cushions) after each exercise test.

⚠ For those test subjects who are not able to use the handgrips, a handgrip fixation set should be used.

⚠ Heart rate monitoring systems, BP measurements or SpO2 monitoring may be inaccurate. Over exercise may result in serious injury or death. If the test person feels faint stop exercising immediately.

⚠ The installation should only be done by authorized persons who follow the installation instructions.

⚠ Do not spill any liquid over the device.

⚠ No modification of this equipment is allowed.

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

⚠ Use of this equipment adjacent to or stacked with other equipment (other then medical equipment intended to be used as described in the intended use) should be avoided because it could result in improper operation.

⚠ The test subject should keep the feet in the pedals or hold the hand grips during the total duration of the exercise test.

⚠ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ergometer, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ The operator should have knowledge about absolute and relative contraindications. The operator should have knowledge about the Warnings and Cautions before using the device.

⚠ The (support of the) Control Unit can’t be used as handlebar or support.

⚠ 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.

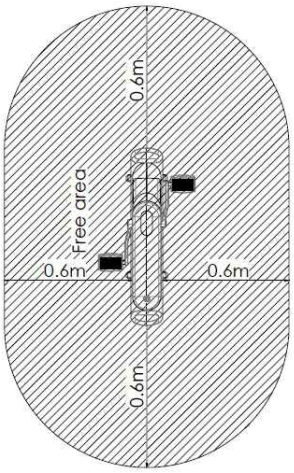
⚠ This device should only be sold by, or under the supervision of authorized persons.

⚠ Take care that the cable of the control unit cannot get stuck between the cranks when using the ergometer.

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.

3.1 - Free area



The free area around the ergometer shall be not less than 0,6 m greater than the training area in the directions from which the equipment is accessed. The free area must also include the area for emergency dismount. Where equipment is positioned adjacent to each other the value of the free area may be shared.

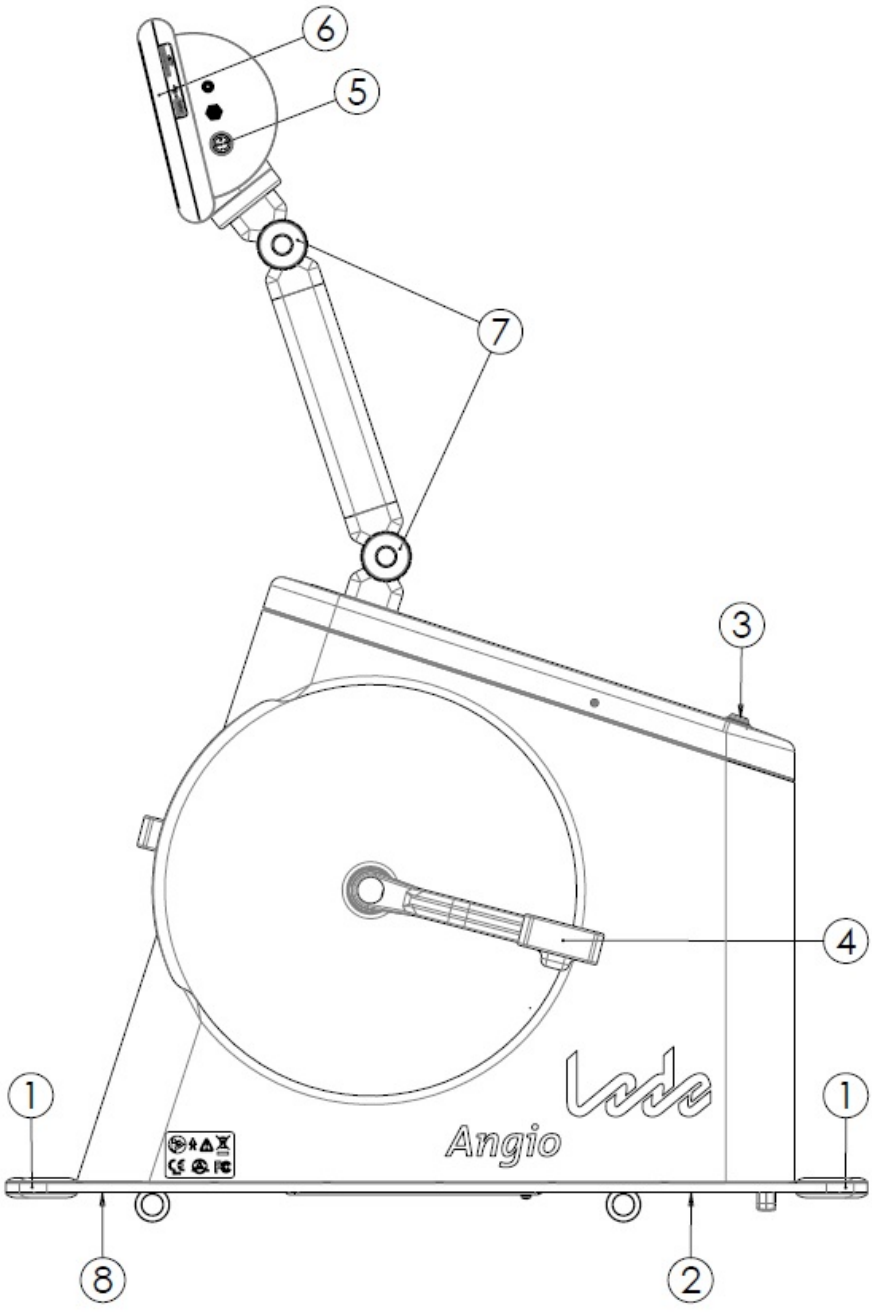
4 - Validity

This manual covers all Angio versions starting with the following serial number:

9679xx Angio cpet: S/N 20170001 -

Date of issue: 2017-01-31

4.1 - Description of parts



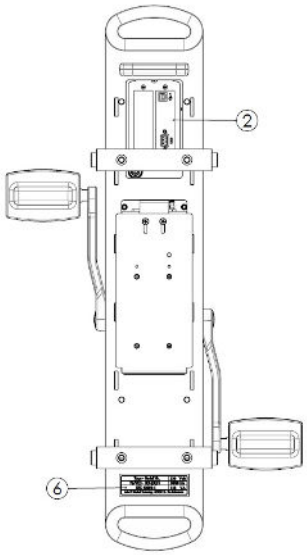
1.Handgrips for transport
2.Communication ports
3.Main On/off switch
4.Hand curble or Pedal (APPLIED PART)
5. Connector - not in use
6.Display
7.Adjustable support control unit (not for arm ergometers)
8.Type plate

Note that if the SpO2 option is included, the sensor is also an APPLIED PART
Note that a USB A-B cable is standard supplied. For rehab products this cable can only be used for service purposes. For cpet products, it can be used for connection to ECG and pulmonary testing devices as well.

Note: check the angle of the display: the patient must be able to have a clear view on the display to see the pedal revolution (rpm).

Note: be aware of hands near the display-arm! Tighten the knobs of the display-arm to prevent dropping.

4.2 - Angio - description of parts bottom side



2 - cable connections
6 - Identification plate

5 - Installation

5.1 - General installation of the device

- Unpack the device while leaving the transport straps in place.
- Place the device in the location where it will be used.
- Remove transport straps and remaining packaging materials.
- Connect the power cord to the line output at the required voltage (see type plate).
- Remove all objects from the device
- Switch on the unit with the on/off button
- Use the on/off button in order to switch the ergometer off.

For a detailed desciption of the installation procedure, we refer to the Installation Instruction available for authorized service personnel.

5.2 - Cable Management

The connection for the power cord and optional connectors for external devices are placed out of sight on the bottom side of the device.

To make sure that connectors are not damaged through pulling them, you need to use the strain relief.

1. Place the ergometer on its side.
2. Remove the strain relief by pushing the arms in the cavity inwards.
3. Lead the wires through the holes in the strain relief as shown in the picture and place it back in the ergometer.
Note. There is place for the thick AC cord in the middle and 2 other thinner cables on the sides.
4. Put the ergometer back in upright position.

6 - Terminal - external control

6.1 - External control with optional communication card

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 Cart.
2. Download the interfacing instructions from the internet at www.lode.nl after you have registered your device.
3. Select “Terminal mode” on the control unit to allow external commands. (See for detailed instructions the user manual of your external device).

6.2 - External control with LEM or LCRM

1. If your device has an optional RS232 or USB port, connect it directly to the PC on which the Lode software is installed. If your device has a RJ45 connector plug connect 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 Software on your PC.

3. Select “Terminal” mode to allow external command. The terminal mode is automatically recognized by LEM and LCRM. (See for detailed instructions the user manual of LEM or LCRM).

6.3 - Display

When your device is executed with a single display in display mode, it will only display data. It is not able to steer the ergometer. It is intended to be used in terminal mode. You can change the settings for communication and language of the device.

To be able to control the ergometer you will need the optional 945834 Control Unit with touch screen 7" for ergometer or 945835 Programmable Control Unit for ergometer.

For the functioning of the display and/or control units, we refer to the manuals M945810, M945834 and M945835 which can be found on the supplied CD with additional information. The most recent version in many other languages can always be downloaded from Lode website.

7 - List of symbols used

Read manufacturer's guide, advises and instructions and manual

Potential Equalization Conductor

CE and notified body

FCC 18 RF ISM tested

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

"ON" position of the on/off switch: IEC 60417-5007 "ON" (power)

"OFF" position of on/off switch: IEC 60417-5008 "OFF" (power)

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

External Input

External Control Connector

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

USB

General warning

8 - Maintenance

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.

9 - Cleaning

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.

⚠ The operator should clean the device (handgrips, cushions) after each exercise test.

⚠ Do not spill any liquid over the device.

10 - Calibration

The ergometer should be calibrated once a year. In case any damage is observed of the ergometer Lode B.V. or his representative should be informed in order to execute the necessary repair(s). Service of the ergometer is restricted to factory-trained personnel only.

11 - Accessories

Control Unit with 7" touch screen for ergometer

Partnumber: 945834

Multifunctionality

Control Unit with Touchscreen

Programmable Control Unit with 7" Touchscreen for ...

Partnumber: 945835

Programmable

Programmable Control Unit

Blood Pressure with ECG trigger for bicycle ergometer

Partnumber: 945828

with ECG trigger

Blood Pressure Measurement with ECG trigger

Heart rate for bicycle ergometers

Partnumber: 945821

Heart rate in beats per minute

Heart rate for bicycle ergometers

SpO2 for control unit with touch panel (bicycle)

Partnumber: 945823

Saturation and heart rate

SpO2 for control unit with touch panel

Pedal shoes (pair)

Partnumber: 917803

Extra stability during cycling

Pedal shoes for foot fixation

Pedal shoes pediatric (pair)

Partnumber: 917833

Pedal shoes for childen

Pedal shoes for children

Adjustable cranks

Partnumber: 928804

Optimal force application

For different leg/arm length

Handgrips (pair)

Partnumber: 917812

Versatile ergometry

Handgrips (pair)

Handgrip fixation set

Partnumber: 917822

Handgrip fixation set

Handgrip fixation set

USB to Serial converter

Partnumber: 226012

Easy connection

USB to Serial converter

12 - Specifications

Workload

Minimum load	7 W
Maximum peak load	1000 W
Minimum load increments	1 W
Maximum continuous load	750 W
Hyperbolic workload control	✓
Linear workload control	✓
Fixed torque workload control	✓
Maximum rpm independent constant load	150 rpm
Minimum rpm independent constant load	30 rpm
Optional heart rate controlled workload	✓
Electromagnetic "eddy current" braking system	✓

Accuracy

Workload accuracy from 7 to 100 W	3 W
Workload accuracy from 100 to 500 W	3 %
Workload accuracy from 500 to 1000 W	5 %

User Interface

Readout Distance	✓
Readout RPM	✓
Readout Heartrate	✓
Readout target HR	✓
Readout Energy	✓
Readout Torque	✓
Readout Time	✓
Readout Power	✓
Set Display	✓
Set Resistance	✓
Set P-Slope	✓
Set Mode	✓
Manual operation mode	✓
Preset protocol operation mode	✓
External control unit	✓
Selfdesigned protocol operation mode	✓

Dimensions

Product weight	40 kg	88.2 lbs

Order info

Power requirements

V AC	100-240 V
Phases	1
Frequency	50/60 Hz
Power consumption	160 W
Power cord IEC 60320 C13 with CEE 7/7 plug	✓
Power cord NEMA	✗

Standards & Safety

IEC 60601-1:2012	✓
ISO 13485:2016 compliant	✓
ISO 9001:2015 compliant	✓

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 - pending	✓

Environmental conditions

Maximum operational temperature	35 °C
Minimum operational temperature	14 °C
Maximum operational air pressure	106 kPa
Minimum operational air pressure	80 kPa
Maximum operational non-condensing humidity	90 %
Minimum operational non-condensing humidity	30 %
Maximum storage & transport temperature	60 °C
Minimum storage & transport temperature	-20 °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 %

Partnumber	967900