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1 - Intended Use

For the intended use and intended users of the device please refer to the manual of the Lode ergometer or treadmill.

2 - Precautions

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

⚠️ Inspect cables and pneumatic hoses for cracks, fraying or kinks and the microphone for signs of bending. DO NOT use if there are any signs of damage. The proper working of the BPM system should be checked on a regular basis (12 month).

⚠️ No clothing is allowed between the cuff and the patient’s arm.

⚠️ The system does not contain any user serviceable parts and should only be serviced by an authorized service representative.

⚠️ An ECG trigger or gating signal is required when taking auscultatory BP measurements on this device. Without this trigger, the module will not provide valid BP data.
Accuracy of any blood pressure measurement may be affected by the position of the subject, his or her physical condition and use outside of the operating instructions detailed in this manual. Interpretation of blood pressure measurements should be made only by a physician or trained medical staff.

The system may not operate correctly if used or stored outside the relevant temperature or humidity ranges described in the Performance specifications.

To obtain accurate blood pressure readings, the cuff must be the correct size, and also be correctly fitted to the patient. Incorrect size or incorrect fitting may result in incorrect readings.

DO NOT attach the cuff to a limb being used for IV infusions as the cuff inflation can block the infusion, which can potentially harm the patient.

This device should not be used when Korotkoff sounds may be altered by other devices or techniques.

If the blood pressure cuff is on the same limb as a pulse oximeter probe, the oxygen saturation results will be altered when the cuff occludes the brachial artery.
3 - Introduction

3.1 - Introduction Blood Pressure Option

With this option it is possible to perform stand alone or external controlled blood pressure measurements.

After installation the Blood Pressure module is recognized automatically at start up of the ergometer, indicated on the startup screen for a few seconds.
3.2 - Special situations and Blood Pressure Measurement

Presence of atrial or ventricular fibrillation, arrhythmias, pacemakers, etc. may interfere with the normal functionality of the BP monitor.

Specifications Heart rate triggered Blood Pressure Measurement:
Measurement: auscultatory, using R-wave gating and k-sound analysis, during all static and active phases of stress testing. Systolic pressures correlate to a K-1 Korotkoff sound. Diastolic pressures correlate to K-5 Korotkoff sound. The device is designed to function in the presence of a normal ECG sinus rhythm. There are some physical conditions (i.e. Bundle Branch Block, Arrhythmias, Atrial Fibrillation, Ventricular Fibrillation, Pacemakers, etc.) that may limit the ability of BP Monitor to obtain an accurate reading.

Notes on Blood Pressure Data:
Any blood pressure reading can be affected by
- the measurement site
- the position of the patient
- exercise
- the patient's physiologic condition

Environmental or operational factors which can affect the performance of the device and/or its blood pressure reading are pacemakers and common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases, patient motion, trembling, and shivering.

⚠️ Do not use on neonates, children, and patients known to be readily susceptible to bruising.
4 - List of symbols used

Connection for Blood Pressure

Connection for air Blood Pressure

Connection Heart Rate trigger for blood pressure measurement

Start Blood Pressure Measurement

Stop Blood Pressure Measurement
5 - Using the Blood Pressure option

5.1 - Connect the Blood Pressure cuff

On the rear side of the Control Unit you will find the connector for the air hose and the connector for the microphone of the blood pressure arm cuff.
5.2 - Connect trigger cable

A heart rate trigger is required to measure blood pressure. This allows the blood pressure module to determine in which time interval the heart rate should be measured when the cuff pressure reduces.

The trigger cable is connected at one end to the control unit next to the other blood pressure connections.

The other side of the cable is connected to the ECG device.

If no ECG device is available, the special Lode heart rate belt can also be connected to receive a Heart Rate trigger..

When used in a Lode Cardiac Rehabilitation setting the trigger can also be provided by the Lode ECG streamer.

Note: without a trigger, a blood pressure measurement is not possible.
5.3 - Display blood pressure data on the screen

When in the menu SELECT DISPLAY OPTIONS of the SETTINGS Blood Pressure is selected to be displayed, you can see the value in the screen.

5.4 - Protocolize blood pressure measurement

When your control unit has the programmable option, you can protocolize the blood pressure measurement. During any stage you can choose to have a blood pressure measurement.
6 - Patient Hook up

Correct patient hook-up is very important. Experience has shown that a lot of troubles can be avoided when the rules below are kept in mind. Especially BP measurement using Korotkoff tones under stress requires accurate preparation.

6.1 - Apply the cuff

On the inside of the upper arm you can feel the brachial artery. Palpate the brachial artery to ensure proper placement. The best place for the microphone is where you can most clearly feel the pulse. Upper clothing should be taken off!

Pulled up garments should not jam the upper arm.

6.2 - Position the cuff

The cuff should be placed on the upper arm, so that it is positioned about 2 cm above the elbow close to the heart level. Place the microphone on the position that you palpated.
6.3 - Mounting the cuff

Caution: Never place the cuff so that the microphone is located in the elbow.
Pull the cuff so tight, that it neither moves nor ties off the arm of the patient. By fasten the cuff too tight or too loose, error measurements are caused.
Wrap the end of the cuff around the upper arm and close the Velcro fastening.

Ensure that the air hose from the monitor to the cuff is not compressed, crimped or damaged. During ergometry the air hose should be handled and attached in such a way, that vibrations and movement artefacts are avoided. Use the ring strap to fix the tubes to the wrist to avoid tensions on the cuff due to moving and pulling tubes.

During the measurement, which starts with inflation, the arm with the cuff should be kept in rest. With ergometry it is most convenient for the patient to take the arm from the handlebar of the ergometer and relax the arm with the cuff.

The intervals of the measurements should not be too short. Intervals of 2 minutes and more result in long pauses between the stenoses, so that venous congestion and artiospasm can be avoided.
7 - Error messages

7.1 - Check microphone

Corrective Action:
- Check that the cuff is in the correct position.
- Check that the microphone is at the correct location on the arm.
- Check that there is no clothing between arm and cuff.
- Check the microphone connectors at the cuff and at the device.
- Replace microphone.

7.2 - Arm movement

Corrective Action:
- The patient's arm may have been moving too much. Instruct patient to relax the arm when the measurement starts and use wrist strap.
- Check that the patient is not clinching hands which cause muscles to become tense.
- Check that the microphone is at the correct location on the arm.
- Replace microphone.

7.3 - BP Values Out of Range

Corrective Action:
- The patient's arm may have been moving too much. Instruct patient to relax the arm when the measurement starts and use wrist strap.
- Check the patient. Patient may have serious BP-related issue.
- Check that the cuff is in the correct position.
- Check that the correct size cuff is being applied.
- Check that there is no clothing between arm and cuff.
7.4 - Check Cuff

Corrective Action:
- The patient's arm may have been moving too much. Instruct patient to relax the arm when the measurement starts and use wrist strap.
- Check that the cuff is properly tightened.
- Check that the cuff and microphone are in the correct position.
- Check that the correct size cuff is being applied.
- Check that there is no clothing between arm and cuff.

7.5 - Check ECG signal

Corrective Action:
- Check that the ECG leads are properly attached to the patient.
- Check that the correct ECG trigger type is setup correctly.
- Check that the trigger source is indeed sending the trigger.
- Check that the ECG trigger wire is connected to the module.

7.6 - Artefact / erratic ECG signal

Corrective Action:
- Check that the ECG leads are properly attached to the patient.
- Check that the correct ECG trigger type is setup correctly.
- Replace ECG leads.

7.7 - Check Cuff

Corrective Action:
- The patient's arm may have been moving too much. Instruct patient to relax the arm when the measurement starts and use wrist strap.
- Check the patient. Patient may have serious BP-related issue.
- Check that the cuff is in the correct position.
- Check that the correct size cuff is being applied.
- Check that there is no clothing between arm and cuff.
7.8 - Check tube for block

Corrective Action:
- Check that the hose has no sharp bends or is pinched.
- Check that the patient is not stepping on or kinking the hose.
- Check that the cuff bladder tubing is not kinked or compressed.

7.9 - User Abort

Corrective Action:
- Check the patient.
- Take another BP reading.

7.10 - Check tube for airleak

Corrective Action:
- Check that the hose is connected to the system and the cuff.
- Check that the cuff is properly tightened.
- Check that the cuff is in the correct position.
- Check that the correct size cuff is being applied.
- Check that the cuff is not leaking air.
- Check that the hose connections are not damaged or loose.

7.11 - Service (11)

Corrective Action:
- Check the patient.
- Check that the cuff is in the correct position.
- The patient's arm may have been moving too much.
- Take another BP reading.
7.12 - Check Cuff and Tube

Corrective Action:
- Check that the correct size cuff is being applied.
- Check that the hose has no sharp bends or is pinched.
- Check that the cuff is in the correct position.
- Check that the patient is not stepping on or kinking the hose.
- Check that the cuff bladder tubing is not kinked or compressed.

7.13 - Service (13)

Corrective Action:
- Check that VPV and Vlogic are within the voltage specifications.
- Check the data/power input connection.
- Service may be required. Call a Lode representative.

7.14 - Service (14)

Corrective Action:
- Check that LK1 jumper is not fitted.
- Make sure proper command was sent to module.
- Service may be required. Call a Lode representative.

7.15 - Service (15)

Corrective Action:
- If possible, perform calibration.
- Service may be required. Call a Lode representative.
7.16 - Service (16)

Corrective Action:
- If possible, perform calibration.
- Service may be required. Call a Lode representative.

7.17 - Arm movement

Corrective Action:
- Check patient arm movement. Instruct patient to relax the arm when the measurement starts and use wrist strap.

7.18 - Muscle tension or check microphone

Corrective action:
- Patient is clinching hand. Instruct patient to relax arm when measurement starts.
- Improper K sound microphone placement
- Defective K sound microphone
8 - Maintenance

8.1 - Annual check

It is recommended that the monitor’s calibration be checked annually. This check should be performed by qualified service personnel.

8.2 - Cleaning and disinfection

Entry- and connection cables, like the air-hose from the cuff should not be sterilized in hot steam or cold gas or plunged in disinfectants.

8.3 - Cleaning the cuff

The following cleaning methods have been applied 20 times to the cuff without any apparent negative effects:

Medical Disinfectant Spray
The cuff may be sprayed with a mild disinfectant solution (e.g. Cidezyme®, ENZOL®, or 10% bleach solution), rinsed with distilled water, and line dry. Ensure that no liquid enters the bladder tubing.

Medical Disinfect Wipe
Use a mild disinfectant wipe (e.g. Sani-Cloth®) and thoroughly wet cuff surface and line dry.

Machine Wash
Remove bladder and K-sound Microphone to machine wash the cuff shell. Machine wash warm (50–140°F, 10–60°C) with a mild detergent and line dry.

8.4 - Cleaning the microphone

The K-sound Microphone can be cleaned using a mild disinfectant wipe (e.g. Sani-Cloth®) and letting the microphone line dry.
# Accessories

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Cuff for measuring blood pressure

Adult Cuff

Microphone set for Cuff

Extra Large Cuff

Pediatric Cuff

Cuff for measuring blood pressure

Cuff for measuring blood pressure

ECG Acquisition trigger set
10 - Specifications

**Accuracy**
- Minimum systolic measurement: 50 mmHg
- Maximum systolic measurement: 250 mmHg
- Minimum diastolic measurement: 20 mmHg
- Maximum diastolic measurement: 150 mmHg

**Connectivity**
- TTL input: 3-5 V
- Pulse length: 45 - 95 ms
- Maximum delay between RS-peak and pulse: 40 ms
- Variances in delay time (jitter): <5 ms

**Order info**

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