

Hardware User's Manual

Basic unit for indirect blood pressure

NIBP



References:

LE5001 (76-0173)

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Limitation of Liability








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1. SYMBOLS TABLE

Recognising the symbols used in the manual will help to understand their meaning:

| DESCRIPTION | SYMBOL |
|--|---|
| Warning about operations that must not be done because they can damage the equipment |  |
| Warning about operations that must be done, otherwise the user can be exposed to a hazard. |  |
| Protection terminal ground connection. |  |
| Warning about a hot surface which temperature may exceed 65°C |  |
| Warning about a metal surface that can supply electrical shock when it's touched. |  |
| Decontamination of equipments prior to disposal at the end of their operative life |  |
| Waste Electrical and Electronic Equipment Directive (WEEE) |  |

2. GOOD LABORATORY PRACTICE

Check all units periodically and after periods of storage to ensure they are still fit for purpose. Investigate all failures which may indicate a need for service or repair.

Good laboratory practice recommends that the unit be periodically serviced to ensure the unit is suitable for purpose. You must follow preventive maintenance instructions. In case equipment has to be serviced you can arrange this through your distributor. Prior to Inspection, Servicing, Repair or Return of Laboratory Equipment the unit must be cleaned and decontaminated.



Decontamination prior to equipment disposal

In use this product may have been in contact with bio hazardous materials and might therefore carry infectious material. Before disposal the unit and accessories should all be thoroughly decontaminated according to your local environmental safety laws.

3. UNPACKING AND EQUIPMENT INSTALLATION



WARNING: Failure to follow the instructions in this section may cause equipment faults or injury to the user.


- A. No special equipment is required for lifting but you should consult your local regulations for safe handling and lifting of the equipment.
- B. Inspect the instrument for any signs of damage caused during transit. If any damage is discovered, do not use the instrument and report the problem to your supplier.
- C. Ensure all transport locks are removed before use. The original packing has been especially designed to protect the instrument during transportation. It is therefore recommended to keep the original carton with its foam parts and accessories box for re-use in case of future shipments. Warranty claims are void if improper packing results in damage during transport.
- D. Place the equipment on a flat surface and leave at least 10 cm of free space between the rear panel of the device and the wall. Never place the equipment in zones with vibration or direct sunlight.
- E. Once the equipment is installed in the final place, the main power switch must be easily accessible.
- F. Only use power cords that have been supplied with the equipment. In case that you have to replace them, the spare ones must have the same specs that the original ones.



- G. Make sure that the AC voltage in the electrical network is the same as the voltage selected in the equipment. **Never connect the equipment to a power outlet with voltage outside these limits.**



WARNING

For electrical safety reasons you only can connect equipment to power outlets provided with earth connections .

This equipment can be used in installations with category II over-voltage according to the General Safety Rules.

The manufacturer accepts no responsibility for improper use of the equipment or the consequences of use other than that for which it has been designed.

PC Control

Some of these instruments are designed to be controlled from a PC. To preserve the integrity of the equipment it is essential that the attached PC itself conforms to basic safety and EMC standards and is set up in accordance with the manufacturers' instructions. If in doubt consult the information that came with your PC. In common with all computer operation the following safety precautions are advised.



- WARNING**
- To reduce the chance of eye strain, set up the PC display with the correct viewing position, free from glare and with appropriate brightness and contrast settings
 - To reduce the chance of physical strain, set up the PC display, keyboard and mouse with correct ergonomic positioning, according to your local safety guidelines.

4. MAINTENANCE



WARNING: Failure to follow the instructions in this section may cause equipment fault.

- **PRESS KEYS SOFTLY** – Lightly pressing the keys is sufficient to activate them.
- Equipments do not require being disinfected, but cleaned for removing urine, faeces and odour. To do so, we recommend using a wet cloth or paper with soap (which has no strong odour). **NEVER USE ABRASIVE PRODUCTS OR DISSOLVENTS.**
- **NEVER** pour water or liquids on the equipment.
- Once you have finished using the equipment turn it off with the main switch. Clean and check the equipment so that it is in optimal condition for its next use.
- The user is only authorised to replace fuses with the specified type when necessary.

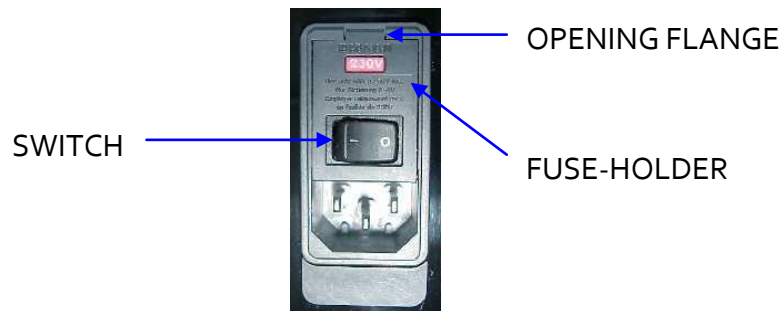


Figure 1. Power inlet, main switch and fuse holder.

FUSE REPLACEMENT

In case of an over-voltage or other incident in the AC net making it impossible to turn on the equipment, check fuses according to the following procedure.

- 1 Remove power cord from the power inlet.

- 2 Open fuse-holder by pulling the flange with a regular screwdriver.



Figure 2. Open fuse-holder door.

- 3 Extract fuse holder using the screwdriver.

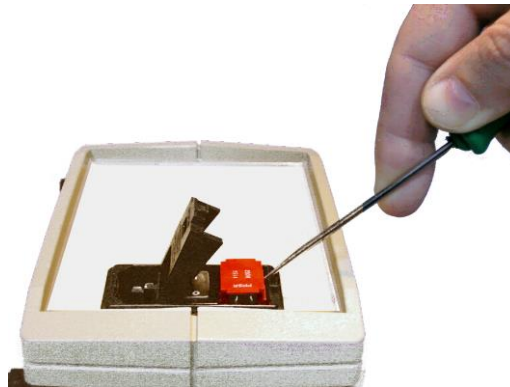


Figure 3. Extract fuse-holder.

- 4 Replace fuses if necessary. Insert fuses in the fuse-holder in the correct position.



CORRECT



INCORRECT

Figure 4. Fuses position.

- 5 Insert again fuse-holder, both possible positions are correct because power supply is universal.
- 6 If the fuses blow again, unplug the equipment and contact technical service.



For electrical safety reasons, never open the equipment. The power supply has dangerous voltage levels.

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6. INTRODUCTION

The LE 5001 is a microprocessor-based instrument, specifically designed to take non-invasive blood pressure readings on experimental animals (mice, rats or dogs).



Figure 5. LE 5001 Non-Invasive Blood Pressure Meter.

The system used for taking measurements is based on the sphygmomanometric technique (used to take pressure in human beings). Thus, the unit features a pressure cuff, whose function is to occlude the passage of blood in the animal's tail, and a transducer, which captures blood pulses. Generally, both are placed on the animal's tail to operate over the caudal artery.

The LE 5001 detects the systolic or maximum pressure (SP) values, diastolic or minimum pressure (DP) values and the mean value, calculated as:

$$MP = DP + 0.33 \cdot (SP + DP)^1$$

Moreover, heart rate (HR) is also picked up by the transducer. Its value is displayed continuously, and then stored along with the corresponding systolic, diastolic and mean pressure values. A measurement is comprised of the blood pulse (heart rate) and systolic and diastolic pressure values.

When using the **Sedacom** software option (to be purchased separately), all measurement data can be sent to a PC using the RS 232 communication.

NOTE: the RS232 communication cable provided with the device is used for connecting the device to any associated software (**Sedacom**, etc.). Even when the device is used without software at first instance, this cable is to be preserved and kept in a secure place in case the need of using the system with a software arises in the future. In this last case, if the user lost the cable, a new one should be purchased to his local sales delegate (ref. CONRS232). The warranty duration of this cable is the same as the warranty duration of the device.

¹ From Ciba Geidy Scientific tables, Ed. C Lenther, 1990

7. EQUIPMENT DESCRIPTION

7.1. CONTROL UNIT FRONT PANEL

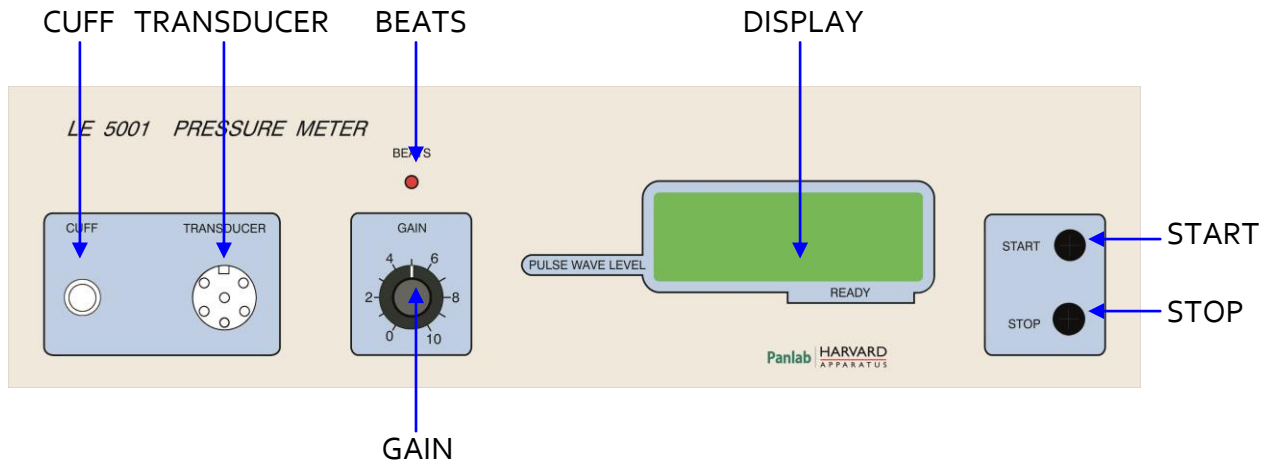


Figure 6. Control Unit Front Panel.

- **CUFF:** Pneumatic connection for the tail cuff. It sends air from the internal pump to the cuff in order to occlude the caudal artery when taking measurements.
- **TRANSDUCER:** DIN 6 connector used to connect pulse transducer.
- **BEATS:** Red coloured led that flashes at the same frequency that the heart beats when the transducer is placed on the animal's tail.
- **GAIN:** Potentiometer used to adjust the signal coming from the transducer.
- **DISPLAY:** 4 row, 20 column display. It is used to display the result of measurements, and several messages depending on the mode the instrument is in.
- **START:** Button used to start the measurement when the signal is appropriate. This button is also used to test the pump in the technical service mode. If there is no signal or the signal level is lower than the necessary level (INSUFFICIENT LEVEL), or if there is too much signal (PULSE LEVEL HIGH) the start button will not act. If the pulse level is correct (PULSE LEVEL READY) the start button will begin taking measurements.
- **STOP:** Button used to cancel a currently-running measurement. It is also used to test the pump in technical service mode to perform a full pump deflation.

7.2. CONTROL UNIT REAR PANEL

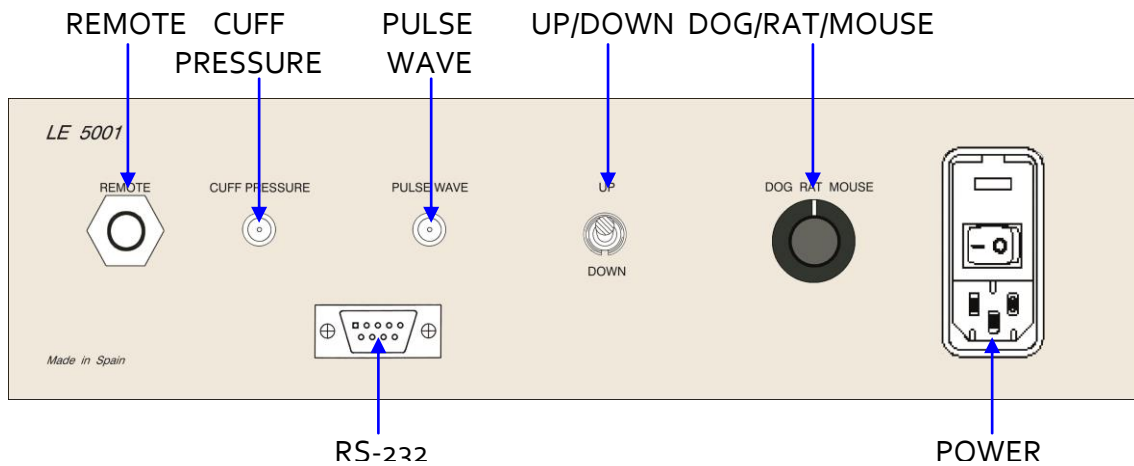


Figure 7. Control unit rear panel.

- **REMOTE:** 6,35mm mono jack plug for foot switch. It has the same function as the START button on the front panel.
- **CUFF PRESSURE:** BNC connector, it is an analog output of the pressure waveform. The physical-electrical conversion is (0V = 0mm Hg, 500mV = 350mm Hg). It can be connected to a data recording system.
- **PULSE WAVE:** BNC connector, it is an analog output of heart pulses. It goes from $\pm 500\text{mV}$. There is not a physical-electrical relationship because GAIN control on the front panel changes the level of signal. It can be connected to a data recorder system.
- **UP/DOWN:** Selector of mode of systolic pressure detection. Results obtained in both modes are different.
 - UP: Systolic pressure is detected when pump inflates. This mode is for DOG.
 - DOWN: Systolic pressure is detected when pump deflates through the exhaust valve. This mode is for RAT and MOUSE.
- **DOG/RAT/MOUSE:** 3-position filter. It selects the window of frequencies that the instrument will detect for different animals.
 - DOG: From 48 BPM to 840 BPM.
 - RAT: From 270 BPM to 960 BPM.
 - MOUSE: From 360 BPM to 1020 BPM.
- **RS-232:** DB9 female connector used to connect LE 5001 to computer serial port. It is used to send data to the SEDACOM software.
- **POWER:** Power switch and fuse holder.

7.3. DISPLAY

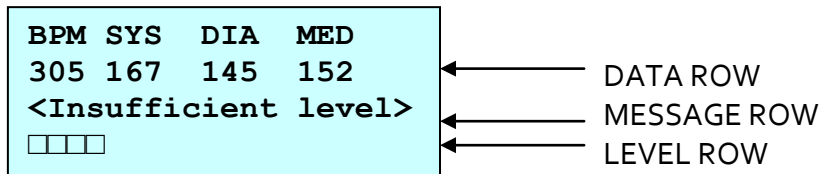


Figure 8. Display.

7.3.1. DATA ROW

The first two rows on the display show experiment data. The upper row contains the labels and the lower one features the numerical values. When an experiment has not been completed and there are no numerical values the display will show ---.

- **BPM:** Animal's heart beat frequency in pulses per minute.
- **SYS:** Systolic pressure.
- **DIA:** Diastolic pressure.
- **MED:** Mean pressure calculated with the formula $MP = DP + 0.33 \cdot (SP + DP)$

7.3.2. MESSAGE ROW

This line shows several messages depending on the instrument's current status. They are listed below:

1. **AUTO CALIBRATION**

The system takes a few seconds to auto calibrate after the instrument is turned on.

2. **PULSE LEVEL READY**

This message is displayed when the pulse level received by the instrument is suitable for carrying out a measurement. If this message is shown, press **START** to initiate the measurement process. Otherwise, if you press the aforementioned button the unit will do nothing and the **GAIN** potentiometer should increase.

3. **INSUFFICIENT LEVEL**

The pulse intensity reaching the instrument is insufficient to take a measurement. The bar row indicating the level will not reach the area marked **READY** on the front panel.

GAIN should be increased by turning the potentiometer clockwise to increase the signal level reaching the instrument until the **Pulse level ready** message appears on the display.

4. Pulse level high

The signal level is too high and the instrument cannot measure (pressing the **START** button has no result). The **GAIN** must be reduced by turning the potentiometer counter clockwise until **Pulse level ready** appears on the display.

5. Measuring

This message will be displayed after pressing **START** and while the measurement is being carried out (the pump is working and pressure increases, once the pulses have disappeared, pressure is slowly released through an exhaust valve until the signal recovers its original level).

6. Deflating

Once measurement has been completed, the air in the pump must be emptied to prepare the instrument for a new measurement. This is done with an electro-valve. This message will be displayed while it remains open.

7. Pressure > 300 mmHg

The pressure has reached 300 mm Hg, but for some reason systolic pressure has not been found. The system will stop the pump and go into a deflation.

8. Diastolic not found

Once a correct measurement of systolic pressure has been taken, the diastolic pressure cannot be taken properly. "---" will appear as the numeric value.

7.3.3. LEVEL ROW

This is a graphic representation of signal level. If the bar does not reach the **READY** area, the message **Insufficient Level** will be displayed.

8. EQUIPMENT CONNECTION

8.1. LE 5001

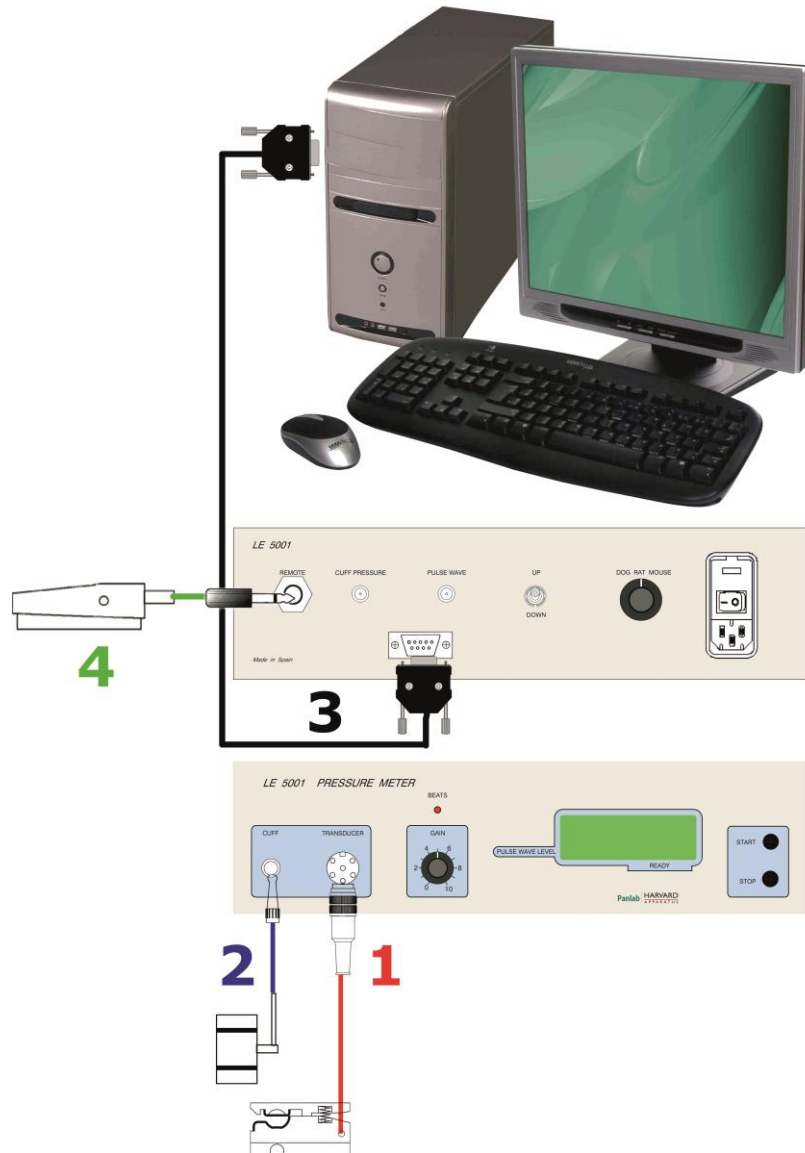


Figure 9. Equipment connections.

The necessary connections are detailed in the next table.

| | FROM | TO | CABLE |
|---|---------------------------|----------------------|------------------|
| 1 | LE 5001 Transducer | Transducer | DIN 6 cable |
| 2 | LE 5001 Cuff ² | Cuff | Silicone pipe |
| 3 | LE 5001 RS-232 | Computer serial port | RS-232 cable |
| 4 | LE 5001 Remote | Foot switch | 6.35mm Mono Jack |

² Pneumatic connection.

8.2. WORKING WITH HEATER AND SCANNER

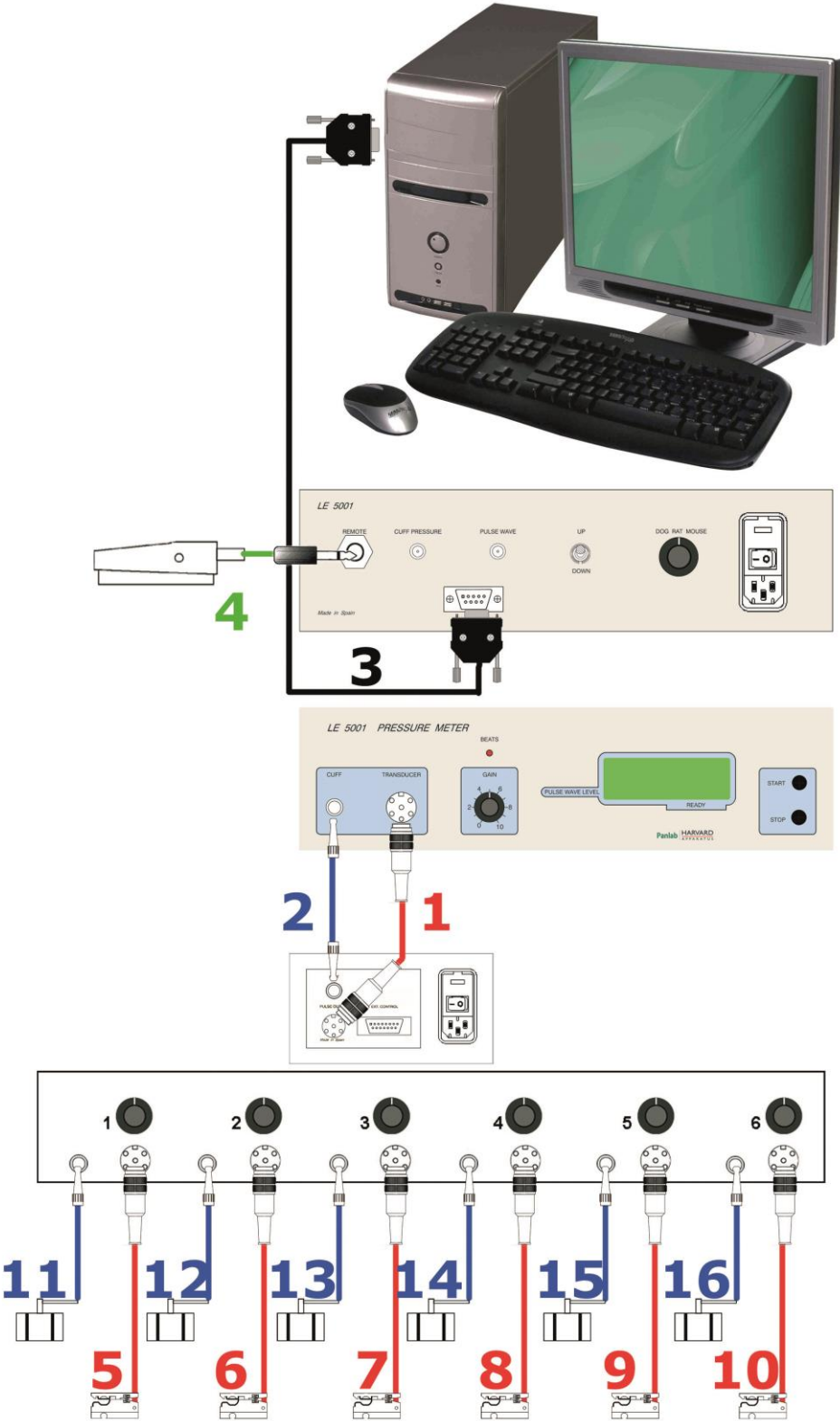


Figure 10. Connection between LE 5001 and LE 5650.

The LE 5001 can be connected to a LE 5650 Heater and Scanner to take manual readings from 6 animals, measuring one after another. The necessary connections are as follows.

| | FROM | TO | CABLE |
|----|-----------------------------|----------------------|----------------------|
| 1 | LE 5001 Transducer | LE 5650 Pulse Output | DIN 6 to DIN 6 cable |
| 2 | LE 5001 Cuff ³ | LE 5650 Cuff | Silicone pipe |
| 3 | LE 5001 RS-232 | Computer serial port | RS-232 cable |
| 4 | LE 5001 Remote | Foot switch | 6.35mm Mono Jack |
| 5 | LE 5650 Transducer 1 | Transducer 1 | DIN 6 cable |
| 6 | LE 5650 Transducer 2 | Transducer 2 | DIN 6 cable |
| 7 | LE 5650 Transducer 3 | Transducer 3 | DIN 6 cable |
| 8 | LE 5650 Transducer 4 | Transducer 4 | DIN 6 cable |
| 9 | LE 5650 Transducer 5 | Transducer 5 | DIN 6 cable |
| 10 | LE 5650 Transducer 6 | Transducer 6 | DIN 6 cable |
| 11 | LE 5650 Cuff 1 ³ | Cuff 1 | Silicone pipe |
| 12 | LE 5650 Cuff 2 ³ | Cuff 2 | Silicone pipe |
| 13 | LE 5650 Cuff 3 ³ | Cuff 3 | Silicone pipe |
| 14 | LE 5650 Cuff 4 ³ | Cuff 4 | Silicone pipe |
| 15 | LE 5650 Cuff 5 ³ | Cuff 5 | Silicone pipe |
| 16 | LE 5650 Cuff 6 ³ | Cuff 6 | Silicone pipe |

³ Pneumatic connection.

8.3. WORKING WITH NIBP CHART USB

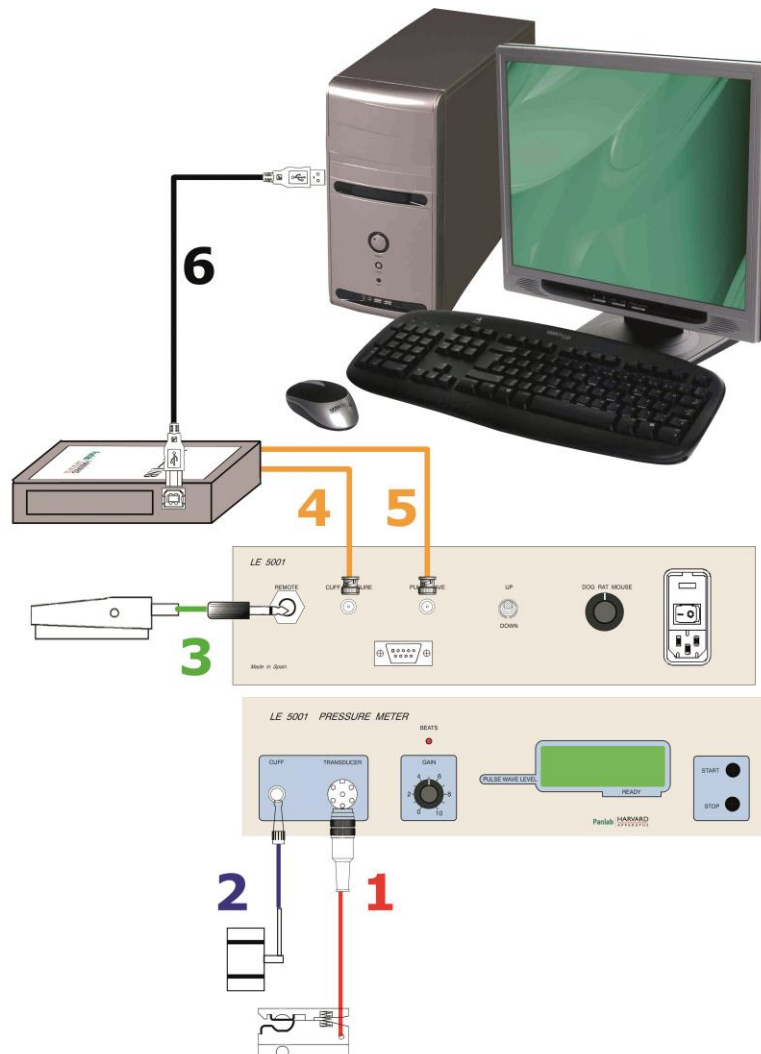


Figure 11. Connection with NIBP Chart.

The necessary connections are detailed in the following table.

| | FROM | TO | CABLE |
|---|---------------------------|-----------------------|------------------|
| 1 | LE 5001 Transducer | Transducer | DIN 6 cable |
| 2 | LE 5001 Cuff ⁴ | Cuff | Silicone pipe |
| 3 | LE 5001 Remote | Foot switch | 6.35mm Mono Jack |
| 4 | NIBP Chart Pressure | LE 5001 Cuff Pressure | BNC cable |
| 5 | NIBP Chart Pulses | LE 5001 Pulses | BNC cable |
| 6 | NIBP Chart USB | Computer USB port | USB cable |

In order to work with the NIBP Chart USB the NIBP Chart software must be installed on the computer. Read the user manual for further information on this software.

⁴ Pneumatic connection.

9. FACTORS TO TAKE INTO ACCOUNT

The technique for carrying out indirect (non-invasive) blood pressure measurements does not offer immediate results. It requires a process of adaptation by the animals, a proper placement of the transducer, a cuff and suitable environmental conditions. Generally, simply placing the transducer and cuff on the animal, making the necessary connections, switching on the instrument and starting to take measurements without any further ado will not offer satisfactory results.

This section proposes a number of recommendations that should be followed by the experimenter.

9.1. ON THE PLACEMENT OF THE PRESSURE CUFF AND PULSE TRANSDUCER

Generally, the position of the pressure cuff and the pulse transducer on the animal tail is not critical.

Normally, the user decides on the most suitable placement in the initial measurement, naturally taking into account the fact that the decision will be guided by a transducer position that makes it possible to obtain the highest pulse signal, and where occlusion is easiest. This should always be done with the animal properly prepared (See Vasodilatation). This manual describes some tips that are for guidance only:

- The animal's tail should be kept clean. This will improve contact between skin, cuff and pulse transducer.
- The cuff-pulse transducer unit can be used either together or separately. There is no need to press the tail excessively with the transducer. The pressure applied by the spring is sufficient to keep it attached to the tail, and also increases its sensitivity.
- To avoid minor tail movements that may cause artefacts, and improve transducer contact at the same time, it should be held using the guide on the accessory plate of the PANLAB traps (ref. LE 5095, in which case it is a good idea to work with the cuff/transducer jointly).
- Place the transducer over the end of the tail, normally 2 or 3 cm from the tip, where the tissue has less muscular mass and pulse sensitivity is greater. Put the cuff on before the transducer, about 2 or 4 cm in front of it. Greater

distances between both devices may give rise to parasitic movements. Obviously, the above measurements are valid for rats, not for mice.

- Due to the characteristic vascular system of the mouse's tail, the diametric position of the transducer may be fundamental to facilitate detection of a pulse.

9.2. ON THE PROPER TREATMENT OF THE ANIMALS AND THEIR ENVIRONMENT

- The room or laboratory where the measurements are to be taken should be free from environmental noises that may affect the animal's tranquillity.
- The animal should be treated and placed in the trap as unaggressively as possible.
- It is advisable to always take measurements at the same time, making sure that the animal has fasted for at least three hours prior to beginning the experiment. This will minimise the effects of faeces.
- It may even be useful to cover the animal's eyes for it to relax more.
- In female animals the menstrual cycle should be taken into account. For males, the increased testicle size due to heat in the enclosed space of the trap should be considered.
- Rodents must undergo a vasodilatation process.

9.3. WHY MUST THE ANIMAL BE VASODILATED?

One basic and IMPORTANT premise must be realised: animals' (particularly rats and mice) blood pressure is a physiological variable that can change very quickly, presenting disparate values that are greatly affected by external stimuli and the animal's state of mind.

If the animal is not in a "normal" (i.e. unstressed) condition when its pressure is taken, the pressure values obtained will not be those expected. It is not like taking blood pressure in human beings. The precautions to be taken to diagnose abnormal stress should be obvious.

A stressed rodent may transmit the muscular tremors produced by anxious breathing to its tail. These tremors will mask the signal of the heart beat to be captured by the transducer, which will probably not pick up the pulsation of the blood due to the occlusion of the cuff. Rather, it will continue to transmit the muscular tremors to the pressure meter, which will lead to an erroneous interpretation by the equipment, since it will behave as if collapse, needed to determine the value of systolic pressure, had not taken place.

Another reason that it is necessary to have a relaxed animal is because the aim is to measure the "baseline" values of its pressure and not stress-induced values, which are always sporadic and much higher.

The fastest and most comfortable way of eliminating animal stress is to vasodilate them by increasing body temperature. Heat in rats/mice produces exactly the same effect as in human beings.

Obviously, relaxation can be achieved with other methods, although they involve great precaution in the handling of the animals which generally render systematic measurements of indirect pressure either impossible or very impractical.

9.4. RECOMMENDED METHODOLOGY

- Heat sources such as infrared lamps, hot plates, etc. may be used for vasodilatation. Nevertheless, with these sources it is sometimes difficult to control the temperature the animal is submitted to; whereas ventilated heaters with thermostats offer greater possibilities (PANLAB offers various such devices in its catalogue).
- IT IS VERY IMPORTANT to bear in mind that if the animal is overheated, as shown by sweating, it will be necessary to wait a considerable time before its pressure can be taken, since it will have been adversely conditioned, giving rise to an anxiety response.
- The whole animal, and not just specific areas such as the tail, should be heated.
- Animals can be preheated in their cages and then placed in the traps, although always without causing any unnecessary trauma, and giving them time to adapt to being unable to move. If the traps are not subject to any other heat source the effect of the vasodilatation will last for some time.
- It is advisable to cover the animal's eyes (dark places are reassuring), although they should be allowed to breathe freely, and any noise that could be an adverse stimulus avoided.
- Heating temperature may vary for animals and even different breeds. The following values are given as guidance only:

RATS: between 29°C and 32°C

MICE: between 30°C and 34°C

Higher values may jeopardise the accomplishment of the objective. Experience has shown us that the best results are obtained by drawing out heating time rather than by increasing the temperature.

The following description outlines a typical protocol that should provide satisfactory results in the measuring processes. Naturally, it is offered as an example only,

meaning that the experimenter can make any changes to the methodology presented they deem necessary depending on their own experience, and apply them to their specific experimental situation.

The following points should be applied when carrying out vasodilatation.

1. Over the first few days –three should be more than enough– the animal should be made accustomed to staying in the trap for thirty minutes with the cuff and the transducer placed as shown. It may be a good idea to carry out a few measuring tests to get the animal used to the pressure the system applies to its tail.
2. Once this period has elapsed, the system will probably take reliable measurements. Thus, after 20 min of vasodilatation measurements can begin. If the measurements are not satisfactory, wait 10 minutes and try again.

Throughout this time, the heart rate should be seen increasing in intensity and stability, and a constant cadence should be seen in the flashing of the BEAT. Progressive movement of the LEVEL bar, and stability of the frequency value, which is more significant, should also be evident.

9.5. ANAESTHETISING THE ANIMALS

The experimenter may also anaesthetise the animals, if there are any doubts regarding the vasodilatation process. In any case, and if vasodilatation is not performed, the temperature around the animals must always be kept at a minimum of 25°C.

Anaesthesia brings in another variable that may substantially modify the animal's vasocirculatory behaviour: different types, forms and dosages of anaesthesia may cause distortions in the measurement of the indirect pressure on the tail. It may even be difficult to ascertain the value.

The hypothermia effect of anaesthesia should also be considered. This reduction in body temperature triggers a fall in the flow of blood circulating through the vessels of the tail. It may therefore be necessary to substantially increase the temperature, which in this case may be done locally (heating the tail only).

Disproportionate heating temperatures do not make measurement easier. Generally, there is a temperature value determined by experimenters' experience, and that depends on the animals, anaesthesia, breed, etc., which is the one most suitable for taking measurements.

The diametric position of the transducer may be important, as the sensor part may coincide with a vessel with high flow that facilitates detection of the pulse. Since anaesthesia also causes a fall in the heart rate, a filter may be necessary for dogs (on the back of the Unit) as the frequency values are close to those of this animal.

10. OPERATING PRINCIPLE

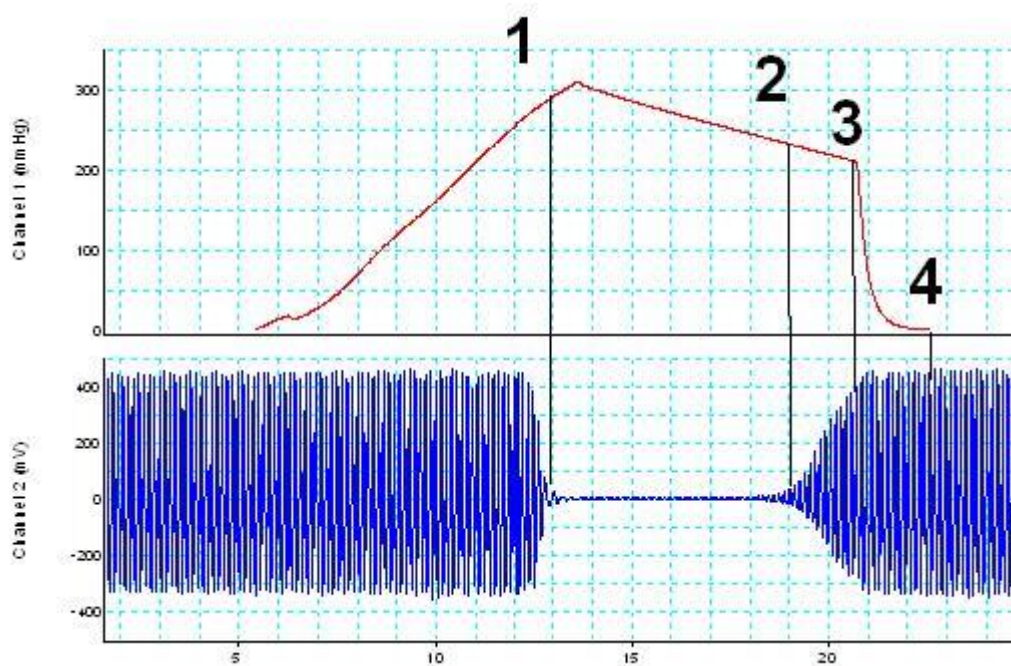


Figure 12. Waveforms in a measurement. Up (pressure) and down (pulses).

Waveforms of Figure 12 have been obtained by connecting CUFF PRESSURE and PULSE WAVE analog outputs to a data logger.

1. As soon as the "START" button is pressed the air pump starts and pressure in the sleeve starts to increase (see Figure 12). As of a certain pressure value, the amplitude of the pulse wave starts to fall and will eventually reach zero (point **1** of the Figure 12). As of this time, and following another brief pressure increase, the latter will start to fall, and the sleeve membrane will deflate. Point **1** is the systolic pressure taken in **UP** mode.
2. The pressure value in the sleeve at the time when the blood pulses reappear (point **2**) is equivalent to the systolic pressure in **DOWN** mode.
3. The pressure in the sleeve continues to fall until it reaches the value of diastolic pressure, which is the pressure value corresponding to the instant when the pulse wave recovers its initial value (point **3**). The air in the sleeve is immediately released until pressure reaches zero, and the instrument is ready to take a new measurement (point **4**).

It may be convenient, particularly when starting with this technique, to see the analog display of the pulse to determine its quality.

Figure 13 shows a pulsation that is unsuitable for taking pressure: it is erratic and unstable, indicating that the animal is still stressed.

Figure 14 shows a correct pulsation.

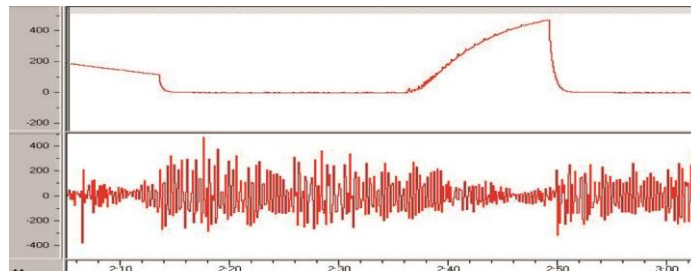


Figure 13. Unsuitable pulse.

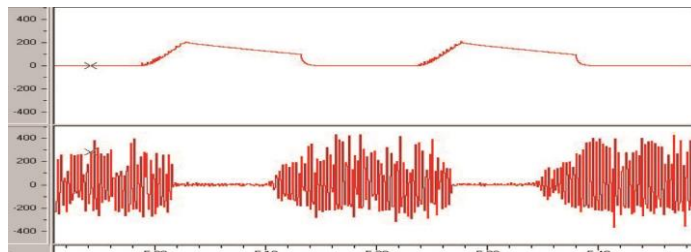


Figure 14. Correct pulses.

The pulse wave (PULSE WAVE plug outlet) and the pressure variation (PRESSURE CUFF) of the cuff can be reproduced on paper with recorders, oscilloscopes or a data capture system such as PowerLab, BioPac or to the NIBP Chart software.

11. STARTING UP THE UNIT

Before taking any measurements, wait 5 minutes to allow the instrument to reach its normal working temperature.

- Connect the cuff to the CUFF plug. Following the direction of the yellow arrow, insert it until it locks into place (indicated with a click). To switch off, push the outside cover in the direction of the arrow until it switches off automatically.

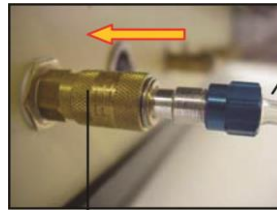


Figure 15. Connecting and disconnecting cuff.

- Connect the pulse transducer to the TRANSDUCER input. **WARNING!** The slot on the male connector must be aligned with the input slot (always above it). To secure the Pulse transducer as an additional safety measure, the front cylinder of the connector should be screwed in to the right to secure its position. To disconnect the transducer, first unscrew said front cylinder to the left. **WARNING** Never unscrew the main connector cylinder body.

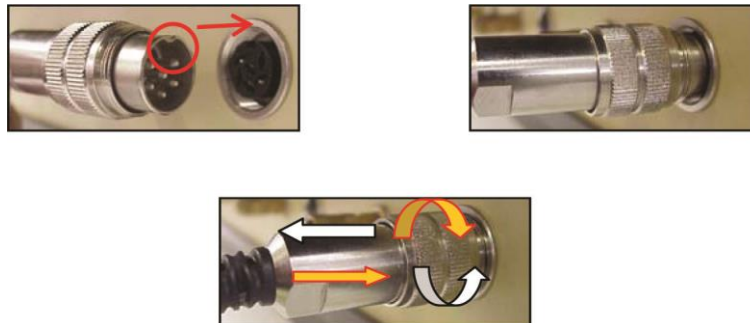


Figure 16. Connecting and disconnecting transducer.

- Fit the cuff and the pulse transducer to the tail of the animal, either together or separately. Check that the transducer presses on the tail lengthwise, i.e., that the tail has the best possible physical contact with the sensor part of the transducer (rubber concavity).

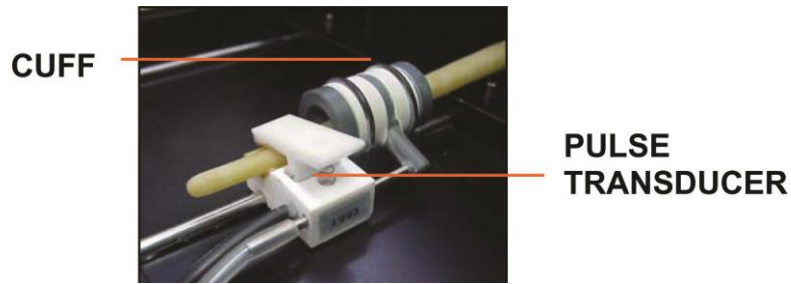


Figure 17. Cuff and transducer placement on the tail.

- Adjust the instrument GAIN until a proper pulse signal level is achieved on the pulse level display, avoiding unnecessary amplification increases. Such increases should be avoided because if the graph were to remain on the outside area it might not inform on the presence of artefacts or important frequency instability (the graph would oscillate). Once the message "(PULSE LEVEL READY)" is shown and the pulse level bar reaches the READY label on the digital display, a proper signal amplification has been achieved. The BEATS LED will flash at each heartbeat, and the current heart rate is shown under the BPM label on the digital display.
- If a scanner is being used, select the animal using the scanner selector. Be sure that a proper pulse level is reached with all animals. If any animal does not reach a proper pulse level, adjust its transducer position until an adequate signal level is achieved, or readjust the GAIN controller.
- Take special care with the stability of the pulse signal level, as the accuracy of the diastolic pressure measurement is strongly dependent on it. Animal movements are also detected by the pulse transducer and would mask the blood pressure signal.
- If the maximum gain is reached without obtaining an adequate and stable pulse level, check the transducer fitting or increase the vasodilatation level.
- Press the START BUTTON, and the measurement procedure will start as indicated in the previous chapter.
- Once the cuff pressure is sufficient to totally occlude the blood flow, the pulse signal disappears, and the pressure keeps increasing slightly until beginning a backward movement. When the pulses reappear, the display will show the systolic pressure value.
 - If the system's pressure reaches 320 mmHg (because the cuff has not collapsed), and the pulse level does not decrease, the message "Pressure 300 mmHg" notifies the user of this and the trial is cancelled (the message "deflating" appears while the inner pressure of the system is being zeroed).

- If the diastolic pressure is not found for any reason, the appliance will also cancel the measurement.
- After a short delay, a valve opens, slowly decreasing the cuff pressure.
- The pressure value (the current value of which is shown under the DIA label on the digital display) will go down until the pulse level reaches its initial level again. At this time, the diastolic pressure is reached, and the current diastolic pressure value will be kept under the DIA label on the digital display. The mean blood pressure is then calculated (as stated in the Introduction to this manual) and its value shown under the MED label on the digital display.
- If a new animal is going to be studied, connect its tail cuff and transducer to the instrument or, if a scanner is available, select the animal number using the scanner selector. Repeat this procedure as of step 7. Alternatively, new trials with the same animal can be performed.

12. SENDING DATA TO A COMPUTER (SEDACOM)

The purchase of the **Sedacom** software is needed for transferring the data to a computer (please contact your local provider for more information). The **Sedacom** software reference is composed by a USB Flash key containing the software Installer, License for use and **Sedacom** User's Manual). Follow next instructions:

- Please refer to the **Sedacom** User's Manual for instructions on how to install and use the software with the present device.
- A serial port (RS232) communication cable (provided with the present device) is needed for connecting the present device to the computer in which the **Sedacom** software is installed. Please refer to the present User's Manual for instructions on how to connect this cable to the device.
- If the computer does not have any serial port, the RS232/USB adapter is needed (ref. CONRS232USB, contact your local provider for more information)

13. CHECKING OPERATION

13.1. PUMP CALIBRATION

The procedure described below is for users to calibrate the pressure value on the display, which corresponds to the pressure in the cuff at all times.

Proceed as follows:

1. Connect a manometer to the CUFF input on the front panel.
2. Open the equipment box so that you can access to the pump, to do this remove the 4 philips screws on the corners of top lid.
3. Remove top lid.
4. Extract the pump.
5. Open the pump by unscrewing the screw marked with a red circle and then remove partially the cover so that you can access to the escaping valve.

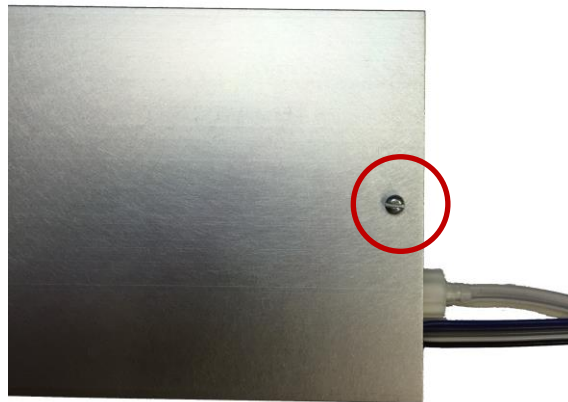


Figure 18. Pump screw.

6. Turn the device on while holding down the STOP button. This sets it in calibration mode. The following message will appear on the display: «**TECHNICAL SERVICE**». Release the STOP button. The last line will show the current internal pressure (in mmHg).
7. Press the START button to activate the air pump and then press it again once a determined pressure value has been reached (e.g. about 200 mmHg). The pressure value will be displayed briefly on the digital display, as it will immediately start to fall when the exhaust valve is opened. To stabilise the reading, you must cover the escaping valve hole with your finger. The escaping valve hole is located inside of the pressure pump (see next figure).

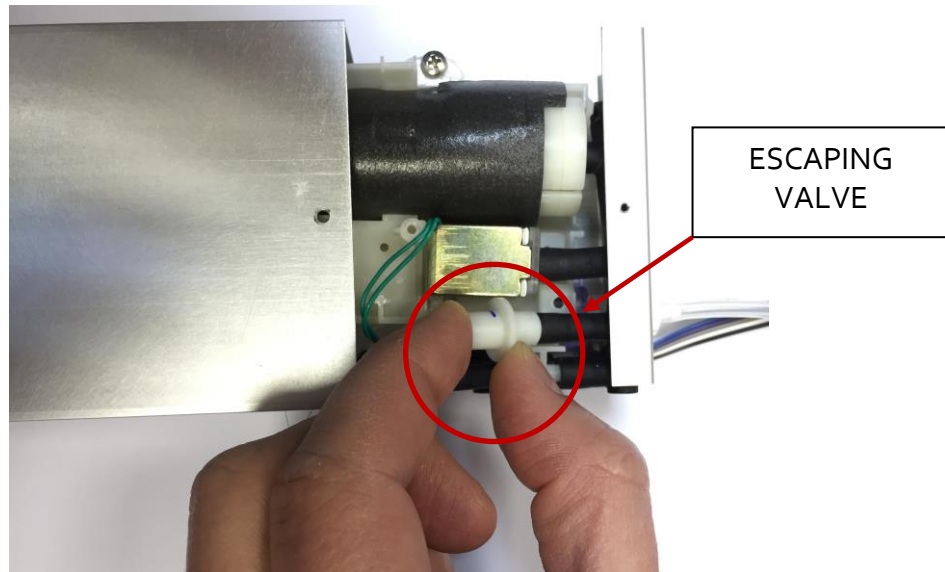


Figure 19. Pump escaping valve.

8. If the difference is greater than 3%, call for technical assistance to solve the problem.
9. Use the “**STOP**” button to release the air inside the system.
10. Once this process is finished, hold the “**STOP**” button down for at least 3 seconds (or switch the apparatus off and back on), and the instrument will be ready.

This calibration procedure need not be performed frequently, only when there is doubt as to pressure values. It can also be used to detect leaks in the pneumatic circuit.

To check the tail cuff, insert a solid element (i.e., a pencil) into it as a substitute for the animal’s tail and repeat the procedure described above. You can thus check for possible leaks in the membrane/cuff set.

13.2. SIMULATING SYSTOLIC PRESSURE

A fast way to manually check if the unit is detecting maximum pressure is to suppress the pulses supplied by the tail transducer using GAIN.

If no results are being obtained when taking measurements on an animal because pressure is above 300 mmHg, check whether it is due to non-occlusion of the blood flow (problems with vasodilatation or the cuff) by manually zeroing the GAIN control during a measurement and while pressure is increasing. This simulates a collapse, and the pressure should start to fall. The unit will return a fictitious systolic pressure

reading, but the “manual” interruption of pulse will have served to check that it is working properly.

Another way of checking without using an animal is to manually press the transducer until the READY level is achieved and then press START. Wait until the pressure increases to a given value and then interrupt the vibrations (pulses) and check that the pressure falls again.

13.3. TRANSDUCER

A transducer in a good state of repair will NOT give pulses (BEAT), when left without vibrations and at maximum gain (GAIN on the right), although the odd intermittent impulse may be observed.

13.4. PROCEDURE TO CLEAN PULSE TRANSDUCERS

To clean the transducers we will use alcohol, talcum powder and a cotton swab. Please follow these instructions to avoid damaging the transducer during the cleaning procedure.



Figure 20. Alcohol and talcum powder.

- 1) Wet the cotton swab with alcohol.



Figure 21. Wet the cotton with alcohol.

- 2) Put the cotton swab parallel to the sensor and brush softly by turning the cotton swab. Never brush the sensor by dragging the cotton over it.

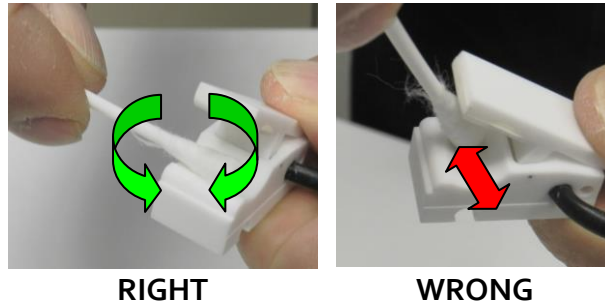


Figure 22. Brush softly the sensor with the cotton.

- 3) Wait until the alcohol has evaporated and apply talcum powder with another cotton swab by rotating softly in parallel position to the sensor again.

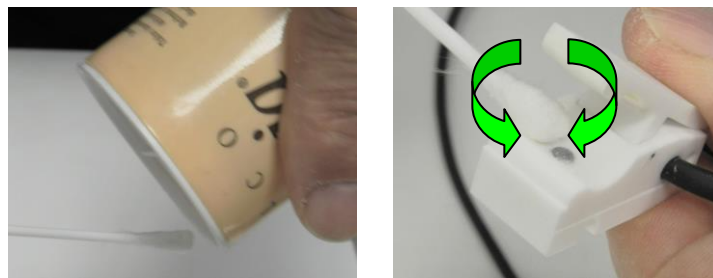


Figure 23. Rotating brush with cotton covered with talcum powder.

13.5. REPLACING THE CUFF MEMBRANE.

Cuff membranes should be checked regularly. Over time, the membranes lose their elasticity and pores appear, leading to pressure losses in the system. When such wear has occurred, they should be replaced. Naturally, the service life of the membranes will depend on how well serviced they are and the number of operations carried out. Generally, they should be changed when the first signs of loss of flexibility or drying are observed. The membrane must be an original PANLAB component. The use of parts made by other manufacturers is not recommended, as there is a major difference in the elasticity of the rubber between different makes, causing unpredictable cuff response.

Proceed as follows to replace cuffs (in this example, for rats):

1. Remove the two cylinder-shaped rings from the cuff ends, as shown in the following figures:

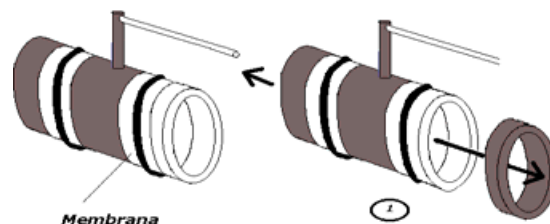


Figure 24. Removing plastic ends.

2. Repeat the operation with the O-rings (black rubber rings) that affix the membrane. Remove the damaged membrane.

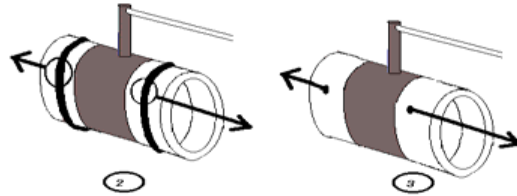


Figure 25. Removing O rings and membrane.

3. Insert the new membrane into the cuff. Make sure that it is not taut to prevent additional strain on the cuff pressure. Spontaneous folds and wrinkles are indicative of good positioning.

In other words, an improper positioning would look like next figure.

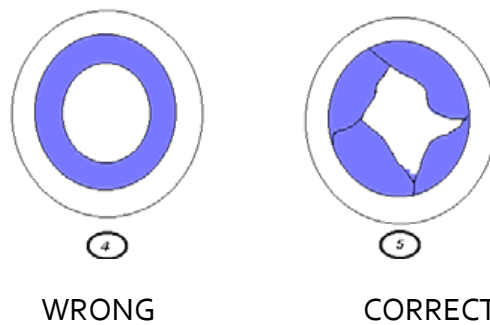


Figure 26. Membrane tension.

4. Fold the edge of one of the two overflowing parts of the membrane, covering the peripheral circumference of the cuff.
5. Fit the O-ring to the cuff to secure the end of the membrane.
6. Repeat point 4 with the other end, making sure that the membrane walls are not taut.
7. Fit the other O-ring and close the ends with the rings.

The procedure for replacing the membrane of cuffs for mice is very straightforward, as in these cases the membrane must be taught and well-adjusted.

13.6. CUFF AND TRANSDUCER MAINTENANCE

It is VERY IMPORTANT to keep the membranes dusted with talcum powder at all times. It prevents them from hardening and cracking.

Moreover, do not over-inflate the cuffs when not on the animal's tail as they may easily explode. Rubber transducer parts should also be kept dusted with talcum powder if the unit is not expected to be used for an extended period.

13.7. CLEANING THE RESTRAINER



WARNING: In order to clean the restrainer never use alcohol nor alcoholic derived products, otherwise stripes will appear in the transparent plastic.

To clean the restrainer you can use a lightly wet cloth and then dry it with a dry cloth. If it's too dirty you can wet the cloth with a soapy solution, then remove foam with a wet cloth and finally dry it with a dry cloth.

14. TROUBLESHOOTING

This table features instructions to solve the most frequent problems.

| PROBLEM | SOLUTION |
|--|--|
| The pulse transducer gives off signals (sometimes erratic, regular) without the animal connected (the BEAT light flashes erratically). | <ul style="list-style-type: none"> The transducer is damaged. It must be replaced. |
| The sign signal cannot be adjusted and the "Insufficient Pulse Level" signal stays on all the time. | <ul style="list-style-type: none"> Check that the transducer is properly fitted to the tail of the animal. The pulse signal (given by the animal) is insufficient; increase the level of vasodilatation. |
| Pressure increases to the maximum (330mmHg) but systolic pressure is not detected. | <ul style="list-style-type: none"> Collapse did not take place because the animal is nervous. Check vasodilatation. |
| Pressure does not increase (the air pump definitely works). | <ul style="list-style-type: none"> There is a filtration or leak somewhere in the pneumatic circuit. Try to check the circuit by sections. If the filtration or leak is in the expansion of the cylinder, replace the whole pump. The CUFF membrane is perforated. |
| Pressure does not increase; the air pump does not work. | <ul style="list-style-type: none"> The whole cylinder must be replaced. |
| When you press START button the pump does not work. | <ul style="list-style-type: none"> The pump only will work if the signal level is correct and the message "Pulse Level Ready" appears in the display. Neither if the messages "Insufficient Level" nor "Pulse Level High" are displayed the pump will work. |

15. PREVENTIVE MAINTENANCE

| | EXPERIMENT | WHEN NECESSARY |
|--------------------------------------|-------------------------------------|-------------------------------------|
| CLEANING THE TRANSDUCER | <input checked="" type="checkbox"/> | |
| CLEANING THE CUFF | <input checked="" type="checkbox"/> | |
| CLEANING THE RESTRAINER ⁵ | <input checked="" type="checkbox"/> | |
| REPLACE CUFF MEMBRANE | | <input checked="" type="checkbox"/> |
| RESET THE GAIN | <input checked="" type="checkbox"/> | |
| CHECK CABLES CONNECTION | <input checked="" type="checkbox"/> | |

⁵ Just in case you are using restrainer.

16. TECHNICAL SPECIFICATIONS

| | |
|--|--|
| <p>POWER SUPPLY Input voltage: Frequency: Fuse: Maximum Power: Conducted Noise:</p> | <p>Universal 100-240 V~ 50/60 Hz 2 fuses 5mm*20mm 2A 250V Fast 18 W EN55011 /CISPR11 class B</p> |
| <p>PULSE SENSOR Feeding voltage: Resolution: Range dog: Range rat: Range mouse: Total error:</p> | <p>5VDC 1 BPM (Pulses per minute) From 48 BPM to 840 BPM. From 270 BPM to 960 BPM. From 360 BPM to 1020 BPM. +/- 2 BPM o +/-0.5% of reading</p> |
| <p>PRESSURE SENSOR Resolution: Range: Maximum over pressure: Total error linearity, sensitivity and hysteresis at 25°C: Precision:</p> | <p>1mmHg -50 a +300 mmHg -400 a +4000 mmHg +/- 2% reading or 1mmHg (the highest) +/- 3% reading or 1mmHg (the highest)</p> |
| <p>ENVIRONMENTAL CONDITIONS Operating temperature: Operating relative humidity: Storage temperature:</p> | <p>10°C to +40°C 0% to 85% RH, non-condensing 0°C to +50°C, non-condensing</p> |
| <p>COMUNICATIONS OUTPUT Standard Interface: Connector:</p> | <p>RS232C Delta 9 contacts female connector</p> |
| <p>DIMENSIONS Width x Height x Depth: Weight:</p> | <p>340 mm x 110 mm x 340 mm 5.44 kg</p> |

DECLARACIÓN DE CONFORMIDAD
DECLARATION OF CONFORMITY
DECLARATION DE CONFORMITÉ

| | |
|---|--|
| Nombre del fabricante: Manufacturer's name: Nom du fabricant: | Panlab s.l.u. www.panlab.com info@panlab.com |
| Dirección del fabricante: Manufacturer's address: Adresse du fabricant: | Energía, 112 08940 Cornellà de Llobregat Barcelona SPAIN |
| Declara bajo su responsabilidad que el producto: Declares under his responsibility that the product: Déclare sous sa responsabilité que le produit: | NON INVASIVE BLOOD PRESSURE METER |
| Marca / Brand / Marque: | PANLAB |
| Modelo / Model / Modèle: | LE 5001 |

Cumple los requisitos esenciales establecidos por la Unión Europea en las directivas siguientes:
Fulfills the essential requirements established by The European Union in the following directives:
Remplit les exigences essentielles établies pour l'Union Européenne selon les directives suivantes:

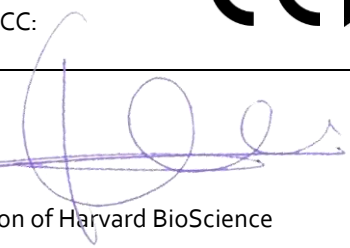
| | |
|--------------------|--|
| 2006/95/EC | Directiva de baja tensión / Low Voltage / Basse tension |
| 2004/108/EC | Directiva EMC / EMC Directive / Directive CEM |
| 2012/19/EU | La Directiva de Residuos de Aparatos Eléctricos y Electrónicos (WEEE) / The Waste Electrical and Electronic Equipment Directive (WEEE) / Les déchets d'équipements électriques et électroniques (WEEE) |
| 2011/65/EU | Restricción de ciertas Sustancias Peligrosas en aparatos eléctricos y electrónicos (ROHS) / Restriction of the use of certain Hazardous Substances in electrical and electronic equipment (ROHS) / Restriction de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques (ROHS) |
| 2006/42/EC | Directiva mecánica / Machinery directive / Directive mécanique |

Para su evaluación se han aplicado las normas armonizadas siguientes:
For its evaluation, the following harmonized standards were applied:
Pour son évaluation, nous avons appliqué les normes harmonisées suivantes:

| | |
|--------------------------------|-------------------------------|
| Seguridad / Safety / Sécurité: | EN61010-1:2011 |
| EMC: | EN61326-1:2012 Class B |
| FCC: | FCC47CFR15B Class B |
| Safety of machinery: | EN ISO 12100:2010 |

En consecuencia, este producto puede incorporar el marcado CE y FCC:
Consequently, this product can incorporate the CE marking and FCC:
En conséquence, ce produit peut incorporer le marquage CE et FCC:



| | |
|--|--|
| En representación del fabricante: Manufacturer's representative: En représentation du fabricant: |  Carme Canalís General Manager Panlab s.l.u., a division of Harvard BioScience |
| Cornellà de Llobregat, Spain 21/10/2014 | |

(GB) Note on environmental protection:



After the implementation of the European Directive 2002/96/EU in the national legal system, the following applies:

Electrical and electronic devices may not be disposed of with domestic waste. Consumers are obliged by law to return electrical and electronic devices at the end of their service lives to the public collecting points set up for this purpose or point of sale. Details to this are defined by the national law of the respective country. This symbol on the product, the instruction manual or the package indicates that a product is subject to these regulations. By recycling, reusing the materials or other forms of utilising old devices, you are making an important contribution to protecting our environment.

(E) Nota sobre la protección medioambiental:



Después de la puesta en marcha de la directiva Europea 2002/96/EU en el sistema legislativo nacional, se aplicará lo siguiente:

Los aparatos eléctricos y electrónicos, así como pilas y baterías, no se deben tirar a la basura doméstica. El usuario está legalmente obligado a llevar los aparatos eléctricos y electrónicos, así como pilas y baterías, al final de su vida útil a los puntos de recogida municipales o devolverlos al lugar donde los adquirió. Los detalles quedaran definidos por la ley de cada país. El símbolo en el producto, en las instrucciones de uso o en el embalaje hace referencia a ello. Gracias al reciclaje, a la reutilización de materiales i a otras formas de reciclaje de aparatos usados, usted contribuirá de forma importante a la protección de nuestro medio ambiente.

(F) Remarques concernant la protection de l'environnement :



Conformément à la directive européenne 2002/96/CE, et afin d'atteindre un certain nombre d'objectifs en matière de protection de l'environnement, les règles suivantes doivent être appliquées.

Elles concernent les déchets d'équipement électriques et électroniques. Le pictogramme "picto" présent sur le produit, son manuel d'utilisation ou son emballage indique que le produit est soumis à cette réglementation. Le consommateur doit retourner le produit usager aux points de collecte prévus à cet effet. Il peut aussi le remettre à un revendeur. En permettant enfin le recyclage des produits, le consommateur contribuera à la protection de notre environnement. C'est un acte écologique.

(D) Hinweis zum Umweltschutz:



Ab dem Zeitpunkt der Umsetzung der europäischen Richtlinie 2002/96/EU in nationales Recht gilt folgendes:

Elektrische und elektronische Geräte dürfen nicht mit dem Hausmüll entsorgt werden. Der Verbraucher ist gesetzlich verpflichtet, elektrische und elektronische Geräte am Ende ihrer Lebensdauer an den dafür eingerichteten, öffentlichen Sammelstellen oder an die Verkaufsstelle zurückzugeben. Einzelheiten dazu regelt das jeweilige Landesrecht. Das Symbol auf dem Produkt, der Gebrauchsanleitung oder der Verpackung weist auf diese Bestimmungen hin. Mit der Wiederverwertung, der stofflichen Verwertung oder anderer Formen der Verwertung von Altgeräten leisten Sie einen wichtigen Beitrag zum Schutz unserer Umwelt.

(I) Informazioni per protezione ambientale:



Dopo l'implementazione della Direttiva Europea 2002/96/EU nel sistema legale nazionale, ci sono le seguenti applicazioni:

I dispositivi elettrici ed elettronici non devono essere considerati rifiuti domestici. I consumatori sono obbligati dalla legge a restituire i dispositivi elettrici ed elettronici alla fine della loro vita utile ai punti di raccolta collerici preposti per questo scopo o nei punti vendita. Dettagli di quanto riportato sono definiti dalle leggi nazionali di ogni stato. Questo simbolo sul prodotto, sul manuale d'istruzioni o sull'imballo indicano che questo prodotto è soggetto a queste regole. Dal riciclo, e re-utilizzo del material o altre forme di utilizzo di dispositivi obsoleti, voi renderete un importante contributo alla protezione dell'ambiente.

(P) Nota em Protecção Ambiental:



Após a implementação da directiva comunitária 2002/96/EU no sistema legal nacional, o seguinte aplica-se:

Todos os aparelhos eléctricos e electrónicos não podem ser despejados juntamente com o lixo doméstico. Consumidores estão obrigados por lei a colocar os aparelhos eléctricos e electrónicos sem uso em locais públicos específicos para este efeito ou no ponto de venda. Os detalhes para este processo são definidos por lei pelos respectivos países. Este símbolo no produto, o manual de instruções ou a embalagem indicam que o produto está sujeito a estes regulamentos. Reciclando, reutilizando os materiais dos seus velhos aparelhos, esta a fazer uma enorme contribuição para a protecção do ambiente.