



General Medical Equipment and Medical Equipment Maintenance Laboratory tasks

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Pulse Oximetry and Oxygen Saturation (SpO₂)

Aim of the lecture:

- To learn the principle of SpO₂ measurement and to become familiar with the measurement process
- To learn how to verify the accuracy of different types of pulse oximeters and to determine, if the accuracy of the device is in accordance with the accuracy values given by the manufacturer or the given standard
- To be able to define the causes of possible artifacts and know the conditions for correct measurements in different situations and for different types of patients

Introductory questions:

Please, answer the questions in the beginning of the laboratory task.

- What devices are used to measure SpO₂ and what is their principle? What are the physiological values of SpO₂?
- What are the factors that might affect the accuracy of SpO₂ measurements? Please, list at least three of them.
- How external environmental factors such as altitude or temperature affect the measured SpO₂ values?

Tasks and measurements:

Use the CONTEC pulse oximetry simulator to verify the measurement accuracy of the available pulse oximeters (Edan M10 and CONTEC CMS 60-C or any other) and vital signs monitor measuring peripheral blood oxygen saturation (SpO₂). When connecting the SpO₂ simulator finger to the oximeters, ensure that the LEDs and photosensitive elements on the finger and oximeter are correctly positioned relative to each other.

- For each device, simulate at least three blood oxygen saturation values at a minimum of three heart rate values for each saturation value (It means that minimum of the measured values is 9 for each tested device).
- Observe the deviations of the measured values from the actual values. Compare each instrument with each other.
- Test the alarms of each instrument. Decide whether the alarms are triggered in accordance with the data provided by the manufacturer in the device manual.
- Attach the sensor to a volunteer; simulate motion artifacts and interference caused by ambient light entering the sensor when the sensor clip is not properly closed. Try to simulate more artifacts (if it is possible) according to the list with tips for proper and correct measurement procedure. For this list, please see chapter “Principles for proper SpO₂ measurements” below or see the user manual for the Edan H10 finger oximeter on the pages 27–33.
- Decide if each device is accurate enough compared to the values in the manuals of the manufacturers. Based on your decision, is it possible to use these pulse oximeters for measuring of the blood pressure of real patients?

Additional questions, answer them in the laboratory protocol:

- What is the normal range for oxygen saturation in a healthy individual at sea level?
- What are some common limitations or sources of error in pulse oximetry measurements?
- How might factors such as poor peripheral perfusion or nail polish affect the accuracy of pulse oximetry readings?

Principles for proper SpO₂ measurements:

Motion Artifacts: Movement during measurements can lead to inaccurate readings. Advise the patient to remain still during the measurement for the optimal results.

Poor Peripheral Perfusion: In cases of poor blood flow to the extremities (fingers or toes), readings may be less accurate. Ensure proper placement and consider alternative places for measurement. Also, conditions that result in low blood flow, such as shock or hypotension, may lead to inaccurate readings. Consider alternative methods or seek professional medical advice in such situations.

Nail Polish and Artificial Nails: Dark nail polish or artificial nails can interfere with the pulse oximeter's ability to transmit light, affecting the accuracy of readings. Recommend removing nail polish or choosing a different part of the body for the SpO₂ measurements.

Cold Extremities: Low temperatures can reduce blood flow to the extremities, potentially affecting measurements. Warm the fingers or toes if they are cold before taking readings.

Skin Pigmentation: Dark skin pigmentation may affect the accuracy of pulse oximetry readings. Be aware of potential limitations and measurement inaccuracy in patients with darker skin tones.

Ambient Light: Strong ambient light, such as sunlight, can interfere with the pulse oximeter's sensors. Ensure measurements are taken in a well-lit but controlled environment. Also, modern LED ceiling lights can significantly reduce measurement accuracy because the wavelength of these lights can interfere with the light source of the pulse oximeter on the specific wavelengths used.

Sensor Fit: Ensure the pulse oximeter sensor is properly fitted on the patient's finger or chosen part of the body. A loose or overly tight fit can affect the accuracy of measurement.

Conditions Affecting Hemoglobin: Certain medical conditions, such as carbon monoxide poisoning or methemoglobinemia, can affect the accuracy of pulse oximetry. Be aware of these conditions and their potential impact on measurement.

Altitude: Pulse oximetry measurement may be affected at high altitudes due to lower oxygen levels. Consider adjusting for altitude if necessary.

References:

- CONTEC CMS 60-C User's Manual
- CONTEC MS 100: SpO₂, Pulse Rate and Blood Oxygen Simulator User's Manual
- EDAN M10: Finger Pulse Oximeter User's Manual

Non-invasive Blood Pressure (NIBP) Monitoring

Aim of the lecture:

- To understand the principles and physical background of different types of NIBP measurements and to become familiar with the measurement process
- To learn how to correctly perform a non-invasive blood pressure measurement examination

Introductory questions:

Please, answer the questions in the beginning of the laboratory task.

- What are the main two methods of non-invasive blood pressure measurements?
- What is the Type A measurement uncertainty? How it can be calculated? Describe the steps from which Type A uncertainty is constructed.

Tasks and measurements:

1. Measure blood pressure on a volunteer using both main methods. For each method do at least 3 measurements. For proper and correct measurement procedure, please see chapter “Principles for proper non-invasive blood pressure measurements” below.
 - a. Auscultation method aneroid and pseudo-mercury (mercury-free digital auscultation) tonometers



Aneroid tonometer



Pseudo-mercury tonometer

- When measuring using the auscultation method, use a cuff with a balloon and a stethoscope.
- Put the cuff on the non-dominant hand.
- The person performing the examination presses the cuff while listening with the stethoscope. The examined person follows the principles for proper measurement, which are written below.
- Place the stethoscope in the elbow socket. Pressurize the cuff to a minimum of 180 mmHg.
- When the pressure is continuously and slowly released, the sound of blood flowing through the arteries will be heard in the stethoscope. These sounds are called Korotkoff sounds.
- The pressure at the first sound is systolic, the diastolic pressure is in the cuff when the last echo is heard.

b. Oscillometric method (Rossmax X3 and Omron HEM-907)

- Put the cuff on the non-dominant hand.
- Turn on the automated tonometer.
- Perform the measurement by pressing the start button.
- The examined person follows the principles for proper measurement, which are written below.

2. Perform the same measurements with several activities and settings that will affect the accuracy of the measurement. Compare the results with your first measurements taken in accordance with principles for proper non-invasive blood pressure measurements.

a. Test the effect of a body position on the measured blood pressure. Take the blood pressure measurement while standing and compare with the results in point 1.

b. Test the effect of body movement on the measured blood pressure. When measuring your blood pressure, move (shake) the arm on which the cuff is fitted.

3. Perform the blood pressure measurement with the wrist tonometer ROSSMAX BQ705. Take a measurement with this tonometer, once with the arm above the head, the second time with the arm along the body. Can a blood pressure measurement error occur if the subject raises their arm above their head? If so, determine approximately how big the error could be.

Additional questions, answer them in the laboratory protocol:

- What is the physiological blood pressure?
- What type of the pressure is measured during the oscillometric method? What blood pressure values are calculated from this measurement?

- How the blood pressure measured by auscultation method would be affected if the cuff were deflated too quickly? Draw the graph of such a measurement.

Principles for proper non-invasive blood pressure measurements:

When measuring non-invasive blood pressure, it is important to follow several basic rules and procedures so that the measured values are as accurate as possible. Here are some tips to watch out for:

Correct cuff size: Use a cuff that is appropriate for the size of the patient's arm. A cuff that is too small can give incorrect results, while a cuff that is too large can lead to underestimation of values.

Correct cuff placement: Place the cuff on the arm so that it is at the level of the heart. Improper placement may affect results.

Correct stethoscope placement: Make sure that you have placed the stethoscope in the right place. This place is located on the inside of the elbow joint. The bell of the stethoscope should fit firmly and with its entire surface to this place.

Loose clothing: Make sure the patient has loose clothing on the upper body, especially on the arm where the cuff is placed.

Calm and well-being: The patient should be calm and relaxed. The measurement should take place in a quiet environment without disturbing factors.

Improper leg position: The patient should be sitting with the support on the back, the feet should be placed evenly on the floor and the arm should be resting on the table or the support.

Do not cross the legs: The patient should not cross his legs during the measurement, as this may affect blood circulation.

When repeating measurements: If you are making repeated measurements, keep in mind that the pressure may vary during the day.

References:

- ROSSMAX BQ705 User's Manual
- ROSSMAX X3 User's Manual
- OMRON HEM-907 User's Manual
- CONTEC NIBP Simulator User's Manual

Electrocardiography (ECG)

Aim of the lecture:

- To understand the principle of measuring the electrical activity of the heart using an ECG simulator and measurements on a selected volunteer
- To demonstrate the entire process of measuring the electrical activity of the heart on a selected volunteer
- To measure heart rate variability on a selected volunteer and to become familiar with the events and conditions that can cause artifacts in the ECG signal

Introductory questions:

Please, answer the questions in the beginning of the laboratory task.

- What is a voltage follower (buffer amplifier) and what specific function does it perform when connected in an electrical circuit for ECG signal processing? What other steps are used in ECG signal processing (list at least 2)?
- What is an international standard? Why it is appropriate to follow the requirements of such standards?

Tasks and measurements:

1. Using the ECG simulator, simulate the patient's cardiac activity on a diagnostic ECG.

- a. Test the device alarms when the upper and lower set HR limits are exceeded.
 - b. Test the device alarms for ventricular fibrillation.
2. Using the ECG simulator, simulate the patient's cardiac activity with artifacts on a diagnostic ECG.
 - a. Set an ECG signal with the 50 Hz noise on the simulator. Try to turn on and turn off the proper filter on diagnostic ECG to see the effectivity of the filter.
 - b. Do the same for the respiratory artifacts and muscle (EMG) artifacts.
3. Connect a volunteer to the device and record the ECG waveform from the limb leads (don't forget to ensure good contact between the skin and the leads). Turn off all filters on the electrocardiograph. Simulate common artifacts and signal interference as described below:
 - a. Route the cables leading from the measuring electrodes close to the electrical source so that signal interference occurs.
 - b. Take several deep breaths in and out and observe the movement of the isoline. Where does the isoline move when you exhale and why?
 - c. Simulate EMG artifacts by isometrically pushing the arm against an obstacle (table, wall).
 - d. Try adjusting the filters on the electrocardiograph to filter out any of the above artifacts or signal interference.
4. After setting the filters, record the resting ECG of the volunteer and print the ECG recording (to print, use the function "freeze"). For proper measurement of the ECG signal, please see the chapter called "Principles for proper ECG measurements" below.
5. Determine graphically the angle of the cardiac axis and compare with the angle determined by the instrument.

Additional questions, answer them in the laboratory protocol:

- What procedure would you take to identify and solve lead problems, such as high resistance or imperfect connection of the leads, during an ECG measurement?
- What errors can occur when the leads are switched during recording an ECG and how can this affect the interpretation of cardiac activity?

Principles for proper ECG measurements:

When measuring an ECG, it is important to follow several basic rules and procedures so that the measured values are as accurate as possible. Here are some tips to watch out for:

Electrode Placement: Incorrect electrode placement can lead to distorted waveforms and inaccurate readings. Follow standardized placement guidelines, and ensure the skin is clean and free from lotions or oils that may interfere with electrode-skin contact.

Patient Movement: Any movement by the patient during the EKG recording can introduce artifacts and affect the accuracy of the results. Advise the patient to remain as still as possible during the procedure.

Muscle Tremors: Muscle tremors, especially in elderly or anxious patients, can distort EKG waveforms. Ensure a calm environment and consider the use of straps or restraints if necessary.

Baseline Interference: Baseline noise, often caused by poor skin preparation or electrode contact, can obscure the EKG signal. Verify proper skin preparation, and ensure electrodes are securely attached.

Lead Reversal: Incorrect lead placement or connection can result in inverted or distorted waveforms. Double-check lead placement and verify proper connection to the EKG machine.

Electromagnetic Interference: Electrical devices in the vicinity, such as cell phones or other electronic equipment, can introduce interference into the EKG signal. Ensure the testing environment is free from electromagnetic interference.

Patient Positioning: Patient positioning can affect EKG waveforms. Ensure the patient is relaxed and in a comfortable position. Incorrect positioning, especially in relation to limb leads, can lead to abnormal readings.

Skin Resistance: High skin resistance can result in poor electrode-skin contact, leading to signal loss or distortion. Confirm good skin preparation and use conductive gel if necessary.

Lead Wires and Cable Issues: Check lead wires and cables for any signs of damage or wear. Faulty cables can lead to signal loss or introduce noise into the recording.

Medication Effects: Certain medications, particularly those that affect heart rate or conduction, can impact EKG waveforms. Be aware of the patient's medication history and its potential influence on the EKG.

Patient Factors: Individual patient characteristics, such as obesity or chest deformities, can affect lead placement and signal quality. Adjust electrode placement as needed for individual patient anatomy.

References:

- EDAN SE-601 User's Manual
- CONTEC MS400 User's Manual

Mechanical Lung Ventilator

Aim of the lecture:

- To become familiar with the technical terms and symbols for mechanical ventilation
- To know the individual modes of lung ventilation
- To understand resistance (R) and compliance (C) measurements

Introductory questions:

Please, answer them in the beginning of the laboratory task.

- What is the respiratory system resistance and compliance?
- What main ventilation modes do you know?
- What is PEEP?
- Why do we compensate the endotracheal tubes during mechanical ventilation?
- What is the recommended high pressure safety limit?
- What are the protective recommendations for mechanical ventilation?
- Why is the orientation of the coaxial patient circuit important?



MONNAL T75 Mechanical Lung Ventilator

Tasks and measurements:

1. Read the description of the ventilator Monnal T75 and its intended use in the User's manual (1.2 and 1.3).
2. Assemble the expiratory valve with the flow sensor (9.3) and connect them to the ventilator.
3. Perform the installation and commissioning (3).

Note: If the oxygen wall outlet is not available decrease FiO_2 to 21% during ventilation. Nebulization will not be available.

4. Read and follow the instructions for the use of the ventilator (4).
5. Initialize the ventilation for the new patient (4.4).
6. Start with the VCV ventilation (4.7.1) and read the information about all the modes of ventilation.
7. Identify all the measured parameters and their meanings.
8. Display of pressure and flow rate curves (4.10).
9. Test the expiratory plateau and inspiratory plateau (5.1 and 5.2).
10. Perform the resistance and compliance measurement (5.3).
11. Set the PCV mode of ventilation.
12. Write down the measured parameters.

13. Press menu and TC (Tube compensation). Set the compensation level to 100%, Tube type “Endotracheal” and Tube diameter to 7.5 mm.
14. Check the differences in measured parameters. Discuss the changes.
15. Set the CPAP mode of ventilation.
16. Check the differences between the modes of ventilation and between the adjustable parameters.
17. Use the coaxial breathing patient circuit and test the effect of orientation on ventilation and measured parameters.
18. Stop the ventilation and switch off the device.

References:

- MONNAL T75 User’s Manual

Syringe and Infusion Pump

Aim of the lecture:

- To become familiar with the typical technical terms for fluid pumps
- To understand the principle of operation of syringe and infusion pump and their advantages and disadvantages
- To learn how to work with fluid pumps

Introductory questions:

Please, answer them in the beginning of the laboratory task.

- What does it mean purging?
- What is a drop sensor?
- What is a bolus?

Tasks and measurements:

1. Read the product specification of the MP-30 Syringe pump/MP-60 Infusion pump and precautions for use, operating principle, preparations for use and operating instructions.

Note: Menu password – 1234; Maintenance password - 1666

Syringe Pump



MP-30 Syringe pump

2. Power on the syringe pump.
3. Fill in the data for a new patient.
4. Install the syringe and connect the infusion set or any tubing.

Note: Put water in the syringe before installing.

5. After loading a syringe on the syringe pump, remove the air bubbles from the syringe and the IV line (Purging).
6. Set the infusion mode to “Rate mode”.
7. Set the rate and volume to be introduced (VTBI).

Note: The rate and volume are based on the available equipment.

8. Start infusion.
9. During infusion, click [Bolus] to enter the bolus setting interface. Set any two of Bolus VTBI, Bolus rate and Bolus Time, click [Bolus Start] to enter the bolus interface, click [Bolus Stop] to stop the bolus.
10. Try to start the infusion using Time mode.
11. Check the history records.
12. User maintenance
 - a. check how to do the cleaning and disinfection,
 - b. check the interval for the periodic maintenance,
 - c. check the power cable,
 - d. trigger the alarm – No syringe and Syringe installation error.

- i. Check method: Simulate the syringe process, pull up the clamp when infusing, [NO SYRINGE] appears on the screen and three beeps at intervals of 15 seconds is given out with the red alarm indicator flashing.
- ii. Check method: Simulate the syringe process, press the clutch when infusing, [NO SYRINGE] appears on the screen and three beeps at intervals of 15 seconds is given out with the red alarm indicator flashing.

Infusion Pump



MP-60 Infusion pump

2. Power on the infusion pump.
3. Fill in the data for a new patient.
4. Install the infusion bag and connect the infusion set.

Note: Put water in the infusion bag before installing.

5. When the liquid level is at 1/3 of the drop chamber, open the roller clamp.
6. Infuse liquid into the tube to purge the air, and then close the roller clamp.
7. Press [OPEN] to open the pump door.
8. Press [Anti-Free-Flow Clamp] to open the anti-free-flow clamp, place the tube inside the clamp, and press the key again to clamp the tube.
9. Place the tube inside the air bubble sensor and pressure sensor in sequence, then stretch the tube. Make sure the tube is inside both ends of the tube slit, and then push the pump door to close it.

Note: If available, install the drop sensor. Be careful about the correct placement. For more information, read the Manual.

10. Use purging to get rid off all the air bubbles.
11. Set the infusion rate and start the infusion.

12. Change the infusion mode.

13. User maintenance

- a. check how to do the cleaning and disinfection,
- b. check the interval for the periodic maintenance,
- c. check the power cable.

References:

- User's manual MP-30
- User's manual MP-60

Maintenance of Non-invasive Blood Pressure (NIBP) Monitors

Aim of the lecture:

- To learn how to verify the measurement accuracy of different types of blood pressure monitors and to be able to determine if the accuracy of the device is in accordance with the range of the accuracy values given by the manufacturer or the national standard
- To learn how to correctly perform a non-invasive blood pressure measurement examination using the available tonometers

Introductory questions:

Please, answer the questions in the beginning of the laboratory task.

- What are the Korotkoff sounds? What phenomena causes these sounds?
- What is the Type C evaluation of uncertainty of the measurement? How it can be calculated? Describe the individual elements from which Type C uncertainty is constructed.
- What is a calibration protocol? Why is it important to use such a protocol?

Tasks and measurements:

1. Verify the accuracy of the aneroid and pseudo-mercury (mercury-free digital auscultation) tonometers. Write down the results in a table and create the correction curve.



Aneroid tonometer



Aneroid tonometer



Pseudo-mercury tonometer

- Assemble a measuring apparatus consisting of a tonometer, a pressure source (a balloon with a valve – if needed) and a NIBP simulator. Turn on the NIBP simulator and set the correct measurement mode.
 - Proceed with the pressure leak test for all tonometers. Pressurize the system to 200 mmHg and measure the values of the pressure in the system every 10 seconds for 2 minutes. Are the measured values within the range of values specified by the manufacturer?
 - For the verification of the accuracy of the tonometers, use the NIBP simulator in the pressure gauge mode. Compare the measured pressure on the tested tonometer with the pressure displayed by the NIBP simulator at 15 pressure values (from 60 mmHg to 200 mmHg with step of 10 mmHg).
 - Decide if the tonometers are accurate enough according to the manual of each device. Create a correction curve for each tonometer.
2. Verify the accuracy of the two automatic tonometers (Rossmax X3 and Omron HEM-907) using the NIBP simulator.
- Assemble a measuring apparatus consisting of a tonometer, a pressure source (if needed), and a NIBP simulator.
 - Proceed with the pressure relief test. Pressurize the system to 310 mmHg and measure the value of the relief pressure in the system. Compare your measured value from the NIBP simulator with data given by manufacturer. Are the measured tonometers safe?

Note: For a successful measurement, make sure that the compressors of both devices (the tested tonometer and the NIBP simulator) are turned on at the same time. Otherwise, the tonometer's valve to the atmosphere is open and the system cannot be pressurized.

- For the verification of the accuracy of the Omron HEM-907 tonometer, use the NIBP simulator in the pressure source mode. Set the tonometer to the “Check” mode by turning right knob under the display of the device. Do the test for 15 values of the pressure (from 60 mmHg to 200 mmHg with step of 10 mmHg). Based on the information from the manufacturer, compare the values from the simulator and the tonometer and decide if the tonometer is accurate enough.
 - For three different pressure and heart rate settings, measure the values with both tonometers. Set the systolic/diastolic pressure to 120/80 mmHg, 100/70 mmHg and 160/100 mmHg. Perform measurements at these three simulator settings, repeat each three times and make an average value.
 - Write the results in a table and compare with the set values.
 - Decide if each device is accurate enough compared to the values in the manuals of the manufacturers. Based on your decision, is it possible to use these tonometers safely for measuring blood pressure of patients in hospital?
3. Measure blood pressure on a volunteer using both main methods. For proper and correct measurement procedure, please see chapter “Principles for proper non-invasive blood pressure measurements” below.

Additional questions, answer them in the laboratory protocol:

- What is a correction curve? In your laboratory protocol, make a correction curve for all auscultation tonometers which you have tested in this experiment.
- What is the leak rate, what are the normal values and where you can find these values? Are the measured tonometers in the range of values of the leak rate specified by manufacturer or do they need to be repaired/replaced?

Principles for proper non-invasive blood pressure measurements:

When measuring non-invasive blood pressure, it is important to follow several basic rules and procedures so that the measured values are as accurate as possible. Here are some tips to watch out for:

- Correct cuff size: Use a cuff that is appropriate for the size of the patient's arm. A cuff that is too small can give incorrect results, while a cuff that is too large can lead to underestimation of values.

- Correct cuff placement: Place the cuff on the arm so that it is at the level of the heart. Improper placement may affect results.
- Correct stethoscope placement: Make sure that you have placed the stethoscope in the right place. This place is located on the inside of the elbow joint. The bell of the stethoscope should fit firmly and with its entire surface to this place.
- Loose clothing: Make sure the patient has loose clothing on the upper body, especially on the arm where the cuff is placed.
- Calm and well-being: The patient should be calm and relaxed. The measurement should take place in a quiet environment without disturbing factors.
- Improper leg position: The patient should be sitting with the support on the back, the feet should be placed evenly on the floor and the arm should be resting on the table or the support.
- Do not cross the legs: The patient should not cross his legs during the measurement, as this may affect blood circulation.
- When repeating measurements: If you are making repeated measurements, keep in mind that the pressure may vary during the day.

References:

- ROSSMAX BQ705 User's Manual
- ROSSMAX X3 User's Manual
- OMRON HEM-907 User's Manual
- CONTEC NIBP Simulator User's Manual

Electrical Safety of Medical Devices

Aim of the lecture:

- To become familiar with the technical terms and symbols used in electrical safety measurements
- To learn to work with an electrical safety measuring device
- To check the electrical safety of medical devices

Introductory questions:

Please, answer the questions in the beginning of the laboratory task.

- What electrical safety tests will you perform?
- Check how the measurement uncertainties are calculated.
- What are the safe limits for each test?
- What is the difference between protective class II and class I?
- What does it mean "Open Neutral" and "OpenPE"?

Tasks and measurements:

Important note: Always follow the instructions in the User's Manual!

1. Select a medical device for electrical safety testing
 - a. Defibrillator S5 B
 - b. Electrosurgical unit SMT BM 125
 - c. Or any other



Examples of medical devices for electrical safety testing

2. Classify the medical device by protection class.
3. Identify all applied parts of the device.
4. Perform a visual check of the device (for any missing or damaged parts).
5. Perform a self-test of the device according to the User's Manual for MDtest.

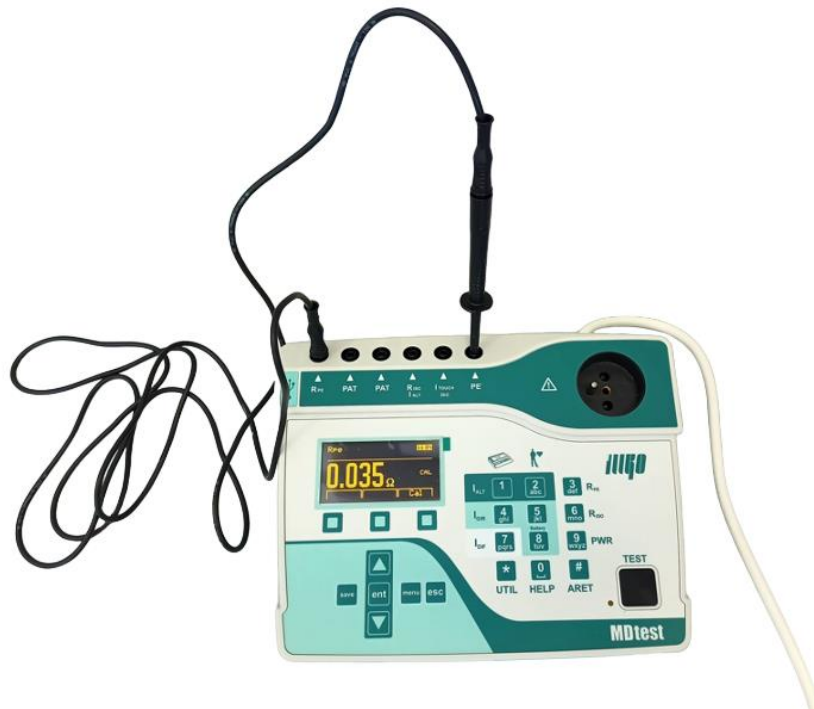


MDtest

6. Follow the instructions in User's Manual for MDtest.

7. Perform an Earth bond test:

- Test lead resistance compensation



Test lead resistance compensation

- Protective earth resistance

8. Insulation resistance:

- Mains – Protective earth
- Applied part - Protective earth
- Mains – Applied part

9. Enclosure leakage current according to EN 62353

- Alternative method
- PE current during operation
- Differential leakage current

10. Leakage current from the Application parts according to EN 62353

- Alternative method



An example of measuring leakage current from the application parts using an alternative method

- Direct method
- (Direct method, DUT with an internal electrical power source)

11. Power, mains voltage and current consumption in test socket

12. If all tests pass put a label with your name and inspection date on the medical device.

References:

- MDtest User's Manual
- A Practical Guide for Medical Equipment and Electrical System Testing

Maintenance of Electrocardiograph (ECG)

Aim of the lecture:

- To become familiar with the form, flow of functional tests of the medical devices, with the most common sources of malfunctions of medical devices and to learn to identify them.
- To learn how to navigate through the manufacturer's user and service manual. Based on these manuals, learn how to perform classic service interventions on a medical device.

Introductory questions:

Please, answer the questions in the beginning of the laboratory task.

- How are you going to proceed in a situation where you (as an expert in biomedical engineering and working in a hospital) are called to repair an ECG device that is not working. Describe your decisions in bullet points as they would follow each other (feel free to make a decision tree).
- What is the standard period that a safety inspection of a medical device should be performed?

Tasks and measurements:

1. Do the test of the functionality of the device. According to the manufacturer's service manual: check the functionality of the display, the printer, battery, and the front panel buttons. For this safety check, follow the manufacturer's instructions in service manual (Chapter 5.2, pages 32-38).
2. Disconnect the device from the power supply and disassemble it. For disassembly, please follow the instructions in the service manual (Chapter 6.1, pages 51-56). During the disassembly, perform the following tasks:
 - a. Identify the power supply circuit. How can be this circuit identified just by looking to the inside of the device?
 - b. Identify the galvanic isolation of the patient and mains parts of the circuit board.
 - c. Identify the ECG board and the shielding of sensitive modules from electromagnetic radiation. How does this shielding work?
 - d. Remove the fuse from the source and check it, if it is OK, put it back.
 - e. Disconnect the monitor display and keyboard (to simulate its replacement).
 - f. Disconnect the printer (to simulate its replacement).

g. Find a battery and simulate its replacement by finding the battery connector.

3. After completing the previous points, reassemble and test the monitor, everything that worked at the beginning of the exercise must work after assembly. To ensure that everything is working, do the functionality test of the device (see task No. 1).

Additional questions, answer them in the laboratory protocol:

- How can preventive maintenance be performed on the ECG recording devices and why is it important for reliable operation?
- How the electrical safety of the ECG recording devices can be ensured and what precautions should be taken to protect against electrical hazards?

Principles for proper measurements of the electrical safety of the diagnostic ECG:

Carefully read the manufacturer's safety instructions before starting any repair work. Always work in accordance with standard safety procedures and wear the necessary protective equipment.

Documentation: Before beginning any work, thoroughly document the condition of the instrument. Record serial numbers, date of last maintenance and repairs made.

Test Mode: Activate test mode, if available, before beginning a full repair. Make sure you have access to the manufacturer's technical manuals for testing and calibration.

Corresponding replacement parts: Use only original manufacturer's replacement parts. Ensure proper compatibility and specifications of spare parts.

Electrostatic Protection: Observe anti-electrostatic precautions when handling sensitive electronic components.

Recording changes: Record every repair and maintenance performed in the service documentation. Record any changes to software or firmware.

Post Repair Inspection: Perform thorough testing in accordance with the manufacturer's procedures after repairs have been made. Make sure that all functions of the device are working properly.

Visually check cables and connections: Visually inspect all cables and connections for damage before any work is done. If problems are found, do not make repairs until necessary precautions are taken.

Regular insulation checks: Perform regular insulation checks on electrical conductors. If weak spots or faults in the insulation are found, take measures to repair or replace the affected parts.

Water Protection: When working with electrical parts, ensure that they are protected from water and moisture. Observe the relevant standards for water resistance.

Professional review: Periodically undergo electrical inspections and checks of the instrument as recommended in the manufacturer's technical documentation.

Professional Qualifications: Repairs to electrical parts should only be performed by qualified electricians or technicians with the appropriate qualifications and experience in medical equipment.

References:

- EDAN SE-601 User's Manual
- EDAN SE-601 Service Manual

Functional Inspection of Mechanical Lung Ventilator

Aim of the lecture:

- To become familiar with the technical terms and symbols for mechanical ventilation
- To verify the functional safety of mechanical lung ventilator
- To check the electrical safety of mechanical lung ventilator

Introductory questions:

Please, answer them in the beginning of the laboratory task.

- How often do we have to change the O₂ sensor?
- Why is the test of electrical safety important?
- What is the principle of operation of the ventilator?
- What are the consumable parts and what are the spare parts of the ventilator?



MONNAL T75 Mechanical Lung Ventilator

Tasks and measurements:

For the USERS (User's manual):

1. Check that you have all the necessary documents for the device: user manual, EC declaration of conformity, training protocol for working with the device or any other required by your institution.

2. Read the description of the ventilator Monnal T75 and its intended use in the User's manual (1.2 and 1.3).
3. Control the list of available consumables and accessories according to chapter 10.
4. Control the HEPA Air intake filter according to the instructions (9.5).
5. Read the Maintenance operations performed by the user (11.1) and by the technician (11.2).
6. Perform the battery life check (11.1.1).

Note: Battery life check can take more than 3 hours. Perform only if there is enough time.

7. Control or change the O₂ cell.
8. Read the technical description (12).
9. Read the requirements for the electrical power sources and information for the internal battery (12.2).
10. Perform the maintenance according to the Checklist (14.1).
11. Perform the testing of the alarms (12.5).

Note: Some of the tests are not possible to do. If the oxygen wall outlet is not available decrease FiO₂ to 21%.

For the Technicians (use the Maintenance manual):

12. Switch of the device.
13. Check the flow chart (13.3).
14. Perform the visual inspection procedure (17.3.1).
15. Control the air filter according to the instructions (13.1.2).
16. Control the filter valve nozzle (13.1.3).

Note: Use pliers to unscrew the D7 filter valve nozzle.

17. Control or replace the anti-ozonant lip seal (13.1.4).
18. Replace the internal battery (14.3).
19. Perform the Procedure of emergency shutdown (14.4).
20. Perform the Electrical safety tests (17.3.3).
21. Perform the Ventilation check.

References:

- MONNAL T75 User's Manual
- MONNAL T75 Maintenance manual
- MDtest User's Manual
- A Practical Guide for Medical Equipment and Electrical System Testing

Maintenance of Syringe and Infusion Pump

Aim of the lecture:

- To know how to perform periodical functional check of the syringe and infusion pump
- To learn how to test the flow rate, volume, and occlusion pressure alarm accuracy
- To learn how to change spare parts of fluid pumps

Introductory questions:

Please, answer them in the beginning of the laboratory task.

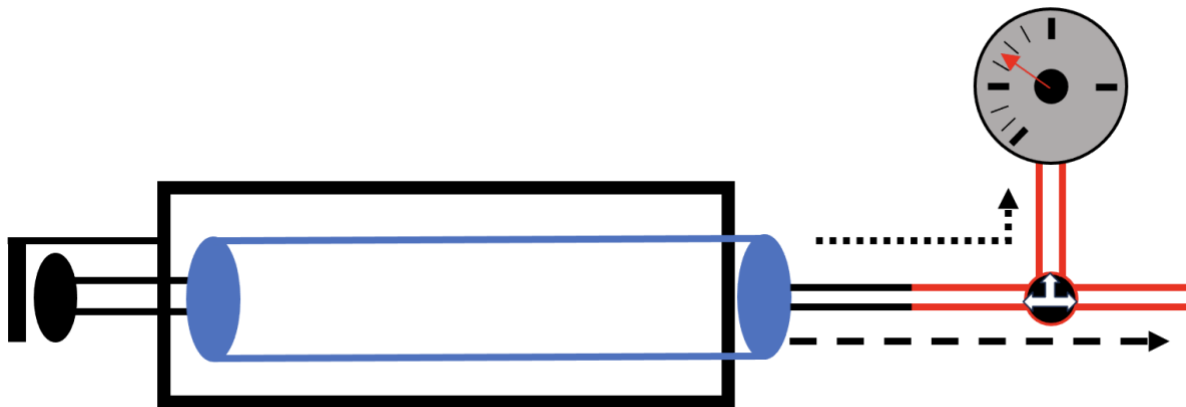
- What is the accuracy of the MP-30 Syringe pump/MP-60 Infusion pump?
- What is the sensitivity of the air bubble sensor?
- What is the needed equipment for functional check of fluid pumps?

Tasks and measurements:

1. Read the product specification of the MP-30 Syringe pump/MP-60 Infusion pump and precautions for use, operating principle, preparations for use and operating instructions.

Note: Menu password – 1234; Maintenance password - 1666

2. Check the operational qualification checklist in Service manual (Chapter 2) MP-30.
3. Connect the testing set according to the instructions:



A scheme of a Volume accuracy and Occlusion alarm accuracy testing set

4. Test the Volume accuracy of Syringe pump using graduate, timer and weighing scale.

Check method: use the 50mL syringe pump with a 60 mL/h rate, fill the syringe and extension tube with distilled water and access the graduate. Start, run 10 minutes in a 60 mL/h rate and observe the liquid volume in the graduate where 9.8-10.2 mL is acceptable.

5. Test the Occlusion alarm accuracy of Syringe pump.

Check method: use the 50mL syringe pump with a rate of 25 mL/h and an occlusion level of P2, occlude the extension tube. Start the infusion, there should be an alarm in 1 minute. [SYRINGE OCCLUSION] appears on the screen and a series of beeps at intervals of 15 seconds is given out with the red alarm indicator flashing.

6. Test the Flow rate accuracy of Syringe pump.

Check method: use the 50mL syringe pump with a 60 mL/h rate, fill the syringe and extension tube with distilled water and access the graduate. Start, run 10 minutes in a 60 mL/h rate. In the Sampling interval of 0.5min, observe the accuracy.

7. Read how to perform Syringe brand calibration and Sensor calibration.

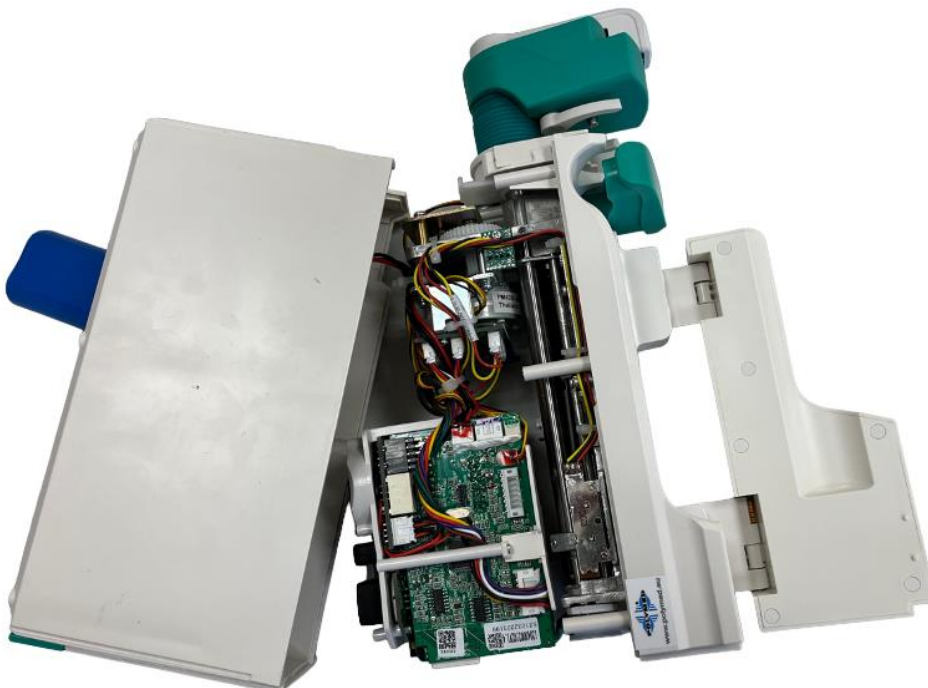
8. Change the Internal battery of the MP-30 Syringe pump/MP-60 Infusion pump.

- Turn the power off and disconnect the power cord.
- Use a screwdriver to loosen the battery cover fixing screws at the bottom of the pump.
- Remove the battery cover.
- Disconnect the battery cable connector.
- Remove the battery.
- Insert the connector of the battery cable into the battery.
- Insert the new battery into the battery compartment.
- Attach the battery cover.
- Use a screwdriver to tighten the screws securing the battery cover.



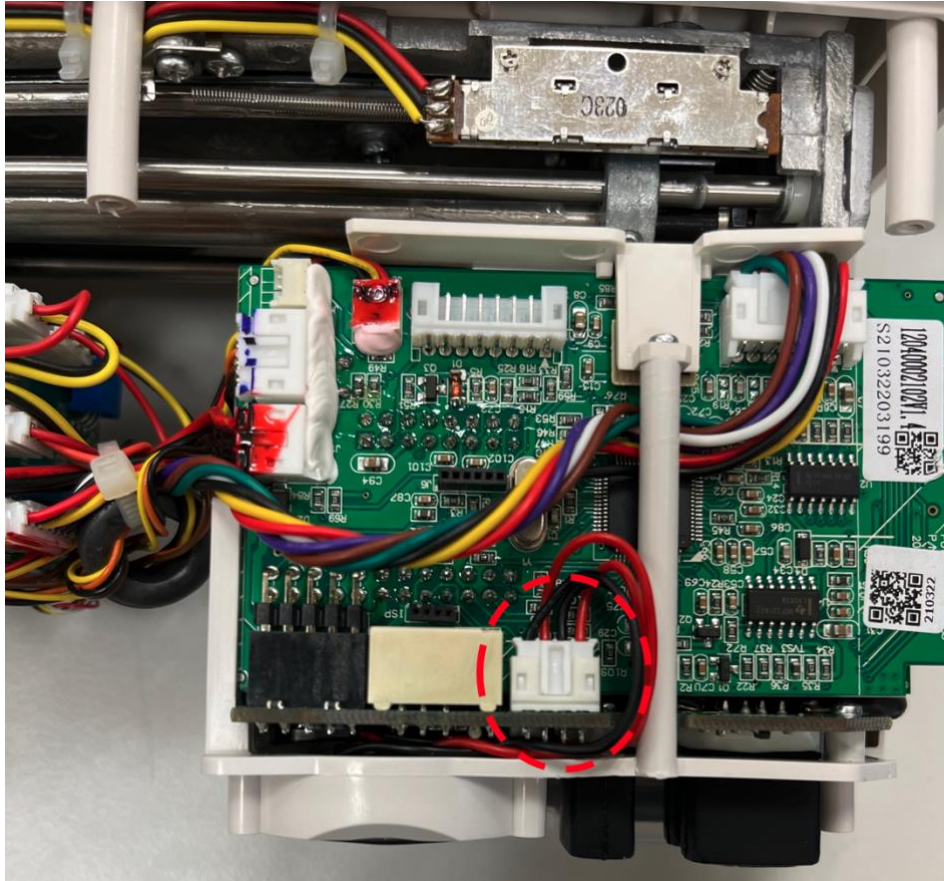
Internal battery of the MP-30 Syringe pump/MP-60 Infusion pump

9. Change rear cover of the MP-30 Syringe pump/MP-60 Infusion pump according to the Service manual.



Cover of the MP-30 Syringe pump/MP-60 Infusion pump

10. Disconnect the speaker and check if the audible alarm is not working.



Internal parts of the MP-30 Syringe pump

11. Perform the Electrical safety test of the MP-30 Syringe pump/MP-60 Infusion pump according to the instructions in the Service manual.

12. Test the Air bubble in tubing alarm in the MP-60 Infusion pump.

Checking method: Simulate the infusion process and create a bubble by tilting the drip chamber during the infusion. There should be a visible alarm [Air Bubble] on the screen, red alarm light flashing, and audible alarm cycling every 15 seconds like beep-beep-beep ...beep-beep...beep-beep-beep ...beep-beep....

References:

- User's manual MP-30
- User's manual MP-60
- Service manual MP-30
- Service manual MP-60

- MDtest User's Manual