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Gesellschaft für Meß- und Regeltechnik mbH

User Guide

Osmolality Measurement in medical and pharmaceutical field

Colloid Osmometer / Oncometer

OSMOMAT® 050

Notes, Safety Notices and Warnings

The symbols and abbreviations defined below may appear on the packaging material, on the serial number plate or in the operating instructions:

IVD	In-vitro diagnostic device
CE	This product meets the requirements of EEC Directive 98/79 relating to in-vitro diagnostic devices.
	Attention (refer to documentation)! Please follow the safety notices in the equipment operating instructions.
LOT	"Use by …" The date that follows indicates the expiration date as *year-month*.
	The name of the product batch follows.
REF	Article number or order number

The following pages provide a step-by-step introduction to using, maintaining and servicing the measurement equipment. Passages requiring special attention are marked as follows:

	This symbol warns of the danger of corrupting measurement results, for example, by improper use of the measuring cell.
	This symbol warns of the danger of damaging the unit or the measurement system, for example, as a result of improper servicing.

Table of contents

1 Introduction

1.1 Applications of the OSMOMAT 050

The Gonotec OSMOMAT® 050 colloid osmometer is a non-invasive in vitro diagnostic device for in-vitro analysis of human blood and other samples. Its purpose is to provide information to help identify, diagnose, monitor and treat physiological conditions, states of health, and diseases.

The equipment may only be operated by specialists or those persons whose training or skills have provided them with the necessary practical experience *(see MPBetreibV: German Medical Devices Operator Ordinance)*.

The OSMOMAT 050 colloid osmometer is particularly suited for routine measurements in medical applications as well as the molecular weight determination in aqueous solutions in industry and research applications. The OSMOMAT 050 colloid osmometer determines the colloid osmotic pressure (*COP*) of blood plasma. The main diagnostic considerations for determining the colloid osmotic pressure in medical applications apply e.g. in case of blood loss, hyperalbuminemia, as well as in albumin therapy to prevent lung edemas and all diseases resulting in changes to the colloid osmotic pressure. Approx. 150 µL of a sample solution are required, making it suitable for measuring even small sample volumes. The measuring speed permits rapid series measurements.

In the hospital, the colloid osmotic pressure is an important parameter among others for monitoring infusion- and dilution therapies and for diagnosing anomalies in the water balance thus supporting decisions with respect to additional examinations.

The OSMOMAT 050 has been applied successfully in the following fields:

Clinical pediatrics	Urology
Anesthesia / intensive care medicine	Nephrology
Cardiology	Botany
Gynecology	Clinical chemistry
Physiology	… and many more

1.2 Application Restrictions of the OSMOMAT 050

The OSMOMAT 050 is not suitable for measuring whole blood samples.

1.3 Measurement Method of the OSMOMAT 050

The measurement principle of the OSMOMAT 050 is based on a measuring cell, consisting of an upper and lower half, each with a volume of approx. 10 µL, separated by a semipermeable membrane ***(Fig. 1-1)***. The so-called reference cell, located below the membrane, is equipped with a pressure transducer (pressure converter, measuring bridge). The upper half of the measuring cell, also known as sample cell, is connected to the automatic rinsing mechanism. In standby state, both cells contain a solvent *(such as Ringer's solution, isotonic NaCl solution)* to prevent pressure drops and ensure that the pressure measurement membrane is relaxed.

After adding a sample with a higher colloid osmotic (oncotic) pressure (e.g. serum or plasma) to the sample cell, permeation of solvent causes underpressure in the reference cell based on the laws of osmosis (because the membrane is impenetrable to proteins, this can only be achieved by a flow of solvent). This is measured by a pressure transducer, amplified electronically, and displayed as positive, direct colloid osmotic pressure (COP value), either in mm Hg (mm of mercury), cm H_2O, or k-Pascal. By default, the reading is displayed in mm Hg. The measurement unit can be switched by pressing the corresponding buttons on the digital display.

Different types of semipermeable membranes with varying permeability ("pore size") can be used for macro molecules with different molecular weights. This results in a characteristic reference number for each type of membrane (the so-called "membrane cut-off", indicated in dalton units). Membranes with a cut-off of 10,000 or 20,000 dalton have proven to be very useful in practical applications.

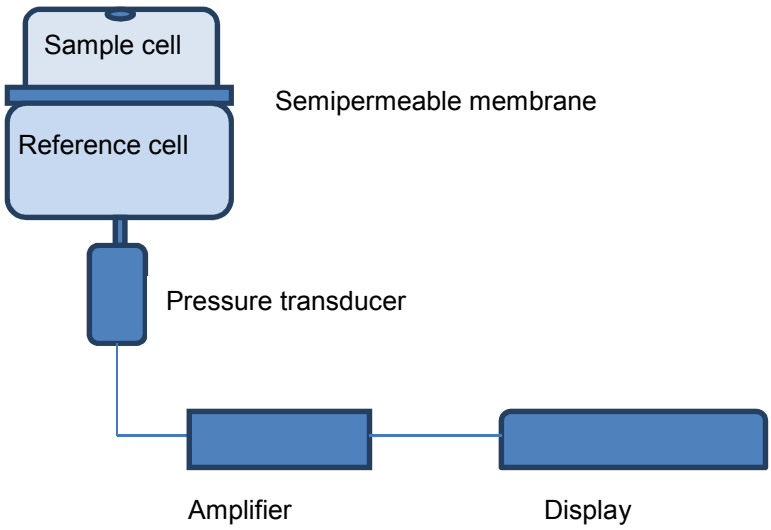


Figure 1-1: Schematic figure of the measuremet principle

1.4 Reproducibility of the OSMOMAT 050

Measurement display	3 digits
Measuring range	73 mm HG, 100 cm water column, or 9.99 kPa
Resolution	0.1 mm HG over the entire measurement range
Reproducibility	< ±0.5 mm HG

1.5 Unpacking the OSMOMAT 050 Colloid Osmometer

The OSMOMAT 050 should be unpacked immediately upon receipt and checked for obvious signs of damage sustained during shipping. If any damage is found, notify the manufacturer:

Gonotec GmbH	Tel.: (030) 7809588-0
GSG-Hof	Fax: (030) 7809588-88
Reuchlinstr. 10-11	E-mail: contact@gonotec.com
D-10553 Berlin	Web: www.gonotec.com

Toll-free service number for Germany: 0800 / 7846027

The reusable packaging for this equipment was specially designed to ensure safe and hygienic transport. **Please save the packaging in case the unit needs to be shipped back to Gonotec** for repair or servicing.

1.6 Packaging Contents

Check to make sure the contents of your shipment are complete. We cannot accept responsibility for any missing items reported at a later date.

Accessories and consumables included in the shipment

Item number	
20.9.0100	1 power cord
20.9.0160	1 RS-232 cable
	1 package of small parts including:
00.9.0102	2 fine-wire fuses **230V 250mA**
00.9.0104	*(at 110V 0.5A)*
50.9.0040	1 small O ring *(26 x 2 mm)*
50.9.0060	2 pump tubes *(9.5 cm)*
50.9.0070	2 tube nipples
50.9.0030	10 silicon septa
50.9.0020	1 package containing 5 membranes **20,000** *dalton*
50.9.0160	1 package containing 2 plungers
50.9.0100	1 precision syringe 250 µL
50.9.0150	1 tweezers
50.9.0140	1 tool for widening the tube ends
50.9.0180	1 bottle of cleaning solution
	1 package containing:
50.9.0080	1 tuberculin syringe (plastic) with special cannula *(16 mm)*
50.9.0090	1 plastic syringe (30 mL) with pump tube and clamp
50.9.0130	2 plastic bottles, labeled *(Ringer's solution and waste)*
	1 user guide 050

2 Overview of the OSMOMAT 050

2.1 Overview of Display and Connectors

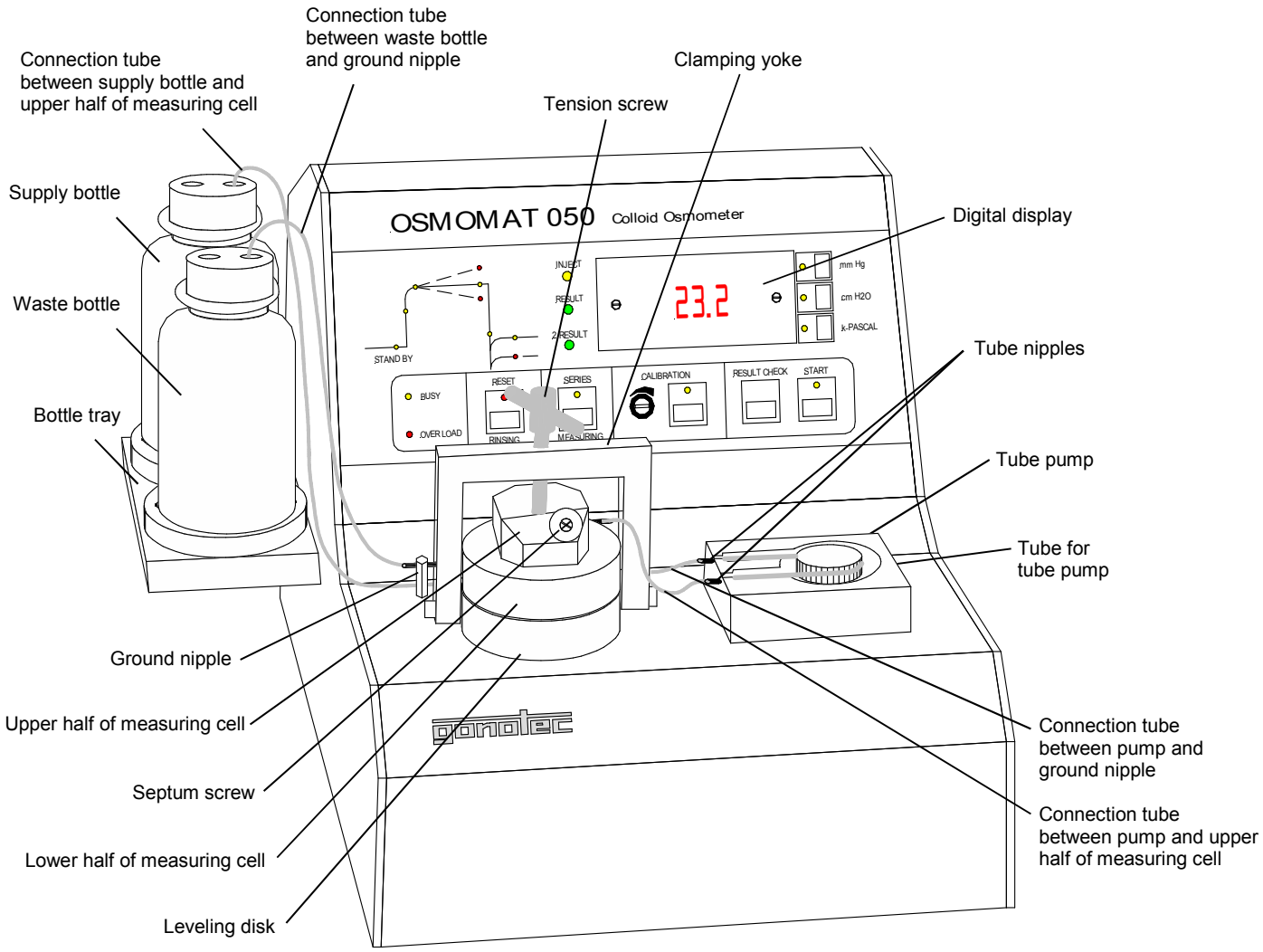


Fig. 2-1: Front view of OSMOMAT 050

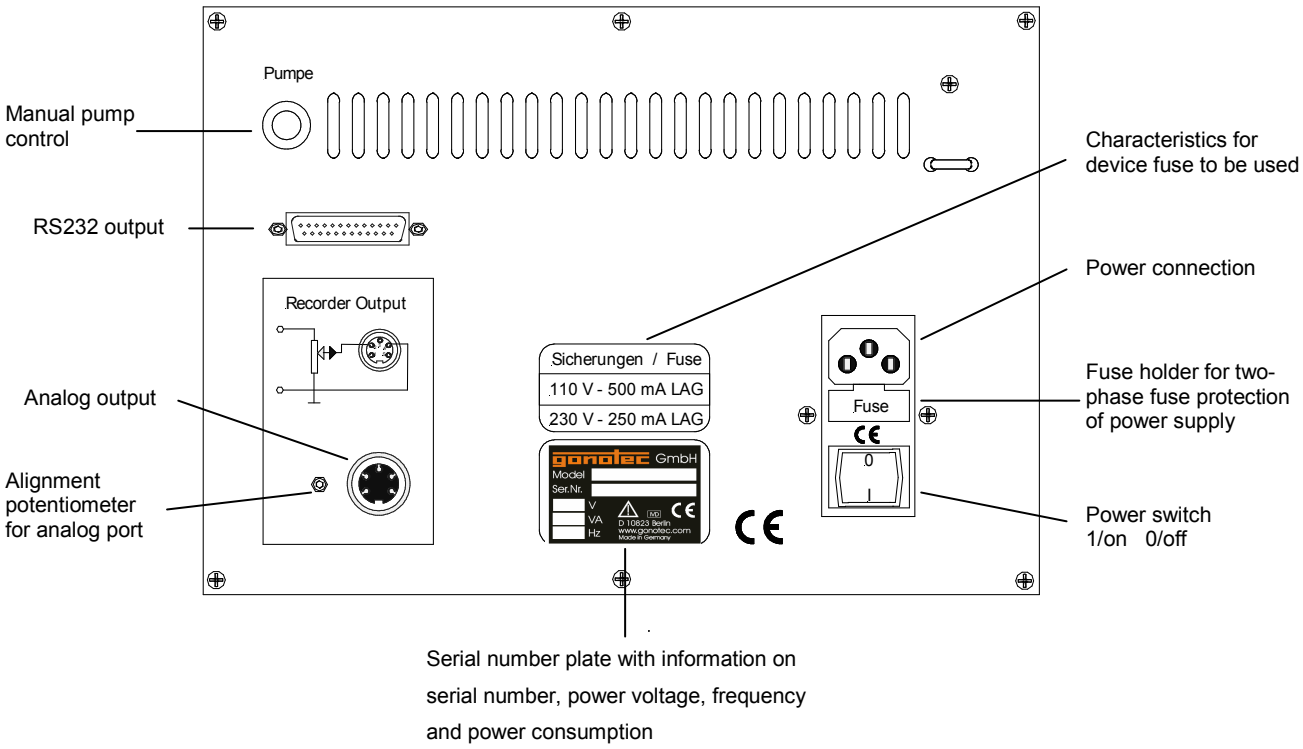


Fig. 2-2: Rear view of the Osmomat 050

2.2 Power Supply

The standard model is operated with 230V (+/- 30V) at 50/60 Hz. The power consumption is 20VA. Special models using 115V or 100V are also available.

2.3 Dimensions and Weight

Dimensions (width x height x depth): 360 x 250 x 355 mm
Weight: approx. 5.1 kg excluding bottles

2.4 Safety and Handling Information

The OSMOMAT 050 colloid osmometer is an electric laboratory measurement device. It should therefore be handled according to the safety provisions and precautions for electric measurement, control, and laboratory equipment.

If the equipment is to be **decommissioned**, make sure it is sufficiently **disinfected**. This will make sure that the equipment has been **decommissioned** in accordance with local accident prevention guidelines (UVV).

To prevent damage to the pressure transducer during extended periods of inactivity or in case of decommissioning, **the following steps must be performed**:

Always switch on device when performing work on the measuring cell or the pressure transducer (see chapter 3).
Open measuring cell and remove membrane and filter paper.
Repeatedly rinse measuring cell using distilled water (especially the pressure transducer).
Suction off residual water using special cannula, dry cell by using paper, and loosely replace screw cap with dry filter paper inserted.

The unit does not emit harmful substances either during operation or when switched off.

Symbols on the unit and serial number plate correspond to the requirements of the following standards: DIN EN 61010-1, DIN EN 375 and DIN EN 980 (harmonized standard for medical devices according to § 3 No. 17 of the German Medical Device Law MPG).

2.5 Known Risks Associated with the Use of the OSMOMAT 050

In our experience using the OSMOMAT since 1979, we have not found it to present any direct hazards or risks to the user. Such hazards and risks cannot be excluded entirely for technical equipment, however.
This operating instruction helps you gain a basic understanding of the design, the measurement principle, maintenance and servicing of the unit.

3 Setup and Initial Operation

The unit must be placed in a location ***free from vibrations*** and must be protected from direct sources of heat such as sunlight, heaters or furnaces. The ambient temperature should be between 10°C and 35°C (50-95°F).
It is strictly necessary to place the device on a very sturdy surface. Otherwise, the sensitive pressure measurement and the automatic end point detection may be disturbed.
Use the power cord provided to connect the OSMOMAT 050 from the power connector on the back of the unit to a power outlet. Make sure the unit's ground is enabled via the shockproof grounding.
If the power cord plug does not match the conventional power outlets in your location, you may substitute another power cord. It is essential, however, that the cable's green/yellow wire is connected to the safety grounding.

It is also important to ensure that the voltage indicated on the serial number plate matches that of your electricity network. Incorrect voltage will cause the fuse in the power supply unit to blow.

The OSMOMAT 050 can now be switched on via the power switch on the back of the unit (next to the power connector).

All work (unscrewing, screwing together or adding solvents) must only be performed with the device switched on and in calibration mode (can be set by pressing the "CALIBRATION" button).

Excess pressure which may result in the destruction of the pressure transducer is indicated on the display. This happens in three stages. In the first stage, the display shows 99.9 and flashes. If the pressure increases, the "overload" LED lights up in the second stage. If the pressure still increases, an alarm sounds. When the alarm sounds, the pressure gauge is at approx. 50% of the burst pressure. If you continue to screw together or open the system, the highly sensitive pressure transducer will be destroyed.
The WARRANTY is voided for a pressure transducer destroyed due to over- or underpressure.
Before beginning an initial measurement, you must add solvent to the measuring cell, insert the prepared membrane, and calibrate the device (see chapter 4 and 5).
When the measuring cell is filled and the membrane is inserted, the device is in standby mode and ready for measurement, indicated by the green standby-LED.
You can start the measurement by pressing the "START" button. This will check the zero point internally and prompt the user to inject the sample after approx. 10 seconds (indicated by the flashing INJECT LED and the LED on the measuring cell).
The device should always remain switched on while the measuring cell is filled and closed, even if it is not used for an extended period of time. The system automatically rinses the measuring cell at regular intervals, keeping the OSMOMAT 050 ready for measurement.

While the device is not in use, the measuring cell may dry out, especially in the area of the pressure transducer. The salt crystals that form adhere to the pressure measurement membrane and can destroy it. Regular rinsing prevents the drying out.

Make sure to top off the Ringer's solution and empty the waste bottle regularly.

If the device is left in standby mode for an extended period of time without topping of the Ringer's solution, the measuring cell will dry out quickly, which may result in the destruction of the pressure measurement membrane.

If the device is not used for an extended period of time (several weeks), the measuring cell must be opened and rinsed using distilled water. Afterwards, the device can be switched off.

When working on the pressure transducer, the device must always be switched on.

4 Preparing the Measuring cell for Measurement

To prepare the measuring cell, you need the tools and accessories included with the standard accessories as well as a suitable solvent, distilled water and the prepared semipermeable membrane and filter paper **(see chapter 4.4)**.

4.1 Making the Tube Connections during Initial Startup

The tubes included with the standard accessories are connected according to **Figure 4-1: Making the tube connections**.

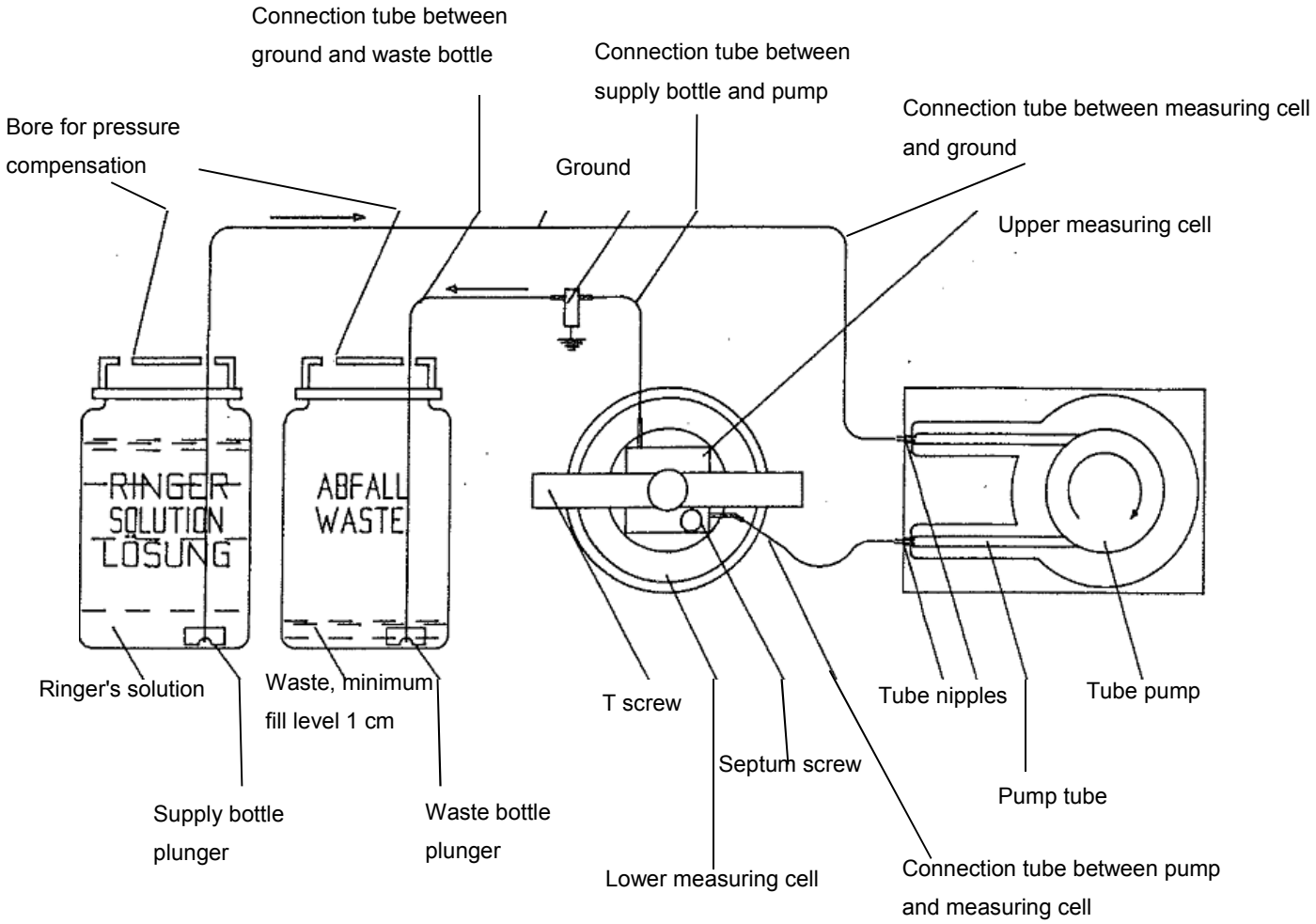


Figure 4-1: Making the tube connections

⚠ ***Use only the Tygon tubes supplied by the manufacturer. Other tubing material is permeable to air, which causes air bubbles that may severely impact or prevent the measurement.***

The tubes are pushed onto the stainless steel tubes by about **5 mm**. The tool for widening the tube ends (50.9. 0140) included with the standard accessories is used for this purpose. The tube end is held using sandpaper and widened using the moistened tip of the tool.
The connection tubes for the supply and waste bottles are passed through a bore of the unscrewed cap and pushed onto the corresponding plungers **(Figure 4-2).** The plungers hold the tubes on the bottom of the bottles. The second opening on the cap provides unrestricted atmospheric pressure compensation.

Figure 4-2: Plunger

	Tube lengths
Connection tube between supply bottle and pump	59 cm
Connection tube between ground bolt and waste bottle	45 cm
Connection tube between pump and measuring cell	6 cm
Connection tube between measuring cell and ground bolt	5 cm
Pump tube	9,5 cm

Table 4-1 Tube lengths

4.2 Ringer's Solution as Solvent

The Ringer's solution should be a pure Ringer's electrolyte solution without added lactates or other substances. If necessary, the solution can be self made.

Sodium chloride	0,8 g
Potassium chloride	0,02 g
Calcium chloride	0,02 g
Sodium bicarbonate	0,1 g
use distilled water to fill up to	100 cm³

In exceptional cases, you can also use an isotonic saline solution with a concentration of *0.9% NaCl*.

The solvent used for preparing the lower half of the measuring cell must not contain any amount of solved gas/air. If necessary, it must first be degassed by heating up just under the boiling point or by degassing under vacuum. We recommend using the *30 mL plastic syringe* included in the accessories for a simple way to degas the solvent **(Figure 4-3).**

Figure 4-3: Plastic syringe with tube clamp

Approx. 20 mL of the solvent are aspirated using the connected silicon rubber tube. Next, the tube is clamped shut using the tube clamp and a vacuum is created by firmly pulling the syringe plunger. The liquid is shaken and then the tube clamp is opened again. The gas can escape. This operation is repeated three to four times to degas the solvent. The degassed solvent is later added to the lower half of the cell directly from the syringe **(Figure 4-8)**

4.3 Filling the Supply and Waste Bottles

Add the Ringer's solution mentioned earlier to the supply bottle and screw on the cap.
Place the supply bottle in the rear position on the bottle tray.
The waste bottle collects the measured sample and the used solvent required to rinse the measuring cell. The waste bottle must have a constant **fill level of minimum 10 mm** required during measurement and calibration as hydrostatic reference value for the zero point.
For safety reasons (risk of infection), we recommend adding a small amount of a commercially available disinfectant and daily emptying and rinsing of the bottle when the device is in use.

4.4 Preparing the Semipermeable Membrane

4.4.1 Selecting suitable membranes

The semipermeable membrane is a main component of the osmotic cell. The defined pore size allows only the lower molecular solvent and the electrolytes to permeate, while the higher molecular substances of the measurement solution are retained. In addition, the membrane material seals the osmotic cell.
The pore size or pore size range is the typical factor for the retention and is called "cut-off". The membranes used for membrane osmometry usually have a cut-off between 5,000 and 30,000 dalton. The pore sizes specified by the membrane manufacturers are reference values only. They do not indicate the actual pore size or an existing pore size distribution.
Increasing the cut-off may result in lower colloid osmotic pressures.
Only membranes with very thin layers containing a supporting material for mechanical reasons (so-called two-layer membranes) can provide adequate permeability. Depending on the manufacturer, both layers are made of the same or different materials. Aqueous solutions can be used for virtually all membrane materials.

⚠ ***It is strictly necessary that the membrane has a diameter of 25 mm [+0, -0.5 mm]!***

Membranes from other manufacturers can be slightly bigger and in that case must be trimmed with scissors.
We recommend a membrane material with a *cut-off* (retention)
of higher than 10,000 g/Mol and
of higher than 20,000 g/Mol.
The membranes are typically supplied dry with the pores filled with glycerin. The dry membranes supplied by Gonotec are each separated by filter paper. The membrane must be conditioned in water before installation in the measuring cell of the OSMOMAT 050.

4.4.2 Conditioning the membrane

The membrane is placed with the shiny side onto the surface of distilled water while keeping the supporting layer (dull side) dry.
The water penetrates the pores from below and displaces the glycerin. After a short time, small water droplets are visible on the supporting side, and the membrane shows a slight discoloration.
The membrane remains on the water surface until it is evenly discolored. Depending on the pore diameter, this can take from a few seconds to an hour.
Next, the membrane is completely submerged into the water and ready for installation into the membrane osmometer for measurement of aqueous solvents.

⚠ ***It is important to install the membrane in the measuring cell with the active (shiny) layer facing up.***

If necessary, you can verify which of the two sides is the active layer.
Carefully remove the membrane from the water using tweezers. The active side of the membrane has hydrophobic properties, while the supporting layer is hydrophilic.

Figure 4-4: Conditioned membrane

The white spot was caused by an air bubble located below the membrane. In this case, briefly lift up the membrane, remove the air bubble, and wait until the membrane has an even gray coloring.

4.5 Preparing the Filter Paper and Degassing the Solvent

A piece of filter paper must be placed below the semipermeable membrane to act as a leveling disk for the membranes recommended by us. This filter paper increases the small thickness of the membranes from 0.10 to 0.15 mm to an overall thickness of 0.3 mm and creates the correct bonding pressure when screwing together the measuring cell.

The filter paper is not required when using membranes with a thickness of 0.3 mm.

It is supplied by us along with the membranes and acts as a separating layer between the membranes.

The filter paper must be degassed before use in the measuring cell.

Degassing the filter paper requires a lot of care because all air bubbles must be removed from the paper. It is recommended to degase use to degas the filter paper together with the Ringer's solution with the 30 mL syringe **(see chapter 4.2)**

Pull the plunger out of the syringe, place the filter paper in the syringe cylinder, and reinsert the plunger. Do not fold the filter paper. Next, aspirate approx. 15 mL of Ringer's solution into the syringe, remove the air from the syringe, and clamp shut the aspiration tube using the tube clamp. By pulling the plunger firmly, a vacuum is created, which causes steam bubbles to form and removes the remaining air from the filter paper texture. The filter paper may remain inside the syringe together with the Ringer's solution until used in the measuring cell.

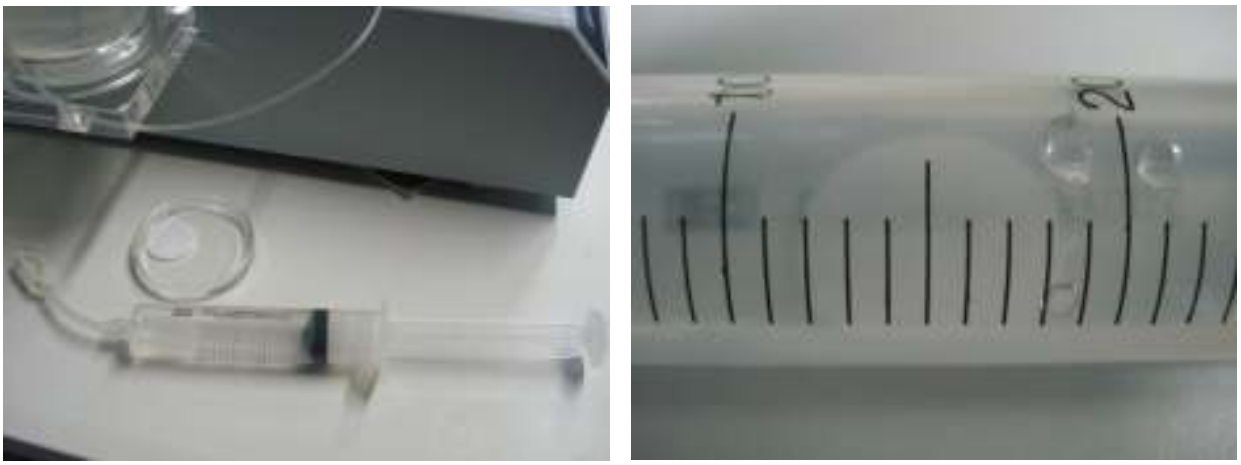


Figure 4-5: Syringe with Ringer's solution and filter paper

4.6 Opening the Measuring cell

As described in chapter 3, you must first switch on the device. Press the "CALIBRATION" button to check the pressure ratios and protect the pressure transducer. The indicator light of the button lights up, and after approx. 10-20 seconds the digital display shows "00.0". The display has a direct connection to the pressure gauge and shows the pressure ratios of the pressure transducer.

4.6.1 Initial Startup with Dry Measuring cell

When the system is delivered, a piece of filter paper is placed in the lower half of the measuring cell to prevent damage during shipping. To open the measuring cell, loosen the tension screw and flip back the clamping yoke. Then remove the upper half of the measuring cell.
Remove the O ring and the filter paper from the cell. It will be reused during assembly.

4.6.2 Removing the Membrane When the Measuring cell is Filled

If the measuring cell is already filled, great care must be taken during unscrewing while closely monitoring the pressure reading. If the alarm sounds, stop unscrewing immediately. After pressure compensation, the alarm is silenced and you can proceed to open carefully. Loosen the tension screw, flip back the clamping yoke, and remove the upper half of the measuring cell.
Remove the O ring and the old membrane together with the filter paper using the tweezers. Clean the O-ring with water and keep it immersed in water until installation.

4.7 Cleaning and Filling the Lower Half of the Measuring cell

To clean the lower half of the measuring cell, first fill it with water up to the upper rim and then clean it using a cotton tip or paper tissue. Next, fill it with ethanol and insert the tuberculin syringe with special cannula (from the standard accessories) into the vertical bore at the bottom of the lower half of the measuring cell **(Figure 4-6)**. This bore connects the measuring cell with the pressure transducer. Using the supplied cannula ensures that the pressure membrane is not destroyed.

Never use other cannulas, especially longer ones, because they would puncture the delicate membrane of the pressure transducer.

Aspirate ethanol into the bore using the tuberculin syringe. Repeated eject/aspirate cycles clean the bore and deaerate the area above the pressure transducer, which means that all the air bubbles are removed.

Next, immediately remove the ethanol using a paper tissue **(Figure 4-7)** and add distilled water.
If the alcohol remains in the measuring cell too long, it affects the plastic material, which becomes opaque.

.

Figure 4-6: Filling the lower measuring cell

Figure 4-7: Cleaning the lower measuring cell

Use the tuberculin syringe again to aspirate the distilled water into the bore in the lower half of the measuring cell. Watch closely to ensure that no air bubbles form. Next, remove the water from the measuring cell using a paper tissue.

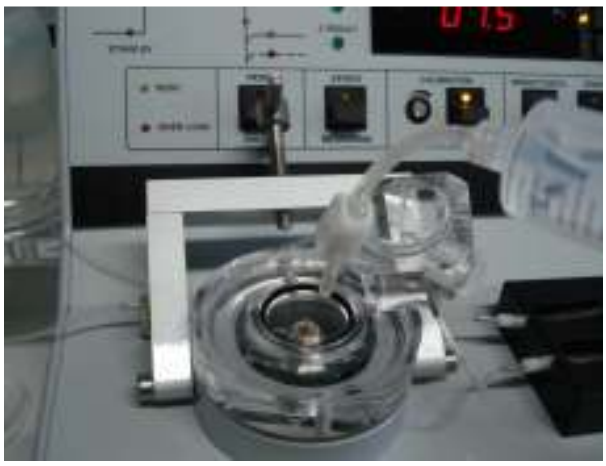


Figure 4-8: Adding the degassed solvent

The lower half of the measuring cell is now cleaned, and you can add the solvent.
Use the 30 mL syringe to add the degassed Ringer's solution **(Figure 4-5)**. After adding the degassed solvent, rinse the bore of the lower half of the measuring cell using the tuberculin syringe again. During injection, do not push the syringe plunger all the way to the end to prevent air bubbles from being pushed into the bore.

The purpose of this cleaning procedure is to free the entire bottom of the measuring cell as well as the bore and the area above the pressure transducer from tiny adhering air bubbles. Air bubbles in the measurement system prolong the measuring time and falsify the measurement result.

4.8 Screwing Together the Measuring cell

Add degassed Ringer's solution up to the rim of the cleaned and deaerated lower half of the measuring cell. Install the O ring (26 mm). Next, remove the degassed filter paper from the 30 mL syringe and place it at the bottom of the measuring cell without air bubbles. Remove the conditioned semipermeable membrane from the water, flip it once, and place it on top of the filter paper in the measuring cell with the active side facing up. Carefully push it down with a finger so that it is positioned precisely in the center of the measuring cell **(Figure 4-10)**.

Now, you can install the upper half of the measuring cell **(Figure 4-9)**. Rest the upper measuring cell on the rear edge and carefully lower it toward the front. No air bubbles must be visible inside the O ring. Use a finger to secure the upper half of the measuring cell **(Figure 4-11)**. Fold the clamping yoke over the cell and tighten it very carefully.

Figure 4-10: Installed membrane and O ring

Figure 4-9: Installing the upper measuring cell

Figure 4-11: Securing the upper measuring cell

Screwing together the measuring cell results in significant overpressure in the lower half of the cell. This overpressure decreases quickly because the solvent permeates through the pores of the semi-permeable membrane. The screwing together is performed manually without tools.
The overpressure created during this operation can easily destroy the sensitive pressure transducer. Therefore, the measuring cell has to be screwed together carefully in small intervals.
If the pressure increases to above 99.9 cm water column, the display starts flashing **(Figure 4-12)**. If the pressure increases further to approx. 550 cm water column, the "overload" warning light comes on **(Figure 4-13)**. When an alarm sounds, you must immediately stop the screwing operation, otherwise the pressure transducer will be destroyed. You may resume after the pressure has decreased enough so that the "overload" LED goes off.

Figure 4-12: Overpressure indicated by flashing digits

Figure 4-13: Overpressure indicated by "overload" LED

The measuring cell is screwed together in small increments until the end stop is reached by firmly turning by hand.

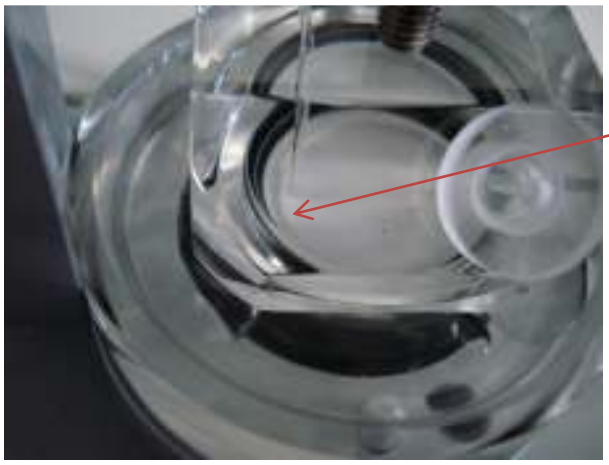


Figure 4-14: Upper measuring cell completely tightened

The semipermeable membrane becomes slightly transparent and a uniform, somewhat dark ring is visible at the edge of the membrane **(Figure 4-14)**.
The displaced Ringer's solution, collected in the overflow channel of the lower half of the measuring cell, can be removed using a paper tissue.

5 Calibrating the OSMOMAT 050

5.1 Calibration Using the Hydrostatic Pressure Difference

The prerequisite for calibrating the OSMOMAT 050 is the assembly of the measurement system according to **chapter 4.8** and the stabilization of the pressure inside the cell.
Calibration is performed directly by creating a hydrostatic pressure difference.
To fill all tubes without air bubbles, press the "Pumpe" button at the back panel until the tube going to the waste bottle is also filled without air bubbles.

Calibration procedure:

1. Press the "RESET" button. The measurement system is rinsed again and the "STAND BY" LED lights up.

Figure 5-1: Reset

2. Press the "CALIBRATION" button. The display automatically changes to cm water column, irrespective of the measurement unit set.

Figure 5-2: Calibration

Figure 5-3: Display 00.0 in cmH2O

After a few seconds, the display shows "00.0". The baseline of the measurement system for the value "00.0" is set with the fill level taken into account. The waste bottle must be placed on the bottle tray and the tube system has to be filled without air bubbles.

3. Move the bottle from the tray to the table surface. The height difference between tray and table surface is exactly 10 cm. Setting a stable measurement value of approx. 10 cm water column should not take longer than 10 seconds.

Figure 5-4: Setting the value for 10 cm water column

4. Adjusting the potentiometer will set the measurement value to exactly 10.00 cm water column.

Figure 5-5: Adjustment to 10 cm water column

5. To verify the correct setting, move the bottle back to the tray. This will revert to the zero point.

Figure 5-6: Checking the zero point

The setting of the zero point should also take less than 10 seconds. The measurement system is still subject to a slight drift directly after installing the membrane. The zero point deviates slightly. Therefore, calibration shouldn't be performed until the pressure ratios have completely stabilized. Also, it should be repeated once or twice.

6 Measuring the Colloid Osmotic Pressure

6.1 Prerequisites for Measurement

The OSMOMAT 050 prepared according to **item 4** and calibrated according to **item 5** as well as a precision syringe with special cannula for injecting the sample (included with the accessories: order no. 50.9.0100) are required to perform a measurement. This special cannula has a needle-shaped tip with a lateral opening which creates a clean, self-sealing hole when puncturing the silicon septum. Standard injection cannulas cut out rubber particles during injection, clogging the measuring cell and rendering the silicon septum unusable.
The STANDBY LED indicates that the OSMOMAT 050 is ready for measurement.
If the unit was not used for an extended period of time, you should press the “RESET” button prior to measurement. This will rinse the measuring cell and reset the zero point.

6.2 Sample Material

Any aqueous sample with macro molecules can be measured. In medical applications, the colloid osmotic pressure of blood samples is measured.

To prevent coagulation, heparin should be added to the plasma sample. The dosage should be below 100 units/mL. "Excessive heparin concentrations as well as using other anticoagulative additives such as EDTA or sodium citrate result in false high values for the colloid osmotic pressure.

To obtain the plasma, the blood should be centrifuged soon after collection and stored at 4°C in the refrigerator."[1]

“Storage for up to 7 days is possible without significant changes to the colloid osmotic pressure. However, the sample should not be frozen”.[2]

The minimum sample volume required is 150 µL.

“The samples must be homogeneous and should have the same temperature as the measurement device when measuring the colloid osmotic pressure. Cooled samples with a temperature difference of almost 20°C compared to the measurement device exhibit significant differences when measuring the colloid osmotic pressure”.[3]

6.3 Display of the OSMOMAT 050

The figure below shows labeled buttons and LEDs and serves to clarify the measuring procedure.

Please read this chapter completely before performing a measurement.

Figure 6-1: Display

[1] A. Grünert: Der kolloidosmotische Druck

[2] Marty, A T: Plasma oncotic variation and cardiopulmonary independence in normal humans

[3] A. Grünert: Der kolloidosmotische Druck

6.4 Performing the Measurement

1. Press the START button.
   The zero point is re-checked internally, indicated by "BUSY"- LED lighting up **(Fig. 6-2)**. After approx. 10 seconds, the “INJECT”- LED and the LED on the lower measuring cell flash and prompt to inject the sample **(Fig. 6-3)**.

2. Aspirate a sample volume of 150-250 µL
   Make sure to fill the syringe without air bubbles.

Figure 6-2: Checking the zero point

Figure 6-3: Injection prompt

3. Injecting the sample
   Insert the cannula through the septum as far as it will go. It is impossible to puncture the membrane during this procedure. Inject the sample into the measuring cell using three equal cycles of approx. 50 µL **(Fig. 6-4)**. This push-injection increases the rinsing effect and creates an overpressure which is the trigger impulse to start the measurement program of the OSMOMAT 050. It must be prevented to inject air bubbles or foam. Therefore, the syringe plunger should not be pushed all the way to the end.
   After injection, remove the syringe and clean it using water.

Figure 6-4: Injection in three stages

4. Recording the pressure value

After inserting the needle through the septum and injecting the sample, the “INJECT”- LED goes off and LED 2 indicates that the measurement sequence has started.

Figure 6-5

It takes approx. 30 seconds up to a maximum of 4.5 minutes for the balance of the osmotic underpressure to stabilize in the lower measuring cell filled with solvent. This balanced state is detected by the electronics and the measurement value is shown on the digital display.

Figure 6-6

At the same time, the LED 2 and LED 3 go off and the “RESULT”- LED comes on.
This presents the measurement result, which is representative of the osmolal concentration of the colloids (colloid osmotic pressure).
The display is in mmHg. Pressing the "cm H2O" or "k-Pascal" button will show the result in the corresponding measurement unit. You can also select the measurement unit prior to starting the measurement.

6.5 Recording and Storing the Second Measurement Value

An automatic measurement cycle consists of recording and storing the measurement result, storing a second measurement result, rinsing the measuring cell, and checking the zero point.

The functions in addition to storing and displaying the first measurement value allow the evaluation of the quality of the measurement result in connection with the adjustment characteristic **(see Page 34, Figure 6.9)**. After the RESULT LED and LED 3 light up, the OSMOMAT 050 waits again for the same time elapsed from injection until display of the first measurement value to accept and store the second measurement value.

After the second measurement value is stored, LED 4, 5, or 6 light up. The measurement value is stored until a new measurement is performed. Afterwards, the measuring cell is automatically rinsed and LED 7 lights up.
A comparison of both measurement values shows the adjustment characteristic.
If the adjustment characteristic matches the **curve shape 1 in Figure 6.9**, LED 5 lights up.

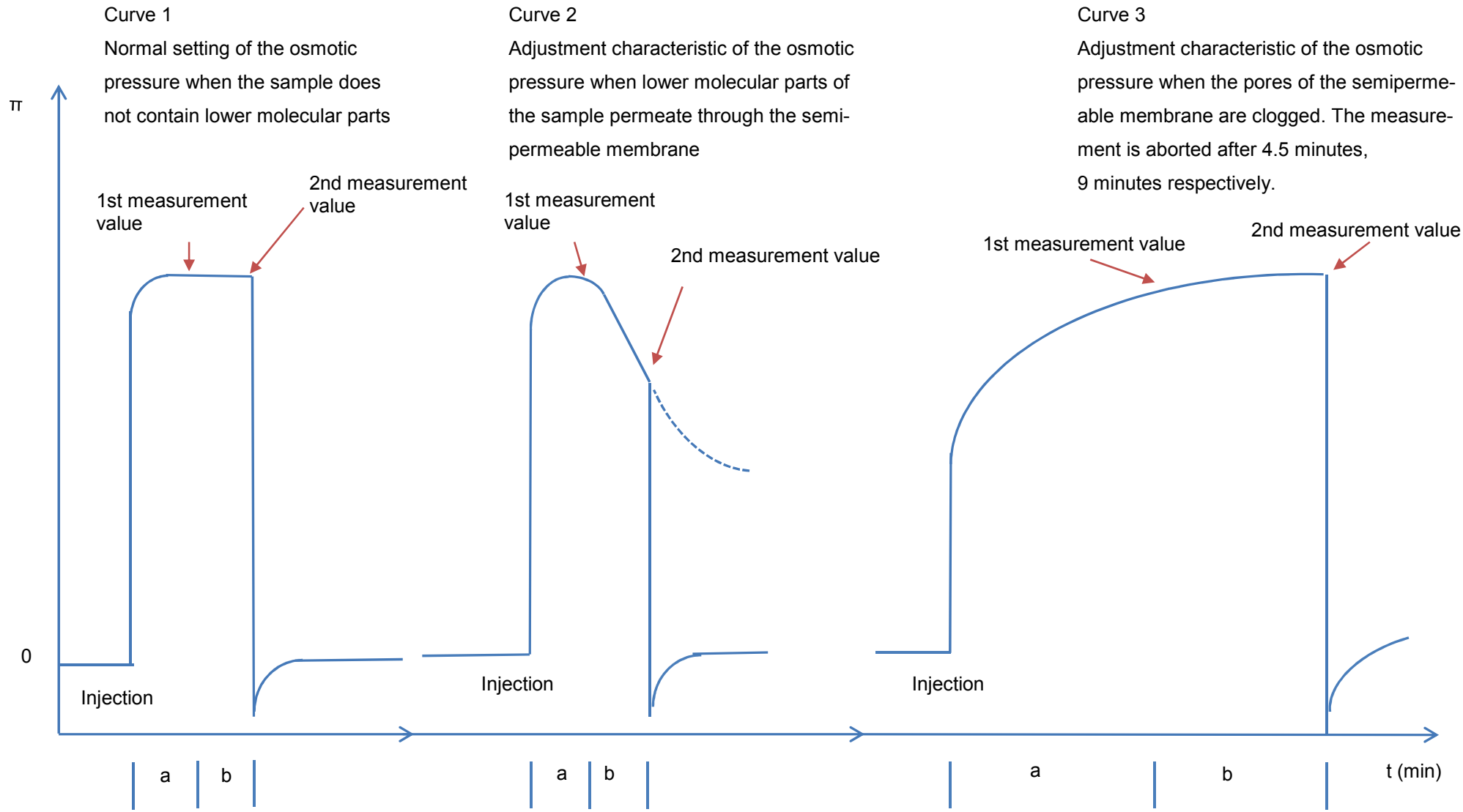
Figure 6-7: Display with adjustment characteristic according to curve 1

Pressing the “RESULT CHECK”- button will display the second measurement value.
If the 2nd measurement value deviates from the first value by more than two digits, LED 6 lights up ***(Figure 6-8)***, lower molecular parts permeate.

Figure 6-8: Display with adjustment characteristic according to curve 2

If obtaining the result takes a very long time due to a sluggish adjustment characteristic ***(curve 3, Figure 6.9)***, the measurement value is accepted after 4.5 minutes and the second measurement value is stored after an additional 4.5 minutes, LED 4 lights up.

After storing the second measurement value, five rinse cycles using solvent are performed in the measuring cell. During rinsing and zero point setting, LED 7 lights up. After zero point setting is complete, LED 8 lights up. A shift of the zero point is indicated by LED 9.



Measurement time "a" always corresponds to "b". The criterion for recording the 1st measurement value is a stable value or a reversal point.

Figure 6-9: Adjustment characteristic

7 Classification of Malfunctions by Component-Group

The following presents an overview of the individual component groups, identifying the function of each component, its potential malfunctions, the effects of the malfunctions on the measurement system, the possible causes of the malfunctions and the procedure for correcting each malfunction. Some errors can be remedied directly by the user or an in-house medical equipment technician; other errors require return of the unit to the manufacturer.

Components Function	Malfunction	Possible Cause	Measure
Lower measuring cell Membrane	Long adjustment time after inserting a new membrane	Air bubbles in lower half of measuring cell Membrane impermeable (pore size too small or membrane stored too long)	Open and clean cell again, fill with degassed solvent and insert a new membrane Insert fresh membrane with cut-off 20,000 dalton
	No measurement value: measurement value is 0 when measuring a sample (no problems during calibration)	Membrane inserted incorrectly (active side facing down) Measuring cell is not yet screwed together tightly enough	Insert a new membrane into the cell (active side facing up) Screw cell together more tightly
	Reproducibility of measurement value is unsatisfactory (measurement value too low)	Pump tube too old (flagged). Part of the injected sample flows toward the pump System partially clogged between measuring cell and waste bottle Strong fluctuations of ambient temperature (direct sunlight, draft, etc.) Air bubbles in tube between measuring cell and waste bottle Waste bottle is empty, therefore no defined zero point exists The plunger in the waste bottle does not hold the tube on the bottom of the bottle Measuring cell is not yet screwed together tightly enough Entry of measuring cell is clogged	Replace pump tube Clean / replace tube nipple All tubes behind the measuring cell, the plunger of the waste bottle, the channel and the outlet cannula in the upper half of the measuring cell must be cleaned Move device to different location Rinse out air bubbles Fill waste bottle with a bit of water (approx. 10 mm) Check position of plunger Screw measuring cell together more tightly Open and clean measuring cell

Components Function	Malfunction	Possible Cause	Measure
	The red "Overload" LED lights up (when injecting a sample or during automatic rinsing of the measuring cell using solvent)	The system is partially clogged between the measuring cell and the waste bottle	All tubes behind the measuring cell, the plunger of the waste bottle, the channel and the outlet cannula in the upper half of the measuring cell must be cleaned
	Liquid leaks from the tube connection between measuring cell and pump when injecting the sample	Entry of measuring cell is clogged	Open and clean measuring cell
Pressure transducer	Device rinses the measuring cell in periodic intervals and no longer switches to STAND-BY position Device finds no baseline characteristic	Pressure transducer is defective (pressure measurement membrane destroyed) The measuring cell was dry for an extended period of time and salt crystals have formed	Pressure transducer must be replaced Open measuring cell and rinse using distilled water
	Solvent leaks from the septum during injection. Salt crust forms below the septum screw	Septum leaking	Replace septum

8 Maintenance of the OSMOMAT 050

8.1 Requirements of the Medical Devices Operator Ordinance

The regulatory scope of Germany's Medical Devices Operator Ordinance includes the maintenance and servicing of medical devices. Sections **2 (Special Regulations for Active Medical Devices)** and **3 (Medical Devices with Measurement Functions)** regulate the safety and measurement checks to be performed on medical devices.
These checks are mandatory for medical devices listed in *Annexes 1 and 2 of the Medical Devices Operator Ordinance*.

8.2 Safety Checks (§ 6 of Medical Devices Operator Ordinance)

The OSMOMAT 050 is not listed in Annex 1 of the Medical Devices Operator Ordinance. Public authorities do not require the unit to undergo safety checks.

Safety checks should be conducted by the on-site safety coordinator in accordance with relevant accident prevention guidelines.

8.3 Measurement Checks (§ 11 of Medical Devices Operator Ordinance

The Osmomat 050 is not listed in Annex 2 of the Medical Devices Operator Ordinance. No measurement checks are stipulated by the Ordinance.
Nonetheless, the user should perform the following checks:

- ***Checking and filling the solvent bottle***
- ***Emptying the waste bottle***
- ***Calibrating the device***

The calibration frequency should comply with local quality assurance guidelines.

8.4 Internal Quality Control of the OSMOMAT 050

A microcontroller monitors the unit's functions based on the program flow. The failure of individual functional groups in the unit results in a malfunction that either triggers an error message or shuts down the unit.

If checks are to be performed, reference solutions can be produced as follows:

1) Mixing heparinized pool plasma of a larger number of healthy patients
-> Resulting osmotic pressure should be 25 mmHg +/- 2
2) Dissolve 5% human albumin in a physiological saline solution
-> Resulting osmotic pressure should be 19.5 mmHg +/- 2

8.5 Replacing a Defective Power Fuse

Before replacing a defective power fuse, ***unplug the unit from the power supply! Risk of electric shock!***

To replace the fuses, use a small screwdriver to remove the fuse holder on the rear of the unit. The two fuses can now be replaced. The unit has two-phase protection. Use the following fuses:

230V power supply: ***0,25A slow/LAG***
115V power supply: ***0,5A slow/LAG***

One set of fuses is included with the standard accessories.

8.6 Forfeiture of Measurement System Warranty

To protect the highly sensitive pressure transducer from overpressure during cell preparation, the pressure ratios in the measuring cell and at the pressure gauge have to be continually monitored. This requires the OSMOMAT 050 to be switched on. If the pressure reaches a critical point which could result in damage to the measurement system, an audible warning signal is given.
Mechanical damage to the pressure transducer is excluded from the warranty service!

8.7 Specifications for RS 232 Interface

Baud rate: Transmission speed: 1200 bps.

Data format: One start bit, 8 data bits, and 2 stop bits are sent

Signals:

	TXD -	Transmit Data (output)
	Idle level	-3V >> U >> -7.5V
	Active level	+3V << U << +7.5V
	DTR -	Data Terminal Ready (output)

This signal indicates the transmission readiness of the OSMOMAT 050, i.e. it becomes active before a telegram is sent.

Idle level	-3V >> U >> -7.5V
Active level	+3V << U << +7.5V
DSR -	Dataset Ready (input)

This signal can prevent transmission of a telegram. The OSMOMAT 050 starts transmitting only after DSR becomes active. The user does not need to activate this signal, since it is equipped with an internal 15 k-Ohm 'pull-up' resistance.

Idle level	-3V >> U >> -15V
Active level	+3V << U << +15V

8.8 Transmission Software

We recommend using our TERMINAL SOFTWARE for easy data transmission to a PC and a data acquisition that is optimized for the osmometer. In principle, any other terminal software can be used, but the data format will have to be adjusted.

9 Appendix

9.1 Consumables

Item no.	Item	Packaging unit/qty
50.9.0010	Membranes, cut-off 10,000 dalton	5
50.9.0020	Membranes, cut-off 20,000 dalton	5
50.9.0030	Silicon rubber septa	10
50.9.0040	O ring (26 x 2 mm) for measuring cell	5
50.9.0050	Connecting tube (Tygon 1.12 m, 0.04" internal)	1
50.9.0060	Tubes for peristaltic pump (Tygon 9.5 cm, 3/32" internal)	5
50.9.0070	Tube nipples for tube pump	2
50.9.0080	Plastic tuberculin syringe with special cannula 16 mm	2
50.9.0090	30 mL plastic syringe with tube and clamp	1
50.9.0100	250 µL precision syringe with special cannula for septum injection	1
50.9.0130	Plastic bottles 250 mL (supply/waste bottles)	2
50.9.0140	Tool for widening the tube ends	1
50.9.0150	Tweezers for membranes	1
50.9.0160	Plunger for supply/waste bottles	2
50.9.0180	Bottle of cleaning solution	1

9.2 Accessories and Spare Parts

Item no.	Item	Packaging unit/qty
00.9.0102	Package with 10 fine-wire fuses, 0,25A slow, 220V	1
00.9.0104	Package with 10 fine-wire fuses, 0,5A slow, 110V	1
20.9.0100	Power cord, 2 meters	1
20.9.0120	Connector cable for recorder	1
20.9.0160	Data cable for RS 232 interface OSMOMAT 030/050/010	1
50.2.0020	Lower measuring cell	1
50.2.0030	Upper measuring cell	1
50.2.0040	Peristaltic pump, complete	1
50.3.0010	Pressure transducer, complete	1
50.5.0030	Mainboard (050-KOP/1), from series 1990	1
50.9.0170	Septum screw	1

9.3 Classification of the IVD

The Gonotec OSMOMAT® 050 colloid osmometer is a non-invasive in-vitro diagnostic product according to EEC Directive 93/42 (Medical Devices Law). The OSMOMAT® 050 colloid osmometer is not named in Annex II, list A or B, of the Directive 98/79/EEC for in-vitro diagnostics. Compliance is declared per Annex III. Number 6 of Annex II is disregarded, since the unit's intended use does not include personal use.

9.4 EC Compliance Statement - OSMOMAT® 050

Gonotec GmbH
GSG-Hof Reuchlinstr. 10-11
D-10553 Berlin

We hereby declare that the OSMOMAT® 050 colloid osmometer complies with Directive 98/79/EEC. Compliance is declared per Annex III of the Directive. The CE mark on the unit acknowledges this.

Date:

Signature of managing director:

9.5 Provisions of Certification

CE compliance requires that the unit is installed and operated in the manner described in this manual. Any departure from the specifications or independent modifications of the unit without the express consent of Gonotec GmbH may result in a violation of CE requirements. Such actions invalidate the compliance statement and transfer responsibility to the originator of said actions.

10 Limited Warranty

Gonotec product	Duration of Limited Warranty
Software	90 days
Pressure transducer	180 days
Osmometer	2 years

A. Extension of the Limited Warranty

Gonotec warrants the end user that Gonotec products shall be free from manufacturing and material defects for the above periods of validity from the purchase date. The end user must provide proof of the purchase date.

For software products, Gonotec's limited warranty applies only to the non-execution of programming instructions. Gonotec does not guarantee that the operation of a product will proceed without errors or interruptions.

Gonotec's limited warranty applies only to defects that arise during normal operation of the product. It does not apply under the following conditions:

Inadequate servicing or improper modification;

Use of software, interfaces, print media or accessories not supported or supplied by Gonotec; or

Use of the equipment in a manner not covered by the product specifications.

If Gonotec is notified within the warranty period of a defect in a software product, in media or in the pressure transducer and if the Gonotec warranty applies to the defect, Gonotec shall replace the defective product. If Gonotec is notified within the warranty period of a defect in a hardware product and if the Gonotec warranty applies to the defect, Gonotec shall repair or replace the defective product at its discretion.

If Gonotec is unable to repair or replace a defective product to which the Gonotec warranty applies, Gonotec shall refund the purchase price of the product within a reasonable period following notification of the respective defect.

Gonotec is not obligated to repair or replace a product or refund its purchase price until the customer returns the defective product

to Gonotec.

Replacement products may be new or almost new, as long as their functionality is at least that of the replaced product.

The Gonotec limited warranty is applicable in all countries in which Gonotec sells the applicable product. The following countries and regions are exceptions: All countries outside the EU. In these countries, the warranty is only valid in the country in which the product was purchased. Contracts for additional warranty services, such as on-site service, may be available from an authorized Gonotec sales partner.

B. Limitation of the Warranty

TO THE EXTENT PERMISSIBLE UNDER THE APPLICABLE LOCAL LAWS, NEITHER GONOTEC NOR ITS SUPPLIERS SHALL ASSUME ANY ADDITIONAL WARRANTY SERVICES OR ACCEPT ANY OTHER CONDITIONS, EXPRESS OR IMPLIED, WITH REGARD TO THE GONOTEC PRODUCTS.

C. Limitations of Liability

To the extent permissible under the applicable local laws, the legal remedies named here shall be the sole and exclusive legal remedies available to the customer.

TO THE EXTENT PERMISSIBLE UNDER THE APPLICABLE LOCAL LAWS AND WITH THE EXCEPTION OF THE OBLIGATIONS EXPRESSLY NAMED HERE, NEITHER GONOTEC NOR ITS SUPPLIERS SHALL BE LIABLE FOR DIRECT OR INDIRECT, SPECIFIC, INCIDENTAL OR CONSEQUENTIAL LOSSES, WHETHER BASED ON A CONTRACT, A TORTIOUS ACT OR ANOTHER LEGAL THEORY, AND NOTWITHSTANDING PRIOR NOTIFICATION OF THE POSSIBILITY OF SUCH A LOSS.

Respective Jurisdiction

This warranty statement guarantees the customer certain legal claims. The customer may have other legal claims that go beyond ttube outlined here. Such claims vary by state in the US, by province in Canada and by nation elsewhere in the world.

Elements of this warranty statement that conflict with local laws can be regarded as amended to comply with the applicable laws. For this reason, certain warranty exclusions and restrictions outlined here may be of no relevance to the customer. In some states of the US, in some Canadian provinces and in some countries outside North America, for example, the following national laws apply:

Exclusion of the fact that the warranty exclusions and restrictions named here restrict the legal rights of a customer (for example: Great Britain)

Restriction of the possibilities for manufacturers to enforce such warranty exclusions and restrictions

Granting of additional warranty claims for the customer, fixing of the validity period for implied warranty services that the manufacturer may not exclude, or non-admission of restrictions relating to the validity period for implied warranty services

THE FOLLOWING APPLIES TO CONSUMER TRANSACTIONS IN AUSTRALIA AND NEW ZEALAND: THE CONDITIONS OF THIS WARRANTY STATEMENT NEITHER EXCLUDE LEGAL RIGHTS APPLICABLE TO THE SALE OF GONOTEC PRODUCTS TO SUCH CUSTOMERS NOR REPRESENT A RESTRICTION OR AMENDMENT OF SUCH RIGHTS, BUT INSTEAD REPRESENT A SUPPLEMENT TO THESE RIGHTS, EXCEPT TO THE EXTENT PERMISSIBLE UNDER THE LAW.

11 Returning Parts for Warranty

11.1 Repair or Credit

All products returned for repair or credit must be prepared as follows:

1. Call or write to request a free return order for equipment that is being returned for warranty repair or credit.You may also request a return order for equipment that is being returned for non-warranty repair, but you will be liable for the cost of the return order.

⚠ 2. **Clean and disinfect the equipment before returning it to us. We will charge a processing fee for cleaning and disinfecting contaminated equipment. Equipment that is strongly contaminated will be returned at the customer's expense.**

3. Enclose written information explaining the reason for returning the equipment.

4. If the equipment is being returned for credit, you must include all accessories (power cord, software disks, manuals, etc.).

5. Return the equipment in its original packaging. If you no longer have the original packaging, you may purchase replacement packaging from Gonotec.

11.2 Before Calling Gonotec

Note: When calling Gonotec, have your unit's serial number ready. The serial number helps our service technicians to more quickly record the unit and determine a procedure.

If possible, switch on the unit before calling Gonotec's technical service. Use a telephone that is close to the unit. You may be asked to provide detailed information while running operations or apply other troubleshooting methods that can only be performed on the unit itself. Ensure that you have the equipment documentation handy.

⚠ **Warning: Before undertaking any work on the equipment, read the safety notices in the appropriate chapters of this manual.**

12 Specifications of the OSMOMAT 050

Cell volume:	< 10 µL
Sample volume:	> 100 µL
Adding sample:	by injection syringe through a septum injector integrated into the measuring cell
Membrane material:	Two-layer membrane, retention of molecular weights > 10,000 – 30,000 dalton depending on type
Zero point setting:	automatic
Measurement time:	< 1 minute up to approx. 3 minutes depending on membrane type
Measuring range:	73 mm HG, 100 cm H2O column, or 9.99 k-Pascal
Reproducibility:	< ± 0.5 mm HG
Calibration:	direct pressure calibration through hydrostatic solvent column or using solutions of known concentration
Measurement display:	3-digit
Recorder output:	2 mV/digit, adjustable ± 10%, for strip chart recorder with 1 Volt maximum deflection
Automation:	1. Automatic rinsing of the upper half of the cell to maintain measurement readiness using the built-in tube pump 2. Storage of measurement results 3. Storage of an additional measurement value following a specific delay after obtaining the first measurement result
Data output:	RS 232 C
Power connection:	230V (±10%), 50-60 Hz, 20 VA Special versions 115V or 100V available
Dimensions and Weight:	Width 36 cm Height 25 cm Depth 35.5 cm 5.1 kg excluding bottles

Subject to technical changes

13 Service Instructions for Replacing a Defective Pressure Transducer

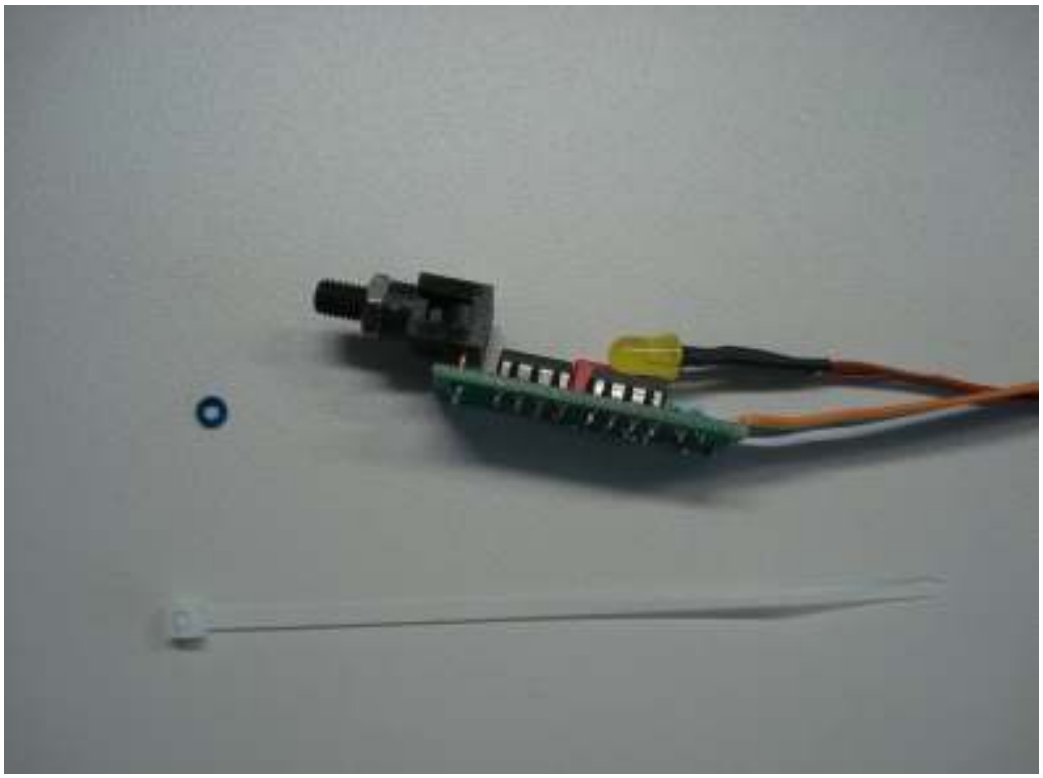
13.1 When is a replacement of the pressure transducer required?

The pressure transducer must be replaced in the following cases:

1. The OSMOMAT 050 no longer switches to STAND BY mode
2. A continuous alarm sounds, even when the measuring cell is open
3. The solvent added to the opened measuring cell flows downward through the pressure transducer

The pressure transducer can be replaced by trained medical technicians by following these instructions.
A new pressure transducer can be ordered using order no. 50.3.0010. The serial number of your device must be communicated because devices up to serial number 101122 also require replacement of the lower measuring cell due to a component change by the manufacturer of the sensor.
Package contents:

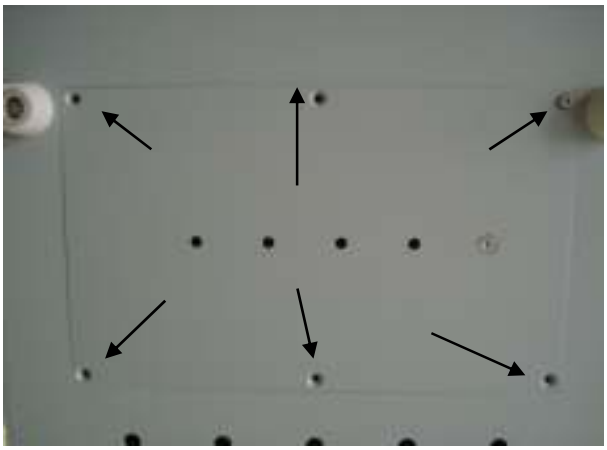
- 1 pressure transducer, complete with board and cable
- 1 O ring
- 1 cable tie



13.2 Instructions

13.2.1 Disassembly

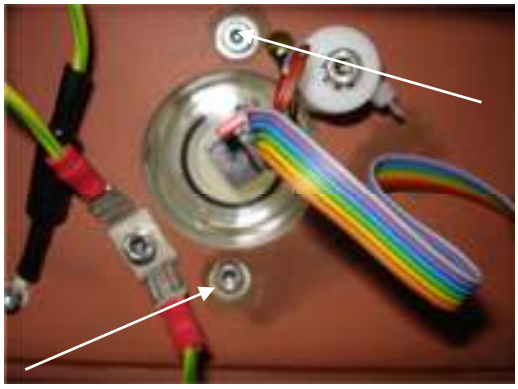
1. Unscrew and remove lower front panel (6 screws).



2. Unplug pressure transducer connector from board.

3. Release LED cable by cutting cable tie.

4. Unscrew and remove lower measuring cell by loosening the two screws below the housing.



5. Remove the lower measuring cell and the large O ring (63.22 x 1.78 mm).

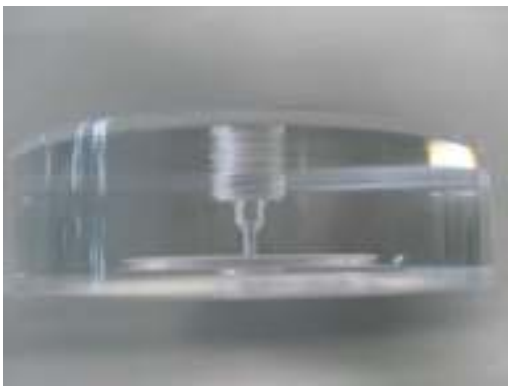
6. Loosen the counter nut and unscrew and remove the pressure transducer from the measuring cell.Remove the small O ring from the measuring cell and do not reuse under any circumstanes
7. Thoroughly rinse the lower half of the measuring cell using water and dry.

13.2.2 Assembly

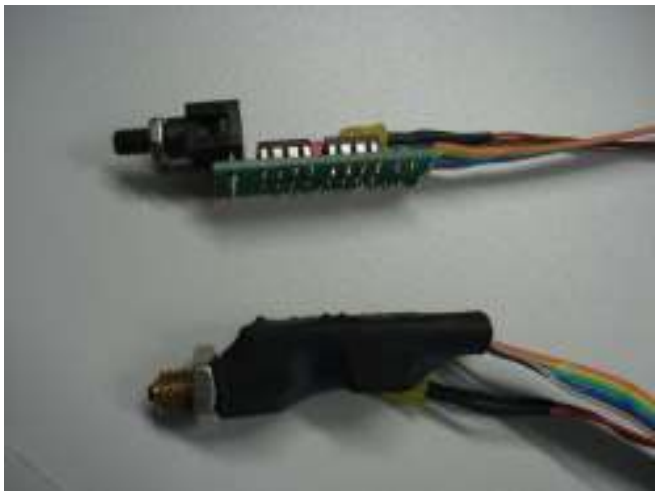
The pressure transducer is delivered with a cable tie and a new O ring.

For devices up to serial number 101122 where the pressure transducer is replaced for the first time, the lower measuring cell must be replaced as well.

New lower measuring cell



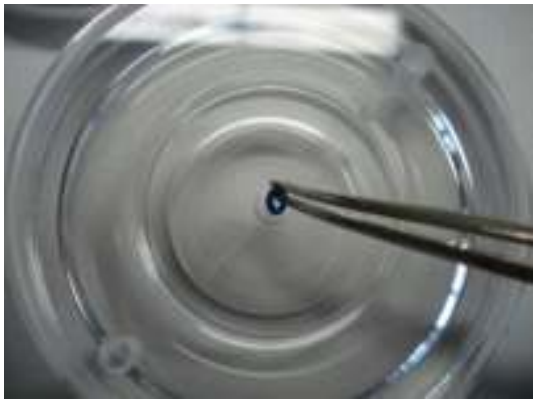
Old lower measuring cell



New pressure transducer

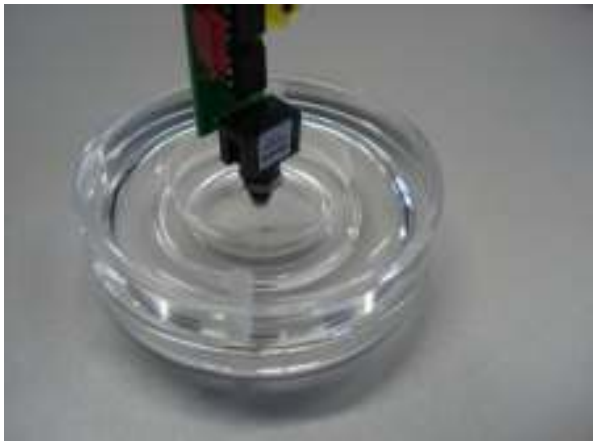
Old pressure transducer

1. If you already have a new lower measuring cell, you have to remove the old O- ring.



2. Clean the lower measuring cell with cleaning solution and rinse it with water very carefully. Install the new O ring (2 mm) in the lower measuring cell.

3. Screw the pressure transducer into the lower half of the measuring cell. It may be necessary to back off the counter nut a bit. Screw in the pressure transducer with moderate force until the O ring is pressed against the cell and the ring becomes visibly deep dark.



4. Screw the counter nut against the measuring cell to secure the system.

5. Assembly of the lower measuring cell
   Replace the large O ring (63.22 x 1.78 mm) in the lower half of the cell and reinstall the cell half into the housing from below using the two screws.
   Insert the yellow LED into the designated bore and secure using cable tie.
   Plug the connector of the pressure transducer into the mainboard and replace the lower housing cover using the six screws.

The OSMOMAT 050 is ready for use again.