www.gonotec.com

gonotec
Gesellschaft für Meß- und Regeltechnik mbH

User Guide

Osmolality Measurement in medical and pharmaceutical field

Cryoscopic Osmometer

OSMOMAT® auto

Notes, Safety Notices and Warnings

The symbols and abbreviations defined below may appear on the packing material, on the unit name 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 of the user guide.
	"Use by …" The date that follows indicates the expiration data as *year-month*.
LOT	Appears beside the name of the product batch.
REF	Item number or order number

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

	This symbol warns of the danger of corrupting measurement results, for example, by improperly using measuring vessels.
	This symbol warns of the danger of damaging the unit or the measurement system, for example, as a result of improper servicing.
	Note or tip.

OSMOMAT® auto model, series 2005 and later

October 2009 Version 1.1

List of Figures

List of Tables

1 Introduction

1.1 Applications of the OSMOMAT auto

The Gonotec cryoscopic osmometer, Osmomat® auto, is a non-invasive in-vitro diagnostic device for in-vitro analysis of human blood, urine, semen and other samples, such as drip solutions. Its purpose is to provide information to help identify, diagnose, monitor and treat physiological conditions, states of health, and illnesses.

The OSMOMAT® auto must be operated exclusively by persons whose training or skills have provided them with the necessary practical experience (cf. German Medical Devices Operator Ordinance, *MPBetreibV*).

The OSMOMAT auto is a fully automatic cryoscopic osmometer that is optimally suited for measuring the total osmolality of aqueous solutions. It requires a sample volume of 50µl and up to 20 samples can be measured and stored fully automatically in one procedure. Simple menu-controlled operation helps to provide a high-performance and efficient measurement system for use in laboratories with higher sample volumes.

The OSMOMAT auto is based on the proven measurement principle of the Osmomat 030. The system developed by Gonotec for initiating crystallization by injecting ice crystals is also used here.

The sample data can be entered via the keypad or a barcode reader prior to the measurement. Measurement results are automatically assigned, stored in the unit (up to 300 samples), and can be output immediately or later via the built-in standard paper printer by user command. Transfer to a PC via the installed RS232 interface is possible.

Osmolality is an important measure of concentration for diluted solutions, such as all bodily fluids. In the hospital or doctor's office, osmolality can be used as one of several parameters to help form a diagnosis or prompt further testing. In the pharmaceutical industry and research, the Osmomat auto is used to test various aqueous solutions (saline drips, etc.) and for process validation.

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

General medicine	Physiology	Urology	Veterinary medicine
Routine and research	Clinical laboratories	Nephrology	Pharmaceutics
Forensic medicine	Intensive care laboratories	Hemodialysis	Pharmacies
Electron microscopy	Pediatrics	Hemofiltration	… and many more
	Gynecology	Botany	

1.1.1 Application Restrictions of the Osmomat auto

- The unit is not intended for determining the osmolality of dilutions.
- Only the osmolality of aqueous solutions can be determined.

Plausibility checks of the results must be performed by the doctor with the support of the pertinent literature.

1.2 Measurement Method of the OSMOMAT auto

The OSMOMAT auto is a cryoscopic osmometer that measures the freezing point depression to determine the total osmolality of aqueous solutions.
The freezing points of pure water and a solution are measured and compared. Whereas water has a freezing point of 0°C, a solution with a saline concentration of 1 osmol/kg has a freezing point of -1.858°C. That means that one mol of a given non-dissociated substance (6.023×10^{23} parts diluted in one kilogram of water) lowers the freezing point of a solution by 1.858°C. The following definitions are used in calculating osmolality:

$C_{osm} = \Delta T / K$	C_{osm} = osmolality [osmol/kg] T = freezing point depression [°C] K = 1.858°C kg/osmol freezing point constant

The osmolality indicates the concentration of all osmotically active dissolved parts in the solvent.
Since the freezing point depression is directly proportional to the dissolved parts, the OSMOMAT auto measures the osmolality directly.

1.3 Reproducibility in the OSMOMAT auto

Measurement display	LCD display, 4 lines with 20 characters
Measuring range	0 to approximately 2500 mOsmol/kg
Resolution	1 mOsmol /kg or 1 mOsmol/digit over the entire measuring range
Reproducibility	
Sample volume 50µl	≤ ±1.0%

1.4 Function of the OSMOMAT auto

The sample solution is cooled with a peltier cooling system while its temperature is electronically monitored. Once the sample solution has reached a specific temperature below the freezing point, crystallization is automatically initiated. The OSMOMAT auto initiates crystallization by injecting the sample with a stainless steel needle that is cooled by a secondary upper cooling system and has small ice crystals formed by moisture in the air on its tip. When crystallization begins, ice forms spontaneously. The heat that was removed during undercooling is released again, the temperature rises spontaneously, and the temperature of the sample rises to the freezing point.

If the sample consists of water (solvent), equilibrium is achieved as long as the sample contains water and ice. The temperature remains constant because further heat removal does not result in a lowering of the temperature but the formation of ice. The time of temperature equilibrium is known as *plateau time*. Only after complete crystallization does the temperature fall again.

If the sample consists of a solution, the pure water in the solution crystallizes spontaneously and the substances move to the rest of the solution. This means that at the time the freezing point temperature is measured, the concentration is higher than in the original solution. A plateau occurs here as well, but it is inclined. The osmolality reading is taken at the resulting reversal point (see Fig. 1). The temperature is measured with a resolution of 1.858 x 10E-3°C.

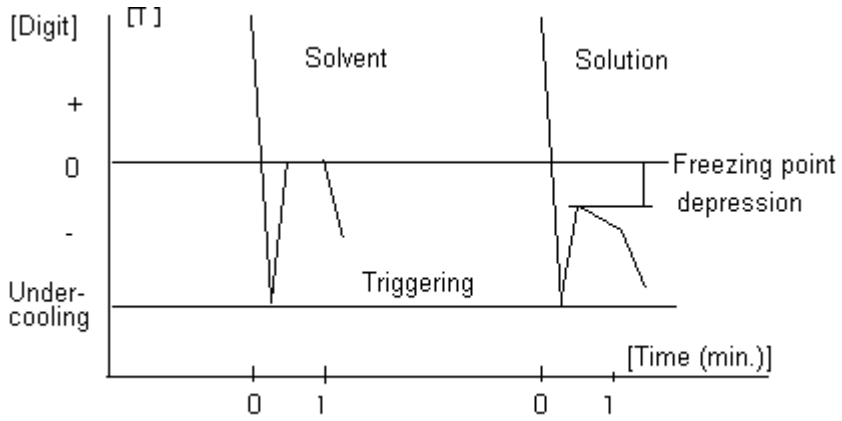


Fig. 1 Freezing Point Depression of Solvent

1.5 Unpacking the Cryoscopic Osmometer OSMOMAT auto

The cryoscopic osmometer OSMOMAT auto 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.: +49 (0)30 7809588-0
GSG Hof Reuchlinstr. 10-11	Fax: +49 (0)30 7809588-88
10553 Berlin	E-mail: contact@gonotec.com
Germany	Web: www.gonotec.com

Toll-free service number within Germany: 0800 / 7846027

The packaging for this equipment was specially designed to ensure safe and hygienic transport. The packaging is re-usable. Please save the packaging in case the unit needs to be shipped back to Gonotec for repairs or servicing.
This will save you the time and money needed to find equally suitable packaging.

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	
OSMOMAT auto	20.9.0100	✓ 1 power cable
	00.9.0104	✓ 2 fine-wire fuses **230V 0.5A**
	00.9.0106	*(at 110V 1.0A)*
	35.9.0010	✓ 1000 measuring vessels
	30.9.0020	✓ calibration standard 300 mOsmol/kg
	35.9.0100	✓ 1 sample holder
	30.2.0030	✓ 1 adjustment tool
	30.9.0030	✓ 1 pasteur pipette (bellow)
	30.9.1010	✓ 8 rolls of printer paper
	35.9.1030	✓ 1 roll of cleaning paper
		✓ 2 Allen wrenches (*1.5 mm/2.5 mm*)
		✓ 1 user guide Osmomat auto
Barcode option	35.9.2000	✓ 1 hand-held barcode scanner with power supply

2 Overview of the OSMOMAT auto

2.1 Overview of Display and Connectors

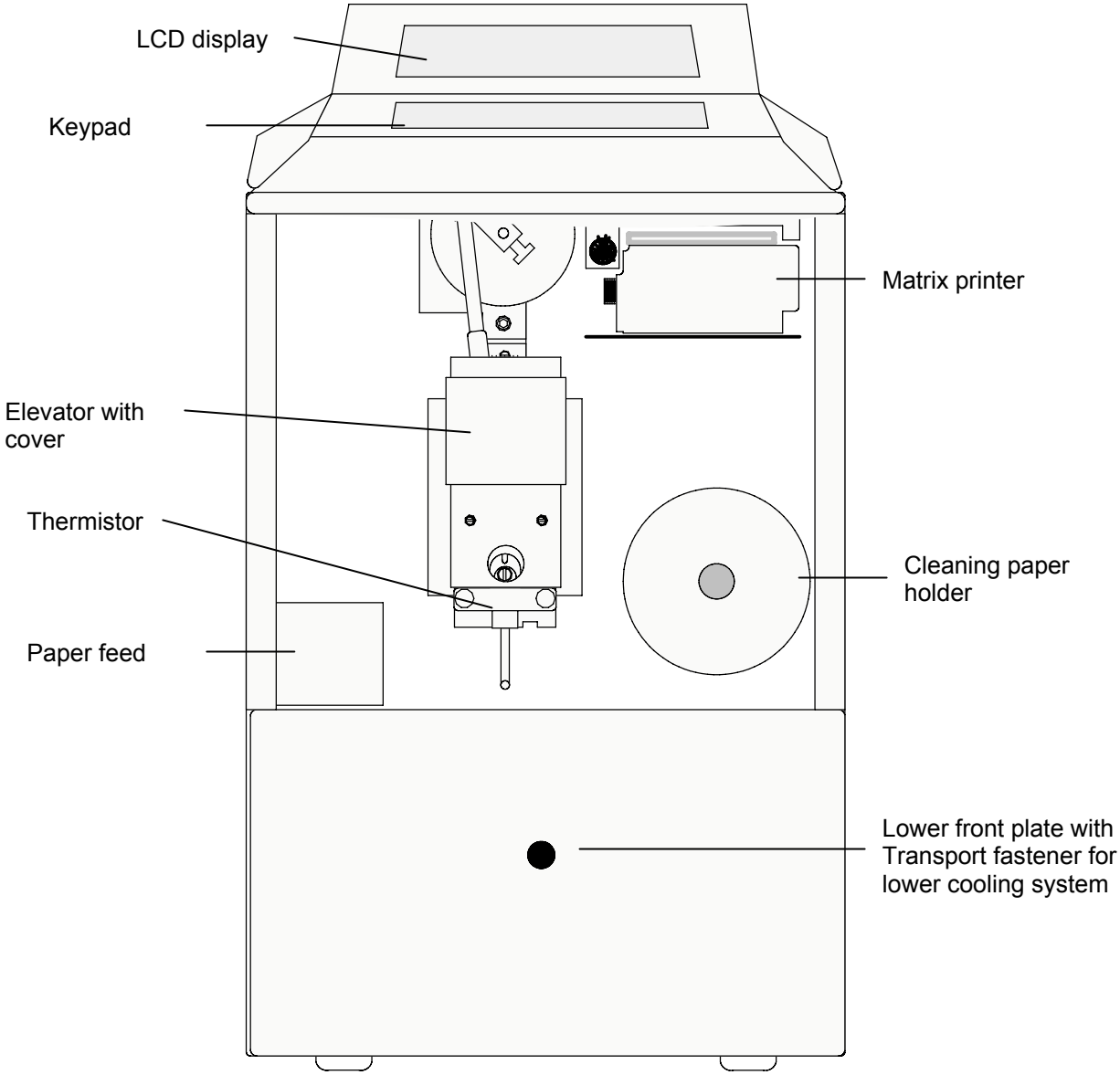


Fig. 2 Front view of the OSMOMAT auto

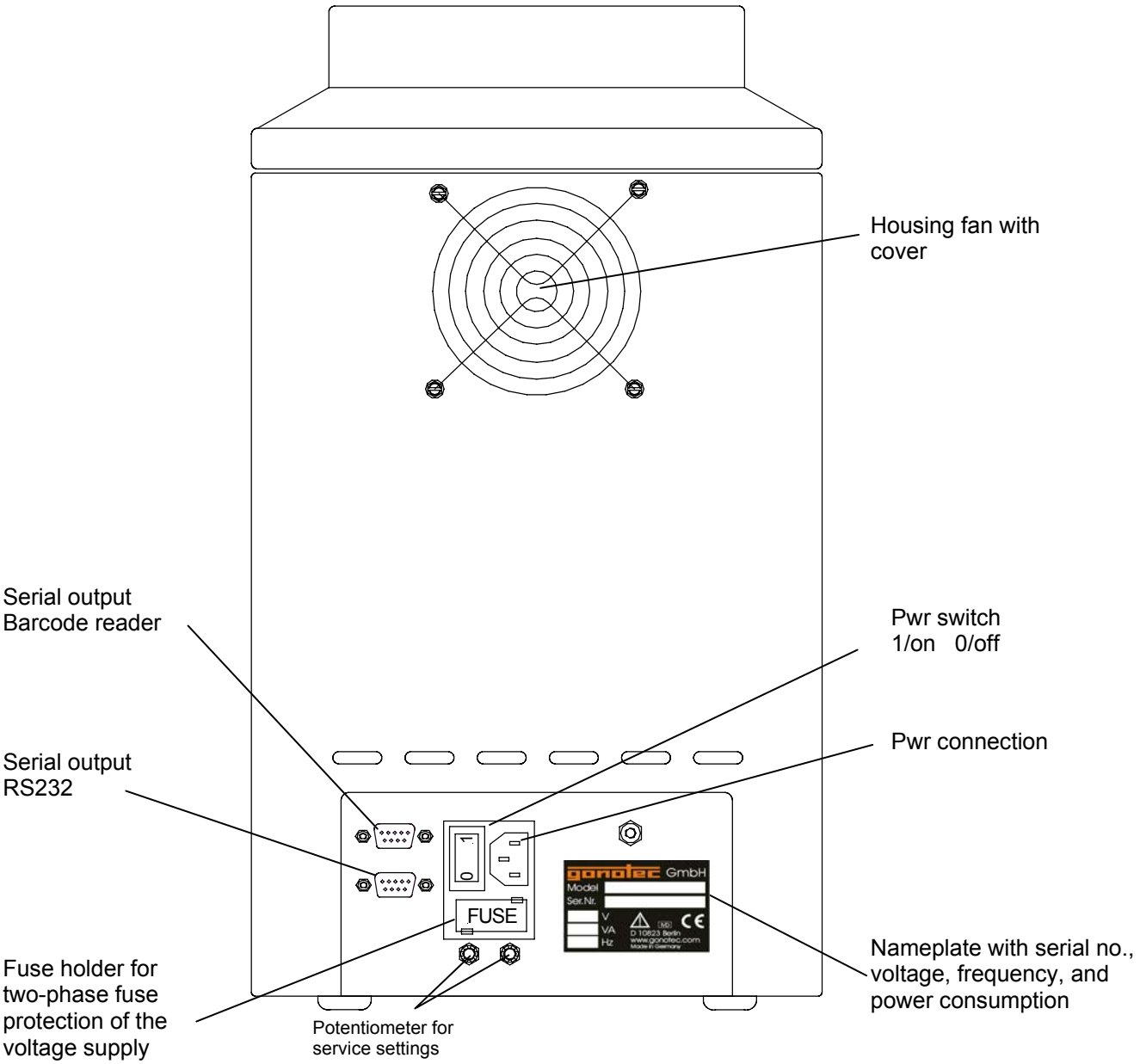


Fig. 3 Rear view of the OSMOMAT auto

2.2 Power Supply

The standard model is operated with 230V (+/- 20V) at 50/60Hz. The power consumption is 120VA. Special models using 115V or 100V are also available.

2.3 Dimensions and Weight

Dimensions (width x depth x height): 275 x 225 x 390 mm

Weight: approximately 11.9 kg

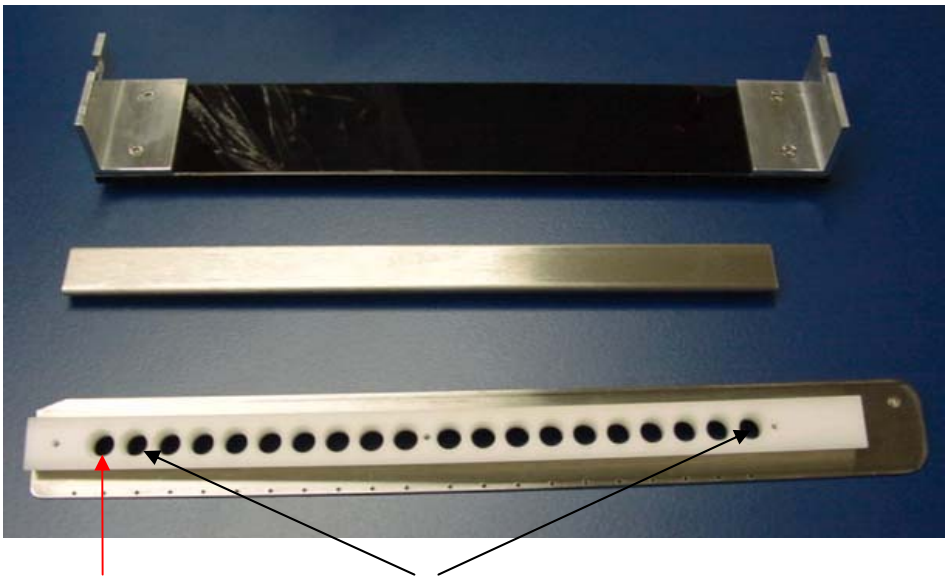
2.4 Sample Holder

■ Components

- Sample stand
- Sample cover
- Sample holder

■ Filling the Sample Holder

The sample holder can accommodate up to 20 samples. The sample spaces are numbered on the sample holder from 1 through 20.
Position 0 is reserved for the initialization sample with distilled water. Refer to section 5 Calibration of the OSMOMAT auto.



Initialization sample 20 sample spaces

The sample cover protects the samples from premature evaporation.
Observe the information in the following chapters *Calibration of the OSMOMAT auto* and *Measurement of a Sample Solution*.

3 Setup and Initial Operation

First, remove all transport protections as shown on the last page and store them for later servicing.

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 30°C (50-95°F).

The air inlets and outlets on the bottom and back of the unit must be unobstructed. Use the provided power cable to connect the OSMOMAT auto 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 cable plug does not match the conventional power outlets in your location, you may substitute another power cable. It is essential, however, that the cable's green/yellow wire be connected to the safety grounding.

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

The OSMOMAT auto can now be switched on via the power switch on the back of the unit (next to the power connector). Two system numbers, the system date and time, and an initialization text for the warm-up phase are shown in quick succession (Fig. 4). The initialization text disappears after approximately 3 minutes and a greeting is displayed. The OSMOMAT auto is ready for measurements and the subsequent operations can now be selected via the menu.

The waiting period of approximately 3 minutes is necessary for the formation of ice crystals at the upper cooling system.

The *Esc* key can be used to switch immediately to the menu but this does not affect the waiting period.

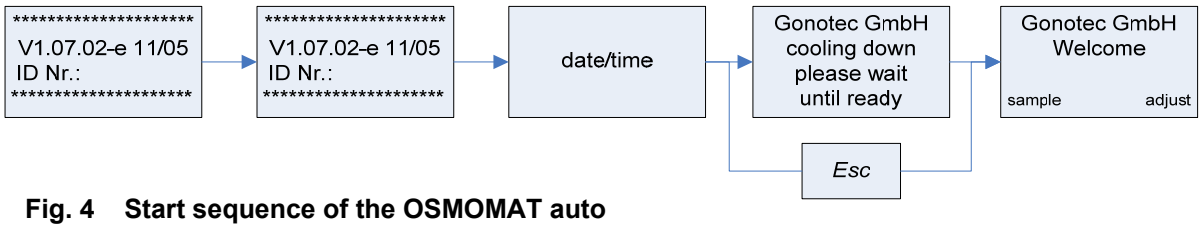


Fig. 4 Start sequence of the OSMOMAT auto

3.1 Safety and Handling Information

The OSMOMAT auto cryoscopic 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.

The unit must be adequately **disinfected** prior to **decommissioning**. Equipment must be **decommissioned** in accordance with local accident prevention guidelines.

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

Symbols on the unit and its name 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*).

3.2 Known Risks Associated with the Use of the OSMOMAT auto

In our experience using the Osmomat auto, it has not been found to present any direct hazards or risks to the user. Such hazards and risks cannot be excluded entirely for technical equipment, however.

This user guide helps you gain a basic understanding of the design, the measurement principle, maintenance and servicing of the unit. Please pay special attention to chapter 10.8, *Replacing a Defective Initiation Needle.*

4 OSMOMAT auto Menu Structure

The menu shown on the display is operated via the arrow keys and number keys.

The individual menu points are selected via the arrow keys and the *Esc* key. The number keys and the *Ctrl* key are used for data entry.

4.1 Display and Keypad Overview

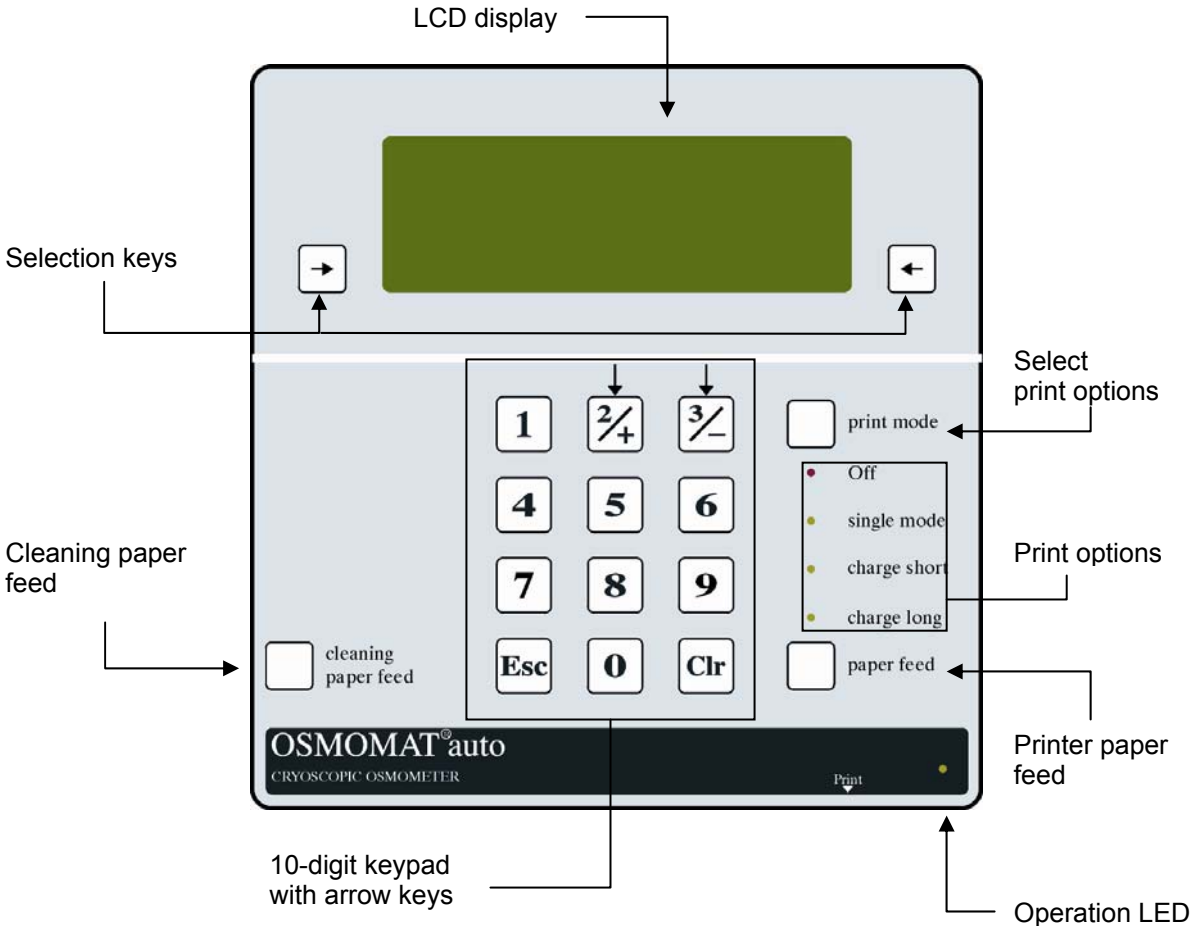


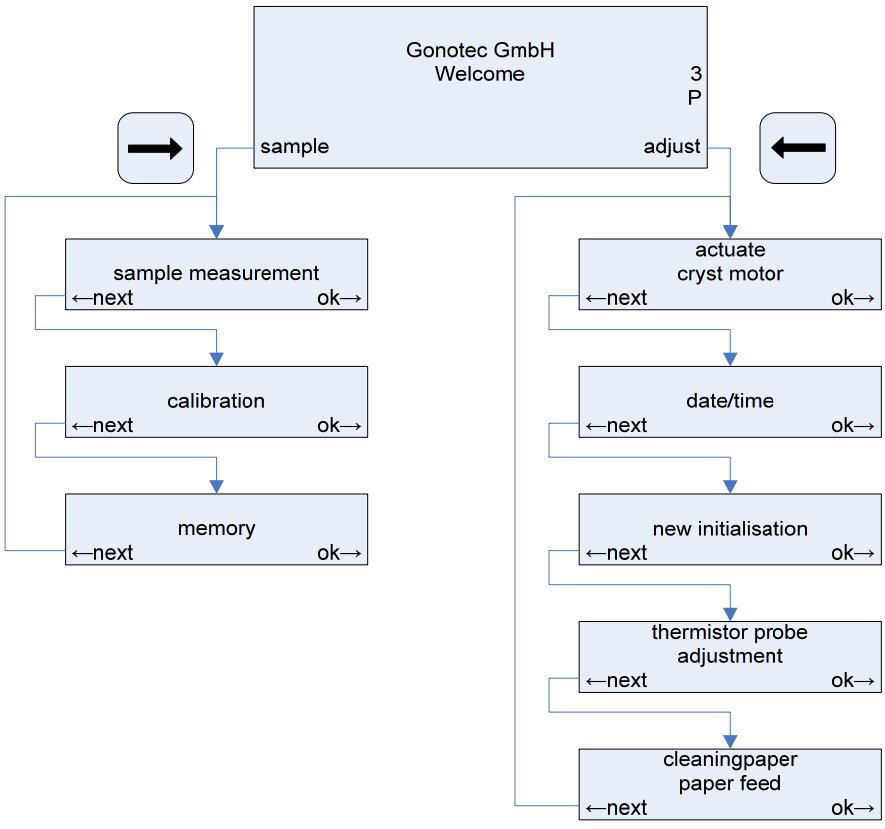
Fig. 5 Keypad of the OSMOMAT auto

4.2 Menu Functions

In the initial display, select measurements or settings and then the appropriate menu and submenu. Select *Continue* to continue in the menu or *OK* to switch to the submenu. Press the *Esc* key to exit the current menu level. Press the *Esc* key repeatedly to return from the submenu directly to the initial display. The functions and option elements are described in the individual chapters.

■ Measurements and Settings

Select > *sample* to perform sample measurements, calibrate the unit, and manage the sample data. Select > *adjust* to change basic settings, such as the date and time and the cleaning paper feed, and to conduct maintenance work, such as testing the initiation function, newly initializing the unit, and adjusting the thermistor probe.



5 Calibration of the OSMOMAT auto

Before the total osmolality of sample solutions can be measured, the OSMOMAT auto must be calibrated with distilled water and a calibration standard.

5.1 Calibration at Two Points

Two clean, dry measuring vessels are first filled via a pipette with 50 µl distilled water and 50 µl Gonotec calibration standard 300 mOsmol/kg. In this process

⚠ ***there must be no visible air bubbles in the liquid!***

The sample holder is numbered 0 through 20 from left to right. The sample holder is to be filled as follows:

Positions **0** and **1** with **distilled water**

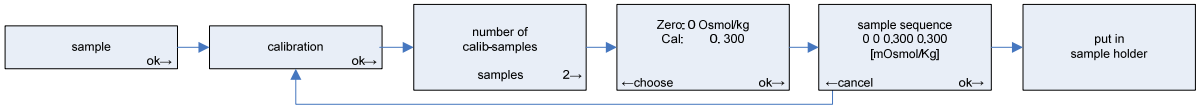
Positions **2** and **3** with **300 mOsmol/kg**

⚠ ***Use the proper sequence when filling the sample holder. Incorrect placement results in incorrect calibration!***

The sample cover is then placed on the sample holder to prevent premature evaporation of the samples.

⚠ ***The sample cover reduces the risk of premature evaporation of the samples. However, it does not protect the samples from leakage.***

To perform the calibration, select > *sample* > *calibration* in the initial display. Select > *number of calib-samples* > *2* in the display to calibrate at two points. Use *choose*, to select the calibration value of the calibration standard to be used > *100 200 300 500 600 700 850 900 1200 1500 1800 2000 2500*. The value for the distilled water is predefined at 0 mOsmol/kg. Confirm your selection with *OK*. The following display > *sample sequence* again shows your calibration settings and the corresponding positions of the solutions in the sample holder – e.g. *0 0 0.300 0.300* for a calibration at two points with distilled water and Gonotec calibration standard 300 mOsmol/kg. Select *OK* to accept the settings. With *Cancel* you can discard the settings and return to the display > *calibration*.



You will now be prompted to insert the sample holder in the unit. The Osmomat auto automatically detects the inserted sample holder and begins the calibration.

The calibration values are now consecutively shown on the display. If the printer is switched on, these values are also printed. After successful calibration, the message > *accept calibrationmeas.?* appears. Confirm the calibration values with *OK*. The unit then automatically prepares for sample measurement. Otherwise select *repeat* to discard the calibration values and recalibrate the unit.

☞ Note: A 2P or 3P is displayed on the right side of the initial display and the displays of the submenu. These signalize the calibration status of the unit. A 2P indicates two-point calibration and a 3P indicates three-point calibration. The status changes according to the calibration performed. This status is retained even after the unit is switched off and restarted but lost after new initialization.

☞ Note: Prior to the calibration procedure, switch the printer on to document the calibration results. Subsequent display or printing is not possible!

5.2 Calibration at Three Points

Two clean, dry measuring vessels are first filled via a pipette with 50 µl distilled water, 50 µl Gonotec calibration standard 300 mOsmol/kg, and 50 µl 850 mOsmol/kg.

⚠ ***There must be no visible air bubbles in the liquid!***

The sample holder is numbered 0 through 20 from left to right. The sample holder is to be filled as follows:

Positions **0** and **1** with **distilled water**
Positions **2** and **3** with **300 mOsmol/kg**
Positions **4** and **5** with **850 mOsmol/kg**

⚠ ***Use the proper sequence when filling the sample holder. Incorrect placement results in incorrect calibration!***

The sample cover is then placed on the sample holder to prevent premature evaporation of the samples.

⚠ ***The sample cover reduces the risk of premature evaporation of the samples. However, it does not protect the samples from leakage.***

To perform the calibration, select > *sample* > *calibration* in the initial display. Select > *number of calib-samples* > 3 in the display to calibrate at three points. The value for distilled water is predefined at 0 mOsmol/kg.

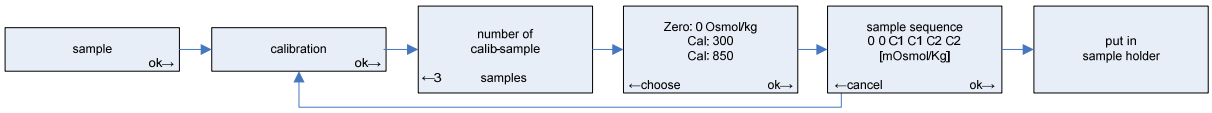
Selection of a first calibration point (c1): With *choose,* select the calibration value of the calibration standard to be used for the first calibration point > *100 200 300 500 600 700 850 900 1200 1500 1800 2000 2500*. Confirm your selection with *OK*. The system automatically specifies the first possible second calibration point.

Selection of a second calibration point (c2): Use *choose*, to change the defined calibration value to the calibration standard to be used for the second calibration point. Confirm your selection with *OK*.

☞ Note: The following applies for 'c2': the minimum distance from c1 is the calibration point after next. For example:

If 'c1' = 100 mOsmol/kg, all calibration points above 300 mOsmol/kg are possible for 'c2'.
If 'c1' = 200 mOsmol/kg, all calibration points above 500 mOsmol/kg are possible for 'c2'.
If 'c1' = 300 mOsmol/kg, all calibration points above 600 mOsmol/kg are possible for 'c2'.
…
If 'c1' = 2000 mOsmol/kg, 3000 mOsmol/kg are possible for 'c2'.

The following display > *sample sequence* shows *0 0 c1c1 c2c2,* the sequence for placing the distilled water (0), the first calibration standard (c1), and the second calibration standard (c2) in the sample holder. Select *OK* to accept the settings. With *Cancel* you can discard the settings and return to the > *calibration* display.
You will now be prompted to insert the sample holder in the unit.
The Osmomat auto automatically detects the inserted sample holder and begins the calibration.



The calibration values are now shown consecutively on the display. If the printer is switched on, these values are also printed. After successful calibration, the message > *accept calibrationmeas.?* appears. Confirm the calibration values with *OK*. The unit then automatically prepares for sample measurement. Otherwise select *repeat* to discard the calibration values and recalibrate the unit.

☞ Note: Prior to the calibration procedure, switch the printer on to document the calibration results. Subsequent display or printing is not possible!

6 Measurement of a Sample Solution

After calibration respectively calibration confirmation, the unit is ready for sample measurements.

⚠ Since the sample measurements must be carried out under the same conditions as the calibration, 50 µl of the sample liquid are filled via pipette into a clean, dry measuring vessel. ***It is essential that there are no air bubbles!***

The sample holder is numbered 0 through 20 from left to right. Fill the sample holder for an individual measurement as follows:

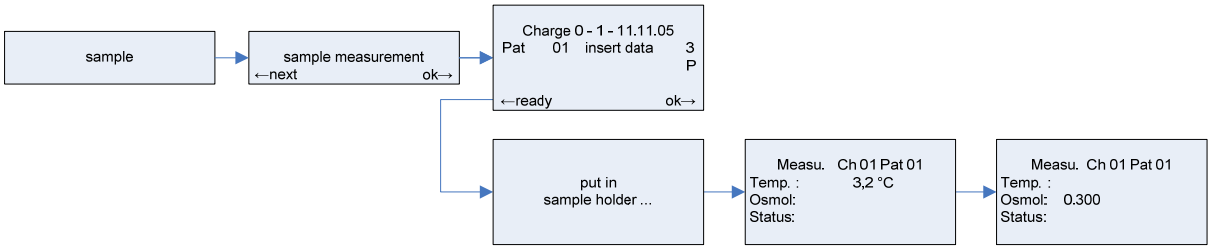
Position **0** with **distilled water**
Position **1** with the **sample solution**

⚠ ***When filling the sample holder, ensure that position 0 is always filled with a measuring vessel with distilled water. If position 0 is not filled, there is no measured value for the first sample!***

The sample cover is then placed on the sample holder to prevent premature evaporation of the samples.

⚠ ***The sample cover reduces the risk of premature evaporation of the samples. However, it does not protect the samples from leakage.***

To perform the sample measurement, select > *sample* > *sample measurement* in the initial display. A display appears for the input of sample-specific data. Select *ready*, if you do not need any data or want to use the data automatically provided by the system. You will now be prompted to insert the sample holder in the unit. The Osmomat auto automatically detects the inserted sample holder and begins the measurement.



You can track the cooling of the sample during a measurement on the display.

■ Measurement Results

The sample measurement results are

- shown as plain text on the display,
- shown as plain text on the printout when the printer is switched on

and

- automatically saved.

The sample results are comprised of a system-defined

- <Ch> batch number and
- <Pat> patient number

measured value in

- <osmol>

or error message as plain text under <Status>

- spon. crystallization
- no crystallization

and optionally of

- sample-specific data

☞ Note: Measurement results from sample measurements are automatically saved. The printer does not need to be switched on for this. Printing can also be performed later from the memory.

6.1 Series Measurement

With OSMOMAT auto, up to 20 samples can be measured and saved fully automatically in one procedure.

Position 0 on the sample holder is reserved for internal system initialization. ***It must be filled with distilled water for every series measurement!***

■ Filling the Sample Holder

Position **0** with **distilled water**

Positions **1** through **20**: can be filled as desired. For example, every second or third position can be filled.

⚠ ***When filling the sample holder, ensure that position 0 is always filled with a measuring vessel with distilled water. If position 0 is not filled, there is no measured value for the first sample!***

⚠ ***Be sure to identify samples uniquely.***

The sample cover is then placed on the sample holder to prevent premature evaporation of the samples.

⚠ ***The sample cover reduces the risk of premature evaporation of the samples. However, it does not protect the samples from leakage.***

Incorrect measured values due to evaporation.

⚠ ***Conduct series of tests so that you can adjust your method of working with the unit to the environmental conditions.***

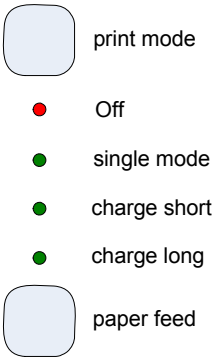
Determine the acceptable time between sample preparation and sample measurement.

7 Print Functions

The OSMOMAT auto is equipped with a dot matrix printer. The printer uses normal paper and an ink ribbon cartridge. The printer paper and the endless ribbon cartridge are consumables and must eventually be replaced. The OSMOMAT auto is fully operable even if the printer is off. The results can be seen on the digital display after each measurement.

☞ Note: Set the desired print function prior to starting the sample measurement. The printer mode can no longer be changed during a measurement. Printing can also be performed later from the memory.

■ Switching On or Off and Making a Selection



Press the *Print Mode* button to switch the print functions on and off and select them.
Press the button until the desired print function is reached.
It is signalized by a lit LED.

OFF
Printer is off

	Measurement operation	Printing from memory	Format	
Single Mode	Printing per sample measurement	Single sample		▪ Current date
				▪ Unit ID:
				▪ Batch number
				▪ Measurement date
Charge Long	Printing after completed batch measurement	Printing of a selected batch		▪ Position number on the sample holder or individually assigned sample data
				▪ Measurement time
				▪ Sample number
				▪ Measurement result in osmol/kg
Charge Short	Printing after completed batch measurement	Printing of a selected batch	One time header printout	▪ Current date
				▪ Unit ID:
				▪ Batch number
				▪ Measurement date
			For every sample	▪ Position number
				▪ Measurement time
				▪ Sample number
				▪ Measurement result in osmol/kg

■ Paper Feed

Press the *Paper Feed* button for as long as you need to feed the paper.

8 Memory Management

The OSMOMAT auto has an internal battery-buffered CMOS memory for 300 pieces of measurement data. The data is retained in the memory even after the unit is switched off or disconnected from the power supply. The manufacturer-specified battery life is 10 years. After expiration of this time, the battery buffer may not be sufficient after the unit is switched off or disconnected from the power supply to retain the data. The data is then permanently lost.

■ Memory Space Assignment

To obtain an overview of the instantaneous memory space assignment, select > *sample* > *memory* > *memory capacity* in the initial display. Confirm your selection with *OK*. The amount of available space is indicated in positions. (One position per sample measurement).

Select *next* to return to the display > *memory capacity*. Use *Esc* to return to the display > *memory* and press *Esc* again to return to the initial display.

■ Searching for Batch and Sample Results

You can search for sample results in the memory by batch. Select > *sample* > *memory* > *look at charge* in the initial display. Confirm your selection with *OK*. The last batch is displayed or *"there is no data in memory"* is displayed when there is no data in the memory. Use *Esc* to return to the display > *memory*.

The batch data and the sample volume are displayed for every batch.

Press the 3/- button to display the batches in decreasing chronological order.
Press the 2/+ button to display the batches in increasing chronological order.
Confirm your selection with *OK* to display the sample results for the batch.
You can end this operation at any time via the *Esc* key.

The date, sample position in the sample holder, and the measurement result in osmol/kg are shown for every sample measurement.

Press the 2/+ button to display the samples in increasing chronological order.
Press the 3/- button to display the samples in decreasing chronological order.
You can end this operation at any time via the *Esc* key.

Note: The batch count is automatically reset with a date change (next day) and begins anew with 01. As a result, there can be several batches with the same batch number but different dates in the memory.
Unique sample identification is ensured by the batch number, date, sample position in the sample holder, or an individually assigned identification number.

■ Printing Batch and Sample Results

Printing is performed from the *sample results* previously selected via the batch.
The *Print* function is available when the printer is switched on.

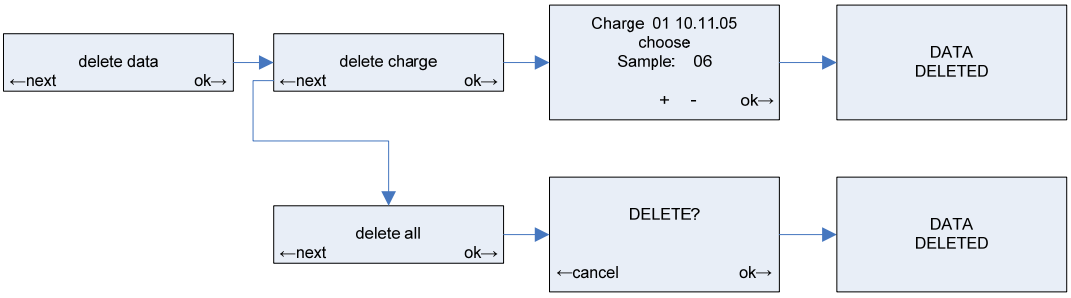
The print format is selected via the *Print Mode* button. See **Print Functions**.

- **Single mode:** Provides printout of the displayed sample
- **Charge short:** Provides quick printout of complete batch of the displayed sample
- **Charge long:** Provides long printout of complete batch of the displayed sample

■ Deleting Data

You can delete data from the memory by batch or completely.
Please note: Deleted data can no longer be retrieved.

1. **By Batch:** Select > *sample* > *memory* > *delete data* > *delete charge* in the initial display. Confirm your selection with *OK*.
   Press the 3/- button to display the batches in decreasing chronological order.
   Press the 2/+ button to display the batches in increasing chronological order.
   Confirm your selection with *OK* to delete the displayed batch.
   You can end this operation at any time via the *Esc* key.



2. **Completely:** Select > *sample* > *memory)* > *delete data* > *delete all* in the initial display. Confirm your selection with *OK*. Confirm with *OK* if you really want to delete all data. Otherwise select *cancel* to cancel the operation.

■ Monitoring the Memory Capacity

The OSMOMAT auto has an automatic monitoring routine to check the memory capacity for measurement data prior to each measurement series.
The memory manager outputs a warning on the display when the memory capacity is less than 20 units of measurement data. Unnecessary data must be deleted prior to the next measurement series.

9 Error Messages and Troubleshooting

The following explains the error messages reported by the unit along with their possible causes and describes the proper use of measuring vessels.

9.1 Spontaneous Crystallization

The freezing point of a solution is measured by first undercooling the solution, without any ice formation, to a predefined temperature. Crystallization is then automatically initiated by injecting ice crystals. A portion of the solution's water content is crystallized out. The crystallization enthalpy causes an immediate rise in temperature up to the freezing point of the remaining, somewhat more highly concentrated solution. During the time in which both ice and solution are present, a freezing plateau then forms. Since ice is constantly forming through the ongoing gradual cooling of the sample, however, the concentration of the remaining solution increases steadily, leading to a steady increase of the osmolality and thereby inclining the freezing plateau to a specific degree. The OSMOMAT auto obtains a reading for the total osmolality by calculating the temperature difference between the freezing point of the water and the reversal point detected while measuring the sample solution. The OSMOMAT auto monitors temperature changes during the undercooling phase. If crystallization begins prematurely, before the undercooling temperature of -7°C is reached, an error message is displayed, the erroneous reading, which is too low in this case, is suppressed, and "SPONT.CRYSTALLIZATION" is displayed under status.

9.2 Preventing False Readings Due to Spontaneous Crystallization

The main cause of spontaneous crystallization is the presence of seed crystals, which prevent undercooling to the proper temperature. Such seed crystals might be salt crystals, gas saturation or any pre-existing ice crystals. Seed crystals of this type can be easily eliminated by briefly heating the sample liquid close to its boiling point and subsequently cooling it. Seed crystals that cannot be eliminated in this manner may be removable through filtration. Salt crystal formation may result when cooling sample solutions containing certain salts on the solubility threshold due to low solubility or high concentration. These salt crystals then act as seed crystals. In such cases, adequate dilution may help, ***though precise results can no longer be expected***. (Also see chapter 9.3.1, *Excessive Osmolality*.) Seed crystals can also adhere to the thermistor probe. Clean the thermistor probe thoroughly using water and a soft paper towel to remove any seed crystals.

If the thermistor probe's glass bead has even a hairline scratch that cannot be removed, replace the sensor. Dirty measuring vessels (dust on the inside surface) can also cause such errors.
Measuring vessels that are re-used may eventually develop cracks in the plastic in which a fine liquid film can cause premature crystallization.

⚠ ***Measuring vessels are designed for single use only.*** *Re-use of measuring vessels can lead to non-reproducible results.*

9.3 Late or No Crystallization

After the sample solution has been cooled to the proper temperature, crystallization is initiated automatically by the injection of ice crystals. There are two possible reasons for a crystallization failure:

9.3.1 Excessive Osmolality

Crystallization is initiated at -7°C.
The OSMOMAT auto can measure solutions with a maximum osmolality of approximately ***3 Osmol***, since this osmolale concentration yields a freezing point temperature of:

$$3 \times 1.858 = 5.574 \approx -5.6°C$$

If the freezing point is very close to the temperature at which crystallization is initiated, however, crystallization will not start despite the very effective method of initiation crystallization via the injection of ice crystals. This condition is further exacerbated if the solution exhibits a rising viscosity.
The only remedy in such cases is to adequately dilute the sample solution.
It must be taken into consideration, however, that the osmolality does not change in proportion to the dilution ratio, since the degree of electrolyte dissociation during dilution is different for each substance.
For routine measurements — e.g. quality inspections — corresponding relative measurement results from diluted samples can be used as a basis for evaluation.

9.3.2 Injection with Ice Crystals Does Not Work

If no crystallization occurs during the crystallization-initiation phase despite the sounding of the acoustic signal and even though the sample liquid does not exhibit excessive osmolality, there are various possible causes. (See also 9.4 Classification of Malfunctions by Component Group).

1. The stainless steel needle that transports the ice crystals is not moving from its upper to lower position. A mechanical problem is preventing the movement of the needle.

Remedy: Unscrew the thermistor probe. The needle can then be straightened ***(caution—risk of injury!)***, repositioned and checked for mechanical maneuverability. The needle movement can be checked for this purpose via the display < *thermistor probe adjustment*.
Select > *adjust* > *thermistor probe adjustment* in the initial display. Select *OK* to move the needle.

2. The ice crystals at the tip of the stainless steel needle do not reach the undercooled liquid sample despite the lack of mechanical problems with the movement of the needle. The ice-covered tip of the stainless steel needle passes through a bore above the measuring vessel during the crystallization-initiation phase. This bore may contain a drop of water or be very dirty. The drop of water may be the result of ice crystals falling from the upper cooling system.

Remedy: Use the Pasteur pipette included with the accessories together with a long tube as a bellows to blow debris out of the bore. First remove the measuring vessel and hold a paper towel underneath the thermistor probe. The bore can first be rinsed using a spray bottle of water to clean out sample residues, which can rub off and accumulate on the interior surface over time. The unit does not need to be switched off for this cleaning process, so measurement is only briefly interrupted.

3. No ice forms in the upper cooling system because the humidity is too low or the unit was put into operation too quickly after being switched on.

Remedy: If the air humidity is very low (for example, in heated or air-conditioned rooms), open the cover of the upper cooling system.

9.4 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.
Calibration cannot help minimize damage in the case of malfunction. It is of no consequence whether these malfunctions occur during calibration or sample measurement.
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.

Component Groups function	Malfunction	Effect	Possible Cause	Measure
Elevator track *Lowers the sample into the lower cooling system*	Sluggish, (noisy)		Mechanical wear due to ball bearing abrasion	Lubricate the track, e.g. with silicone spray or graphite
	Jams	Error message or incorrect reading	Blockage from foreign substances	Remove foreign substance
Lower cooling system *Cools the sample*	No cooling, measurement takes too long, measurement interrupts	No reading Error message	Corrosion	Use fine sandpaper to clean the cooling clamp
			Ventilator dusty	Clean with air-pressure
		Incorrect reading	Incorrect adjusted lower cooling system	Use the adjustment tool to adjust the lower cooling system
			Peltier element defective	Replace the lower cooling system
Printer *Outputs readings*	Prints no results		No paper or ink ribbon empty	Replace paper or ink ribbon cassette
	Does not print		Printer switched off	Switch printer on
			Defective	Replace printer

Table 1 Malfunction of the elevator track/lower cooling system/printer component group

Component Groups function	Malfunction	Effect	Possible Cause	Measure
Upper cooling system *Nucleation*	No cooling or no ice crystals at the upper cooling system	Error message and No reading	Peltier element ruined, e.g. by liquid deposits	Replace upper cooling system
			Corrosion	Clean the cooling nipple using a fine wire brush (fiberglass pin) or fine sandpaper
	Insufficient ice accumulation on the bar of the needle	No crystallization No reading Error message	Incorrect adjusted upper cooling system	Adjust the cooling system
			Bar of needle too short or too long	Adjust the bar of the needle or check for proper length
	Incomplete rotation of the motor disk (with initiation needle)	No crystallization No reading Error message	Photoelectric beam for motor control defective or incorrect adjusted	Make sure the photoelectric beam is working and is positioned properly
			Motor disc loose	Tighten the motor disc

Table 2 Malfunction of the Upper Cooling System Component Group

Component Groups function	Malfunction	Effect	Possible Cause	Measure
EProm/EEProm	Defective	Calibration and measurement impossible or results not verifiable	Aging, External electric shock, Excessive electromagnetic irradiation	Check electromagnetic compatibility of equipment operating near osmometer Check system load of power grid Have medical equipment technician or Gonotec replace EProm
Thermistor probe *Analysis*	Measuring vessel fits loosely on the thermistor probe	Incorrect reading	Incorrect measuring vessel	Use Gonotec measuring vessels
			The thermistor probe's measuring vessel receptacle is damaged	Replace the thermistor probe
	Defective	Incorrect or no reading	Thermistor probe bead broken off or defective	Replace the thermistor probe
	When lowered into the lower cooling system, the thermistor probe moves outside the center of the solution	Incorrect reading	Incorrect adjusted thermistor probe Incorrect measuring vessel	Use the adjustment tool to adjust the thermistor probe and/or lower cooling system

Table 3 Malfunction of EProm/thermistor probe component group

Component Groups function	Malfunction	Effect	Possible Cause	Measure
Initiation needle *Crystallization*	No/few ice crystals transported	Error message: No crystallization	Needle too long or too short	Bring needle to proper length
			Needle not deburred at tip (e.g. after re-installation)	Debur tip of needle
			Needle bent	Straighten or replace needle
	Needle does not move	Error message: No crystallization	Bar of needle disengaged from motor or stuck firmly in place	Check upper cooling system component group
Rear of unit/power switch *Power supply*	Fuses in power switch blow out when unit is switched on	The following parts may be damaged: - Mainboard - Transformer	Unit voltage setting does not match power grid voltage	Check setting for proper unit voltage of 110V or 230V. Check that the fuse plug is seated properly. Insert new fuses.
	It does not turn on		No external power supply	Check cables leading to unit
			Fuses are burned out	Replace fuses If another cause is found, the unit must be sent to customer service

Table 4 Malfunction of the Initiation Needle/Power Switch Component Group

10 Servicing of the OSMOMAT auto

10.1 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 devices listed in *Annexes 1 and 2 of the Medical Devices Operator Ordinance*.

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

The OSMOMAT auto 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.

10.3 Measurement Checks (§ 11 of Medical Devices Operator Ordinance)

The OSMOMAT auto 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:

- ***Calibration of the unit with a standardized osmometry calibration solution***
- ***Comparative measurements with OSMOREF 290 or aqueous solutions of known osmolality***
- ***Logging of measurement readings and any evaluation results***

The frequency of such checks should comply with local quality assurance guidelines.

10.4 Internal Quality Control of the OSMOMAT auto

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 outputs an error message or shuts down the unit. Standardized calibration and reference solutions and an adjustment tool are used to check the internal quality control mechanism.

10.5 Settings

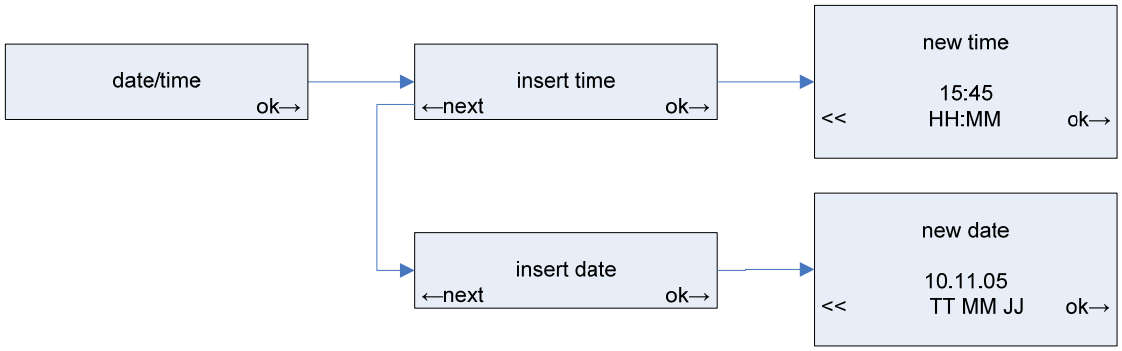
Make basic settings such as the date and time and cleaning paper feed via the menu > *adjust*. Comprehensive maintenance work or error messages can result in a check of the initiation function, new initialization of the unit, and adjustment of the thermistor probe. These functions are also made available here.

■ Setting the Date and Time

Select > *adjust* > *date/time* in the initial display. Confirm with *OK*.

Select > *insert time* and confirm with *OK* to set the time.

The cursor blinks in the time.
Enter the current time using the numbers 0 through 9.
The cursor automatically moves to the next position.
Select << to undo a change.
Confirm with *OK* to accept the change.



Select > *insert date* and confirm with *OK* to set the date.

The cursor blinks in the date.
Enter the date in the format <*Day.Month.Year*> using the numbers 0 through 9.
The cursor automatically moves to the next position.
Select << to undo a change.
Confirm with *OK* to accept the change.

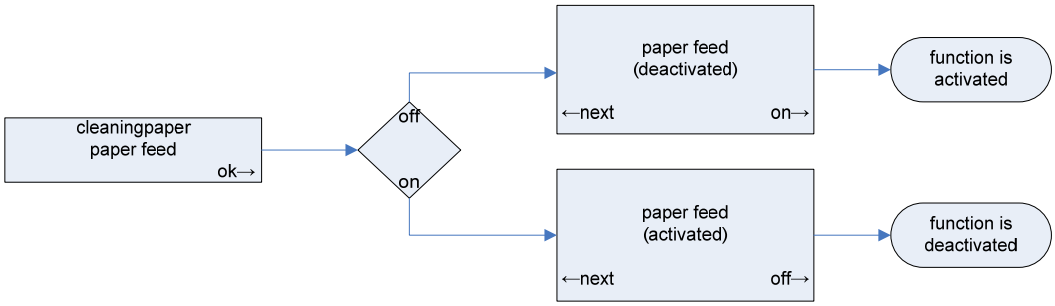
■ Setting the Cleaning Paper Feed

The thermistor probe is automatically cleaned between individual measurements. It pierces a piece of filter paper which is accordingly newly supplied. The used paper comes out of the left side of the OSMOMAT auto and can be ripped off here and disposed of. After the last sample measurement, the remaining contaminated cleaning paper is transported out of the unit. This ensures that no contaminated material is in the unit, particularly after a disruption in a measurement caused either manually or by a malfunction.

This function can be switched off if not needed.

Select > *adjust* > *cleaning paper feed* in the initial display. Confirm with *OK*.

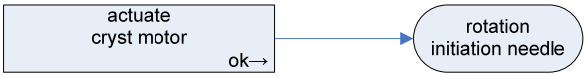
According to the current setting, you now have the option of activating the function by selecting *on* or deactivating it by selecting *off*.



■ Checking the Initiation Function

The initiation function must be checked following replacement of a defective initiation needle, for example.

To check the initiation function, select > *adjust* > *actuate cryst motor* in the initial display. Confirm with *OK* to rotate the initiation needle one time.



■ New Initialization

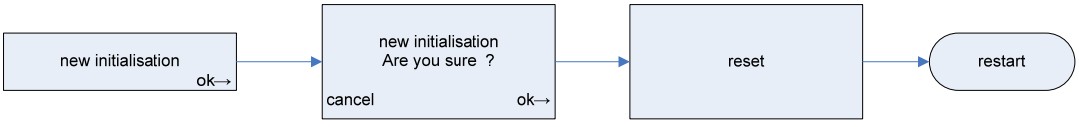
Reinitialize the OSMOMAT auto if additional calibrations are unsuccessful after an unsuccessful or cancelled calibration.

The memory content and the settings for the date and time are retained after re-initialization.

Select > *adjust* > *new initialization* in the initial display. Confirm with *OK* to conduct a new initialization.

The system restarts automatically.

Select *cancel* to cancel the operation.



■ Adjusting the Thermistor probe

The thermistor probe must be checked for centricity in the lower cooling system:

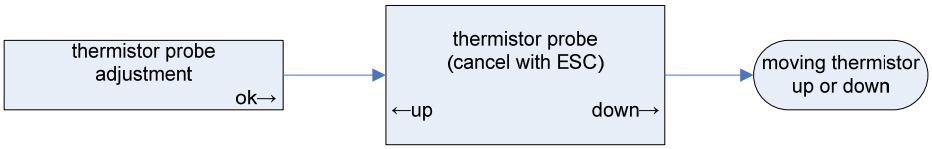
1. After work on the upper and/or lower measurement system,
2. In the event of erroneous and/or deviating measurement results,
3. During the quality assurance routine.

At this point only a description of menu functions is provided. The actual measurement system testing and setting procedure will not be available until the next version of this user guide.

Select > *adjust* > *thermistor probe* in the initial display. Confirm with *OK* to initiate start-up or shutdown of the thermistor probe.

Start-up and shutdown are controlled by a stepper motor. The length of the period for which the button is pressed determines the number of steps.

1. Select *up* to start up the thermistor probe incrementally.
2. Select *down* to shut down the thermistor probe incrementally.
3. Press *Esc* to return the thermistor probe to its preset position



Please note: The automatic lift limit of the elevator is invalidated during this operation. This can result in overwinding of the excenter disk and destroy the measurement system!

10.6 Printer Maintenance

Ensure that no foreign objects enter the unit during unit maintenance work. The mechanics and the measurement system could be damaged when restarted.

■ Printer Paper Change

Press the *Paper Feed* button to eject any remaining paper from the printer.
Do not pull on the paper since this could damage the printing device.

1. Turn the printer to its bottom position.
   Remove the empty roll core from the paper tray.

2. Insert a new paper roll.
   Pay attention to the feed direction of the paper roll.

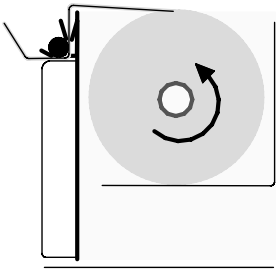


Fig. 7 Correct feed direction for paper roll

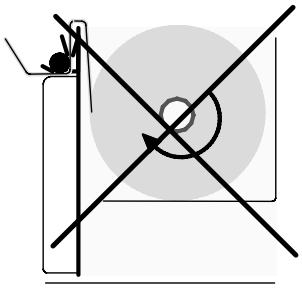


Fig. 6 Incorrect feed direction for paper roll

3. Cut the paper end cleanly and insert it from above into the paper slot.
   Press and hold the *Paper Feed* button until approx. 2 cm of paper is protruding from the housing.

4. Turn the printer until it locks in its upper position and close the door.

■ Ribbon Change

The ink ribbon cassette must be replaced when the printout no longer has sufficient contrast.

1. Tear off any paper protruding from the slot before replacing the ribbon.
2. Press lightly on the right side of the ink ribbon cassette.
   The cassette is released from the printer.
3. Take out a new ribbon and
   use your index finger to twist the knob clockwise
   and tighten the ribbon.
4. Insert the ribbon in the printer. The paper must be
   between the ribbon and the ribbon cassette.
   Tighten the ribbon by twisting the knob again.
5. Press and hold the *Paper Feed* button until approx. 2 cm of the printer paper is protruding from the housing and then close the door.

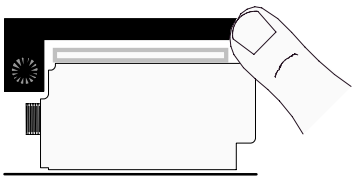


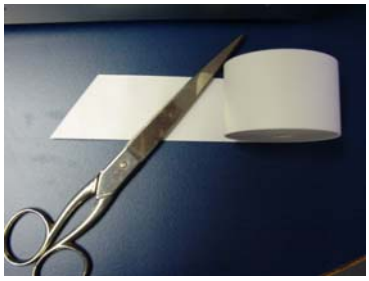
Fig. 8 Replacing the ribbon

10.7 Replacing the Cleaning Paper

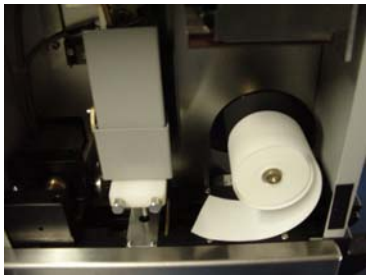
A red marker on the cleaning paper indicates the end of the paper roll during operation.
The remaining paper is sufficient for two or three more charge measurements. After that, the roll must be replaced.

⚠ ***Corrupt measurement results: A check for cleaning paper is not performed automatically. The system also works without cleaning paper. In this case, the sensor is not cleaned and the samples mix with sample residues from previous sample measurements.***

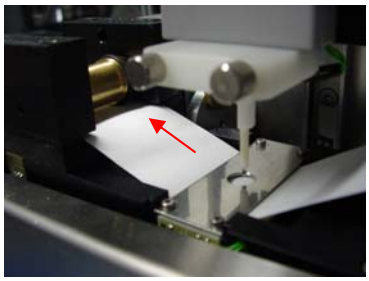
1. Cut the end of the paper roll at an angle.



2. Unscrew the paper roll cover
   and remove the roll core.
   Insert the new roll and reattach
   the cover.



3. Run the paper below the stainless steel plate with a hole.
   Press the *Paper Feed* button and run the
   paper to the drive rollers for the paper feed.



4. Press and hold the *Paper Feed* button until the paper
   protrudes from the housing.

10.8 Replacing a Defective Initiation Needle

There are various reasons why it may become necessary to repair the needle bar or even replace the initiation needle. See "Table 2 Malfunction of the Upper Cooling System Component Group" and "Table 4 Malfunction of the Initiation Needle/Power Switch Component Group". Repairs to the initiation needle must be performed by a **medical device technician**; it is not enough simply to be skilled in handling equipment!
Before working on the initiation needle, please ensure the following:

The **unit power supply is disconnected!**
Risk of electric shock!

The unit has been ***decontaminated—especially the initiation needle!***
Risk of injury from the tip of the needle!

In the event of injury from the tip of the needle, always consult a doctor to check whether any infection with a pathogen occurred.

Step 1

Detach the needle bar from the motor swipe (Fig. 9).

Attach a new needle bar with protective tubing to the motor swipe.

Please note:

1. The needle must be carefully aligned. Bend it into place with your hand if necessary.
2. After the needle bar has been tightened, it must be able to move freely on the sleeve bearing.

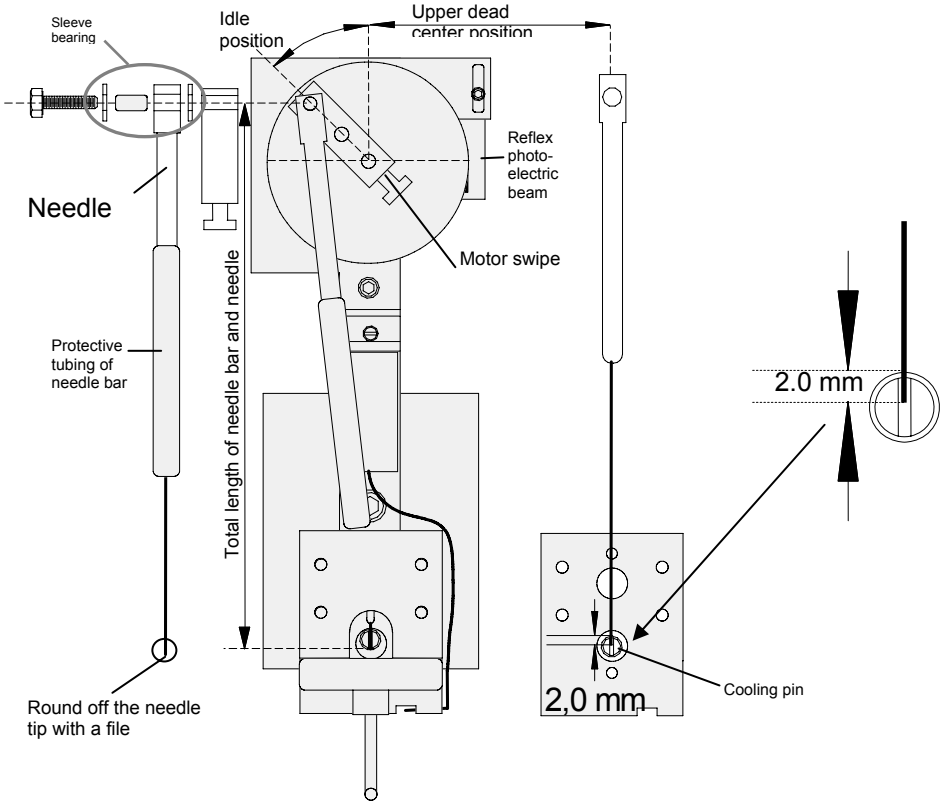


Fig. 9 Replacing a Initiation Needle

Step 2

4. Manually move the motor swipe to the upper dead center position.
5. Use a pair of pliers to adjust the needle to the proper length (end of needle approximately 2 mm under the upper edge of the cooling pin).
6. Carefully round off the cutting edge with a file. (In the idle position of the motor swipe, the end of the needle must not extend below the lower edge of the cooling pin. If necessary, adjust the reflex photoelectric beam by moving it up or down (after first loosening the Allen screws).

Step 3

Adjust the thermistor probe

Step 4

Check the initiation function.

Note: Initiation needle material: stainless steel, cold-hammered quality, diameter 0.6mm

10.9 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 back of the unit. The two fuses can now be replaced. The unit has two-phase protection. Use the following fuses:

230V power supply: 0.5A LAG
110/115V power supply: 1A LAG

One set of fuses is included with the standard accessories.

Be sure to reinsert the fuse holder in its original position.

"115" and "230" are printed opposite one another on the fuse holder. The fuse holder must be inserted so that the label of the valid power voltage (see nameplate* Fig. 1*) is located under the power connector. A small arrow ▲ (Fig. 10) indicates the set power voltage, 230V in this example.

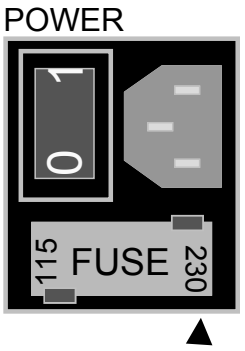


Fig. 10 Power switch

10.10 Using the Correct Measuring Vessel

The service life and precision of the measurement system depend on the correct measuring vessel in use.

■ Intended Use

*The measuring vessels are designed for **single use** only. Reuse of the measuring vessels can result in non-verifiable readings or even a **destruction of the measurement system**.*

We are unaware of any reactions between the sample solution and measuring vessel (in osmometry). However, we advise against using the measuring vessels for other purposes.

For information on the material properties, please refer to product safety data sheet **MPM-30.9.0010.pdf**.

■ Specification

The conic shape of the measuring vessel matches that of the lower cooling system. This ensures a **secure fit**, a high standard of **centricity** for the measuring vessel in the lower cooling system and **consistent immersion depth** of the measuring tip in the sample.

The following has to be observed:
The measuring vessels can move freely in the sample holder.
The sample cover can be placed on the sample holder without force and the measuring vessels do not tilt between the sample cover and the sample holder.

■ Forfeiture of the Measurement System Warranty

Destruction of the measurement system due to the use of improper measuring vessels, even during the warranty period, shall result in forfeiture of the warranty claim of repair or replacement of the measurement system.

11 Calibration Solutions for Osmometry

11.1 GONOTEC Calibration and Reference Material

Classification of the IVD

The calibration and reference materials by Gonotec are non-invasive in-vitro diagnostic products according to EEC Directive 93/42 (Medical Devices Law). They are intended for use in osmometry by qualified personnel to calibrate and/or control the osmometer. The calibration and reference materials must be used in accordance with the unit requirements.
The calibration and reference materials are not named in Annex II, List A or B, of the Directive 98/79 for in-vitro diagnostic devices. Compliance is declared per Annex III. Number 6 of Annex II is disregarded, since the calibration and reference materials' intended use does not include personal use.

EC Conformity Declaration – Calibration and Reference Material

Gonotec GmbH
GSG-Hof Reuchlinstr. 10-11
10553 Berlin / Germany

We hereby declare that the calibration standard for Osmomat 010/030/auto (300 and 850 mOsmol/kg $NaCl/H_2O$) and the reference solution OSMOREF® 290 mOsmol/kg comply with Directive 98/79/EEC. Compliance is declared per Annex III of the Directive. The CE mark on the standards and reference solutions acknowledges this.

Date: 10/24/2009

Signature of managing director: 

Provisions of Certification

CE compliance requires that the calibration standard and the reference solution be used in the manner described in this manual and/or in the package insert. Any departure from the specifications or independent modifications of the calibration standard or the reference solution 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.

11.2 Restrictions on the Use of the Calibration and Reference Materials

- They may not be used to clean contact lenses or the like.
- They may not be used in human injections or infusions, neither in its pure form nor in mixtures with human bodily fluid samples.

11.3 Composition

GONOTEC Calibration standards 100, 300, 500, 850, 2000 mOsmol/kg and OSMOREF® 290 mOsmol/kg NaCl/H_2O

	100 mOsmol	300 mOsmol	500 mOsmol	850 mOsmol	2000 mOsmol	290 mOsmol
Sodium chloride Ph.Eur./USP	3,088 kg	9,463 kg	15,916 kg	27,178 kg	63,960 kg	9,124 kg
Water for injection purposes as bulk Ph.Eur./USP	ad 1000 l	ad 1000 l	ad 1000 l	ad 1000 l	ad 1000 l	ad 1000 l

For precise concentration information, see the analysis certificate on the package insert of each batch.

11.4 Safety and Handling Information

Calibration and reference materials are not dangerous according to EC Directive 67/548/EEC.	
Poison class (Switzerland):	F (no poison class)
German water hazard class (WGK):	1 (weak hazardous to water)
Storage class (German association of chemical industries, VCI):	10-13 (miscellaneous liquids and solids)
Disposal	According to GLP/institute requirements/regulations on the federal, national, and local level

Please note: The calibration and reference materials are **chemicals**. Observe all relevant **precautions** and **regulations** (do not swallow, do not taste, always wear gloves, etc.)

Container: clear glass OPC ampoules

Nominal volume: 1 ml

The ampoules have a breaking ring with a breaking ring color (blue dot). The ampoule can be opened manually by breaking it off at this point. Follow all safety precautions for the handling of glass (splintering, breakage, etc.).

11.5 Storage and Shelf Life

When stored unopened at 5°C to 45°C, the calibration and reference materials have a shelf life up to the expiration date indicated on the packaging.
Do not use the calibration standard after its expiration date!

Once the ampoule has been opened, the calibration and reference material shelf life is:
up to ½ hour at + 22°C.

A strong variance in calibration readings (increasing osmolality) is an indication that the shelf life has elapsed.

11.6 Use of Other Calibration Solutions

Osmolality	Sodium chloride concentration	Freezing point depression
mOsmol/kg H_2O	g NaCl/kg H_2O	in C°
100*	**3,088**	**0,186**
200*	6,260	0,372
300*	**9,463**	**0,558**
400*	12,684	0,744
500*	**15,916**	**0,930**
600*	19,147	1,116
700*	22,380	1,302
850**	**27,178**	**1,579**
1200**	38,370	2,230
1800**	57,560	3,350
2000**	**63,960**	**3,716**
2500**	79,970	4,650

Table 5 NaCl solutions for osmometry

(*) Based on Geigy Scientific Tables 8th edition (congruent to USPC: usp29nf24s0_c785)

(**) Measured with Gonotec Freezing point osmometer OSMOMAT 030-3P

Appendix

Consumables

Item no.	Item	Packaging unit/qty
35.9.0010	Measuring vessel for OSMOMAT auto	1,000
30.9.0020	Calibration standard 300 mOsmol/kg (ampoules of 1ml each)	10
30.9.0100	Calibration standard 100 mOsmol/kg (ampoules of 1ml each)	10
30.9.0290	Reference solution OSMOREF® 290 mOsmol/kg (ampoules of 1ml each)	10
30.9.0500	Calibration standard 500 mOsmol/kg (ampoules of 1ml each)	10
30.9.0850	Calibration standard 850 mOsmol/kg (ampoules of 1ml each)	10
30.9.2000	Calibration standard 2000 mOsmol/kg (ampoules of 1ml each)	10
30.9.1010	Printer paper roll for OSMOMAT 030-D/auto	8
30.9.1020	Endless ribbon cassette for OSMOMAT 030-D/auto	1
35.9.1030	Roll of cleaning paper	1

Accessories and Replacement Parts

Item no.	Item	Packaging unit/qty
35.3.0010	Thermistor probe for OSMOMAT auto (50µl sample volume)	1
30.9.0030	Bellow (Pasteur pipette)	10
30.6.0020	Initiation needle	1
20.9.0160	Data cable for RS 232 interface OSMOMAT 030/050/auto	1
30.2.0030	Adjustment tool	1
20.9.0100	Power cable, 2 meters	1
00.9.0104	Fuses, 0.5A lag, 220V	10
00.9.0106	Fuses, 1.0A lag, 110V	10
35.9.0100	Sample holder (complete)	1
35.9.0050	Allen wrench 1.5 x 60 mm	1
35.9.0051	Allen wrench 2.5 x 60 mm	1

Classification of the IVD

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

EC Compliance Statement—OSMOMAT® auto

Gonotec GmbH

GSG-Hof Reuchlinstr. 10-11

10553 Berlin / Germany

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

Date: 10/24/2009

Signature of managing director: .....

Provisions of Certification

CE compliance requires that the unit be 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.

Limited Warranty

Gonotec product	Duration of Limited Warranty
Software	90 days
Thermistor probe	180 days
Osmometer	1 year

A. Extension of the Limited Warranty

1. Gonotec guarantees 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.
2. 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.
3. Gonotec's limited warranty applies only to defects that arise during normal operation of the product. It does not apply under the following conditions:
   d. Inadequate servicing or improper modification;
   e. Use of software, interfaces, print media or accessories not supported or supplied by Gonotec; or
   f. Use of the equipment in a manner not covered by the product specifications.
4. For Gonotec osmometers, the use of measuring vessels of manufacturers other than those of the measuring vessels supplied by Gonotec does not void the customer's warranty claims or any customer support contracts between Gonotec and the customer.
   If, however, the use of measuring vessels from third-party providers or the cleaning of recycled measuring vessels results in malfunctions or damage to the osmometer or thermistor probe, Gonotec shall assess the normal fees for the time and material required to repair such malfunctions or damage.
5. If Gonotec is notified within the warranty period of a defect in a software product, in media or in a thermistor probe 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.
6. 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.
7. Gonotec is not obligated to repair or replace a product or refund its purchase price until the customer returns the defective product to Gonotec.
8. Replacement products may be new or almost new, as long as their functionality is at least that of the replaced product.
9. 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

1. 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

1. 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.
2. 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.

D. Respective Jurisdiction

1. This warranty statement guarantees the customer certain legal claims. The customer may have other legal claims that go beyond those outlined here.
   Such claims vary by state in the US, by province in Canada and by nation elsewhere in the world.
2. 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:
   a. Exclusion of the fact that the warranty exclusions and restrictions named here restrict the legal rights of a customer (for example: Great Britain)
   b. Restriction of the possibilities for manufacturers to enforce such warranty exclusions and restrictions
   c. Granting of additional warranty claims for the customer, fixing of the validity period for implied warranty services that the manufacturer may not exclude, or nonadmission of restrictions relating to the validity period for implied warranty services
3. 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.

Returning Parts for Warranty Repair or Credit

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

1. Please contact Gonotec first to clarify return documentation (e.g. customs documents).
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 greatly contaminated will be returned at the customer's expense.
3. **Secure the corresponding transport fasteners!**
4. Enclose written information explaining the reason for returning the equipment.
5. If the equipment is being returned for credit, you must include all accessories (power cable, software disks, manuals, etc.).
6. Return the equipment in its original packaging. If you no longer have the original packaging, you may purchase replacement packaging from Gonotec.

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.

Tel.: +49 (0)30 7809588-0

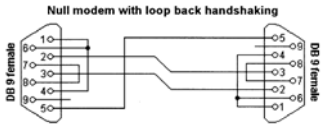
Toll-free (Germany only!):
0800-7846027

Technical Data of the OSMOMAT auto

■ Data output RS232

Baud rate:	9600 bits/s	
Data format:	1 start bit, 8 data bits, 1 stop bit, no parity	
Signals:	TXD Transmit Data (output)	-> PIN 3
	RXD Receive Data (input)	-> PIN 2
	DTR Data Terminal Ready (output)	-> PIN 4
	DSR Data Set Ready (input)	-> PIN 6
	GND Ground	-> PIN 5
Allowable input level:	-3 to -30 V or +3 to +30 V	
Output level:	-5 to -15 V or +5 to +15V , typ.+/- 7V at RL=3kOHM	

DSR and DTR signals are currently supported. We recommend use of a null modem cable with the following bridges (6-4-1 and 7-8).



The data is consecutively sent to the built-in printer and serial interface. If the printer is finished printing a sample, the corresponding data is automatically sent via the serial interface. The output format cannot be changed at the interface.

■ Format of the Telegram

Data is transmitted in the ASCII format.
The string looks as follows:

```
|Sampleno.|Patientno.|result|Dimension|Time|Date|
1.........11...........34.......44........57...65....77

length: 77 characters + carriage + return (+ 0dh + 0ah)

| = hyphen (ASCII 124)
```

■ Overview

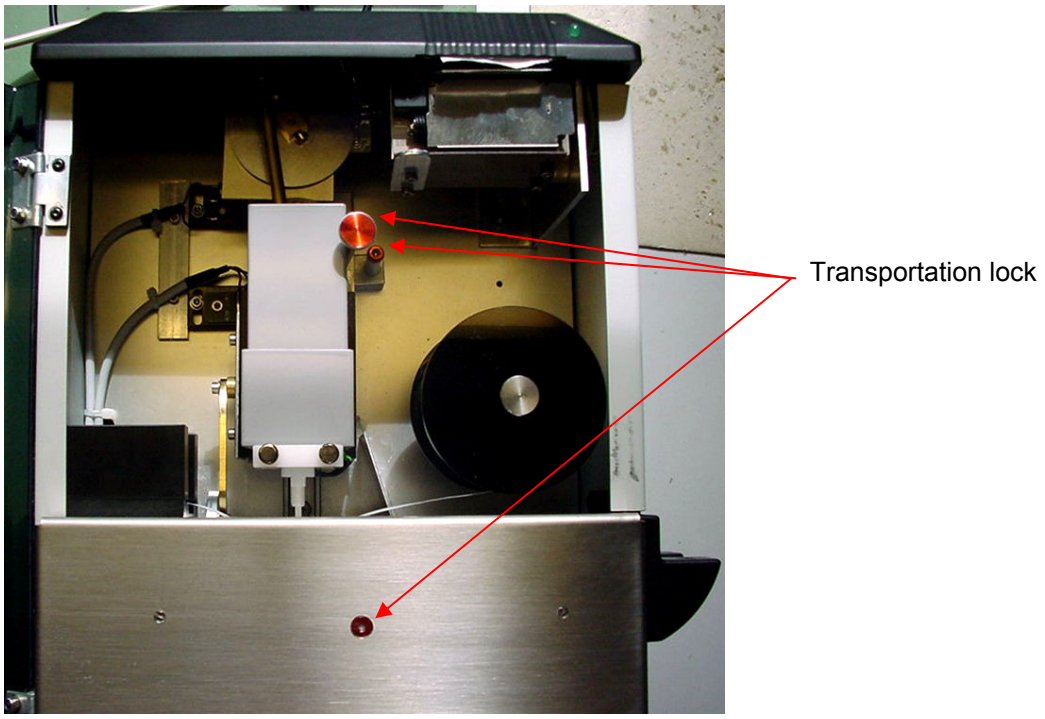
(Standard model)

Sample volume:	50µl
Duration of measurement	Approx. 70 seconds
Reproducibility:	≤ ±1.0%
Measurement display:	LCD display, 4 lines with 20 characters
Measuring range:	Up to approximately 2500 mOsmol/kg
Resolution:	1 mOsmol/kg across the entire measuring range
Crystallization resolution:	By injecting the sample with ice crystals
Cooling:	Using two independent peltier cooling systems with heat dissipation by air
Lower cooling system:	Temperature controlled electronically, consistency better than ±0.1°C
Ambient temperature:	10°C to 30°C
Power connection:	230V (± 20 V), 50/60Hz, 120VA, special models: 110V, 100V
Dimensions:	275 x 225 x 390 mm
Weight:	Approximately 11.9 kg

Printer:	Alphanumeric dot matrix printer, 5x7 matrix, date, time of each measurement
Number of digits:	4-digit programmable sample number 4-digit measurement results
Paper:	Normal paper, 43mm wide
Paper feed:	Automatic or manual
Printer function:	on/off, single mode, charge short, charge long by pressing button
Error message:	Printed in plain text
RS output:	Data output (serial), standard RS 232 C interface
Baud rate:	9600 bps
Data format:	1 start bit, 8 data bits, 1 stop bits (no parity check)
Data line:	TXD
Control line:	DTR, DSR
Connector plug:	Canon, 25-pin
Interface:	Barcode reader input
Calibration:	Calibration at three points. Besides water, two other calibration points are possible.

Remove of Transportation Lock

Turn the instrument on its backside and remove the red-marked transportation locks with the socket wrench (hexagon socket).



Please keep this instruction for an eventual return of the instrument as this allows you to re-install the transportation lock correctly.