User Guide

OSMOMAT 3000*basic* OSMOMAT 3000

Version 1.22 1/6/2016

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⚠ This manual allows for the safe and efficient operation of the OSMOMAT 3000 (hereafter "device"). This manual is part of the device and must be stored in the immediate vicinity of the device and be easily accessible to personnel at any time.

Personnel must carefully read and understand this manual before beginning any kind of work. Compliance with the safety notices and instructions in this manual is the basis for a safe work environment. In addition, local accident prevention regulations and general safety provisions for the intended use of the device must be followed.

Figures in this manual are included for basic understanding and may differ from the actual application.

Other applicable documents

In addition to this manual, the documents included with the device documentation apply. The warnings – in particular safety notices – in this documentation must be observed!

Copyright

Manufacturer contact info

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Table of Contents

Table of Contents

Table of Contents

Table of Contents

1 Overview

Fig. 1: Device overview—front

1 Touchscreen, ↳ *page 30*
2 Upper cooling system (behind movable elevator cover), ↳ *page 29*
3 Temperature sensor with measurement vessel, ↳ *page 29*
4 Lower cooling system, ↳ *page 29*
5 Elevator
6 Printer (Option D), ↳ *page 32* (does not apply to OSMOMAT 3000*basic*)

Device, rear

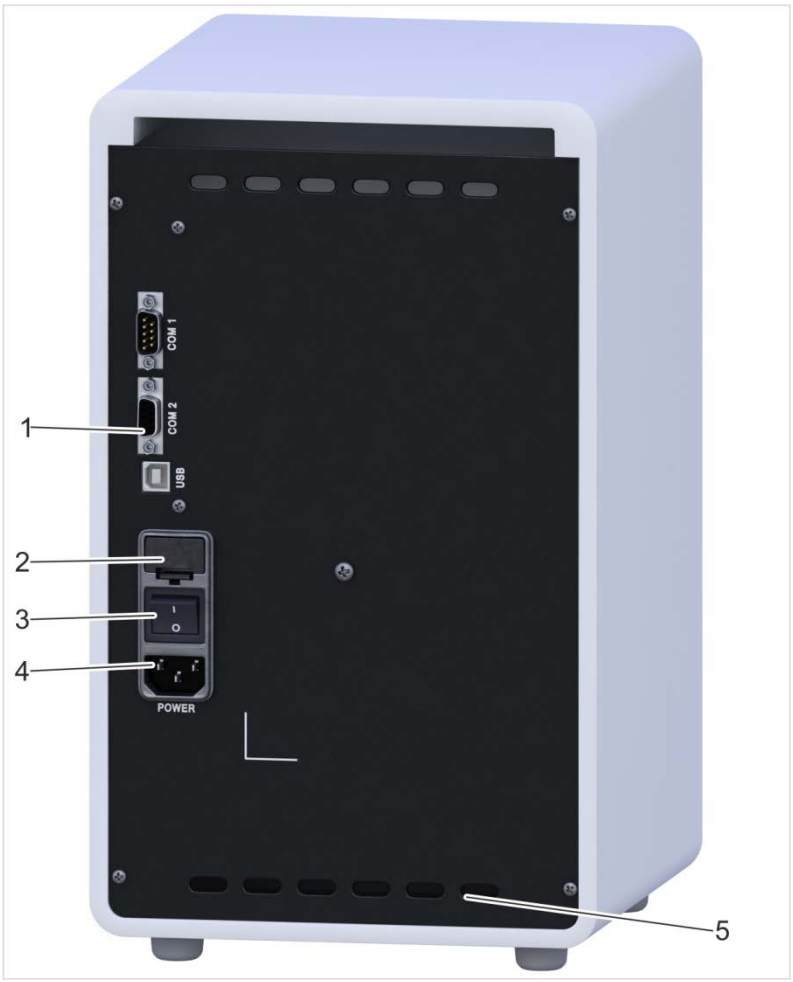


Fig. 2: Device overview—rear

1 Interfaces, *page 33*
(does not apply to OSMOMAT 3000*basic*)
2 Microfuses
3 On/Off switch
4 Power cable connection
5 Fan outlet

Standard accessories

NOTE!
Risk of falsified measurement results!

When using accessories and/or consumables made by manufacturers other than Gonotec GmbH, the reproducibility of the measurement results cannot be guaranteed.

- Always use the accessories and consumables supplied by Gonotec GmbH.
- Re-order consumables, in particular measurement vessels, from Gonotec GmbH (see page 3 for contact information).

1 Measurement vessels, 100 pc.
2 Calibration standard, 10 pc., 1ml each, concentration 300 mOsmol/kg
3 Printer paper, 1 roll (Option D only)

Fig. 3: Overview of consumables

Overview

Accessories

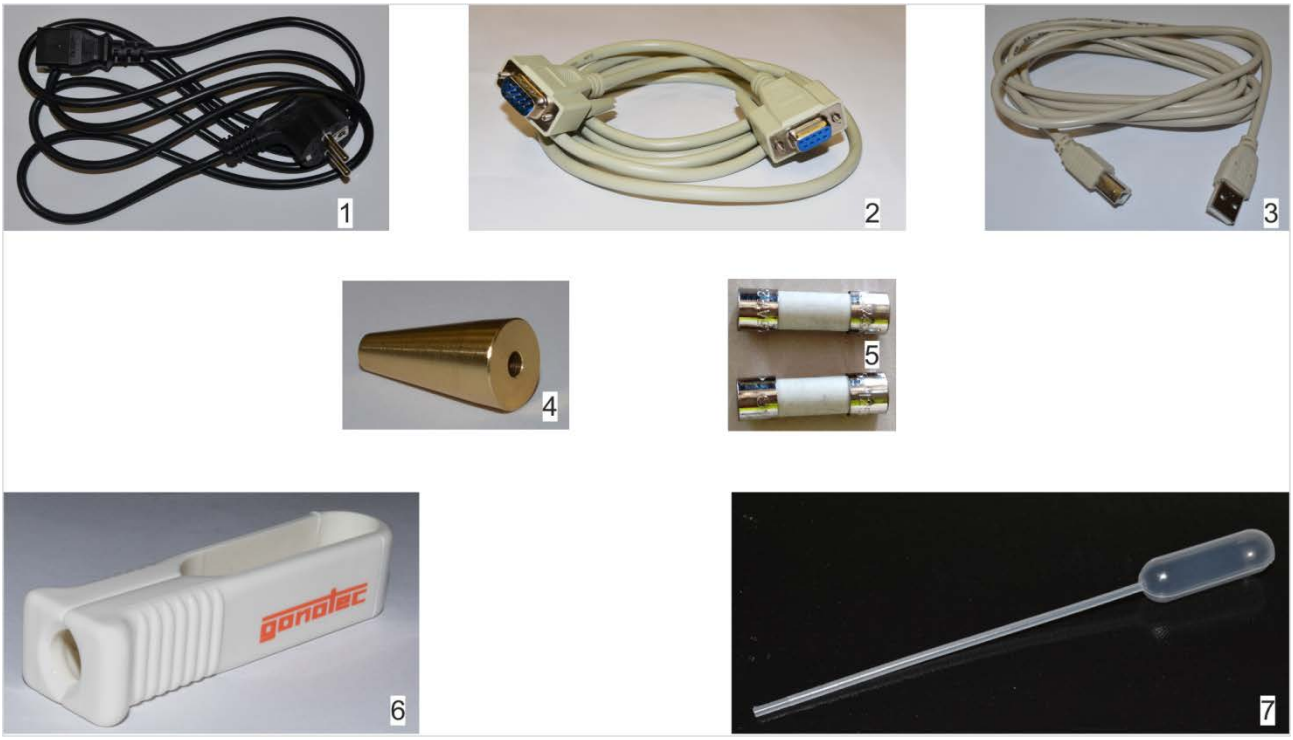


Fig. 4: Overview of accessories

1 Power cable
2 RS-232 cable
(does not apply to OSMOMAT 3000*basic*)
3 USB cable for connection to PC (slave)
(does not apply to OSMOMAT 3000*basic*)
4 Adjustment tool
5 2 microfuses, slow-blow 1.6A (HBC 1500A)
6 Ampoule opener
7 Blow-out device for removing condensate

2 Safety

2.1 Explanation of symbols

Safety notices

The safety notices in this manual are identified by symbols. The safety notices are preceded by signal words indicating the degree of hazard.

DANGER!

This combination of symbol and signal word indicates an immediate dangerous situation that will result in death or serious injury if not avoided.

WARNING!

This combination of symbol and signal word indicates a potentially dangerous situation that may result in death or serious injury if not avoided.

CAUTION!

This combination of symbol and signal word indicates a potentially dangerous situation that may result in minor or light injury if not avoided.

NOTE!

This combination of symbol and signal word indicates a potentially dangerous situation that may result in property damage if not avoided.

NOTE!

This combination of symbol and signal word indicates potential environmental hazards.

Special safety notices

Safety notices use the following symbols to indicate special hazards:

WARNING!

This combination of symbol and signal word indicates a potentially dangerous situation that may result in contamination with biohazardous materials.

Observe the current Ordinance on Biological Substances and refer to the lab protocol.

DANGER!

This combination of symbol and signal word indicates an immediate dangerous situation due to electrical current. Failure to observe a warning identified this way may result in serious or deadly injury.

Safety notices in instructions

Safety notices can apply to specific, individual instructions. These safety notices are embedded in the instruction to avoid interrupting the flow of reading while performing the operation. They use the signal words described above.

Example:

1. Loosen screw.
2. 

   CAUTION!
   Pinch hazard on cover!

   Use care when closing cover.
3. Tighten screw.

Additional identifiers

To highlight instructions, results, lists, references, and other elements, the following identifiers are used in this manual:

Identification	Explanation
1, 2, 3 ...	Step-by-step instructions
⇨	Results of action steps
	References to sections in this manual and other applicable documents
■	Unordered lists
[Button]	Controls (such as buttons or switches), display elements (such as indicator lamps)
Display	Screen elements (such as buttons, function key assignments)

2.2 Intended use

Intended use

The OSMOMAT 3000 device is a non-invasive in-vitro diagnostic product used to determine the osmolality of aqueous solutions.

- Only use the device to measure aqueous solutions.
- Never measure organic, saturated, or highly viscous solutions.
- Never administer measured samples to humans by infusion or injection.
- Never use calibration standards as cleaning solutions, e.g. for contact lenses.
- Only use accessories and consumables supplied by Gonotec GmbH for measurements.

↳ *Accessories and consumables on page 25.*

2.3 Additional hazards

2.3.1 Hazards due to electrical current

Electrical current

DANGER!
Risk of death due to electrical current on device!

Class I devices must be connected to a power socket with protective ground wire.

If the power or device connector is used as a separation device, the connector must be easily accessible at all times.

Remove the power plug from the power socket to safely disconnect the device from mains voltage.

Contact with energized parts of the device results in immediate risk of death due to electric shock. Damage to the insulation of individual components can cause risk of death.

- Only have qualified personnel perform repair and maintenance work on the device.
- If the insulation is damaged, immediately disconnect the power plug and schedule a repair.
- Always route the power cable so it is not subject to stress and cannot be bent, pinched, or rolled over and is not exposed to liquids or heat.
- Keep energized parts away from liquids. Otherwise, shorts may occur.

2.3.2 Risk of infection

Risk of infection

WARNING!
Risk of infection due to sample residue and in case of inadequate hygiene, disinfection, and sterilization procedures!

Exposure to sample residue in non-cleaned, non-sterilized, or non-disinfected components results in an elevated risk of infection.

- Wear lab gloves during any kind of work.
- Observe all local regulations regarding hygiene, disinfection, and sterilization.

We recommend using detergents such as Mikrozid® AF Liquid, Bacillol® plus 3%, or Korsolex® plus 4% commonly found in clinical-chemical labs to clean and decontaminate the device.

2.3.3 Risk of injury

Risk of injury

CAUTION!
Risk of injury from cryst-needle!

When installing and removing the cryst-needle and the temperature sensor, the tip of the cryst-needle is exposed. Movement of the cryst-needle can cause needle puncture injuries.

- Always keep your hands and fingers clear from the area underneath the cryst-needle.

2.3.4 Risks of device damage

Exposure to liquids and moisture

NOTE!
Device damage due to exposure to liquids and moisture!

Exposure to liquids and moisture can cause damage to the electrical components of the device, e.g. due to a short.

- Install the device on a dry workplace.
- Always use a moistened wipe to disinfect the device, but never a wet wipe.
- Never use the device outdoors.

Fan

NOTE!
Device damage due to insufficient air circulation!

Obstruction of the fan outlet at the rear of the device can cause damage to the device.

- Always keep the fan outlet clear.

Shock

NOTE!
Risk of property damage due to exposure of the device to strong shock!

The device includes precision-engineered components which can be decalibrated and/or damaged in case of exposure of the device to strong shock.

- Always install the device on a non-vibrating surface.

ESD

NOTE!
Risk of property damage due to electrostatic discharge!

Electrostatic discharge (ESD) can occur when working on the open device.

- Take ESD precautions.

2.3.5 Reproducibility of the measurement

Incorrect measurement vessels

NOTE!
Impaired reproducibility of measurement due to incorrect measurement vessels!

Repeated use of the measurement vessels and use of incorrect consumables cannot guarantee reproducible measurement results.

- Always use a clean and unused measurement vessel for every measurement.
- Only use measurement vessels supplied by Gonotec GmbH.
- Never use centrifuge tubes or reaction vessels.

Improper handling of the calibration standard

NOTE!
Impaired reproducibility of measurement due to improper handling of calibration standards!

Improper handling and storage of the calibration standards included with the delivery negatively affects the measurement accuracy of the device.

- Always observe the stability of the calibration standards after opening the ampoule (max. 0.5h at 22°C ambient temperature).
- Never use opened ampoules twice or mix them together.
- Never freeze opened ampoules.
- Do not use the calibration standards past their expiration date.

Shock

NOTE!
Increased risk of incorrect measurements!

The device includes precision-engineered components which can be decalibrated and/or damaged in case of exposure of the device to strong shock. This can cause a higher risk of incorrect measurements (spontaneous crystallization).

- Always install the device on a non-vibrating surface.

2.4 Operator responsibilities

The operator of the device must fulfill the responsibilities according to Germany's Medical Devices Operator Ordinance listed in this manual.

In addition, the operator is responsible for learning about and complying with all local laws and associated standards and guidelines applicable at the time the device is used.

The device is used for medical-pharmaceutical applications. Therefore, the operator is subject to the legal responsibilities regarding work safety.

In particular, the following applies:

- The operator has to learn about the applicable work safety regulations and determine additional risks resulting from the specific working conditions at the location the device is used by means of a risk assessment. These must be implemented by means of operating instructions for the device.
- The operator has to learn about the applicable hygiene regulations resulting from the samples at the location the device is used. These must be implemented by means of operating instructions for the device.
- During the entire operating time of the device, the operator has to verify that the operating instructions created by him/her meet the current body of regulations and update them if necessary.
- The operator has to determine and lay down the specific responsibilities for installation, operation, troubleshooting, servicing, disinfection, and cleaning.
- The operator has to make sure that all personnel working with the device have read and understood this manual. In addition, s/he has to provide regular training for personnel and educate them about risks.
- The operator has to equip personnel with the required safety gear and issue mandatory instructions for wearing the required safety gear.
- The operator has to make sure that the service intervals specified in this manual are observed.
- The operator has to make sure that consumables are available in sufficient quantities.

Inventory

The operator has to maintain an inventory according to Germany's Medical Devices Operator Ordinance:

- The following information has to be maintained in the inventory:
  - name, product type, serial number, and year the device was purchased,
  - address of Gonotec GmbH
  - organization-specific ID, if applicable
  - location of operator
  - schedule of safety inspections
- Store CE-certificate together with inventory.
- Store inventory so it is accessible to personnel in charge of operating the device at all times.
- Make documentation available to the responsible authorities upon demand.

2.5 Personnel requirements

WARNING!
Risk of injury due to inadequately qualified personnel!

Work performed on the device by unqualified personnel or the presence of unqualified personnel in the hazard zone of the device creates risks that can result in serious injury and substantial property damage.

- Only have qualified personnel perform any kind of activity.

This manual specifies the following personnel qualifications for the different task areas:

User

Based on his or her expert medical and/or pharmaceutical training, knowledge, and experience, the user is capable of safely executing the tasks assigned to him or her.

The user is not authorized to perform any start-up activities.

The user is capable of independently detecting, evaluating, and avoiding possible risks.

The user has the expert knowledge for the intended use of the device and observes all hygiene regulations for rooms used for medical purposes and the use of medical products.

The user knows the contents of all applicable regulations, guidelines, and standards required by law for the safe use of the device and is capable of meeting the requirements stipulated therein.

Lab supervisor

The lab supervisor coordinates and monitors the technical procedures at the installation site of the device.

Based on his or her professional training and many years of professional experience with medical devices, the lab supervisor is capable of performing the start-up tasks delegated to him or her by the manufacturer.

Service technician

Based on his or her professional training in the area of mechanical and electrical engineering, the service technician is capable of performing the tasks related to troubleshooting and servicing delegated to him or her by the manufacturer.

2.6 Personal safety gear

While performing the different tasks on and with the device, personnel must wear the personal safety gear referenced explicitly in the various sections of this manual.

Description of personal safety gear

The personal safety gear is explained below:

Disposable lab gloves

Disposable lab gloves protect the hands from touching sample residue.

2.7 Environmental protection

NOTE!

Danger to environment due to incorrect handling of handling of environmentally hazardous substances!

Incorrect handling of environmentally hazardous substances, in particular incorrect disposal, can result in significant harm to the environment.

- Always observe the warnings regarding the handling of environmentally hazardous substances and their disposal below.
- If environmentally hazardous substances are inadvertently released into the environment, immediately initiate suitable actions. If in doubt, notify the responsible local authority about the damage and inquire about suitable actions to be initiated.

The following environmentally hazardous substances are used:

Electronic components

Electrical components can contain poisonous substances. These must not be released into the environment. Therefore, a specialist disposal firm must be tasked with disposal.

Sodium chloride

The calibration standards contain sodium chloride. Sodium chloride is mildly hazardous to water and must not be released into the environment.

3 Design and function

3.1 Device overview

Fig. 5: Device overview—front

1 Touchscreen, *page 30*
2 Upper cooling system (behind movable elevator cover), *page 29*
3 Temperature sensor with measurement vessel, *page 29*
4 Lower cooling system, *page 29*
5 Elevator
6 Printer (Option D), *page 32*
(does not apply to OSMOMAT 3000*basic*)

Device, rear

Fig. 6: Device overview—rear

1 Interfaces, *page 33.*
(does not apply to OSMOMAT 3000*basic*)
2 Microfuses
3 On/Off switch
4 Power cable connection
5 Fan outlet

Standard accessories

NOTE!
Risk of falsified measurement results!

When using accessories and/or consumables made by manufacturers other than Gonotec GmbH, the reproducibility of the measurement results cannot be guaranteed.

- Always use the accessories and consumables supplied by Gonotec GmbH.
- Re-order consumables, in particular measurement vessels, from Gonotec GmbH (see page 3 for contact information).

1 Measurement vessels, 100 pc.
2 Calibration standard, 10 pc., 1ml each, concentration 300 mOsmol/kg
3 Printer paper, 1 roll (Option D only)

Fig. 7: Overview of consumables

Accessories

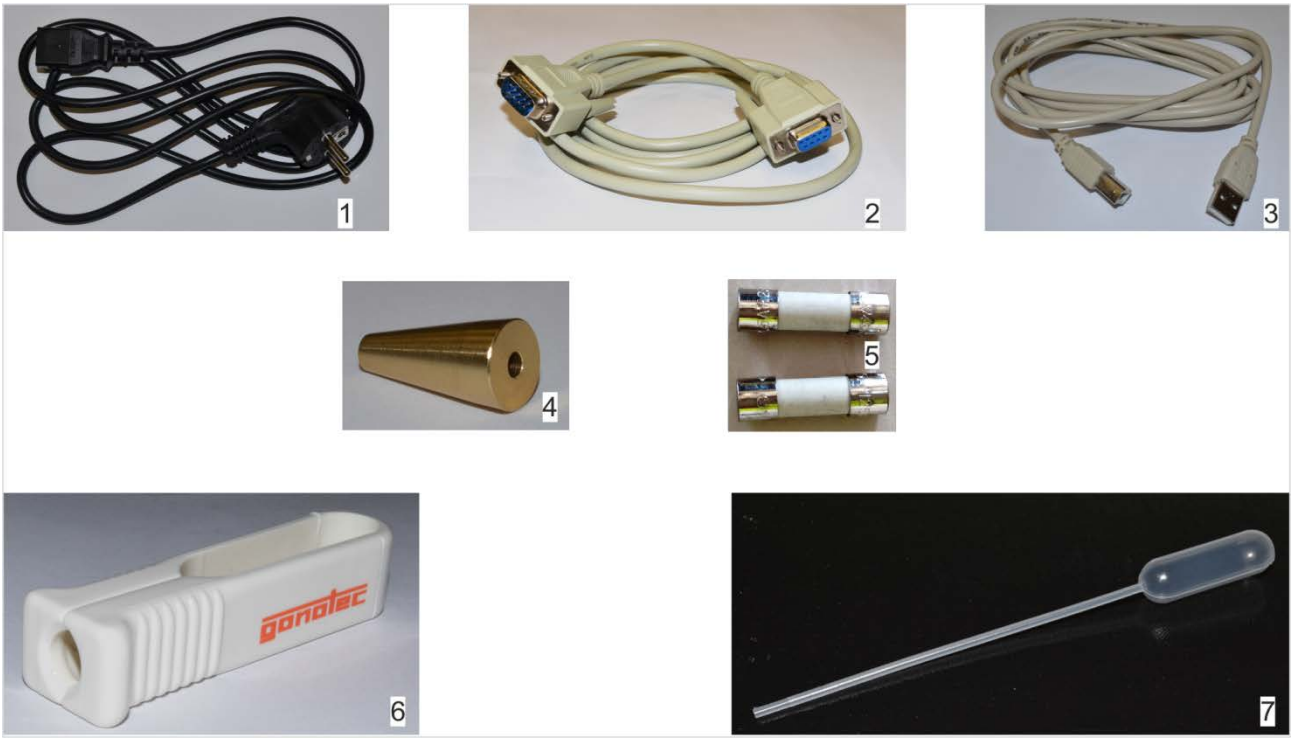


Fig. 8: Overview of accessories

1 Power cable
2 RS-232 cable
(does not apply to OSMOMAT 3000*basic*)
3 USB cable for connection to PC (slave)
(does not apply to OSMOMAT 3000*basic*)
4 Adjustment tool
5 2 microfuses, slow-blow 1.6A (HBC 1500A)
6 Ampoule opener
7 Blow-out device for removing condensate

3.2 Measuring method basics

Osmolality

The device measures the total osmolality of any aqueous solution.

The osmolality of a solution is defined as the number (or amount of substance) of the osmotically active particles (e.g. salt ions, sugar, urea, proteins) present per kilogram of solvent (water).

The osmolality is specified in Osmol/kg or mOsmol/kg.

The device determines the total osmolality of a sample solution based on the freezing point depression (see below).

The implemented measuring method is a relative measuring method where the device is first calibrated based on the freezing points of distilled water and one or two calibration solutions with known osmolality. Next, the osmolality of unknown sample solutions is determined with reference to this 2/3-point calibration.

Freezing point depression

The freezing point of a solvent is depressed by adding soluble or mixable substances. The magnitude of this effect depends less on the type and quantity of the dissolved substance, but rather on the number of particles present in the solution afterwards.

Whereas water has a freezing point of 0°C, an aqueous solution with an osmotically active particle concentration of 1 Osmol/kg has a freezing point of -1.858°C.

That means that one mol of an ideal 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 osmolality of a solution is directly proportional to the measured freezing point depression and can therefore be calculated from this result. The relationship is as follows:

$\mathbf{C_{osm} = \Delta T / K}$	C_{osm} = osmolality [Osmol/kg] ΔT = freezing point depression [°C] K = 1.858°C kg/Osmol (cryoscopic constant)

3.3 Measurement equipment

Fig. 9: Overview of measurement equipment

1 Elevator
2 Upper cooling system (behind movable elevator cover)
3 Handle for lowering the temperature sensor
4 Temperature sensor
5 Lower cooling system
6 Cover
7 Measurement vessel

The sample is pipetted into the measurement vessel (Fig. 9/7). The measurement vessel is placed on the temperature sensor (Fig. 9/4) and lowered into the lower cooling system (Fig. 9/5). The lower cooling system cools the sample down to a defined temperature.

The defined crystallization of the sample is triggered using ice crystals produced in the upper cooling system (Fig. 9/2).

The osmolality of the sample is calculated using the measured freezing point [°C] and the cryoscopic constant and shown on the display.

NOTE!
Risk of incorrect measurement resulting from the presence of air bubbles in the sample!

- The sample must be pipetted **without** air bubbles.

Upper cooling system

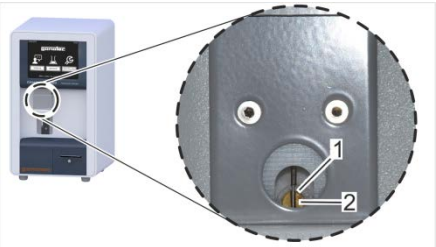


Fig. 10: Upper cooling system

1 Cryst-needle
2 Cooling nipple

The cryst-needle (Fig. 10/1) of the upper cooling system "inoculates" the sample with ice crystals ("crystallization"). This causes the sample to freeze and heat up to its freezing point.

WARNING!
Risk of infection from sample residue!

The cryst-needle is immersed into the sample during measurements. Contact with the cryst-needle increases the risk of infection.

- Wear lab gloves during any kind of work.

Temperature sensor

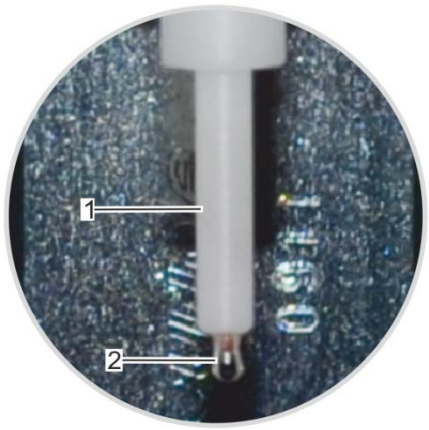


Fig. 11: Temperature sensor

1 Temperature sensor
2 Thermistor

The temperature sensor (Fig. 11/1) measures the current temperature of the sample via the thermistor (Fig. 11/2). After crystallization has been triggered, the temperature sensor measures the freezing point of the sample.

NOTE!
Sensitive component!

The thermistor of the temperature sensor is a sensitive component and must be protected from external influences such as dust or friction.

- When performing any kind of work on the device, place a measurement vessel on the thermistor.
- At the end of the work on the device, place a measurement vessel on the thermistor for protection.

Lower cooling system

The lower cooling system quickly cools the sample down to a defined temperature which is below the freezing point of the solution.
The quick cooling down of the sample causes the sample to remain in the liquid state until the defined crystallization is triggered.

3.4 Touchscreen

Fig. 12: Overview of touchscreen

The device is controlled using the touchscreen (Fig. 12/1)

NOTE!
Property damage due to incorrect operation!

The touchscreen can be damaged by sharp or hard objects or excessive pressure force.

- Only operate the touchscreen using fingers or a touchpen.
- Only tap the touchscreen (do not press).

Enter values

Some menus are password-protected.

Access to these menus is limited to the lab supervisor or authorized service personnel/Gonotec.

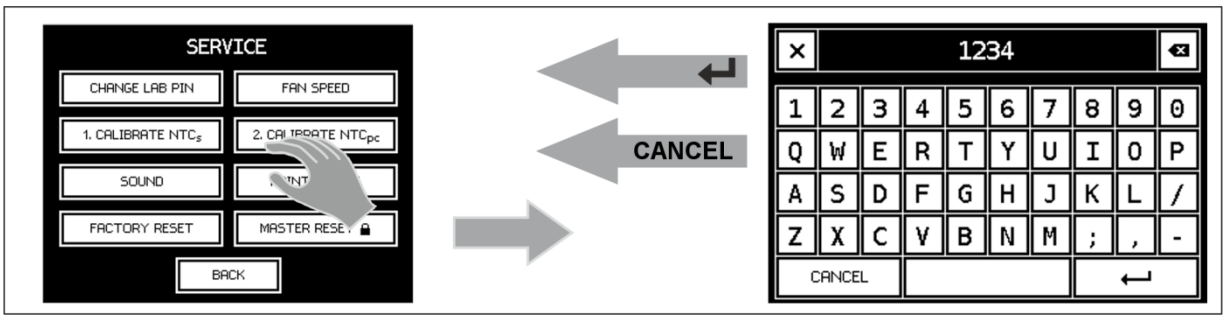


Fig. 13: Enter values

1. To enter values, tap the corresponding entry field in the opened menu.

   ⇨ This opens an on-screen keyboard.

2. Enter the value.

   To close the on-screen keyboard without saving the entered value, tap [Cancel].

3. To save the value, tap ↵.

   ⇨ The newly entered value overwrites the previous value.

3.5 Printer (does not apply to OSMOMAT 3000*basic*)

Fig. 14: Overview of printer

With built-in printer only (Option D)

1 Opening for printer paper
2 Printer pull-out handle

The printer is used to print the measurement results. Rolls of printer paper are included with the delivery.

Change printer paper

Change the printer paper when a red stripe appears on the printer paper (chapter 8.4.5 on page 90).

3.6 Connections and interfaces (does not apply to OSMOMAT 3000*basic*)

The following connections and interfaces are located at the rear of the device:

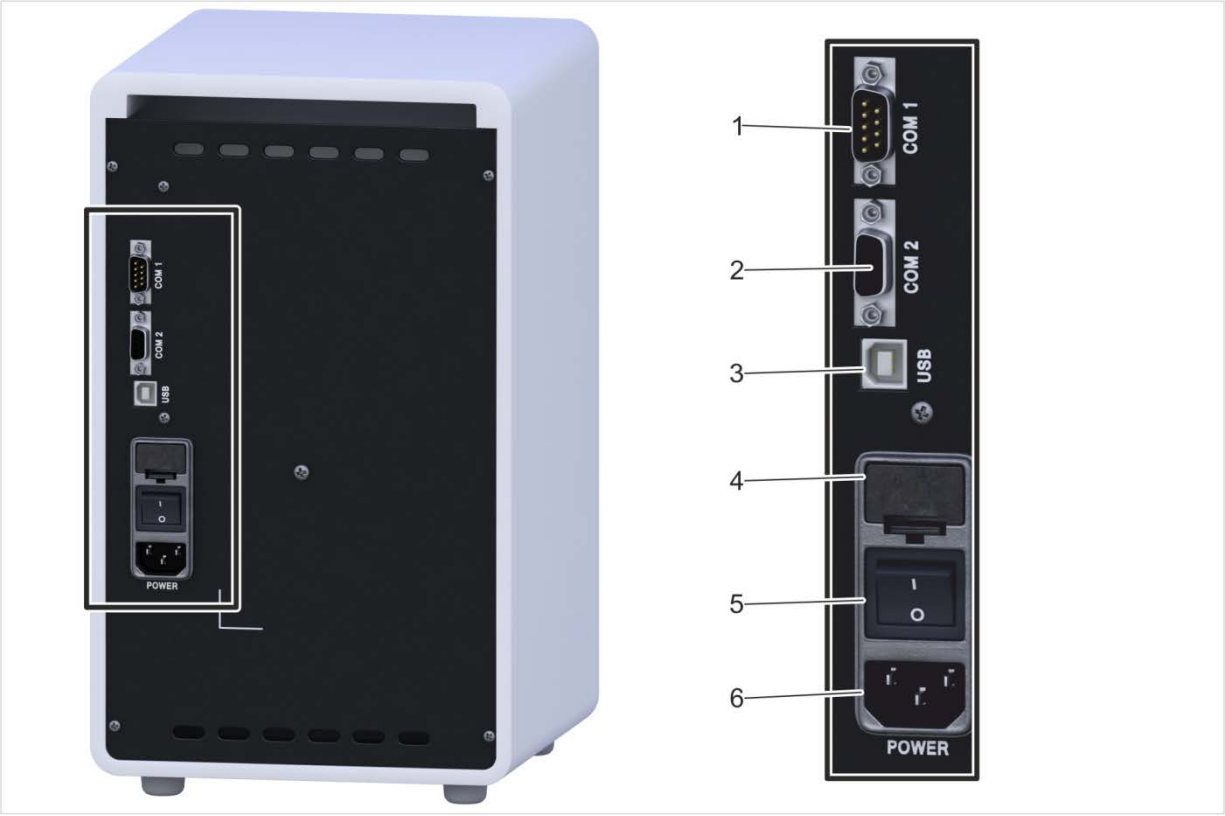


Fig. 15: Connections and interfaces

1 COM1 (only for connecting barcode reader) (does not apply to OSMOMAT 3000*basic*)

2 COM2 interface (RS-232 output) (does not apply to OSMOMAT 3000*basic*)

3 USB port (does not apply to OSMOMAT 3000*basic*)

4 Fuse insert

5 On/Off switch

6 Power plug connection

3.6.1 Interface configuration

COM1 data port

(does not apply to OSMOMAT 3000*basic*)

The upper COM1 (RS232) serial data port is used to connect a barcode reader. The barcode reader is configured at the factory and can be purchased from Gonotec GmbH or your authorized distributor.

WARNING!

Incompatible barcode reader!

The use of a barcode reader other than the barcode reader supplied by Gonotec GmbH is not recommended because potential incompatibilities cannot be ruled out.

COM2 or USB data port

(does not apply to OSMOMAT 3000*basic*)

WARNING!

To protect life and equipment:

Devices and accessories connected to the RS232 or USB connectors must meet the applicable safety standards for medical lab equipment.

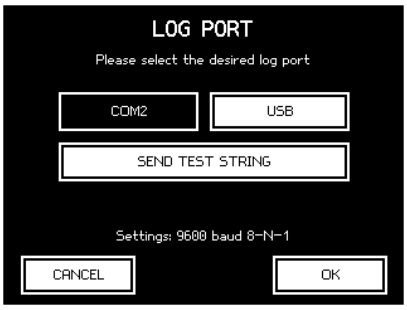


Fig. 16: Set log port

The device can output the recorded measurement results via the COM2 (RS232) serial data port in the middle or the USB port.

To select the data port, select Log Port from the Settings menu item. The following screen lets you select between COM2 and USB.

USB port driver

A software driver is required to use the USB port. There are two methods for installing the driver:

- **Automatic:** Connect the device to the PC using the USB cable and switch on the device. The operating system of the PC detects the interface, automatically installs the required software driver and notifies the user that installation was successful. The USB port can now be used as an additional COM interface.
- **Manual:** The PC does not automatically detect the device or the operating system is missing the required software driver. In this case, please follow the instructions on the included CD. It includes both the installation instructions for the corresponding Windows operating system and the software driver itself.

3.6.2 Log formats

The log output for the Osmomat 3000 may optionally be in one of the following three formats:

Format	*Description*	*Advantages*	*Disadvantages*
CSV	Line by line comma-separated values placed within quotation marks	Compact Can be uploaded into spreadsheets (e.g. OpenOffice or Excel) Easily human-readable Checksum acts as backup	Not a genuine standard format
XML	Standardized, expandable markup language	Standardized Compatible with large number of APIs Human-readable Checksum acts as backup	Not very compact
Legacy CSV	CSV format from previous generations of devices	Compatible with legacy devices and interfaces	Syntax not always clear May cause data to be misinterpreted **For reasons of security we strongly advise against continuing to use this format!**

A more detailed description of the formats is provided below.

3.6.3 Data transfer

Parameter	*Value*
Rate	9600 baud
Data bits	8
Parity	None
Stop bit	1
Coding	ASCII

Data is transferred via the serial interface in the laboratory options with the transfer parameters set as follows.

These settings are also usually referred to as **`9600/8N1`**.

3.6.4 General options

The following options can be set for all formats using the laboratory options.

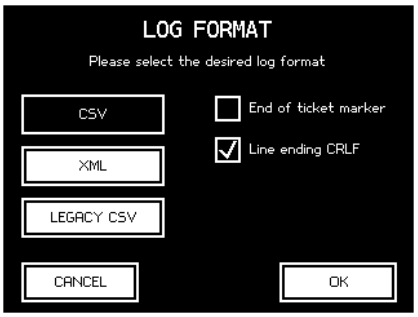


Fig. 17: Log formats

End of line markers:

The end of each displayed line can optionally be marked as follows.

Name	*Description*	*ASCII*
CR	Carriage return	**`0x0D`**
CRLF	Carriage return and line feed	**`0x0D 0x0A`**

The end of the line is marked as ⏎.

End of ticket markers:

An “end of ticket” marker can optionally be selected. This setting means that a line is displayed as follows after each individual sample measurement or after the end of the batch:

```
EndOfTicket⏎
```

3.6.5 CSV format

If CSV format is selected, the log is displayed line by line. Each line is separated by the selected end of line symbol.

Line content

There are three types of line content

Type	*Purpose*
Intro	Message showing version numbers of device software
Title	Column title of the next table of result lines
Result	Measurement result or error message

Line group

Every line within the CSV format contains several semicolon- (ASCII:0x3B) separated values. If necessary, they are enclosed in quotation marks (ASCII:0x22). Whether or not quotation marks are used depends on the value format. They are not used for measurements or times, but they are used for text values.

Intro line

When the Osmomat 3000 is started, the device sends a line with version information to prevent future compatibility problems. This line contains the short name of the device type followed by the version numbers of the mainboard and the components connected to it.
A typical intro line looks like this:

```
OSM3000;Main:V1.22;COM:V1.7;D:V1.10;TEC:V1.6⏎
```

NOTE!
Changing the settings restarts the logbook and also publishes a new intro line.

Title line

The intro line is followed by a line with title names for the values of the next result lines. This line helps to make the text human-readable and generates practical column titles when imported into a spreadsheet:

```
"batch";"sample";date;value;"dimension";"device-no";"check";"message"⏎
```

NOTE!
Changing the settings restarts the logbook and also publishes a new column title.

Result line

After each measurement a result line is sent which contains the following semicolon-separated values in a fixed order:

Column	*Description*
batch	Batch identifier in quotation marks, entered by the user or a sequential number generated automatically. **Or:** Void for single measurements and if batch ID is disabled in the options.
sample	Sample identifier in quotation marks, entered by the user or a sequential number generated automatically. **Or:** Void if sample ID is disabled in the options.
date	Date and time in combined ISO 8601 format (e.g.: **2015-12-31T13:45**).
value	Measurement value as integer. **Or:** Error identifier (see **Error messages** section)
dimension	Unit of the measurement value returned in **value** enclosed in quotation marks (**"mOsmol/kg"**) – regardless of the selected result unit and the language setting of the device! **Or:** Void if **value** contains an error message.
device-no	Serial number of the device in quotation marks.
check	Checksum of previous values in this line (see Checksum section)
message	Human-readable message always in English in quotation marks. **Or:** Void if there is no notification.

3.6.6 XML format

The XML format is sent line by line but a single record will generally extend across several lines. Each record is transferred as a ticket and multiple measurements for one batch are combined into one ticket. Strictly speaking, records are allocated to tickets in the same way as they are published: Each printed record corresponds to one ticket in the XML log.

There are two types of ticket:

Type	*Description*
SAMPLE	Contains exactly one result from a single measurement
BATCH	Contains several results from a batch measurement

3.6.6.1 Ticket

A ticket consists of an *XML tag* which corresponds to one published ticket. If it relates to a single measurement, it contains an additional *XML tag* called **`Measurement`**, which contains the measurement and the associated metadata. If it relates to a batch measurement, one ticket may contain several measurements.

A ticket has the following attributes in addition to the measurements contained in it:

Attribute	*Description*
`class`	Ticket type (**`SAMPLE`** or **`BATCH`**)
`serialno`	Serial number of the device
`versions`	Version information on the device and connected components (see *Intro line* in the *CSV format* chapter)

3.6.6.2 Measurement

A measurement or mismeasurement is described in a ticket in an XML tag called **`Measurement`**, which contains the following values:

Value	*Description*
`BatchId`	Batch identifier, entered by the user or a sequential number generated automatically. **Or:** Not present for single measurements and if batch ID is disabled in the options.
`SampleId`	Sample identifier, entered by the user or sequential number generated automatically. **Or:** Not present if sample ID is disabled in the options.
`DateTime`	Date and time in combined ISO 8601 format (e.g.: **`2015-12-31T13:45`**).
`Value`	Measurement value as integer. **Or:** Not present if it is a mismeasurement.
`Unit`	Unit of the measurement value returned in **`value`** enclosed in quotation marks (**`"mOsmol/kg"`**) – regardless of the selected result unit and the language setting of the device! **Or:** Not present if it is a mismeasurement.
`Failure`	Error identifier (see **Error messages** section) **Or:** Not present if measurement was successful.
`DeviceNo`	Serial number of the device
`CheckSum`	Checksum of previous values in this line (see Checksum section)
`Message`	Human-readable message always in English. **Or:** Not present if there is no notification.

3.6.6.3 Example of a single measurement

In the case of a single measurement the entire ticket is published in one piece when the measurement has been completed, the value **`BatchId`** does not apply.

```
<Ticket class="SAMPLE" serialno="300161103"
versions="OSM3000;Main:V1.22;COM:V1.7;D:V1.10;TEC:V1.6">⏎
      <Measurement>⏎
            <SampleId>PROBE01</SampleId>⏎
            <DateTime>2016-02-19T08:34:30</DateTime>⏎
            <Value>301</Value>⏎
            <Unit>mOsmol/kg</Unit>⏎
            <DeviceNo>300161103</DeviceNo>⏎
            <CheckSum>172ef346c5f36c964ac0710a8421efc1</CheckSum>⏎
      </Measurement>⏎
</Ticket>⏎
```

- **Example of a batch measurement**

If a new batch is initiated, a section is published which opens the ticket as an *XML tag* in the log:

```
<Ticket class="BATCH" serialno="300161103"
versions="OSM3000;Main:V1.22;COM:V1.7;D:V1.10;TEC:V1.6">⏎
```

If measurements are then implemented within the batch, a **`Measurement`** XML tag follows for each measurement such as the following:

```
      <Measurement>⏎
            <BatchId>CHARGE01</BatchId>⏎
            <SampleId>PROBE01</SampleId>⏎
            <DateTime>2016-02-19T08:38:02</DateTime>⏎
            <Value>301</Value>⏎
            <Unit>mOsmol/kg</Unit>⏎
            <DeviceNo>300161103</DeviceNo>⏎
            <CheckSum>339781763744c176c6b43317d880b782</CheckSum>⏎
      </Measurement>⏎
```

Ending the batch also closes the ticket:

```
</Ticket>⏎
```

3.6.7 Legacy CSV format

Format initially used by OSMOMAT 3000 for data transfer.

Select only if required for compatibility with existing LIMS connections configured accordingly. Documentation in the obsolete CSV format can be requested separately.

We strongly advise against continuing to use this format!

3.6.8 Error messages

The following error messages may be used to diagnose an operating error or device failure:

Notification	*Meaning*
ABORT	User cancels by pressing the **EXIT** key
LIFT	User cancels by lifting the sensor
CANTCOOL	Failed to sufficiently cool down sample
NOCRYST	Crystallization failed
SPONCRYST	Spontaneous crystallization of sample

3.6.9 Checksums

The checksum for each result line is calculated from the contents of the values from the columns *Batch ID*, *Sample ID*, *Date/time*, *Measurement*, *Unit* and *Device number*. A possible result line:

```
<Measurement>
  <SampleId>PROBE01</SampleId>
  <DateTime>2016-02-19T08:34:30</DateTime>
  <Value>301</Value>
  <Unit>mOsmol/kg</Unit>
  <DeviceCode>300161103</DeviceCode>
  <CheckSum>172ef346c5f36c964ac0710a8421efc1</CheckSum>
</Measurement>
```

...or…

```
;"PROBE01";2016-02-19T08:34:30;301;"mOsmol/kg";"300161103";
"172ef346c5f36c964ac0710a8421efc1";
```

...and the above contents are strung together to form:

```
PROBE012016-02-19T08:34:30301mOsmol/kg300161103
```

The MD5 checksum for this string is:

```
17 2e f3 46 c5 f3 6c 96 4a c0 71 0a 84 21 ef c1
```

See http://en.toolpage.org/tool/md5 to learn more about MD5 calculation

4 Delivery, packaging, and storage

Delivery condition

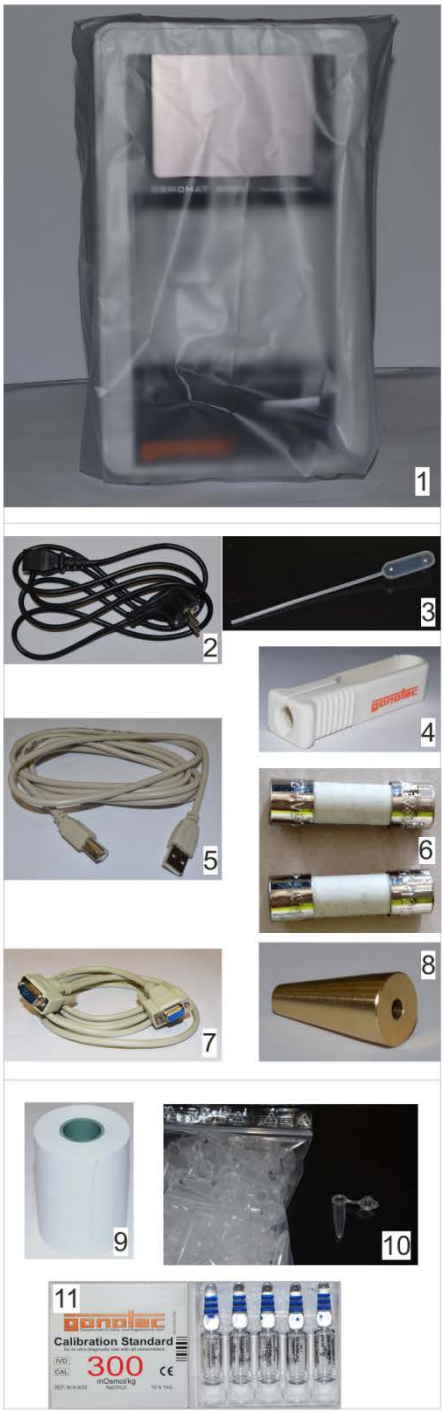


Fig. 18: Delivery condition

1 package containing the following components:

- Device with protective sleeve (Fig. 18/1)
- Accessories (Fig. 18/2–8):
  - Blow-out device (Fig. 18/3)
  - Adjustment tool (Fig. 18/8)
  - 1 package of 2 microfuses: slow-blow 1.6A (Fig. 18/6)
  - Ampoule opener (Fig. 18/4)
  - USB cable (Fig. 18/5) (does not apply to OSMOMAT 3000*basic*)
  - RS-232 cable (Fig. 18/7) (does not apply to OSMOMAT 3000*basic*)
  - Power cable (Fig. 18/2)
- Standard accessories (Fig. 18/9-11)
  - Printer paper (Fig. 18/9) (Option D only) (does not apply to OSMOMAT 3000*basic*)
  - Measurement vessels, 100 pc. (Fig. 18/10)
  - Calibration standard 300mOsmol/kg, 1 package of 10 ampoules/1ml each (Fig. 18/11)
- 1 user manual

Check the delivery for completeness and transport damage immediately following receipt.

Proceed as follows in case of externally visible transport damage:

- Reject delivery or accept delivery only conditionally.
- Note the extent of damage on the transport documents or the delivery note of the carrier.
- Notify Gonotec GmbH and initiate a complaint.

File a complaint about every defect as soon as it is detected. Claims for damages can only be filed within applicable complaint deadlines.

4.1 Packaging

About the packaging

The package is packaged according to the expected transport conditions. Only environmentally friendly materials were used for the packaging.

The packaging is intended to protect the device from transport damage and other damage until the time of installation. Therefore, do not destroy the packaging and do not remove it until just before installation.

Handling of packaging materials

The packaging is multi-use and ensures a hygienic and safe method of transportation. Keep the packaging for possible return of the device for repairs. This will save you the time and money needed to find equally suitable packaging.

If disposing of the packaging material, observe the following:

NOTE!
Danger to environment due to improper disposal!

Packaging materials are valuable resources and can be re-used or recycled in many cases. Improper disposal of packaging materials can cause dangers to the environment.

- Be aware of the environment when disposing of the packaging material.
- Observe applicable local disposal regulations. If necessary, task a specialist firm with disposal.

Symbols on packaging

The symbols on the packaging of the device and calibration standard are explained below:

Fragile

Indicates packages with fragile or sensitive contents.

Handle the package with care, do not drop, and do not expose to shock.

Protect from liquid

Protect packages from liquid and keep dry.

Package orientation

The arrow tips of the symbol point to the top of the package. They must point up at all times to prevent damage to the contents.

No disposal via municipal waste

Indicates that disposal of the device via municipal waste is prohibited. Disposal of the decommissioned device should be via electronics and metal recycling. In addition, decommissioned devices can be returned to the manufacturer for disposal.

Package recycling

Indicates that the packaging can be recycled.

Compliance

This product meets the requirements of EEC Directive 98/79 relating to in-vitro diagnostic devices.

In-vitro diagnostic device

Indicates that the product is an in-vitro diagnostic device.

Item number

Item number

Batch ID

Batch ID of the calibration standard

Biological safety

Biological safety (month, year). Date until which the calibration standard fulfills its original function if stored properly.

Biohazard

Biocontamination warning:
Use care when operating upper cooling system and cryst-needle

4.2 Device storage

Store the device under the following conditions:

- Do not store outside.
- Store under dry and dust-free conditions.
- Do not expose to aggressive media.
- Protect from sunlight.
- Protect the temperature sensor using a measurement vessel.
- Avoid mechanical shock.
- Storage temperature: -10°C to 60°C.
- Relative humidity (non-condensing): 5-90%.
- If stored for more than 3 months, regularly inspect all parts and packaging for general integrity.

4.3 Unpack device

1. Carefully open cardboard box using a knife.
2. Remove device from packaging and place in a suitable location.
3. Keep packaging for possible later return.

5 Installation

5.1 Transport device inside lab

Personnel: ■ User

Safety gear: ■ Disposable lab gloves

1. Power down device using on/off switch on rear side and disconnect power plug.

Fig. 19: Position measurement vessel

2. Position a measurement vessel (Fig. 19/1) on the temperature sensor.

The measurement vessel is securely attached to the temperature sensor when it clicks into place.

Fig. 20: Position transport safety device

3. Tilt transport safety device for temperature sensor and carefully slide behind the temperature sensor (Fig. 20).

Fig. 21: Device with protective sleeve

4. Pull protective sleeve (Fig. 21/1) included with the delivery over device.

5. Lift up device (6.5kg) and carry to installation site.

5.2 Install device

Personnel: ■ User

Safety gear: ■ Disposable lab gloves

Fig. 22: Fan outlet (1)

1.

NOTE!
Risk of property damage!
Only install device indoors.

Install device at installation site.

NOTE!
Risk of incorrect measurements

Select site based on the following criteria:

- free of vibrations
- no direct heat exposure (sun, electric heater, etc.)
- no strong air flows
- free of dust and dirt

Keep fan outlet (Fig. 22/1) on device clear.

Keep fan outlet openings underneath device clear.

Fig. 23: Remove protective sleeve

2. Remove protective sleeve from device (Fig. 23/1).

Fig. 24: Transport safety device

3. Remove transport safety device (Fig. 24/1) from temperature sensor. Proceed as follows:

Fig. 25: Remove transport safety device

4. Carefully pull transport safety device down and pull forward to remove.

5.3 Connect device

Personnel: ■ Lab supervisor

1. Connect power plug to device.

2. Connect power cable to a properly grounded power socket.

3. Connect a PC via RS232 or USB (if applicable).

4. Connect a barcode reader (if applicable).

6 Setup

Personnel: ■ Lab supervisor

1. Complete all activities for installation and connection of the device.
2. Verify that the connections at the rear side of the device are secure.
3. Check the elevator for ease of movement.

   If necessary, grease the elevator guide (chapter 9.4 “*Lubricate elevator*” on page 100).
4. Power up device on rear side using on/off switch.

6.1 Check printer (Option D)

(does not apply to OSMOMAT 3000*basic*)

Fig. 26: Pull out printer

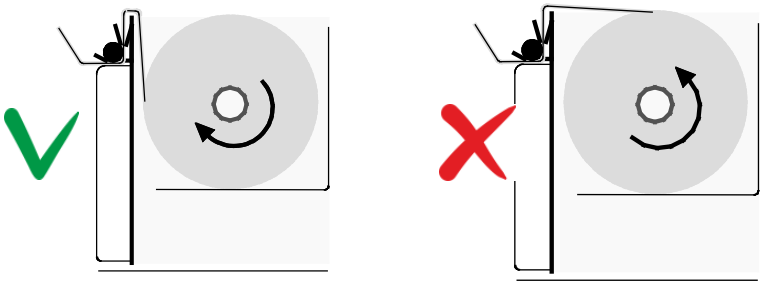


Fig. 27: Paper roll feed direction

✓ Correct feed direction

✗ Incorrect feed direction

5. Check feed direction of paper roll. Open printer (Fig. 26/1) by pulling on silver knob (magnetic latch) and compare feed direction of paper roll with feed direction shown in Fig. 27.

6.2 Check free movement of steel needle

6. Check cryst-needle for free movement.

   Open the Adjust Needle menu (*Start menu* ➔ *Settings* ➔ *Lab Options* ➔ *Maintenance* ➔ *Adjust Needle*).

Fig. 28: Adjust Needle menu

7.

CAUTION!
Risk of injury from cryst-needle!

The tip of the cryst-needle is exposed. Movement of the cryst-needle can cause needle puncture injuries.

- Always keep your hands and fingers clear from the area underneath the cryst-needle.

WARNING!
Risk of infection due to sample residue and in case of inadequate hygiene, disinfection, and sterilization procedures!

Exposure to sample residue in non-cleaned, non-sterilized, or non-disinfected components results in an elevated risk of infection.

- Wear lab gloves during any kind of work.
- Observe all local regulations regarding hygiene, disinfectant cleaning, and sterilization.

Tap *Move Needle* and ensure that the cryst-needle moves freely.

Tap *Back* to complete the check.

6.3 Set calibration defaults

Select calibration procedure

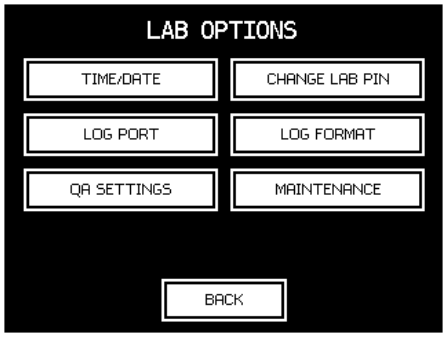


Fig. 29: Lab Options menu

8. Open the menu for configuring the lab options.

In the Start menu, tap *Settings* ➔ *Lab Options*.

The menu can be protected with a lab supervisor password.

See *QA Settings* to learn more about calibration settings.

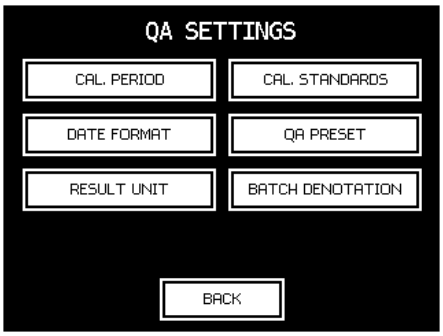


Fig. 30: QA Settings menu

9. Open the menu for configuring the lab options.

To configure the calibration interval, tap *Cal. Period*.

To select the calibration standards you are using, tap *Cal. Standards*.

To set up the calibration method, tap *QA Preset*.

OSMOMAT 3000*basic*:

Cal. Period and *Cal. Standards* selections are not available

Configure calibration interval

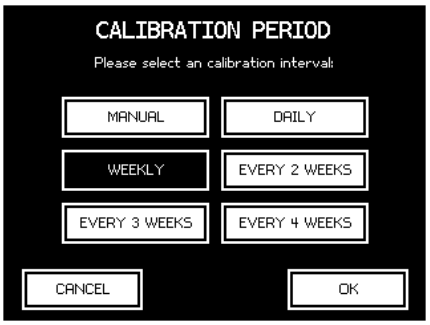


Fig. 31: Configure calibration interval

10. Select a calibration interval.

When selecting *Manual*, the device does not prompt you for calibration (not recommended).

OSMOMAT 3000*basic*:

Selection not available

Select calibration standards

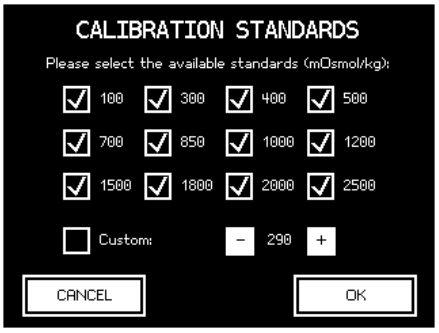


Fig. 32: Select calibration standards

11. Specify the allowed calibration points. They should be close to the expected measurement values.

A calibration point (*Custom*) can be freely selected by the user in increments of 10 and enabled or disabled for selection.

Enter the values in mOsmol/kg.

OSMOMAT 3000*basic*:

Selection not available

Set up calibration method

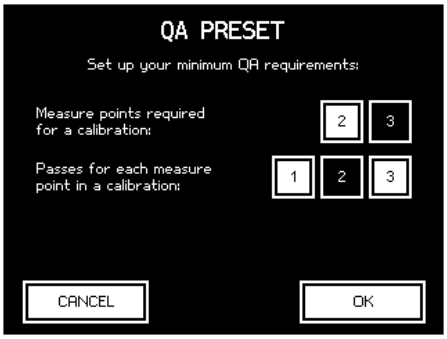


Fig. 33: Set up calibration method

12. Select the calibration method:

- *2-point*: Select 2-point calibration
- *3-point*: Select 3-point calibration

13. Select the number of measurements to be performed for each calibration medium (distilled water and calibration standard).

The system calculates the calibration values from the mean value of these measurements.

The number of measurements for each calibration point does not affect the linearity or reproducibility of the measurement system.
They are only used to arrive at the mean value.

6.4 Date Time

Set date and time

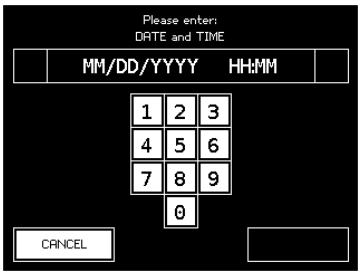


Fig. 34: Set date and time

14. Enter date and time as follows:

DD – Day, two digits [01…31]
MM – Month, two digits [01…12]
YYYY – Year, four digits [2014]
HH – Hour, two digits [00…23]
MM – Minutes, two digits [00…59]

Set date format

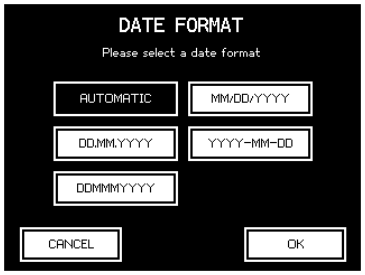


Fig. 35: Select date format

15. Select the date format required:

DD – Day, two digits [01…31]
MM – Month, two digits [01…12]
MMM – Month [Jan…Dec]
YYYY – Year, four digits [2014]

If AUTOMATIC is selected the date format is based on the language selected.

6.5 Measurement series name

Set measurement series name

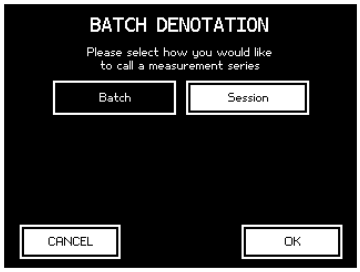


Fig. 36: Measurement series name

16. Select the name for your measurement series.

OSMOMAT 3000*basic*:
Selection not available

6.6 Result Unit

Set result unit

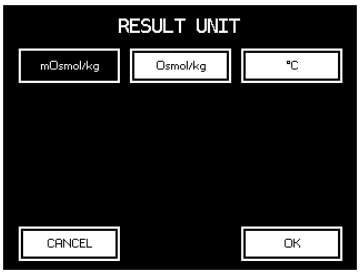


Fig. 37: Select unit

17. Select the unit for the measurement results:

- mOsmol/kg
- Osmol/kg
- °C

OSMOMAT 3000*basic*:
Selection not available

7 Operation

Electrical current

DANGER!
Risk of death due to electrical current on device!

Contact with energized parts of the device results in immediate risk of death due to electric shock. Damage to the insulation of individual components can cause risk of death.

- Only have qualified personnel perform repair and maintenance work on the device.
- If the insulation is damaged, immediately disconnect the power plug and schedule a repair.
- Always route the power cable so it is not subject to stress and cannot be bent, pinched, or rolled over and is not exposed to liquids or heat.
- Ensure easy access to the power socket at all times.
- Keep energized parts away from liquids. Otherwise, shorts may occur.

Risk of infection

WARNING!
Risk of infection due to sample residue and in case of inadequate hygiene, disinfection, and sterilization procedures!

Exposure to sample residue in non-cleaned, non-sterilized, or non-disinfected components results in an elevated risk of infection.

- Wear lab gloves during any kind of work.
- Observe all local regulations regarding hygiene, disinfection, and sterilization.

7.1 Power up device

Personnel: ■ User

Safety gear: ■ Disposable lab gloves

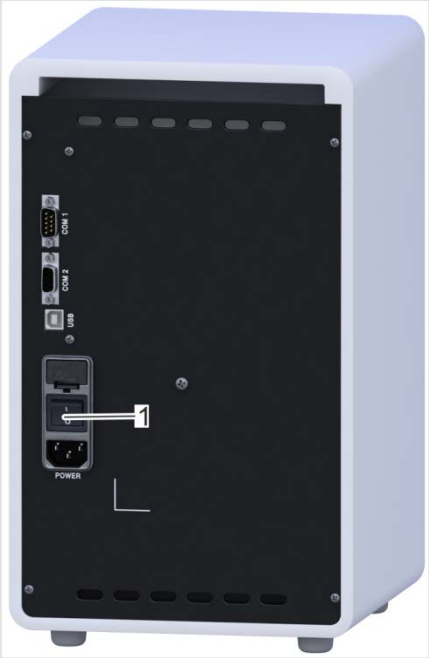


Fig. 38: Power up device

1. Power up device on rear side using on/off switch (Fig. 38/1).

7.2 Modify user preferences

Configure language

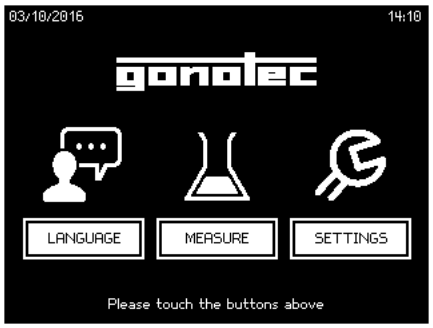


Fig. 39: Select language

Tap *Language* and select a language.

Overview

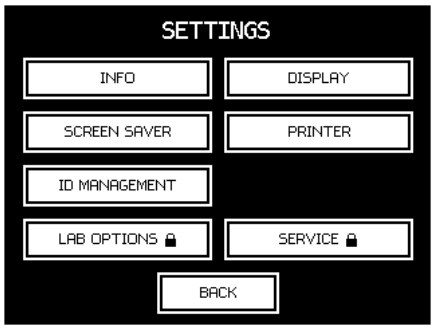


Fig. 40: Overview of user preferences

Tapping *Settings* on the Start menu opens the Settings menu.

The Settings menu lets the user configure the following settings:

- *Info*: Shows the version of the device software
- *Display*: Configure screen contrast
- *Screen saver*: Configure screen saver
- *Printer*: Activate paper feed (Option D only)
  (does not apply to OSMOMAT 3000*basic*)
- *ID Management*: Set ID for sample and series measurements
  (does not apply to OSMOMAT 3000*basic*)

The Lab Options option is protected with the lab supervisor password.

The Service option is protected with the service password. Modifications have to be requested by contacting the manufacturer.

Configure screen contrast

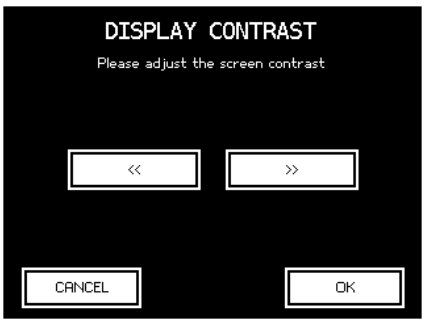


Fig. 41: Configure screen contrast

1. Tap » to increase contrast.
Tap « to decrease contrast.

Configure screen saver

Fig. 42: Configure screen saver

1. Select the duration after which the system activates the screen saver.

Tapping *OFF* will never activate the screen saver.

Activate paper feed
(does not apply to OSMOMAT 3000*basic*)

Fig. 43: Activate paper feed

1. Option D only:

Tap *Paper Feed*.

⇨ The paper feed of the printer is activated briefly.

Tap *Back* to exit the menu.

Set sample and batch ID
(does not apply to OSMOMAT 3000*basic*)

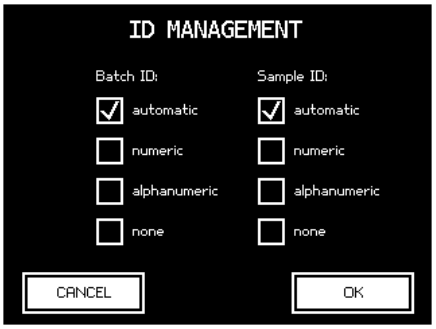


Fig. 44: Set sample and batch ID

1. Select the settings for the IDs for series measurements (*Batch ID*) and individual samples (*Sample ID*). The following options are available:

- automatic: The samples and the charge IDs are assigned running numbers automatically. The counter resets daily. The counter for the individual samples in a series measurement resets when starting a new series measurement.
- numeric: Numeric IDs are assigned manually. During measurements, the system prompts the user to enter the numeric ID of the sample or charge using the virtual keyboard.
- alphanumeric: Alphanumeric IDs are assigned manually. During measurements, the system prompts the user to enter the alphanumeric ID of the sample or charge using the virtual keyboard.
- none: Do not use IDs for samples and batches.

Laboratory options

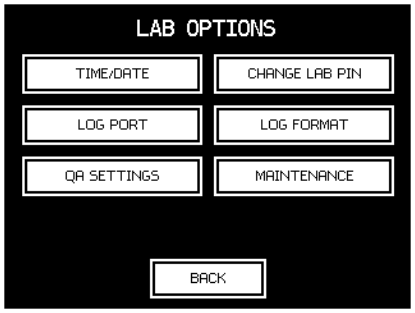


Fig. 45: Overview of lab settings

Tapping *Lab Options* in the Settings menu opens the Lab Options menu.

The Lab Options option is protected with the lab supervisor password.

The *Lab Options* menu lets the user configure the following settings:

- *Time/Date*: Set time and date
- *Change Lab PIN*: Change PIN for access to lab options
- *Log Port*: Set log port (↳ chapter 3.6.1)
  (does not apply to OSMOMAT 3000*basic*)
- *Log Format*: Set log format (↳ chapter 3.6.2)
  (does not apply to OSMOMAT 3000*basic*)
- *QA Settings*: Additional configuration settings (↳ page 49)
  (does not apply to OSMOMAT 3000*basic*)
- *Maintenance*: Options for maintenance and troubleshooting
  (↳ chapter 8.4)

7.3 Measure individual samples

Personnel:
- User

Safety gear:
- Disposable lab gloves

Materials:
- Soft, lint-free paper tissue
- Pipette
- Measurement vessel
- Sample

NOTE!
Impaired reproducibility of measurement due to incorrect measurement vessels!

Repeated use of the measurement vessels and use of incorrect consumables cannot guarantee reproducible measurement results.

- Always use a clean and unused measurement vessel for every measurement.
- Only use measurement vessels supplied by Gonotec GmbH.
- Never use centrifuge tubes or reaction vessels.

NOTE!
Risk of incorrect measurement resulting from the presence of air bubbles in the sample!

- The sample must be pipetted **without** air bubbles.

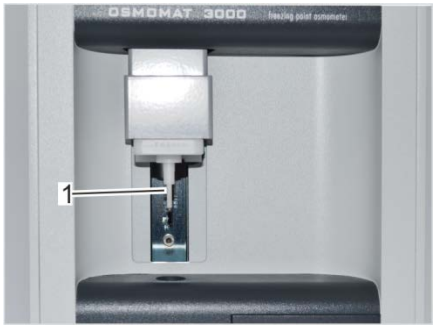


Fig. 46: Clean temperature sensor

1. Clean temperature sensor (Fig. 46/1) using a soft, dry, lint-free paper towel.

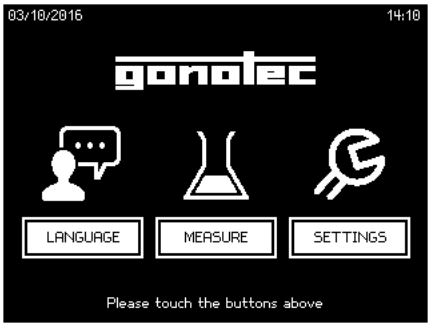


Fig. 47: Start menu

2. Tap *Measure* on the Start menu (Fig. 47).

⇨ If the operating time of the device is less than 3 minutes, a wait screen for ice formation is displayed (Fig. 48).

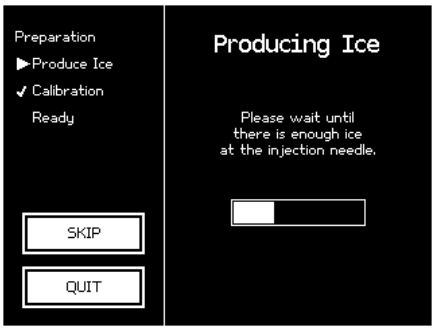


Fig. 48: Ice formation

3. Wait until ice forms on the cryst-needle (Fig. 48).

⇨ After successful ice formation, a calibration prompt (Fig. 49) or the *Ready to Measure* screen (Fig. 50) is displayed (depending on the configured calibration interval).

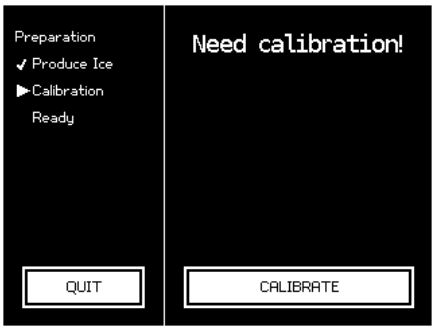


Fig. 49: Calibrate device

4. If necessary, calibrate device (Fig. 49).

↳ Chapter 7.5 "*Calibrate device*" on page 65.

Calibration cannot be skipped.

*The calibration interval is defined by the lab supervisor (does not apply to OSMOMAT 3000*basic*).*

⇨ The device is ready.

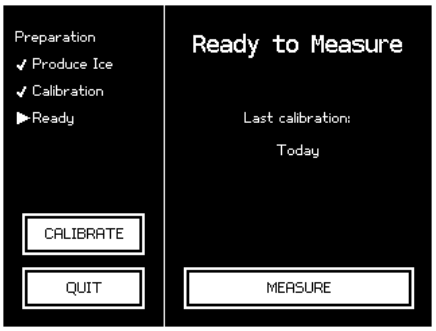


Fig. 50: Device is ready for measurement

5. Tap *Measure* (Fig. 50).

⇨ The measurement menu (Fig. 53) opens.

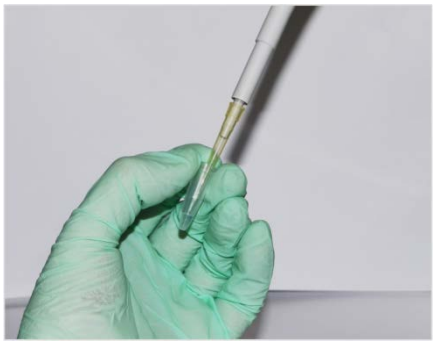


Fig. 51: Pipette sample

6. Pipette a sample volume of 50µl (15µl for Option M) into an unused and clean measurement vessel (Fig. 51).

NOTE!
Risk of incorrect measurement resulting from the presence of air bubbles in the sample!

- The sample must be pipetted **without** air bubbles.

Fig. 52: Position measurement vessel

7. Position measurement vessel on temperature sensor with cover facing front (Fig. 52/1).

> *The measurement vessel is securely attached to the temperature sensor when it clicks into place.*

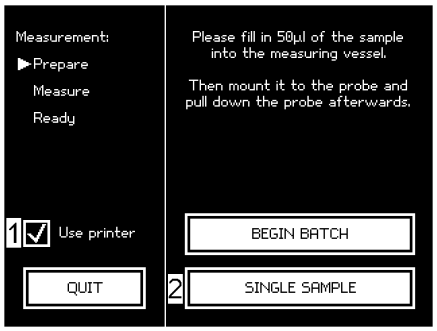


Fig. 53: Measurement menu

8. Option D only:
(does not apply to OSMOMAT 3000*basic*)

Tap *Use printer* on the measurement menu (Fig. 53/1) to output the measurement results to a printer. Make sure that the printer is ready.

9. To start the measurement, tap *Single Sample* (Fig. 53/2).

If necessary, enter the sample ID using the virtual keyboard.

> *The sample ID can be pre-defined in the user preferences. In this case, the system assigns the sample ID automatically (page 55)*

Fig. 54: Move elevator down

10. Move elevator (Fig. 54/1) down.

> *Moving the elevator up during the measurement will abort the measurement.*

⇨ The sample measurement is performed automatically. Pay attention to the displays on the touchscreen.

Operation

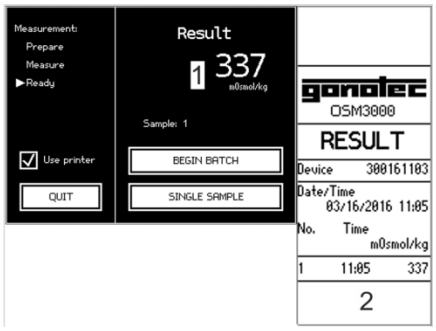


Fig. 55: Measurement

The measurement result displays on the touchscreen (Fig. 55/1) and, if applicable, prints (Fig. 55/2) (Option D).

Reproducibility:

 # ±2 digits in the measurement range [0..400] mOsmol/kg

 # ±0.5% in the measurement range [400..1500] mOsmol/kg

 # ±1.0% starting with 1500 mOsmol/kg

Option M (15µl):

 # ±6 digits [0..300] mOsmol/kg

 # ±2.0% [300..3000] mOsmol/kg

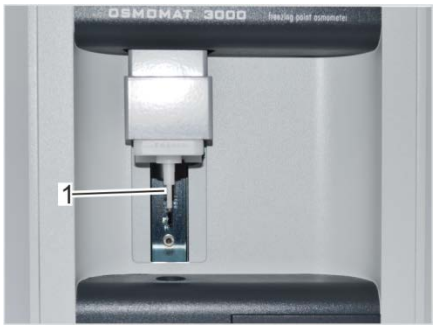


Fig. 56: Clean temperature sensor

11. Move elevator up.

Moving the elevator up during the measurement will abort the measurement.

12. Remove measurement vessel from temperature sensor.

Dispose of measurement vessel and sample according to local regulations.

13. Clean temperature sensor (Fig. 56/1) using a soft, dry, lint-free paper towel.

NOTE!
Risk of carryover!

- Failure to clean the temperature sensor immediately following measurement can result in carryover and incorrect measurement results.

7.4 Batch/series measurement (does not apply to OSMOMAT 3000*basic*)

Personnel:
- User

Safety gear:
- Disposable lab gloves

Materials:
- Soft, lint-free paper tissue
- Pipette
- Measurement vessel
- Samples

NOTE!
Impaired reproducibility of measurement due to incorrect measurement vessels!

Repeated use of the measurement vessels and use of incorrect consumables cannot guarantee reproducible measurement results.

- Always use a clean and unused measurement vessel for every measurement.
- Only use measurement vessels supplied by Gonotec GmbH.
- Never use centrifuge tubes or reaction vessels.

NOTE!
Risk of incorrect measurement resulting from the presence of air bubbles in the sample!

- The sample must be pipetted **without** air bubbles.

Fig. 57: Clean temperature sensor

1. Clean temperature sensor (Fig. 57/1) using a soft, dry, lint-free paper towel.

Fig. 58: Start menu

2. Tap *Measure* on the Start menu (Fig. 58).

⇨ If the operating time of the device is less than 3 minutes, a wait screen for ice formation is displayed (Fig. 59).

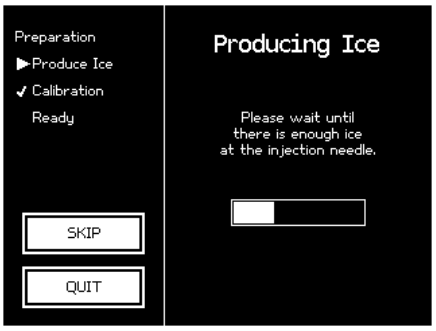


Fig. 59: Ice formation

3. Wait until ice forms on the cryst-needle (Fig. 59).

⇨ After successful ice formation, a calibration prompt (Fig. 60) or the *Ready to Measure* screen (Fig. 61) is displayed (depending on the configured calibration interval).

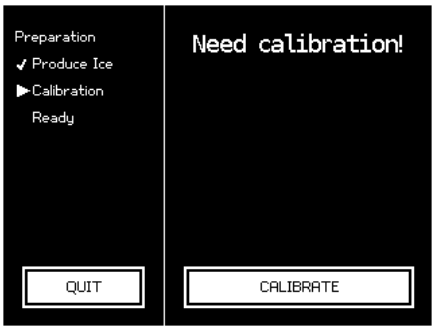


Fig. 60: Calibrate device

4. If necessary, calibrate device (Fig. 60).

Chapter 7.5 "*Calibrate device*" on page 65.

Calibration cannot be skipped.

The calibration interval is defined by the lab supervisor (does not apply to OSMOMAT 3000basic).

⇨ The device is ready.

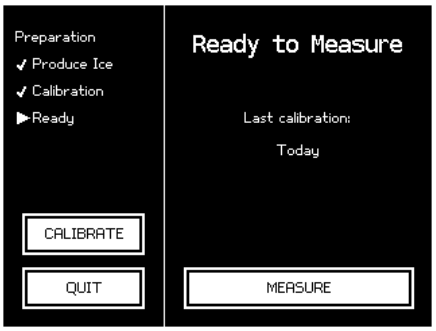


Fig. 61: Device is ready for measurement

5. Tap *Measure* (Fig. 61).

⇨ The measurement menu (Fig. 62) opens.

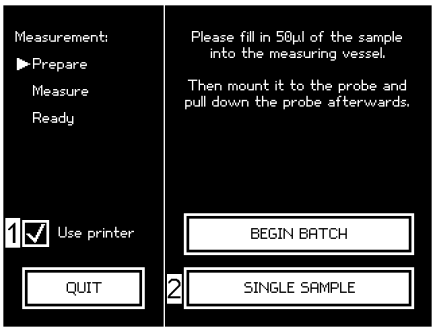


Fig. 62: Measurement menu

6. Option D only:

Tap *Use printer* on the measurement menu (Fig. 62/1) to output the measurement results to a printer.

Make sure that the printer is ready.

7. To start a series measurement, tap *Begin Batch* (Fig. 62/2).

8. Enter the batch ID.

The batch ID can be pre-defined in the user preferences. In this case, the system assigns the batch ID automatically (page 55)

Fig. 63: Pipette sample

9. Pipette a sample volume of 50µl (15µl for Option M) into an unused and clean measurement vessel (Fig. 63).

NOTE!
Risk of incorrect measurement resulting from the presence of air bubbles in the sample!

- The sample must be pipetted **without** air bubbles.

Fig. 64: Position measurement vessel

10. Position measurement vessel on temperature sensor with cover facing front (Fig. 64/1).

The measurement vessel is securely attached to the temperature sensor when it clicks into place.

Fig. 65: Move elevator down

11. Move elevator (Fig. 65/1) down.

Moving the elevator up during the measurement will abort the measurement.

⇨ The sample measurement is performed automatically. Pay attention to the displays on the touchscreen.

The touchscreen shows the measurement result for the current sample.

⇨ Option D:

The measurement result prints.

Reproducibility:

 # ±2 digits in the measurement range [0..400] mOsmol/kg

 # ±0.5% in the measurement range [400..1500] mOsmol/kg

 # ±1.0% starting with 1500 mOsmol/kg

Option M (15µl):

 # ±6 digits [0..300] mOsmol/kg

 # ±2.0% [300..3000] mOsmol/kg

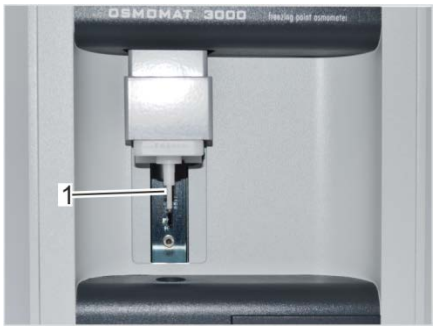


Fig. 66: Clean temperature sensor

12. Move elevator up.

> *Moving the elevator up during the measurement will abort the measurement.*

13. Remove measurement vessel from temperature sensor.

Dispose of measurement vessel and sample according to local regulations.

14. Clean temperature sensor (Fig. 66/1) using a soft, dry, lint-free paper towel.

> **NOTE!**
> **Risk of carryover!**
> - Failure to clean the temperature sensor immediately following measurement can result in carryover and incorrect measurement results.

15. Start the measurement of the new sample by repeating the work steps starting with step 9.

To complete the series measurement, tap *Complete batch*.

⇨ Option D:

Completing the series measurement also completes the printing operation.

> *Exiting the measurement menu (by pressing Exit) will also quit the series measurement.*

7.5 Calibrate device

Calibration methods

Depending on the pre-defined calibration interval, opening the measurement menu will automatically show a calibration prompt (Fig. 49). Calibration can also be started manually (Fig. 50).

The device is calibrated using one of the following calibration methods:

- 2-point calibration: Calibration using distilled water and a calibration standard or
- 3-point calibration: Calibration using distilled water and two calibration standards

2-point calibration means that the device is calibrated using distilled water (zero point calibration) and one calibration standard.

3-point calibration means that the device is calibrated using distilled water (zero point calibration) and two calibration standards.

The calibration method, the calibration standards used for calibration, and the calibration interval are defined by the lab supervisor during start-up (↯ chapter 6.3 “*Set calibration* defaults” on page 49).

Calibrate device

Personnel:
- User

Safety gear:
- Disposable lab gloves

Materials:
- Soft, lint-free paper tissue
- Pipette
- Distilled water
- Calibration standard(s) (e.g. 300 mOsmol/kg)
- Ampoule opener
- Measurement vessels

NOTE!
Impaired reproducibility of measurement due to incorrect measurement vessels!

Repeated use of the measurement vessels and use of incorrect consumables cannot guarantee reproducible measurement results.

- Always use a clean and unused measurement vessel for every measurement.
- Only use measurement vessels supplied by Gonotec GmbH.
- Never use centrifuge tubes or reaction vessels.

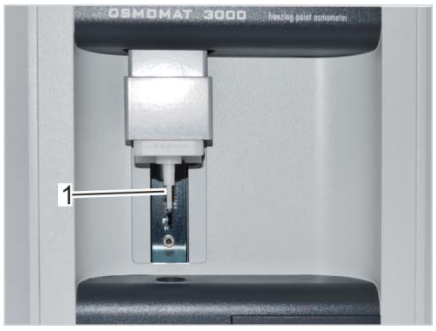


Fig. 67: Clean temperature sensor

1. Clean temperature sensor (Fig. 67/1) using a soft, dry, lint-free paper towel.

Fig. 68: Perform zero point calibration

2. Follow the instructions on the touchscreen.

Fig. 69: Pipette distilled water

3. Pipette a distilled water volume of 50µl (15µl for Option M) into an unused and clean measurement vessel (Fig. 69).

NOTE!
Risk of incorrect measurement resulting from the presence of air bubbles in the sample!

- The sample must be pipetted **without** air bubbles.

Fig. 70: Position measurement vessel

4. Position measurement vessel on temperature sensor with cover facing front (Fig. 70/1).

The measurement vessel is securely attached to the temperature sensor when it clicks into place.

Perform zero point calibration

Fig. 71: Move elevator down

5. Move elevator (Fig. 71/1) down.

⇨ Zero point calibration starts automatically.

Zero point calibration is performed automatically.
Pay attention to the displays on the touchscreen.

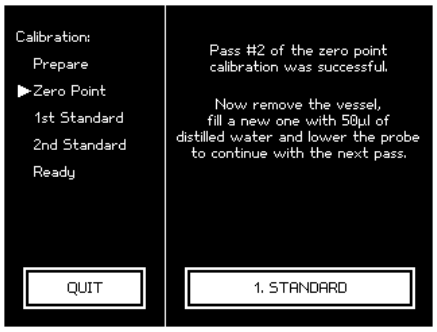


Fig. 72: Calibrate device using calibration standard

6. Move elevator up.

7. Remove measurement vessel from temperature sensor.

Dispose of measurement vessel and sample according to local regulations.

8. Clean temperature sensor (Fig. 67/1) using a soft, dry, lint-free paper towel.

NOTE!
Risk of carryover!

- Failure to clean the temperature sensor immediately following measurement can result in carryover and incorrect measurement results.

9. Repeat steps 3 through 8 until the number of measurements per calibration point specified in the calibration defaults (↳ *page 50*) (max. 3) is reached.

10. Following successful zero point calibration, tap *1st Standard* (Fig. 72) to start calibration using the first calibration standard.

Successful calibration means that it was possible to measure the sample without errors.

This is not a plausibility check, which is not performed until the entire calibration sequence is completed in measurement mode (↳ page 103).

Calibrate device using calibration standard

NOTE!
Impaired reproducibility of measurement due to improper handling of calibration standards!

Improper handling and storage of the calibration standards included with the delivery negatively affects the measurement accuracy of the device.

- Always observe the stability of the calibration standards (max. 0.5h at 22°C ambient temperature).
- Never use opened ampoules twice or mix them together.
- Never freeze opened ampoules.
- Do not use the calibration standards past their expiration date.

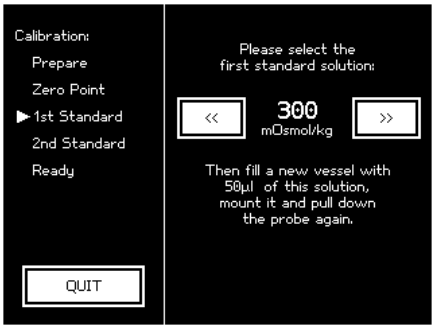


Fig. 73: Select calibration standard

11. Use the arrow keys « and » to select the calibration standard to be used.

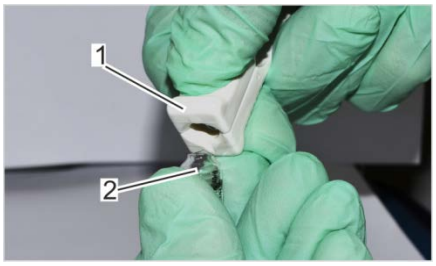


Fig. 74: Open ampoule

12.

WARNING!
Risk of injury at ampoule breaking points!

Use the ampoule opener (Fig. 74/2) to open the ampoules containing the calibration standards (Fig. 74/1).

Fig. 75: Pipette calibration standard

13. Pipette a calibration standard volume of 50µl (15µl for Option M) into a clean and unused measurement vessel (Fig. 75).

NOTE!
Risk of incorrect measurement resulting from the presence of air bubbles in the sample!

- The sample must be pipetted **without** air bubbles.

14. Position measurement vessel on temperature sensor with cover facing front.

The measurement vessel is securely attached to the temperature sensor when it clicks into place.

Fig. 76: Move elevator down

15. Move elevator (Fig. 76/1) down.

⇨ Calibration starts automatically.

Calibration using the calibration standard is performed automatically. Pay attention to the displays on the touchscreen.

16. Move elevator up.

17. Remove measurement vessel from temperature sensor.

Dispose of measurement vessel and sample according to local regulations.

18. Clean temperature sensor (Fig. 76/1) using a soft, dry, lint-free paper towel.

NOTE!
Risk of carryover!

- Failure to clean the temperature sensor immediately following measurement can result in carryover and incorrect measurement results.

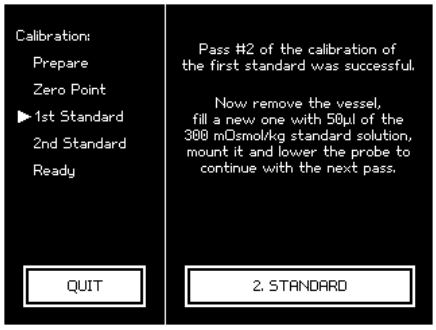


Fig. 77: Second calibration standard

19. Repeat steps 13 through 18 until the number of measurements per calibration point specified in the calibration defaults (↳ *page 50*) (max. 3) is reached.

For a 3-point calibration, repeat steps 10 through 19 using another calibration standard.

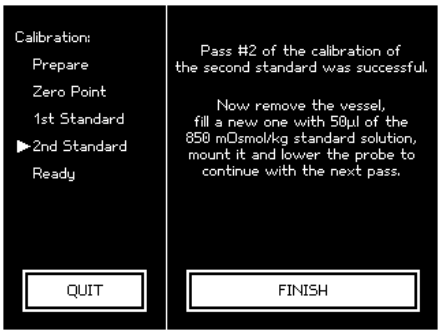


Fig. 78: Complete calibration

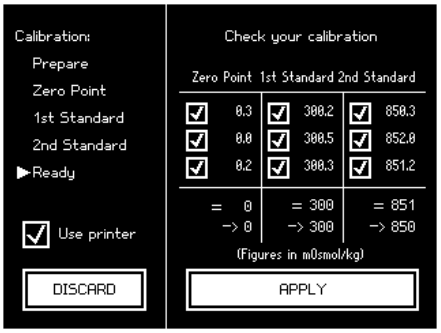


Fig. 79: Calibration results

Fig. 80: Replace probe

Calibration can be completed after performing the number of runs specified in the calibration defaults for the very last calibration point (Fig. 78).

The system now shows the calibration results (Fig. 79). The resulting osmolalities are calculated as the mean across the individual measurements.

This is the result of a 3-point calibration.

20. Verify the calibration results.

If necessary, tap the individual measurement values to ignore them during mean value calculation.

Reproducibility:

 # ±2 digits in the measurement range [0..400] mOsmol/kg

 # ±0.5% in the measurement range [400..1500] mOsmol/kg

 # ±1.0% starting with 1500 mOsmol/kg

Option M (15µl):

 # ±6 digits [0..300] mOsmol/kg

 # ±2.0% [300..3000] mOsmol/kg

21. Tap *Apply* to complete the calibration.

⇨ The device is now calibrated.

22. Verify reproducibility (↳ *page 103*)

or continue with your measurements (↳ *sample measurement on page 54*, ↳ *series measurement on page 61*).

Note regarding 2-point calibration:

For a 2-point calibration, the measurement accuracy of the device depends on the correct internal calibration of the thermistor.

If the calibration check reveals above-average deviations from the linearity, the lab supervisor has to recalibrate the internal thermistor:

For this purpose, open the Replace Probe menu (Fig. 80) (*Start menu* ➔ *Lab Options* ➔ *Maintenance* ➔ *Replace Probe*).

Tap *Calibrate* and perform a 3-point calibration using distilled water and the two calibration standards with 300 and 850 mOsm/kg.

7.6 Power down device

Fig. 81: Power down device

Personnel: ■ User

Safety gear: ■ Disposable lab gloves

1. Power down device using on/off switch on rear side (Fig. 81/1) and disconnect power plug.

2. Position a measurement vessel (Fig. 82/1) on the temperature sensor.

> *The measurement vessel is securely attached to the temperature sensor when it clicks into place.*

Fig. 82: Position measurement vessel

Fig. 83: Device with protective sleeve

3. Disinfect device if powered down for an extended period of time. Wipe device using a wipe moistened with disinfectant.

4. Pull protective sleeve (Fig. 83/1) included with the delivery over device.

8 Troubleshooting

8.1 Safety notices

Electrical current

DANGER!
Risk of death due to electrical current on device!

Contact with energized parts of the device results in immediate risk of death due to electric shock. Damage to the insulation of individual components can cause risk of death.

- Only have qualified personnel perform repair and maintenance work on the device.
- If the insulation is damaged, immediately switch off the voltage supply and schedule a repair.
- Always route the power cable so it is not subject to stress and cannot be bent, pinched, or rolled over and is not exposed to liquids or heat.
- Ensure easy access to the power socket at all times.
- Keep energized parts away from liquids. Otherwise, shorts may occur.

Risk of infection

WARNING!
Risk of injury due to sample residue and in case of inadequate hygiene, disinfection, and sterilization procedures!

Exposure to sample residue in non-cleaned, non-sterilized, or non-disinfected components results in an elevated risk of infection.

- Wear lab gloves during any kind of work.
- Observe all local regulations regarding hygiene, disinfection, and sterilization.

Risk of injury

CAUTION!
Risk of injury from cryst-needle!

When installing and removing the cryst-needle and the temperature sensor, the tip of the cryst-needle is exposed. Movement of the cryst-needle can cause needle puncture injuries.

- Always keep your hands and fingers clear from the area underneath the cryst-needle.

8.2 Notes regarding errors

In case of errors that cannot be resolved using the error table on *page 74*, contact the manufacturer.

Please be prepared when contacting the manufacturer as follows:

1 Use a telephone located close to the device.

2 Power up device.

NOTE!
Danger in case of continuous acoustic alarm!

In case of continuous acoustic alarm, the electronics components of the device can be damaged.

- Power down device again.

3 Note down the serial number of the device.
You can find the serial number on the rear of the device or under *Settings* ➔ *Info*.

4 Have the device documentation available.

Contact info:

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

Phone:	(030) 7809 588-0
Fax:	(030) 7809 588-88
E-mail:	contact@gonotec.com
Web:	http://www.gonotec.com

Fig. 84: Contact Gonotec

8.3 Error table

*Errors marked * are shown as an error message on the touchscreen.*

Error description	Possible Cause	Remedy	Personnel
Elevator gets stuck or makes squeaking noises when lowered	Mechanical wear	Lubricate the elevator guide using silicone spray (↳ *page 100*)	User
	Blockage from foreign substances	Check openings and remove foreign objects	User
Lower cooling system does not cool sample	Mechanical wear	Clean cooling clamp (↳ *page 90*)	Service technician
	Fan is defective or obstructed	Check if fan is operational and replace if necessary (↳ *service manual*)	
	Peltier element is defective	Replace lower cooling system (↳ *service manual*)	
Motor of cryst-needle turns without stopping or does not turn one full revolution	Light barrier on motor disk is defective	Replace light barrier (↳ *service manual*)	Service technician
	Light barrier on motor disk is misaligned	Adjust light barrier	
	Motor disk misaligned or loose	Adjust/tighten motor disk	
No crystallization* or Poor ice crystal formation in upper cooling system	Ambient air too dry	Clean cooling nipple using a fiberglass pin (↳ *page 88*)	User
		Wait at least 2 minutes after switching on device before starting measurement.	
		If the humidity is very low (for example, in heated or air-conditioned rooms), open the cover of the upper cooling system until you can see ice crystals forming.	
	Hole above temperature sensor dirty or blocked by water droplets	Blow out hole using blow-out device	
	Cooling nipple dirty	Clean cooling nipple using a fiberglass pin (↳ *page 88*). Remove any droplets from opening using blow-out device.	

Error description	Possible Cause	Remedy	Personnel
No crystallization * or Poor ice crystal formation in upper cooling system	Peltier element defective	Replace upper cooling system (↬ *service manual*)	Service technician
	Cable connection between cooling system and PCB defective		
	Cryst-needle too long or too short	Adjust cryst-needle to correct length (↬ *page 80*)	
	Cryst-needle not deburred	Debur cryst-needle using fine sandpaper	
	Cryst-needle bent	Manually bend cryst-needle so that it is vertical, replace if necessary (↬ *page 79*)	
	Cryst-needle does not move Cryst-needle dis-engaged from motor or stuck	Verify free movement of cryst-needle (↬ *page 81*)	
	Error in rotation of motor disk (cryst-needle drive)	Align cryst-needle (↬ *page 79*)	Service technician
		Correct length of cryst-needle (↬ *page 80*)	
		Check if light barrier is located properly and replace if necessary (↬ *service manual*)	
		Tighten motor disk	
Measurement procedure takes longer than usual	Fan is defective or obstructed	Check if fan is operational and remove any foreign objects Replace fan (↬ *service manual*)	Service technician
	Peltier element is defective	Replace lower cooling system (↬ *service manual*)	
Spontaneous crystallization*	Sample not prepared correctly	Use sample according to performance data of device (↬ *page 15*)	User
	Temperature sensor not aligned correctly	Align temperature sensor (↬ *page 86*)	Service technician
	Elevator moved up by user	Leave the elevator in the lowered position during the measurement procedure	User

Troubleshooting

Error description	Possible Cause	Remedy	Personnel
Incorrect measurement results	Lower cooling system not aligned correctly	Align lower cooling system (↬ *service manual*)	Service technician
	Incorrect measurement vessel used	Only use measurement vessels of the correct type supplied by Gonotec GmbH	User
	Measurement vessel re-used	Use measurement vessels only once.	
	Measurement vessel not positioned correctly	Position measurement vessel with cover pointing forward When the measurement vessel clicks into place, it is securely positioned on the temperature sensor.	
	Temperature sensor defective	Replace temperature sensor (↬ *page 82*)	Service technician
	Temperature sensor not centered	Align temperature sensor (↬ *page 86*)	
Negative measurement values	Zero point calibration performed using impure water	Repeat calibration (↬ *page 65*)	User
Measurement vessel fits too loosely on temperature sensor	Incorrect measurement vessel used Measurement vessel re-used	Only use measurement vessels supplied by Gonotec GmbH	User
	Measurement vessel not positioned correctly	Position measurement vessel with cover facing forward When the measurement vessel clicks into place, it is securely positioned on the temperature sensor.	User
	Temperature sensor damaged	Replace temperature sensor (↬ *page 82*)	Service technician
Fan malfunction	Fan is obstructed	Check if fan is operational and remove any foreign objects	Service technician
	Fan is defective	Replace fan (↬ *service manual*)	
Fan makes loud noise	Fan is obstructed	Check if fan is operational and remove any foreign objects	

Error description	Possible Cause	Remedy	Personnel
Error message: Needle stuck*	Needle bar disengaged from motor or stuck	Verify free movement of cryst-needle (↳ *page 81*)	Service technician
	Motor slider misaligned	*see also: Motor of cryst-needle turns without stopping or does not turn one full revolution.*	
Microfuses trip when powering up device	Device voltage does not match power grid voltage	Check device voltage setting	Service technician
Device cannot be powered up	Power supply not correctly plugged into power socket	Connect power supply to a power socket	Service technician
	Power socket is dead	Connect device to a live power socket	
	Power cable is damaged	Replace power cable	
	Fuses are burned out	Replace fuses (↳ *page 89*)	
Printer does not print	Paper roll is used up	Replace paper roll (↳ *page 90*)	User
	Ribbon is empty	Replace ribbon (↳ *page 92*)	
Measurement procedure aborted by user*	User moved elevator up during measurement	Repeat measurement	User
Incorrect PIN entry*	Incorrect PIN entry	Re-enter PIN or cancel operation	Lab supervisor
Attempt to change lab supervisor password failed*	Repeat password entry does not match first entry	Change password again	Lab supervisor
Unexpected errors*	Internal system errors	Contact Gonotec GmbH	User

8.4 Resolve errors

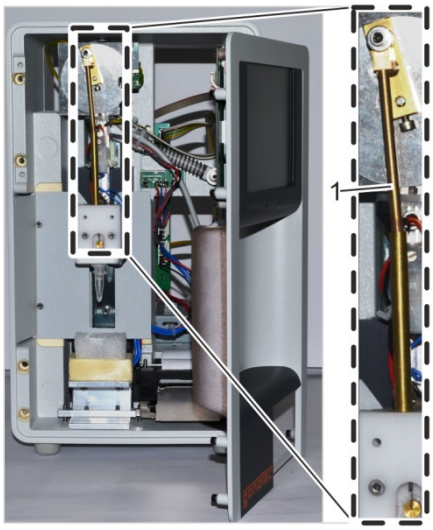
8.4.1 Replace cryst-needle

Personnel: ■ Service technician

Safety gear: ■ Disposable lab gloves

Materials: ■ Allen key SW 2.5
■ Precision key file
■ Wire cutter

WARNING!
Risk of infection from sample residue!
The cryst-needle is immersed into the sample during measurements. Contact with the cryst-needle increases the risk of infection.
- Wear lab gloves during any kind of work.

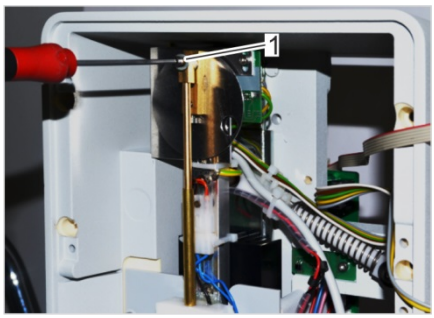


DANGER!
Risk of death due to electrical current!

1. Power down device using on/off switch on rear side and disconnect power plug.
2. Remove device front panel (*on page 95*).

Fig. 85: Position of cryst-needle and details

1 Cryst-needle



3. Remove mounting screw (Fig. 86/1) of cryst-needle while holding cryst-needle in place.

The mounting screw has a coating of locking paint.

Fig. 86: Remove mounting screw

Fig. 87: Remove cryst-needle

4.

Loose washer between cryst-needle and motor disk!

Remove cryst-needle from motor disk. Hold washer (Fig. 87/1) of mounting screw in place.

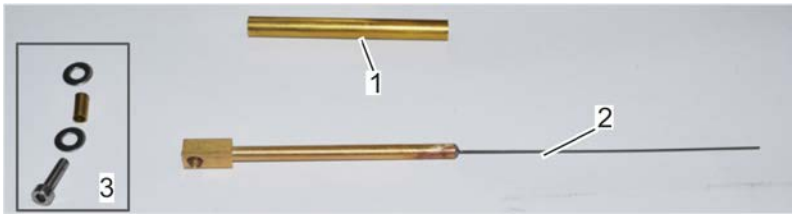


Fig. 88: Cryst-needle components

5. Remove guide tube (Fig. 88/1) and fasteners (Fig. 88/3) of cryst-needle (Fig. 88/2).

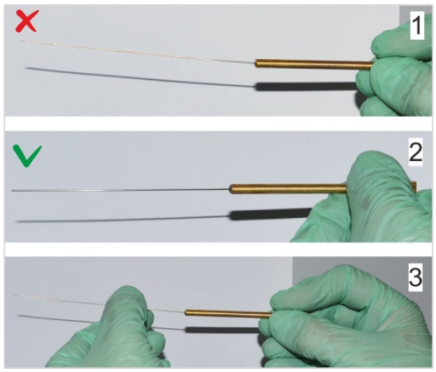


Fig. 89: Straighten cryst-needle

6. Make sure that the new cryst-needle is as straight as possible (Fig. 89/1+2).

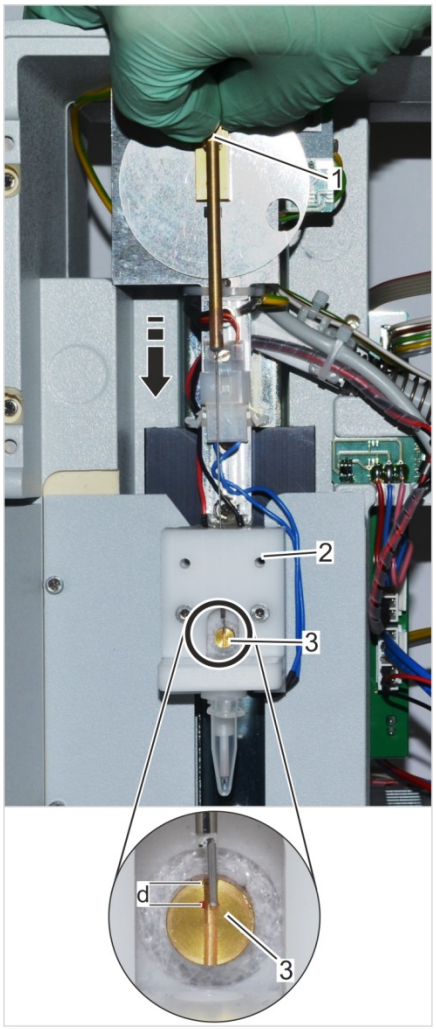
1 - Incorrect orientation

2 - Correct orientation

If necessary, bend cryst-needle so it is straight (Fig. 89/3).

7. Shorten cryst-needle to correct length.

Proceed as follows.



8. Align motor swipe vertically with upper dead center (Fig. 90/1).

⇨ The set screw of the motor swipe points down.

9. Move cryst-needle through guide tube in upper cooling system (Fig. 90/2) onto cooling nipple (Fig. 90/3).

10. Bolt new needle to motor disk.

11. Align cryst-needle with motor swipe and cooling nipple.

The needle end should be located approx. 2mm below the lower edge of the cooling nipple (d=2mm). (Fig. 90/3).

12. If the needle is too long, use a permanent marker to mark the correct length and remove the needle bar again.

13. Trim excess wire using side cutters and debur needle tip using precision key file.

Fig. 90: Adjust length of cryst-needle

Fig. 91: Install cryst-needle

1 Mounting screw
2 Washer
3 Fastening tube
4 Cryst-needle
5 Washer
6 Guide tube

14. Fit cryst-needle to motor disk. Assemble fasteners as follows:

1 - Push washer (Fig. 91/2) and fastening tube (Fig. 91/3) onto mounting screw (Fig. 91/1).

2 - Push mounting screw with washer and fastening screw through head of cryst-needle (Fig. 91/4).

3 - Secure washer (Fig. 91/5) to mounting screw.

4 - Push guide tube (Fig. 91/6) onto cryst-needle.

15. Secure cryst-needle to motor disk (Fig. 86) using mounting screw (Fig. 91/1).

Check free movement of cryst-needle

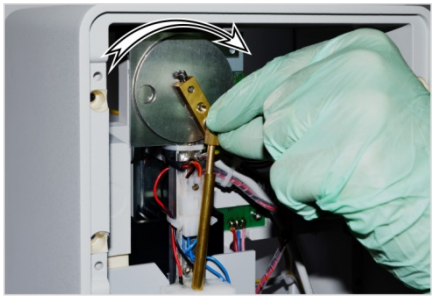


Fig. 92: Check free movement of cryst-needle

16. Turn motor disk with attached cryst-needle clockwise to check cryst-needle for free movement.

If needle gets jammed, detach needle and check if it is bent. (Fig. 89).

17. Install device front panel (*on page 99*).

18. Power up device on rear side using on/off switch.

19. Verify free movement of cryst-needle automatically.

Open the menu for adjusting the cryst-needle (*Start menu* ➔ *Lab Options* ➔ *Maintenance* ➔ *Adjust Needle*).

CAUTION!
Risk of injury from cryst-needle!

The tip of the cryst-needle is exposed. Movement of the cryst-needle can cause needle puncture injuries.

- Always keep your hands and fingers clear from the area underneath the cryst-needle.

Fig. 93: Move needle

20. Tap *Move Needle* to test the free movement.

The needle turns by one revolution.

Tap *Back* to exit the menu.

8.4.2 Replace the temperature sensor

Personnel:
- Service technician

Safety gear:
- Disposable lab gloves

Materials:
- Allen key SW 2
- Adjustment tool
- Tweezers

WARNING!
Risk of injury in case of inadequate hygiene, disinfection, and sterilization procedures!
Contact with the temperature sensor and cryst-needle increases the risk of infection due to sample residue.
- Wear lab gloves during any kind of work.

DANGER!
Risk of death due to electrical current!

1. Power down device using on/off switch on rear side and disconnect power plug.

Remove elevator cover

Fig. 94: Position measurement vessel

2. To protect thermistor, cover temperature sensor with a measurement vessel. The cover of the measurement vessel must point forward.

NOTE!
Risk of thermistor damage due to loose position of measurement vessel!
Resistance is felt when sliding on measurement vessel.
When the measurement vessel clicks into place, it is securely positioned on the temperature sensor.

Fig. 95: Move elevator down

3. Move elevator down using handle (Fig. 95/1).

Fig. 96: Move elevator cover up

4. Move elevator cover (Fig. 96/1) up.

Fig. 97: Remove mounting screws

5. Remove the 2 mounting screws (Fig. 97/1) using Allen key (SW 2).

Fig. 98: Remove elevator cover

6. Remove the complete elevator cover (Fig. 98/1).

Fig. 99: Pull connector

7. Pull connector of temperature sensor (Fig. 99/1).

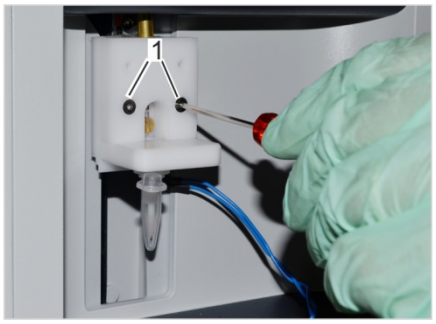


Fig. 100: Remove mounting screws

8. Move elevator up and remove the 2 mounting screws (Fig. 100/1) using Allen key (SW 2).

Fig. 101: Remove temperature sensor

9. Remove temperature sensor with mounting plate toward the front (Fig. 101) while holding guide tube of cryst-needle (Fig. 101/1) in place.

10. If necessary, clean cooling nipple.

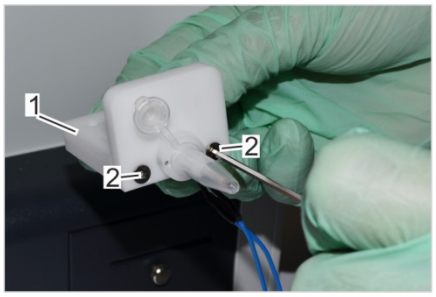


Fig. 102: Remove mounting plate

11. Use Allen key (SW 2) (Fig. 102/2) to remove temperature sensor from mounting plate (Fig. 102/1).

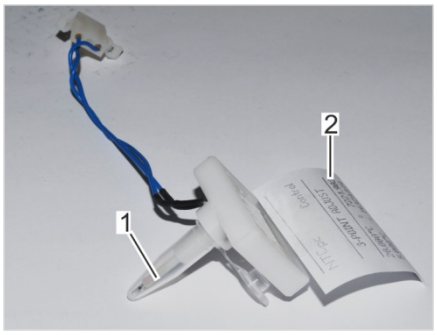


Fig. 103: New temperature sensor with data sheet

12. Fit new temperature sensor to mounting plate (Fig. 102).

Keep the data sheet affixed to the temperature sensor (Fig. 103/2) in the vicinity of the device.

To protect thermistor, cover temperature sensor with a measurement vessel (Fig. 103/1). The cover of the measurement vessel must point forward.

NOTE!
Risk of thermistor damage due to loose position of measurement vessel!

Resistance is felt when sliding on measurement vessel.

When the measurement vessel clicks into place, it is securely positioned on the temperature sensor.

13. Push guide tube onto cryst-needle and pass needle through stainless steel tube of mounting plate (Fig. 101).

Align the temperature sensor

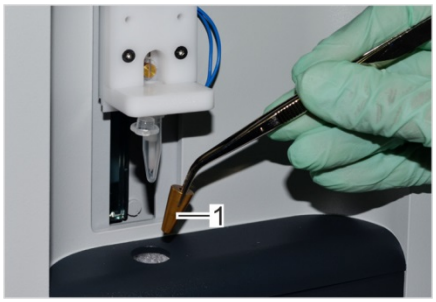


Fig. 104: Install adjustment tool

14. Tighten the 2 mounting screws only lightly.
    The temperature sensor must be aligned using the adjustment tool.
15. Install adjustment tool (Fig. 104/1) in opening of lower cooling system using tweezers.
16. Remove measurement vessel from temperature sensor.

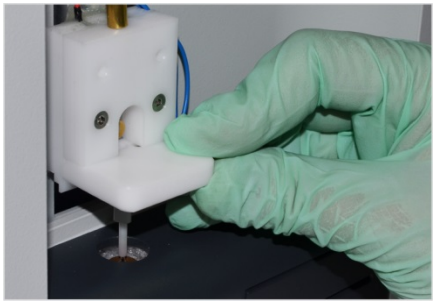


Fig. 105: Align the temperature sensor

17. Align temperature sensor (Fig. 105). Proceed as follows:
    Push temperature sensor **just beyond** adjustment tool.
18. Position temperature sensor on XY plane so that thermistor is perpendicular to center of hole of adjustment tool (Fig. 106 and Fig. 107).
19. Tighten the 2 mounting screws on the aligned temperature sensor.

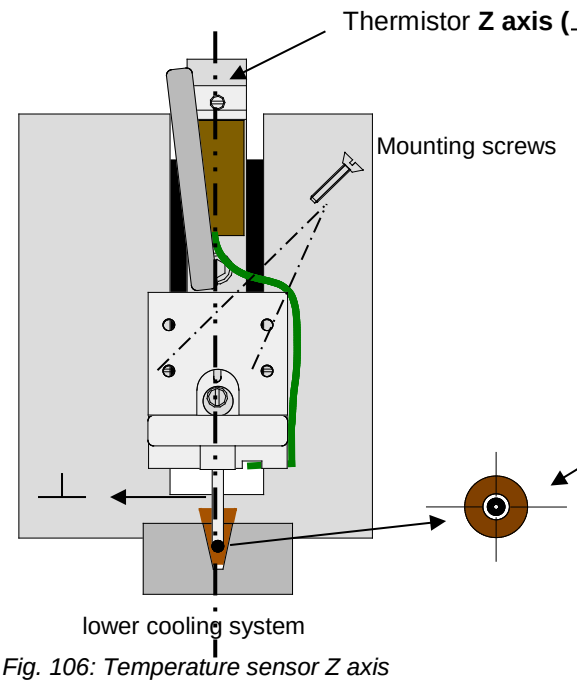


Fig. 106: Temperature sensor Z axis

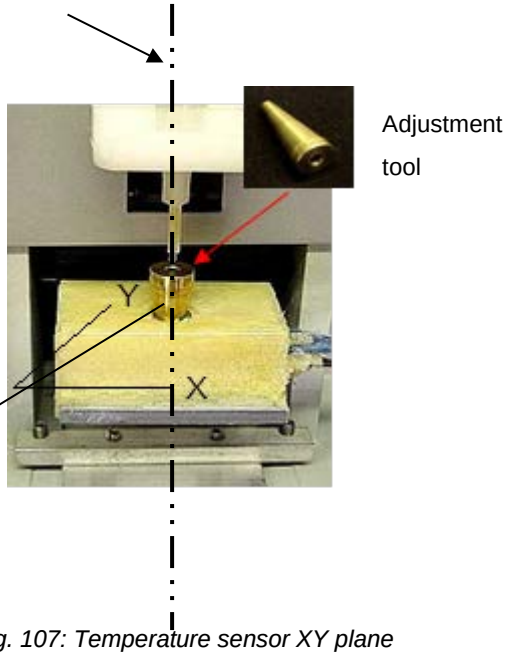


Fig. 107: Temperature sensor XY plane

Install elevator cover

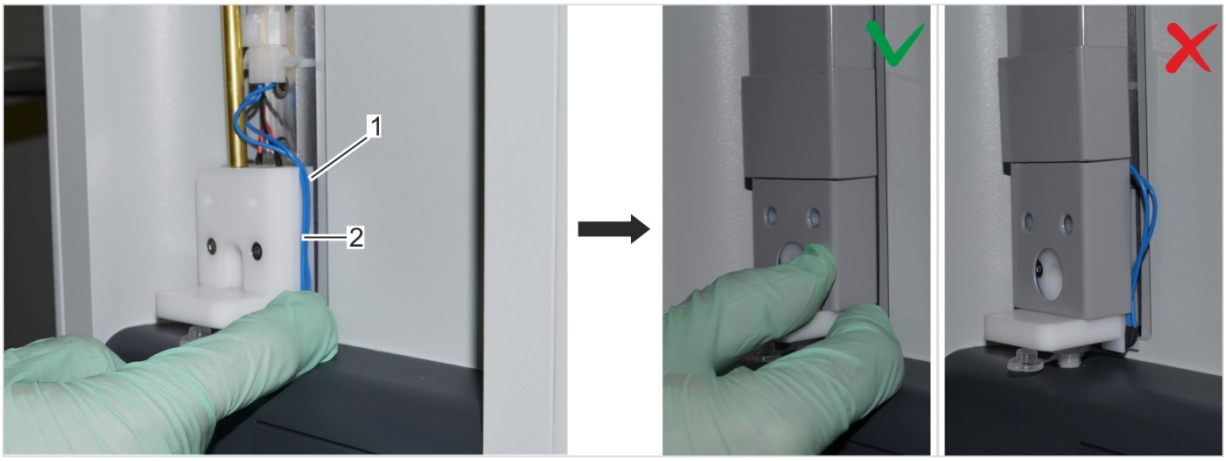


Fig. 108: Elevator cover with correct cable routing

1 Cable
2 Cable guide on temperature sensor

✓ Correct cable routing
✗ Incorrect cable routing

20.

NOTE!
Risk of cable break!

Place cable (Fig. 108/1) on temperature sensor in cable guide (Fig. 108/2) and install elevator cover on device.

Fig. 109: Tighten mounting screws

21. Bolt elevator cover to elevator using the 2 mounting screws (Fig. 109/1).

⇨ The temperature sensor is now installed.

Clean cooling nipple

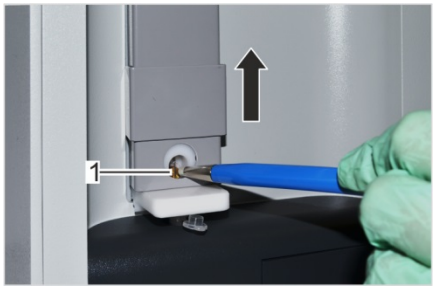


Fig. 110: Clean cooling nipple

22. Clean cooling nipple (Fig. 110/1) using a fiberglass pin. For this purpose, move elevator cover up.

23. Power up device on rear side using on/off switch.

24. Calibrate the new temperature sensor.

For this purpose, open the Replace Probe menu (*Start menu* ➔ *Lab Options* ➔ *Maintenance* ➔ *Replace Probe*).

Fig. 111: Calibrate temperature sensor

25. Copy the values from the included data sheet to the fields and tap *Calibrate*.

⇨ The system starts the device calibration.

Perform a 3-point calibration on the device (↳ *page 65*). Use distilled water and the two calibration standards with 300 and 850 mOsm/kg.

8.4.3 Replace microfuses

Safety gear:
- Disposable lab gloves

Materials:
- Flat blade screwdriver
- Microfuses (slow-blow 1.6A)

DANGER!
Risk of death due to electrical current!

1. Power down device using on/off switch on rear side and disconnect power plug.
2. Open cover (Fig. 112/1) using a flat blade screwdriver.
3. Remove microfuse attachment.

Fig. 112: Open microfuse cover

4. Remove microfuses (Fig. 113/1) from attachment.

NOTE!
Risk of property damage!
The unit has two-phase protection. Use only the following fuses:
Slow-blow HBC fuses (1.6A) with a switching capacity of 1500A

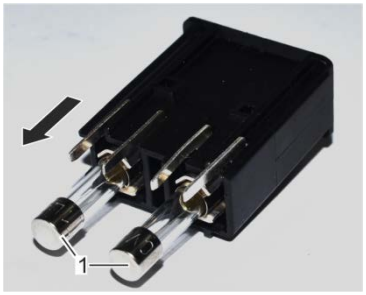


Fig. 113: Remove microfuses

5. Push the microfuses included with the delivery into the attachment (Fig. 114).

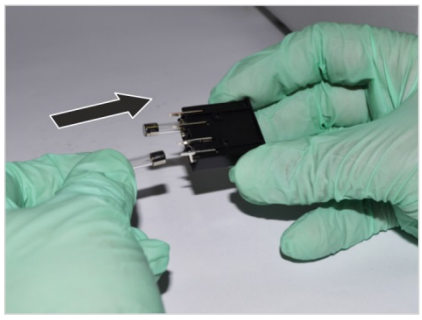


Fig. 114: Install microfuses

8.4.4 Clean cooling clamp

Personnel: ■ Service technician

Safety gear: ■ Disposable lab gloves

Materials: ■ Fine sandpaper

1. Power down device on rear side using on/off switch.

2. Remove device front panel (↳ *on page 95*).

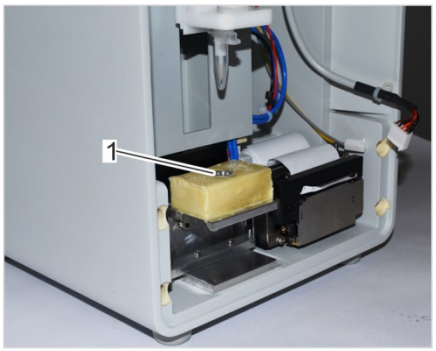


Fig. 115: Clean cooling clamp

3. Clean cooling clamp (Fig. 115/1) on lower cooling system using sandpaper.

4. Install device front panel (↳ *on page 99*).

8.4.5 Replace printer paper (Option D only)

(does not apply to OSMOMAT **3000***basic*)

Personnel: ■ User

Safety gear: ■ Disposable lab gloves

Materials: ■ 1 Paper roll

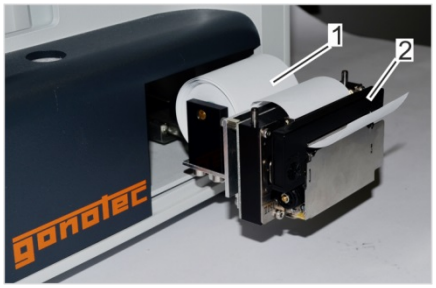


Fig. 116: Printer (pulled out)

1. Power down device on rear side using on/off switch.

1 Paper roll
2 Ribbon

Fig. 117: Pull out printer

2. Pull out printer (Fig. 117/1).

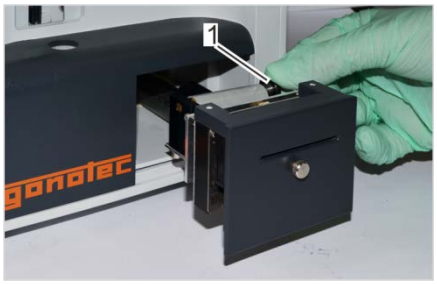


Fig. 118: Turn knurled screw

3. Turn knurled screw (Fig. 118/1) counter-clockwise.

4. Remove empty paper roll from holder and dispose.

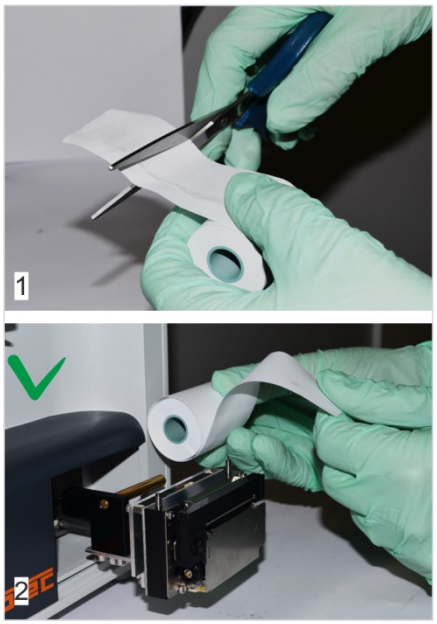


Fig. 119: Install paper roll

5. Cut off beginning of new paper roll (Fig. 119/1) and push onto holder.

Pay attention to correct feed direction of paper (Fig. 119/2).

6. Position knurled screw (Fig. 118/1) and tighten by turning clockwise.

7. Power up device on rear side using on/off switch.

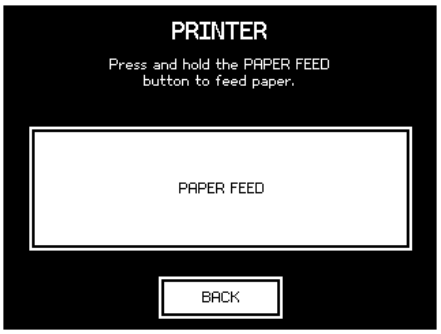


Fig. 120: Activate paper feed

8. On the Start menu, select *Settings* ➔ *Printer*.
Tap *Paper Feed*.

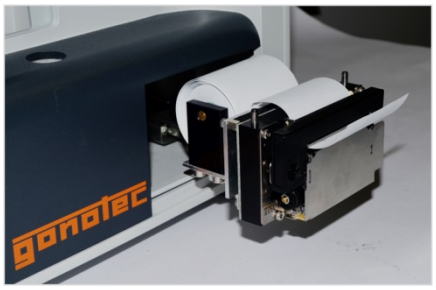


Fig. 121: Paper feed

The paper feed of the printer is activated briefly. (Fig. 121).
Tap *Back* to exit the menu.

9. Replace printer cover and push printer into casing.

8.4.6 Replace printer ribbon (Option D only)

(does not apply to OSMOMAT **3000***basic*)

Personnel: ■ User

Safety gear: ■ Disposable lab gloves

Materials: ■ 1 Ribbon

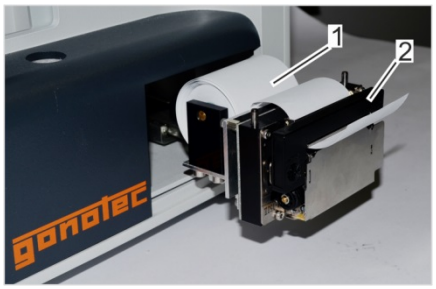


Fig. 122: Printer (pulled out)

1 Paper roll
2 Ribbon

1. Power down device on rear side using on/off switch.

Fig. 123: Pull out printer

2. Pull out printer (Fig. 123/1).

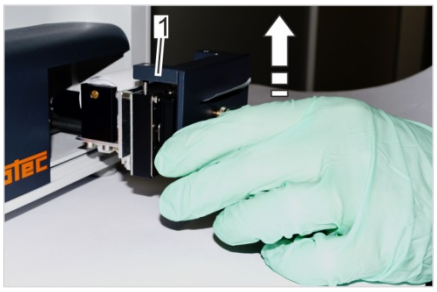


Fig. 124: Remove printer cover

3. Remove printer cover (Fig. 124/1).

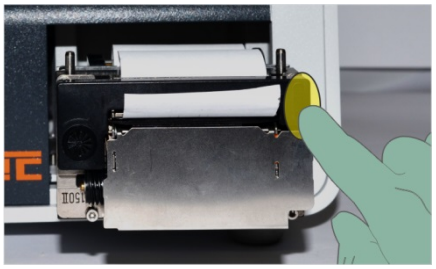


Fig. 125: Push out ribbon

4. Push on Push marking on front side of ribbon (Fig. 125).

⇨ The ribbon is released.

5. Remove the released ribbon.

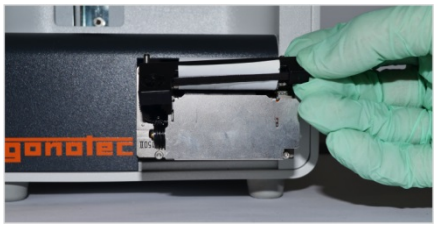


Fig. 126: Feed printer paper

6. Feed printer paper through ribbon (Fig. 126).

7. Press ribbon onto device.

⇨ The ribbon snaps into place.

8. Tighten ribbon by turning knob clockwise.

9. Replace printer cover and push printer into casing.

8.4.7 Reset device to default settings

If the device no longer functions properly due to incorrect settings, you can undo all the modified user settings and reset device to the default settings.

To do this, proceed as follows:

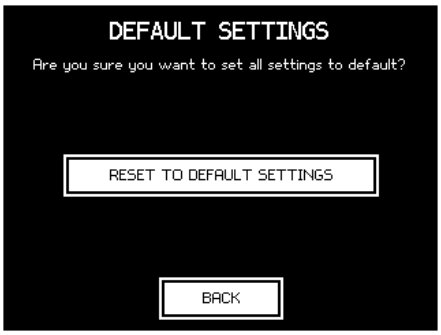


Fig. 127: Reset to Default Settings

1. From the Start menu, select *Settings* ➔ *Lab Options* ➔ *Maintenance* ➔ *Default Settings*.
2. Tap *Reset to Default Settings* (Fig. 127)
3. Configure the user preferences.
   ↳ chapter 7.2 *User Preferences*

Resetting the device will also purge all existing calibration data.

Before performing any measurements on the device following the reset, recalibration is mandatory.
↳ Chapter 7.5 “*Calibrate device*” on page 65

9 Servicing

9.1 Safety notices

Electrical current

DANGER!
Risk of death due to electrical current on device!

Contact with energized parts of the device results in immediate risk of death due to electric shock. Damage to the insulation of individual components can cause risk of death.

- Only have qualified personnel perform repair and maintenance work on the device.
- If the insulation is damaged, immediately switch off the voltage supply and schedule a repair.
- Always route the power cable so it is not subject to stress and cannot be bent, pinched, or rolled over and is not exposed to liquids or heat.
- Ensure easy access to the power socket at all times.
- Keep energized parts away from liquids. Otherwise, shorts may occur.

Risk of infection

WARNING!
Risk of infection due to sample residue and in case of inadequate hygiene, disinfection, and sterilization procedures!

Exposure to sample residue in non-cleaned, non-sterilized, or non-disinfected components results in an elevated risk of infection.

- Wear lab gloves during any kind of work.
- Observe all local regulations regarding hygiene, disinfection, and sterilization.

We recommend using detergents such as Mikrozid® AF Liquid, Bacillol® plus 3%, or Korsolex® plus 4% commonly found in clinical-chemical labs to clean and decontaminate the device.

9.2 Service table

The following sections describe the service activities required to ensure device operation under optimum, error-free conditions.

If regular checks show excess wear, shorten the required service intervals based on actual signs of wear. If you have questions regarding service activities and intervals, contact the manufacturer (for contact information, see page 2).

Interval	Service activity	Personnel
monthly	Check elevator support for ease of movement and lubricate if necessary ↳ *chapter 9.4 "*Preliminary steps*" on page 96*	User
	Perform visual inspection of device ↳ *chapter 9.5 "*Perform visual inspection of device*" on page 102*	User
	Check reproducibility of measurements ↳ *chapter 9.6 "*Check reproducibility of measurements*" on page 103*	Lab supervisor

9.3 Preliminary steps

Remove device front panel

Personnel: ■ Service technician

Safety gear: ■ Disposable lab gloves

Materials: ■ Allen key SW 2

1. Power down device on rear side using on/off switch.

2. To protect thermistor, cover temperature sensor with a measurement vessel (Fig. 128/1). The cover of the measurement vessel must point forward.

Fig. 128: Position measurement vessel

NOTE!
Risk of thermistor damage due to loose position of measurement vessel!

Resistance is felt when sliding on measurement vessel.

When the measurement vessel clicks into place, it is securely positioned on the temperature sensor.

Fig. 129: Move elevator down

3. Move elevator (Fig. 129/1) down.

Fig. 130: Move elevator cover up

4. Move elevator cover (Fig. 130/1) up.

Fig. 131: Remove mounting screws

5. Remove the 2 mounting screws (Fig. 131/1) using Allen key (SW 2).

Fig. 132: Remove elevator cover

6. Remove complete elevator cover (Fig. 132/1).

Fig. 133: Pull out printer

7. Pull out printer (Fig. 133/1) from device.
(does not apply to OSMOMAT 3000*basic*)

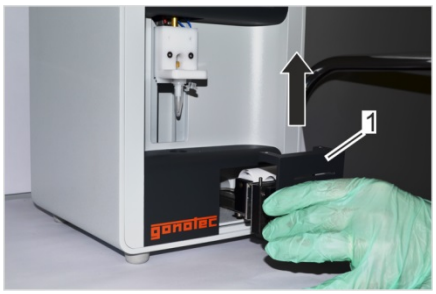


Fig. 134: Remove printer cover

8. Remove printer cover (Fig. 134/1) by pulling up.
(does not apply to OSMOMAT 3000*basic*)

9. Push printer back into device.
(does not apply to OSMOMAT 3000*basic*)

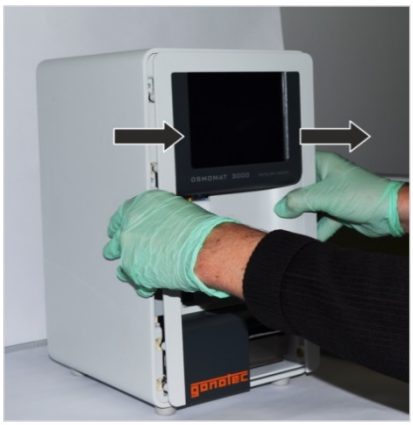


Fig. 135: Remove device front panel

10. Remove device front panel by pulling forward (Fig. 135).
The device front panel is secured to the housing by magnets.

NOTE!
Risk of damage to cables and connectors!

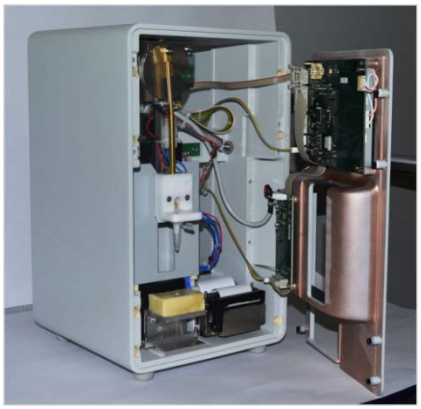


Fig. 136: Device front panel open

11. Carefully place device front panel on its right side (Fig. 136).

⇨ The device front panel is now removed.

Install device front panel

Personnel: ■ Service technician

Safety gear: ■ Disposable lab gloves

Materials: ■ Allen key SW 2

Fig. 137: Install device front panel

1. Install device front panel on device and push into place (Fig. 137).
2. Pull out printer from device using handle.
   (does not apply to OSMOMAT 3000*basic*)
3. Install printer cover on printer and push down.
   (does not apply to OSMOMAT 3000*basic*)

   ⇨ The printer cover is now secured.
4. Push printer back into device.
   (does not apply to OSMOMAT 3000*basic*)

Fig. 138: Elevator cover with correct cable routing

1 Cable
2 Cable guide on temperature sensor

✓ Correct cable routing
✗ Incorrect cable routing

5. **NOTE!**
   Risk of cable break!

   Route cables on temperature sensor through cable guide (Fig. 138/2) and install elevator cover on device.

   Pay attention to correct cable routing.

Fig. 139: Tighten mounting screws

6. Bolt elevator cover to elevator using the 2 mounting screws (Fig. 139/1).

⇨ The device front panel is now installed.

9.4 Lubricate elevator

Personnel: ■ User

Safety gear: ■ Disposable lab gloves

Materials: ■ Silicone spray

NOTE!
Risk of property damage due to wrong lubricant!
The use of lubricating grease can damage the elevator guide.
- Only use silicone spray as lubricant.

Fig. 140: Location of elevator guide

1. Power down device on rear side using on/off switch.

2. Remove device front panel (*on page 95*).

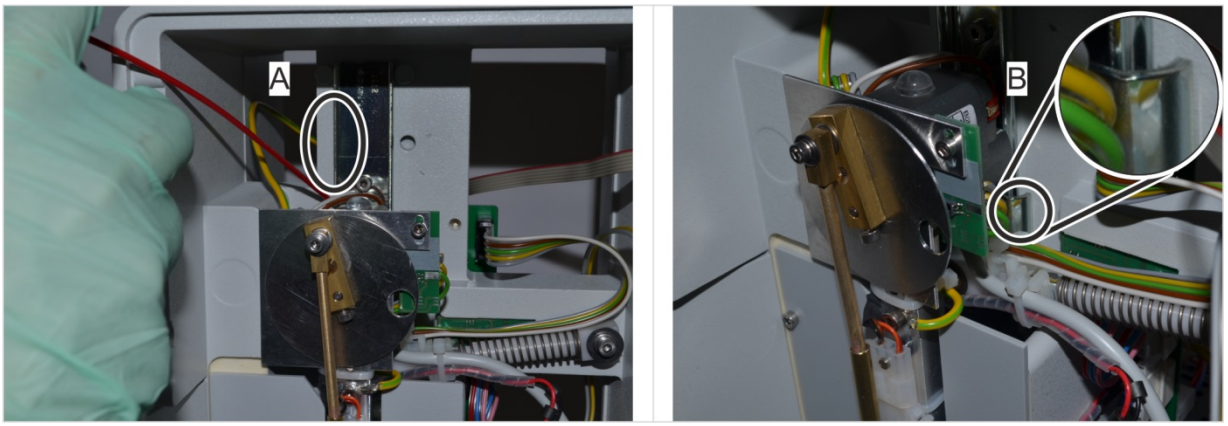


Fig. 141: Lubricate elevator guide

3. Lubricate elevator guide on left (Fig. 141/A) and right side (Fig. 141/B) of ball bearing using silicone spray.

> **Tip**
>
> *The left ball bearing of the elevator guide is not easily accessible.*
>
> *Therefore, lubricate the upper section (Fig. 141/A) on the left side of the elevator guide and move the elevator up and down multiple times.*

4. Install device front panel (*on page 95*).

9.5 Perform visual inspection of device

Personnel:
- User

Safety gear:
- Disposable lab gloves

Materials:
- Fiberglass pin
- Soft cloth
- Tweezers

1. Verify that the cables at the rear side of the device are secure and none of them are broken.

In case of cable breaks, replace the cable.

Fig. 142: Inspect device for foreign objects

2. Check if foreign objects, such as measurement vessels, are located in the openings of the device (Fig. 142/1+2).

Remove any foreign objects using tweezers.

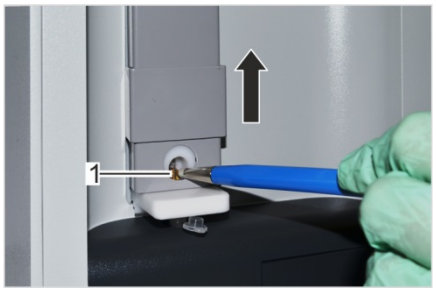


Fig. 143: Clean cooling nipple

3. Clean cooling nipple (Fig. 143/1) using the fiberglass pin. For this purpose, move elevator cover up.

4. Wipe off dirt and dust from housing using a soft cloth.

9.6 Check reproducibility of measurements

The purpose of the measurement check is to verify the specified performance limits of the device.

9.6.1 Sample test protocol measurement check

Mechanical check: Calibration/verification

	ZERO	CAL1	CAL2	REF1	REF2
CAL / mOsmol/kg Sample / mOsmol/kg	Distilled water	.....	.....	.....	.....
Sample 1	.....	.....	.....	.....	.....
Sample 2	.....	.....	.....	.....	.....
Sample 3	.....	.....	.....	.....	.....
Sample 4	.....	.....	.....	.....	.....
Sample 5	.....	.....	.....	.....	.....
Sample 6	.....	.....	.....	.....	.....
Sample 7	.....	.....	.....	.....	.....
Sample 8	.....	.....	.....	.....	.....
Sample 9	.....	.....	.....	.....	.....
Sample 10	.....	.....	.....	.....	.....
Statistics					
Mean value	.....	.....	.....	.....	.....
Variation	.....	.....	.....	.....	.....
Expected value	.....	.....	.....	.....	.....
Expected value met? (yes/no)	.....	.....	.....	.....	.....

Is the osmolality within limits? ☐ yes ☐ no

Thermistor no. ..... Responsible: ……(Name) ……..(Date)

Note: ……

Fig. 144: Sample test protocol measurement check

Reproducibility (50µl):

 # ±2 digits in the measurement range [0..400] mOsmol/kg

 # ±0.5% in the measurement range [400..1500] mOsmol/kg

 # ±1.0% starting with 1500 mOsmol/kg

Reproducibility (15µl Option M):

 # ±6 digits [0..300] mOsmol/kg

 # ±2.0% [300..3000] mOsmol/kg

10 Disposal

After its useful life, the device must be disposed of under environmentally conscious considerations.

Separation of consumables

WARNING!
Risk of death due to exposure to biohazards!

Improper disposal causes a risk of exposure to biohazards. The resulting risk of infection can lead to serious illness including death.

- Dispose of disposable accessories and other contaminated products according to the requirements for the disposal of biohazards.

Scrapping of device

NOTE!
Harm to environment due to improper disposal!

Electronic scrap and electronics assemblies are to be treated as hazardous waste and can cause harm to the environment in case of improper disposal.

- Always task certified specialist firms with the disposal of the device.

Disposal of used electric and electronic equipment (applies to member countries of the European Union and other European countries with a separate collection system for this type of equipment).
The symbol on the product or its packaging indicates that this product is not to be treated like regular household waste. Instead, it must be returned to a recycling center for electric and electronic equipment. By ensuring the proper disposal of this product, you help protect the environment and the health of your fellow human beings. Improper disposal poses a risk to the environment and people's health. Recycling materials helps reduce resource consumption. To learn more about ways to recycle this product, ask your municipality, the municipal waste management services, the dealer where you bought the product, or the manufacturer.

Disposal

- Power down device and disconnect power plug.
- Return the device to the manufacturer or a certified disposal firm. Do not dispose of the device through municipal waste.
- Immediately before returning the medical product to the manufacturer, make sure that the device meets strict hygienic conditions. If necessary, disinfect device.

Implementation of Directives 2012/19/EC on Waste Electrical and Electronic Equipment (short WEEE) and 2011/65/EC on the Restriction of Hazardous Substances in Electrical and Electronic Equipment (short RoHS, Restriction of Hazardous Substances). Gonotec manufactures b2b devices. The devices are classified as medical devices (WEEE category 8) and monitoring and control instruments (WEEE category 9) and registered with the ear foundation (Waste Electrical Equipment Register) accordingly under WEEE reg. no. DE 65424410.

11 Specifications

11.1 Dimensions

Specification	Value	Unit
Weight	6.5	kg
Width	205	mm
Depth	220	mm
Height	360	mm

11.2 Performance parameters

Analytic sensitivity and specificity

Specification	Value	Unit
Measuring range	[0..3000]	mOsmol/kg
Resolution (across entire measuring range)	1	mOsmol/kg

Reproducibility

Specification	Value	Unit
Reproducibility (50µl)	*# ±2 digits [0..400] mOsmol/kg* *# ±0.5% [400..1500] mOsmol/kg* *# ±1.0% [1500..3000] mOsmol/kg*	
Reproducibility (15µl) Option M	*# ±6 digits [0..300] mOsmol/kg* *# ±2.0% [300..3000] mOsmol/kg*	

11.3 Operating conditions

Environment

Specification	Value	Unit
Temperature range	10-35	°C
Relative humidity	10-90 (non-condensing)	%
Maximal operating altitude	2000	m

Useful life

Specification	Value	Unit
Useful life	10	Years

11.4 Connection ratings

Electrical

Specification	Value	Unit
Power cable	Detachable power supply cable	
Power connection	100-240	VAC
Frequency	50-60	Hz
Power consumption, max.	80	VA
Fuse (HBC 1500A)	T 1.6	A
System clock battery Type: CR2032 (UL: MH 13654 (N))	10 years useful life	
Protection class	IP21	
Protection type	I	
Degree of contamination	2	

Interfaces
(does not apply to OSMOMAT 3000*basic*)

Specification	Value
Serial port	2 × RS232 (one RS232 reserved for barcode reader); 1 × USB

11.5 Options

Printer (D)
(does not apply to OSMOMAT 3000*basic*)

Specification	Value
Printer	Alphanumeric dot matrix printer, 5×7 matrix, date, time and sample information on each measurement
Number of digits	≥16 characters per row
Paper	Normal paper, 43mm wide
Print modes	single print, batch printing
	Error message in plain text

Specifications

Smaller sample amount (M)
(does not apply to
OSMOMAT 3000*basic*)

Specification	Value
Sample volume	15 µl
Reproducibility	*# ±6 digits [0..300] mOsmol/kg* *# ±2.0% [300..3000] mOsmol/kg*

11.6 Nameplate

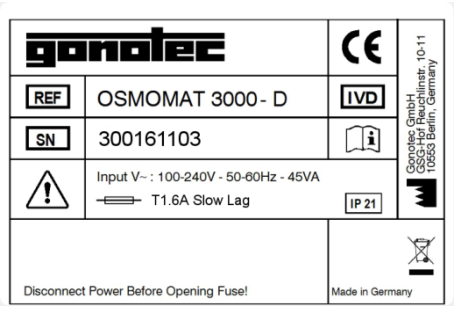


Fig. 145: Nameplate

The nameplate is located at the rear of the device.

12 Index

Index

Appendix

Returning the device

When returning the device for repairs or a refund, please note the following.

Personnel: ■ User

Safety gear: ■ Disposable lab gloves

1. Power down device using on/off switch on rear side and disconnect power plug.
2. 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.
3. 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 not be processed by us and will be returned at the customer's expense.
4. Position a measurement vessel (Fig. 146/1) on the temperature sensor.

   The measurement vessel is securely attached to the temperature sensor when it clicks into place.

Fig. 146: Position measurement vessel

5. Move needle to transport position.

   Open the menu for configuring the lab options.

   In the Start menu, tap
   Settings ➔ *Lab Options*➔ *Maintenance*➔ *Safe Transport*.

   The menu may be protected with a lab supervisor password.

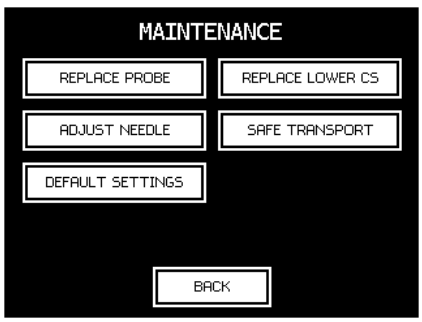


Fig. 147: Maintenance menu

Fig. 148: Safe Transport menu

6. Tap *Park Needle*.

Tap *Back* to exit the menu.

WARNING!
Risk of infection from sample residue!

The cryst-needle is immersed into the sample during measurements. Contact with the cryst-needle increases the risk of infection.

- Wear lab gloves during any kind of work.

Fig. 149: Position transport safety device

7. Tilt transport safety device for temperature sensor and carefully slide behind the temperature sensor (Fig. 149).

Fig. 150: Device with protective sleeve

8. Pull protective sleeve (Fig. 150/1) included with the delivery over device.

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

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

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

12. Do you have a high sample volume and/or cannot afford downtime?

During repairs, we will provide you with a loaner unit at no cost (Germany). Transport costs are only incurred outside the warranty period.

Limited Warranty

Gonotec product	Duration of Limited Warranty
Software	90 days
Temperature sensor	180 days
Osmometer	1 year

A. Extension of the Limited Warranty

1. 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.
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:
   a. Inadequate servicing or improper modification;
   b. Use of software, interfaces, print media or accessories not supported or supplied by Gonotec; or
   c. Use of the equipment in a manner not covered by the product specifications.
4. For Gonotec osmometers, the use of measurement vessels of manufacturers other than those of the measurement 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 measurement vessels from third-party providers or the cleaning of recycled measurement vessels results in malfunctions or damage to the osmometer or temperature sensor, 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 temperature sensor 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.

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 non-admission 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.

OSMOMAT 3000 Intend Use

The Gonotec Osmomat® 3000 cryoscopic osmometer is a non-invasive in-vitro diagnostic device for in-vitro analysis of human blood, serum, 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 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 3000 cryoscopic osmometer is particularly suited for routine measurements in the fields of medicine, industry and research. The OSMOMAT 3000 cryoscopic osmometer determines the total osmolality of aqueous solutions. Osmolality is an important measure of concentration for diluted solutions, such as all bodily fluids. The OSMOMAT 3000 Standard as well as the *basic* model need a sample volume of 50 µl, while the *M* option requires only 15 µl, making it suitable for measuring even minute samples. The measuring speed permits rapid series measurements.

Fields in which the OSMOMAT 3000 has a proven track record include:

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

Classification of the IVD

The OSMOMAT® 3000 cryoscopic osmometer manufactured by Gonotec is a non-invasive in-vitro diagnostic product according to EEC Directive 93/42 (Medical Devices Law). The Osmomat® 3000 cryoscopic osmometer 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® 3000

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

We hereby declare that the OSMOMAT® 3000 cryoscopic osmometer and its options comply with Directive 98/79/EEC. Compliance is declared per Annex III of the Directive. The CE mark on the unit acknowledges this.

Date: 01.09.2014

Signature of managing director: 

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.

Consumables

Item no.	Item	Pc. / VE
30.9.0010	Measurement vessel for OSMOMAT 3000	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 3000-D	8
30.9.1020	Continuous loop ribbon cartridge for OSMOMAT 3000-D	1

Accessories and Replacement Parts

Item no.	Item	Pc. / VE
32.3.0010	Temperature sensor for OSMOMAT 3000 (50µl sample volume)	1
32.3.2010	Temperature sensor for OSMOMAT 3000-M (15µl sample volume)	1
30.9.0030	Blow-out device	10
30.6.0020	Cryst-needle	1
30.9.1050	Ampoule opener	1
20.9.0165	Data cable for RS 232 interface OSMOMAT 3000	1
20.9.0166	USB cable for USB interface OSMOMAT 3000	1
30.2.0030	Adjustment tool	1
20.9.0100	Power cord, 2m	1
00.9.0107	Package with microfuses, slow-blow 1.6A (HBC 1500A)	10

Before Calling Gonotec

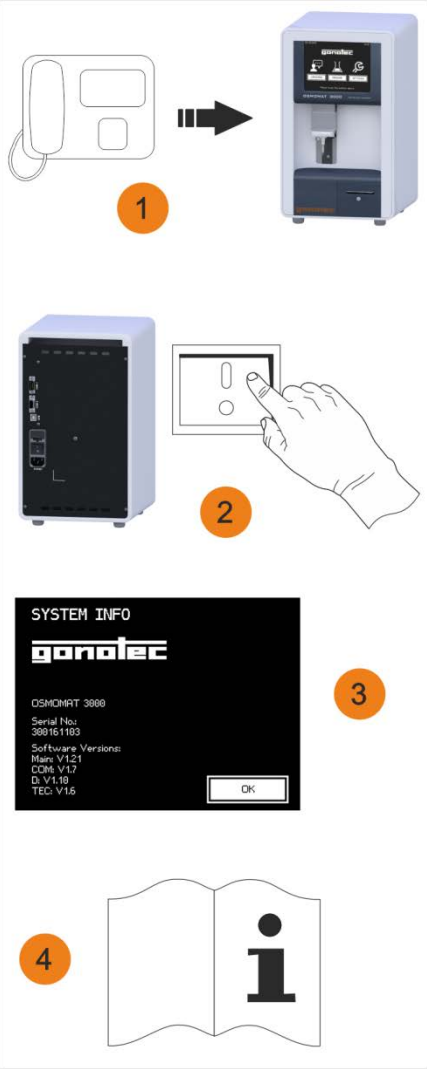


Fig. 151: Contact Gonotec

1 Use a telephone located close to the device.

2 Power up device.

> **NOTE!**
> **Danger in case of continuous acoustic alarm!**
> In case of continuous acoustic alarm, the electronics components of the device can be damaged.
> - Power down device again.

3 Note down the serial number of the device.
You can find the serial number on the rear of the device or under *Settings* ➔ *Info*.

4 Have the device documentation available.

Contact info:

Gonotec GmbH
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