FreezePoint®

Freezing Point Osmometer

MODEL 6000, 6000P, 6000S, 6000SP

USER'S MANUAL

ELITechGroup

EMPOWERING IVD

FREEZEPOINT®

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ELITechGroup Inc.
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Logan, Utah 84321-8212 USA

IVD CE

This manual allows for the safe and efficient operation of the FreezePoint® Model 6000 Freezing Point Osmometer (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 information

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Table of Contents

Section 1: Safety

1.1 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 important information about the device and/or the operations of the device.

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 bio-hazardous 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.

CAUTION!

Pinch hazard on cover!
Use care when closing cover.

2. 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)

1.2 Intended use

Intended use

FreezePoint® 6000 series osmometers are intended for laboratory use by qualified personnel for the determination of total osmolality of aqueous solutions.

Attention when using device

- 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.
- Only use accessories and consumables supplied by ELITechGroup for measurements.

”Consumables, Accessories, and Replacement Parts” on page 107.

1.3 Additional hazards

Hazards due to 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 voltage source.
- 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 contact ELITechGroup Service Department for repairs.
- 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, short circuit 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.
- Cleaning and Disinfection: We recommend regular cleaning of the device with water and cleaning-enhancing additives (e.g., detergents or enzymatic products) using a wet wipe or spray wipe method.

Risk of injury

CAUTION!

Risk of injury from initiation needle!

When installing and removing the initiation needle and the thermistor probe, the tip of the initiation needle is exposed. Movement of the initiation needle can cause needle puncture injuries.

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

Risks of device damage

Exposure to liquids and moisture

⚠ **WARNING!**

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 circuit.

- 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

⚠ **WARNING!**

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.

Impact/vibration

⚠ **WARNING!**

Risk of property damage due to exposure of the device to strong impact/vibration!

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

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

ESD

⚠ **WARNING!**

Risk of property damage due to electrostatic discharge!

Electrostatic discharge (ESD) can occur when working on the open device and cause damage to the touchscreen and/or communication ports.

- Take ESD precautions.

Repeatability of the measurement

Incorrect measurement vessels

! *NOTE!*

Impaired repeatability 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 ELITechGroup.
- Never use centrifuge tubes or reaction vessels.

Improper handling of the calibration standard

! *NOTE!*

Impaired reliability 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 ampule (max. 30 minutes at 72°F (22°C) ambient temperature).
- Never use opened ampules twice or mix them together.
- Never freeze opened ampules.
- Do not use the calibration standards past their expiration date.

Impact/vibration

! *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 impact/vibration. This can cause a higher risk of incorrect measurements (spontaneous crystallization).

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

1.4 Personal 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.

1.5 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.

1.6 Environmental Information

! *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.

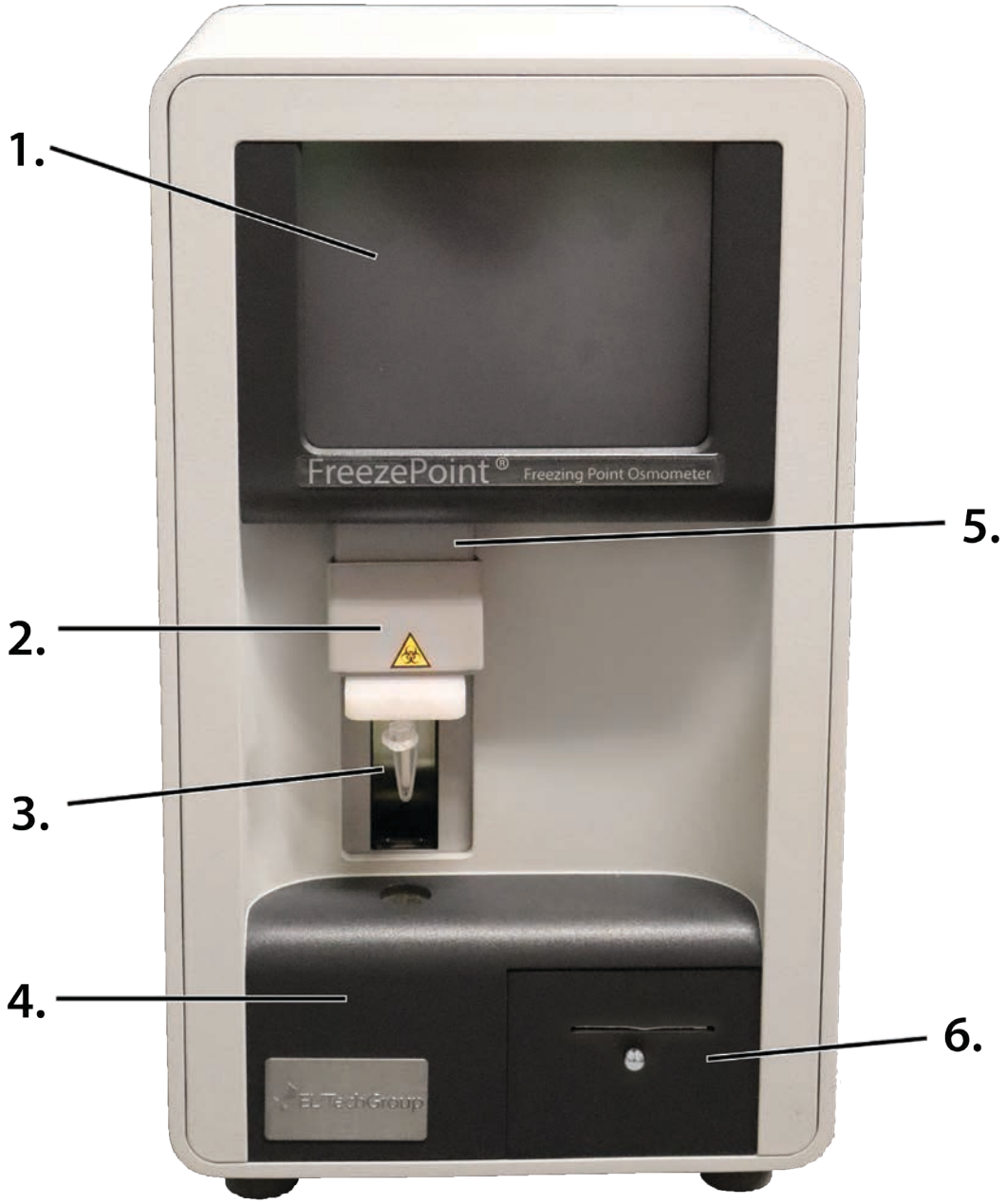
Sodium chloride

The calibration standards contain sodium chloride. Sodium chloride is mildly hazardous and may cause eye, skin, and respiratory irritation.

Solutions are traceable to standards prepared from NIST Standard Reference material (SRM 919b Sodium Chloride)

2.1 Device Overview

Figure 1 Device overview—front



1. Touchscreen page 25
2. Upper cooling system (behind movable elevator cover), page 24
3. Thermistor probe with measurement vessel, page 24
4. Lower cooling system page 24
5. Elevator
6. Printer (Model 6000P / Model 6000SP)

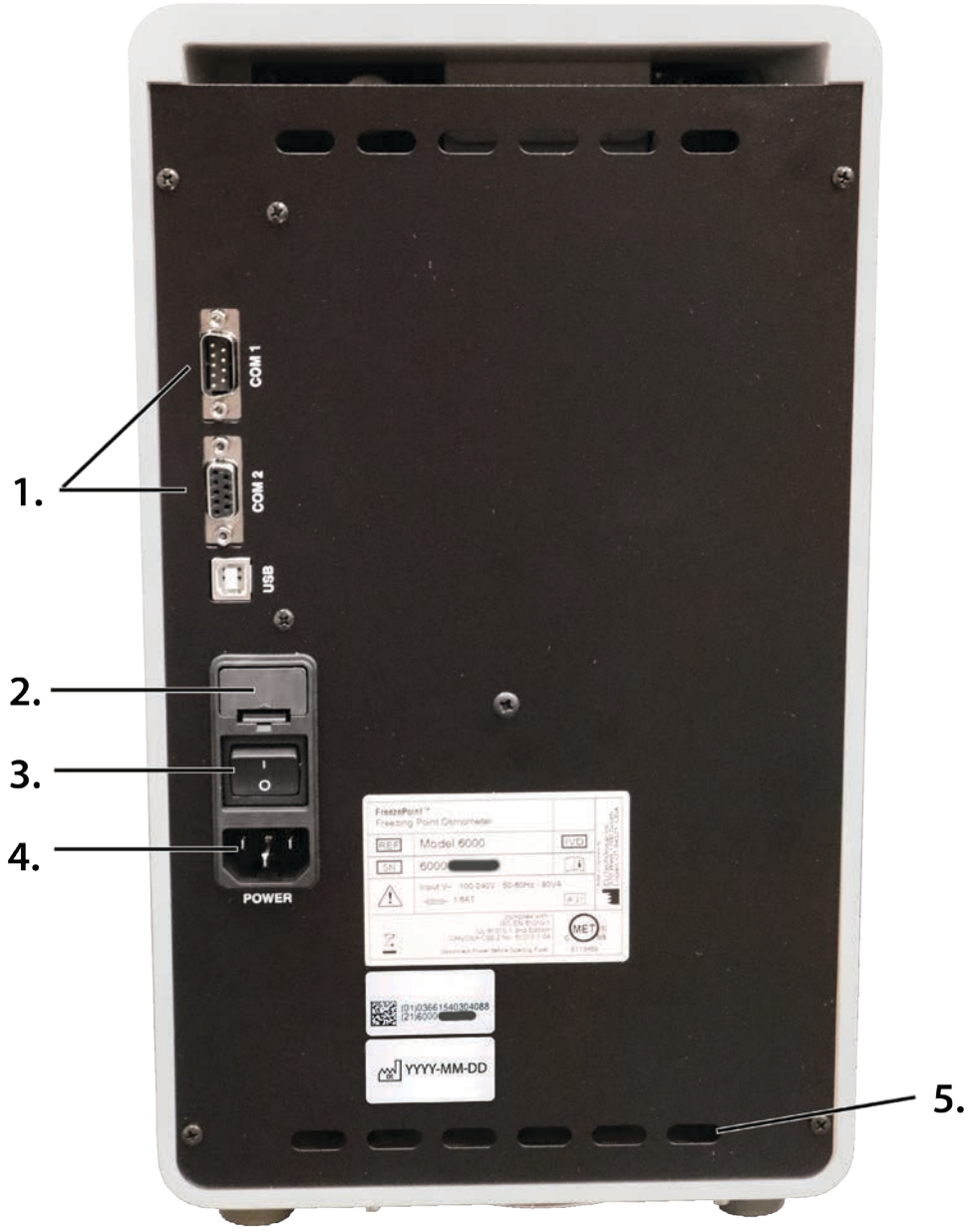


Figure 2 Device overview-rear

1. Interfaces
2. Micro-Fuse compartment
3. On/Off switch
4. Power cable connection
5. Fan outlet

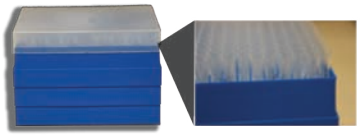
Standard Consumables

! *NOTE: Risk of falsified measurement results!*

When using accessories and/or consumables provided by manufacturers other than ELITechGroup, the reliability of the measurement results cannot be guaranteed.

- Always use the accessories and consumables supplied by ELITechGroup.
- Reorder consumables, in particular measurement vessels and calibration standards, from ELITechGroup (see “Manufacturer contact information” on page 5 for contact information).

Figure 3: Overview of Consumables

1. 
2. 
3. 

4. 

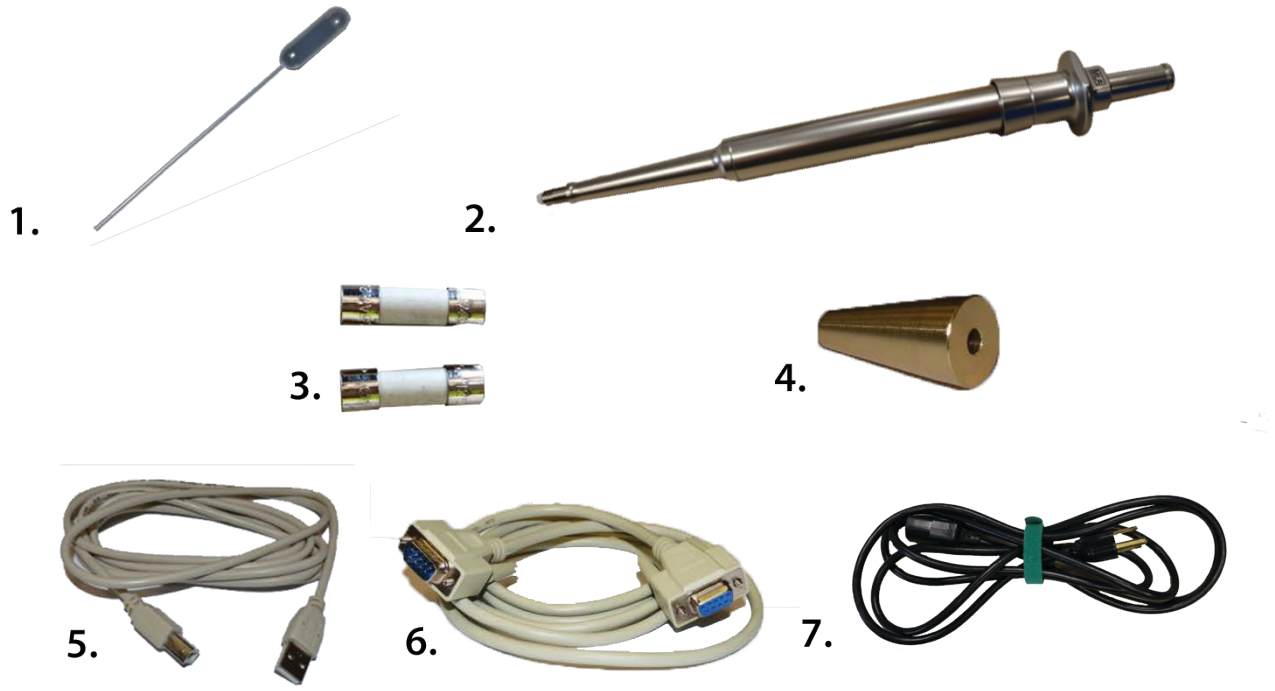
5. 

1. SS-036 Pipettor Tips (1000 ea)
2. SS-275 / SS-279 Measurement Vessels, 1000 ea./100 ea., FreezePoint
3. SS-276 Calibration Standard, 300 mOsmol/kg, FreezePoint
4. SS-277 Calibration Standard, 850 mOsmol/kg, FreezePoint
5. SS-281 Printer paper, 8 rolls (Model 6000 P/SP)

“Consumables, Accessories, and Replacement Parts” on page 107.

Standard Items

Figure 4 Overview of items



Description	Item Number
1. Blow-Out Device, FreezePoint® (Pack of 10)	AC-198
2. Pipette, MLA, 15uL / 50 ul, D-Tipper Silver, Fixed Volume	AC-199 / AC-201
3. Micro-Fuse, Slow-Blow, 1.6A FreezePoint® (Pack of 2)	RP-547
4. Adjustment Tool, FreezePoint®	RP-546
5. USB Cable, FreezePoint® USB	RP-548
6. RS232 Cable, FreezePoint®	RP-549
7. Power Cord, US 120V, FreezePoint®	RP-550

2.2 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 or 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 × 1023 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)

2.3 Measurement Equipment

Figure 5 Overview of measurement equipment

1. Elevator
2. Upper cooling system (behind movable elevator cover)
3. Handle for lowering the thermistor probe
4. Thermistor probe
5. Lower cooling system
6. Cover
7. Measurement vessel

The sample is pipetted into the measurement vessel (7). The measurement vessel is placed on the thermistor probe (4) and lowered into the lower cooling system (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 (2).

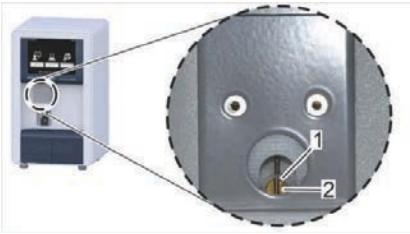
The osmolality of the sample is calculated using the measured freezing point [°C] and the cryoscopic constant and shown on the display.

! *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



1. Initiation needle
2. Cooling pin

The initiation needle (1) of the upper cooling system “seeds” the sample with ice crystals (“crystallization”). This causes the sample to freeze and heat up to its freezing point.

Figure 6 Upper Cooling System

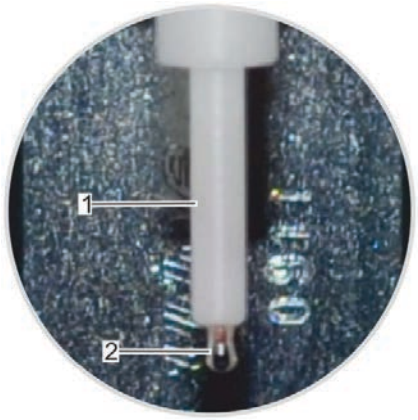
WARNING!

Risk of infection from sample residue!

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

- Wear lab gloves during any kind of work.

Thermistor probe



1. Thermistor probe
2. Thermistor

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

Figure 7 Thermistor probe

! *NOTE!*

Sensitive component!

The thermistor of the thermistor probe 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.
- After using the device, place an empty and unused 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.

2.4 Touchscreen

Figure 8 Overview of touchscreen

The device is controlled using the touchscreen (1)

⚠ **WARNING!**

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 protected by a pin.

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

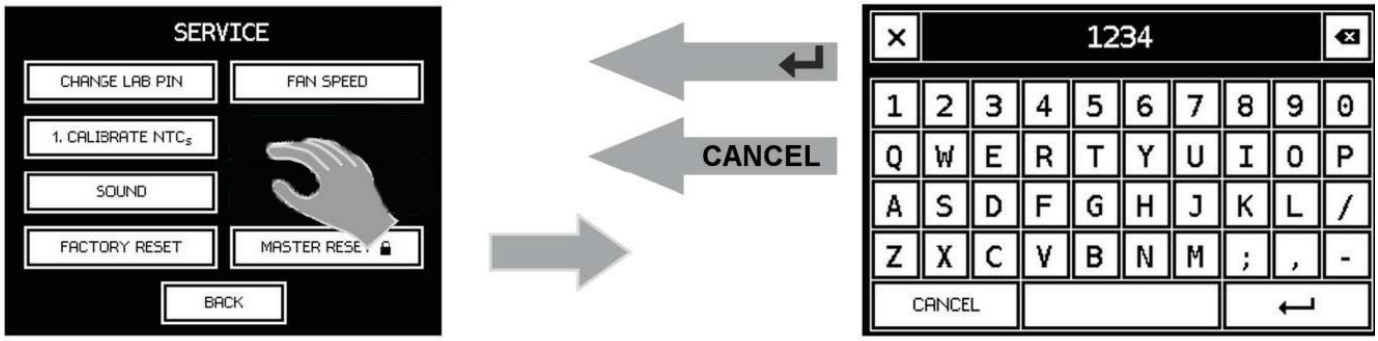


Figure 9

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.

2.5 Printer (Model 6000 P/SP)

Figure 10 Overview of printer

With built-in printer (only Models 6000 P/SP)

1. Opening for the 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 (*”Replace printer paper (Models 6000P / 6000SP only)” on page 86).*

2.6 Connections and interfaces

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

Figure 11 Connections and interfaces

1. COM1 (only for connecting barcode reader)
2. COM2 interface (RS-232 output)
3. USB port
4. Fuse insert
5. On/Off switch
6. Power plug connection

For serial data transmission to a PC or an information system such as LIM/LIS/KIS etc., a corresponding communication software (service) is required on the respective target system. On a PC, this is generally a terminal software that can record data streams of a serial interface, e.g. HyperTerm or PuTTY[1]. The interface configuration of this software (service) is done according to the following interface specification. The serial data stream will be logged on the communication software according to the selected data format.

In modern information systems, this service may already be fully integrated, so that the interface configuration takes place directly in the software. Subsequently, the database fields of the target system (LIM/LIS/KIS etc.) must be adapted to the data format. However, ELITechGroup does not sell or offer such software solutions and therefore cannot provide support for them.

[1] HyperTerm is a Trademark of Hilgraeve, Inc. / PuTTY is free and open-source under MIT-License

Interface configuration

COM1 data port

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 ELITechGroup.

⚠ **WARNING!**

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

Barcode IDs can be composed from the following subset of printable ASCII characters (incl. “space”) as defined in the ANSI X3.4-1986 standard:

```
!#$%'()*+-./0123456789;=?@ABCDEFGHIJKLMNOPQRSTUVWXYZ
[\]^_`abcdefghijklmnopqrstuvwxyz{|}~
```

COM2 or USB data port

⚠ **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.

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 *Settings* ➔ *Lab Options* ➔ *Log Port*. The following screen lets you select between COM2 and USB.

Figure 12 Set log port

Transmit Parameters

The “Send Test String” option lets you test the communication.

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

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 contact the service team at ELITechGroup for the driver.

Log formats

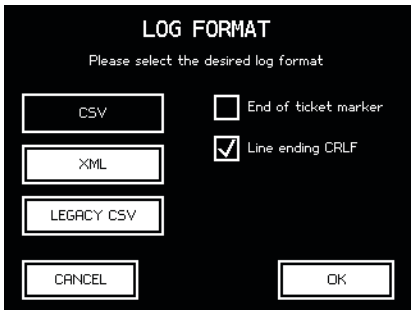


Figure 13 Log formats

To set the data format used by the device, select Settings ➔ Lab Options ➔ Log Format from the menu.

The following options are available:

Line ending CRLF:

Selecting this option places a carriage return (CR) and line feed (LF) at the end of the line.

Deselecting this option places a carriage return only (CR).

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⏎
```

Pair user and batch ID:

To ensure compatibility with legacy log formats, the user and batch ID can be paired to a single ID.

The log output for the device may optionally be output 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 ELITechGroup strongly advises against using this format!**

See the following sections for a detailed description of the various formats.

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 device 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 main board and the components connected to it.

A typical intro line looks like this:

```
FP6000;Main:VX.XX;COM:VX.X;D:VX.XX;TEC:VX.X⏎
```

! *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:

```
“user”;“batch”;”sample”;date;value;”dimension”;”device-no”;
”check”;”message”⏎
```

! *NOTE!*

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

! *NOTE!*

When using the user ID, the title line shows the additional column title “user” at the beginning of the title line, but only if the IDs are not paired!

Result line

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

Column	Description
user	Optional user ID in quotation marks; Only present if the user login is activated and not connected to the batch identifier.
batch	Batch identifier in quotation marks, entered by the user or a sequential number generated automatically. (Possible with user id, see user). **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.: YYYY-MM-DDTHH:MM:SS)
value	Measurement result as integer (in mOsmol/kg). **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. **Or:** specific device ID – if assigned, in quotation marks.
check	MD5-Checksum of previous values in this line (see "Checksums" on page 35).
message	Human-readable message always in English in quotation marks. **Or** Void if there is no notification.

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 record corresponds to one ticket in the XML log.

There are two types of tickets:

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

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).

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.: `YYYY-MM-DDTHH:MM:SS`).
`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" on page 35). **Or:** Not present if measurement was successful.
`DeviceCode`	Serial number of the device. **Or:** Specific device ID (if assigned)
`CheckSum`	MD5-Checksum of previous values in this line (see "Checksums" on page 35).
`Message`	Human-readable message always in English. **Or:** Not present if there is no notification.

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=”300201103” versions=”FP6000;Main:VX.
XX;COM:VX.X;D:VX.XX;TEC:VX.X”>⏎

<Measurement>⏎

<SampleId>SAMPLE01</SampleId>⏎

<DateTime>YYYY-MM-DDTHH:MM:SS</DateTime>⏎

<Value>299</Value>⏎

<Unit>mOsmol/kg</Unit>⏎

<DeviceCode>300201103</DeviceCode>⏎

<CheckSum>756de7e29897809f575ff41fec1a2435</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=”300201103” versions=”FP6000;Main:VX.
XX;COM:VX.X;D:VX.XX;TEC:VX.X”>⏎
```

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>SAMPLE01</SampleId>⏎

<DateTime>YYYY-MM-DDTHH:MM:SS</DateTime>⏎

<Value>301</Value>⏎

<Unit>mOsmol/kg</Unit>⏎

<DeviceNo>300201103</DeviceNo>⏎

<CheckSum> ff524ddb8bf30e3b3bb58d59beed1975</CheckSum>⏎

</Measurement>⏎
```

Ending the batch also closes the ticket:

```
</Ticket>⏎
```

Legacy CSV format

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 using this format!

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.

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>SAMPLE01</SampleId>
<DateTime>YYYY-MM-DDTHH:MM:SS</DateTime>
<Value>299</Value>
<Unit>mOsmol/kg</Unit>
<DeviceCode>300201103</DeviceCode>
<CheckSum>756de7e29897809f575ff41fec1a2435</CheckSum>
</Measurement>
```

...or…

```
;”SAMPLE01”;YYYY-MM-DDTHH:MM:SS;299;”mOsmol/kg”;”300201103”;
“172ef346c5f36c964ac0710a8421efc1”;
```

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

```
SAMPLE01YYYY-MM-DDTHH:MM:SS299mOsmol/kg300201103
```

The MD5 checksum for this string is:

```
75 6d e7 e2 98 97 80 9f 57 5f f4 1f ec 1a 24 35
```

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

Delivery condition

1 package containing the following components:

- Device with protective sleeve (1)
- Blow-out device (2)
- Adjustment tool (3)
- Micro-Fuse, Slow-Blow, 1.6A FreezePoint® - 2 pack (4)
- Pipette (5)
- USB Cable (6)
- RS232 Cable (7)
- Power Cable (8)
- Measurement vessels, 100 pc.(9)
- Calibration standard 300mOsmol/kg, 1 package of 10 ampules/1ml each (10)
- Calibration standard 850mOsmol/kg, 1 package of 10 ampules/1ml each (11)
- Pipettor Tips (1000 ea) (12)
- Printer paper, 2 rolls ea. (13) (Model 6000 P/SP)
- 1 User's Manual

Figure 14 Delivery Condition

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 ELITechGroup 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.

3.1 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:

⚠ DANGER!

Danger to environment due to improper disposal!

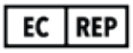
Packaging materials are valuable resources and can be reused or recycled in many cases. Improper disposal of packaging materials can cause dangers to the environment.

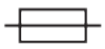
- Be aware of the environment when disposing of the packaging material.
- Observe applicable local disposal regulations. If necessary, task a specialist firm with disposal.

Symbols on packaging

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

Symbol	Standard Reference	Standard Title	Symbol Title	Symbol Explanation
	ISO 15223-1: 2021 Reference no. 5.4.4. (ISO 7000-0434A)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	iso_grs_7010_WOO1	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	General warning sign	To signify a general warning
	ISO 15223-1:2021 reference no. 5.4.1 (ISO 7010 – W009)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	Warning; Biological hazard	Bio-contamination warning: Use care when operating upper cooling system and initiation needle.

Symbol	Standard Reference	Standard Title	Symbol Title	Symbol Explanation
	ISO 15223-1: 2021 Reference no. 5.1.1. (ISO 7000-3082)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Manufacturer	Indicates the medical device manufacturer
	ISO 15223-1: 2021 Reference no. 5.1.2	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Authorized Representative in the European Community/ European Union	Indicates the authorized representative in the European Community / European Union
	ISO 15223-1: 2021 Reference no. 5.1.3. (ISO 7000-2497)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Date of manufacture	Indicates the date when the medical device was manufactured
	ISO 15223-1: 2021 Reference no. 5.1.4. (ISO 7000-2607)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Use by date	Indicates the date after which the medical device is not to be used
	ISO 15223-1: 2021 Reference no. 5.1.5. (ISO 7000-2492)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified. Synonyms for "batch code" are "lot number", "lot code" and "batch number".
	ISO 15223-1: 2021 Reference no. 5.1.6. (ISO 7000-2493)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Catalogue number Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified ISO 15223 Catalogue number ISO 7000 Catalog number
	ISO 15223-1: 2021 Reference no. 5.1.7. (ISO 7000-2498)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified
	ISO 15223-1: 2021 Reference no. 5.3.7. (ISO 7000-0632)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed

Symbol	Standard Reference	Standard Title	Symbol Title	Symbol Explanation
	ISO 15223-1: 2021 Reference no. 5.3.8. (ISO 7000-2620)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Humidity limitation	Indicates the range of humidity t which the medical device can be safely exposed
	ISO 15223-1: 2021 Reference no. 5.2.8. (ISO 7000-2606)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Do not use if package is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	ISO 15223-1 5.4.3	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Consult instructions for use	Indicates that need for the user to consult the instructions for use
	ISO 15223-1:2021 Reference no. 5.4.3. (ISO 7000-1641)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	In Vitro diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device
	IEC 60601-1 (IEC 60529) Reference no. 6.3; Table D.3; Code 2	Medical electrical equipment – Part 1: General requirements. for basic safety and essential performance	Degree of protection	IPX1: N1=X, which means it was not required; N2=1, Protection against vertically falling water drops
	IEC 60417-1 Reference no. ISO 7000-5016	Graphical symbols for use on equipment	Fuse	To identify fuse boxes or their location
	ISO 15223-1:2021 Reference no. “5.1.10(IEC 60417-6050)”	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Model number	To identify the model number or type number of a product. In the application of this symbol, the model number or type number of the product should be accompanied with this symbol
	IEC-TR-60878 Reference no. ISO 7000-1135	Graphic symbols for use on electrical equipment in a medical practice	General symbol for recover/recyclable	To indicate that the marked item or its material is part of a recovery or recycling process

Symbol	Standard Reference	Standard Title	Symbol Title	Symbol Explanation
CE	EU 2017-746 Reference no. ANNEX V	REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/ EEC and 2010/227/EU	CE marking	(43) 'CE marking of conformity' or 'CE marking' means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonization legislation providing for its affixing
CH REP	ISO 20417 Reference no. 6.1.2 d)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Authorized Representative in Switzerland	Indicates the authorized representative in Switzerland
	DIRECTIVE 2012/19/ EU (WEEE)	N/A	Collect separately	Separate collection for waste of electrical and electronic equipment. Do not dispose of battery in municipal waste. The symbol indicates separate collection for battery is required.
	Directive 2002/96/ EC (repealed).	Replaced by DIRECTIVE 2012/19/ EU which does NOT contain this symbol.	Waste stream disposal status	Do not dispose of electronic products in the general waste stream
	ISO 15223-1:2021 Reference no."5.1.9(ISO 7000-3724)"	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Distributor	Indicates the entity distributing the medical device into the locale

3.2 Unpacking and Device Storage

Unpacking 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.
4. After device has been shipped, please align the thermistor probe upon receiving, as it can become misaligned in transit and could cause inaccurate readings (“Align the Thermistor probe” on page 82)

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 thermistor probe using a measurement vessel.
- Avoid mechanical shock.
- Storage temperature: -10°C to 60°C.
- Relative humidity (non-condensing): ≤80%.
- If stored for more than 3 months, regularly inspect all parts and packaging for general integrity.

4.1 Transport device inside lab

Personnel: User

Safety gear:

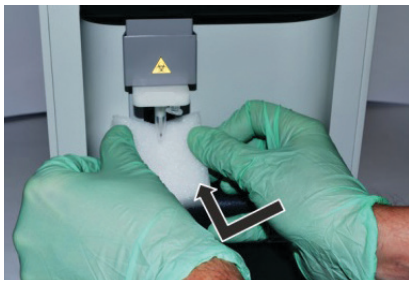
- Disposable lab gloves

1. Power down device using on/off switch on rear side and disconnect power plug.
2. Position a measurement vessel on the thermistor probe.

! *NOTE!*

The measurement vessel is securely attached to the thermistor probe when it clicks into place.

Figure 15 Position measurement vessel



3. Tilt transport safety device for thermistor probe and carefully slide behind the thermistor probe.

Figure 16 Position transport safety device

4. Pull protective sleeve included with the delivery over device.
5. Lift up device 14.3 lbs (6.5 kg) and carry to installation site.

Figure 17 Device with protective sleeve

4.2 Install device

Personnel: User

Safety gear:

- Disposable lab gloves

1. Install device at installation site.

   Keep fan outlet on device clear.

   Keep fan outlet openings underneath device clear.

Figure 18 Fan outlet

⚠ **WARNING!**

Risk of property damage!

Only install device indoors.

! *NOTE!*

Risk of incorrect measurements

Select site based on the following criteria:

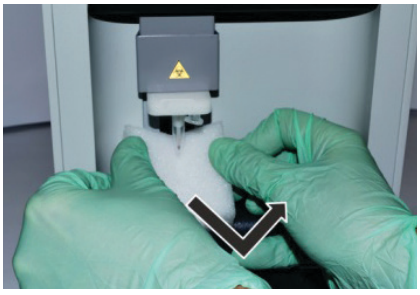
- Free of vibrations
- No direct heat exposure (sun, electric heater, etc.)
- No strong air flows
- Free of dust and dirt

2. Remove protective sleeve from device.

Figure 19 Remove protective sleeve

3. Remove transport safety device from thermistor probe. Proceed as follows:

Figure 20 Transport safety device



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

Figure 21 Remove transport safety device

Connect device

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).

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 (*“8.5 Lubricate elevator” on page 97*).
4. Power up device on rear side using on/off switch.

5.1 Check printer (Models 6000P/SP)

5. Device does not ship with paper installed in the printer. On initial set-up see “Replace printer paper (Models 6000P / 6000SP only)” on page 86 for instructions on installing paper roll.

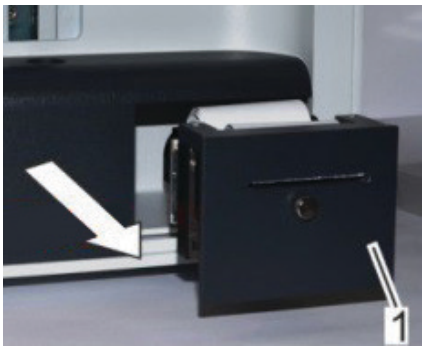


Figure 22 Pull out printer

6. Check feed direction of paper roll. Open printer by pulling on silver knob (magnetic latch).

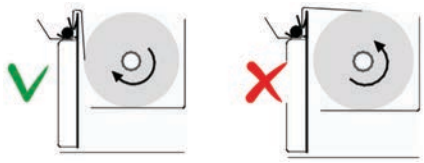


Figure 23 Paper roll feed direction

7. Compare feed direction of paper roll with feed direction shown.

5.2 Check free movement of steel needle

1. Check initiation needle for free movement.
   Open the Adjust Needle menu (*Start menu* ➔ *Settings* ➔ *Lab Options* ➔ *Maintenance* ➔ *Adjust Needle*).

⚠ **CAUTION!**

Risk of injury from initiation needle!

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

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

Figure 24 Adjust Needle Menu

2. Tap **Move Needle** and ensure that the initiation needle moves freely.
   Tap *Back* to complete the check.

5.3 Set calibration defaults

Select calibration procedure

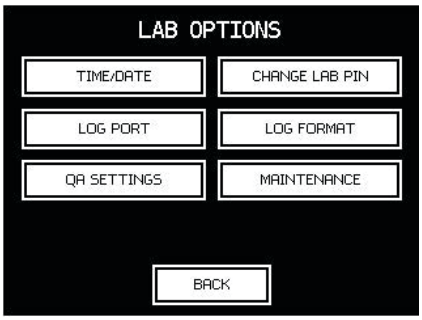


Figure 25 Lab Options menu

1. Open the menu for configuring the lab options.
   In the Start menu, tap *Settings* ➔ *Lab Options*.

! *NOTE!*

The menu can be protected with a lab supervisor pin.

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

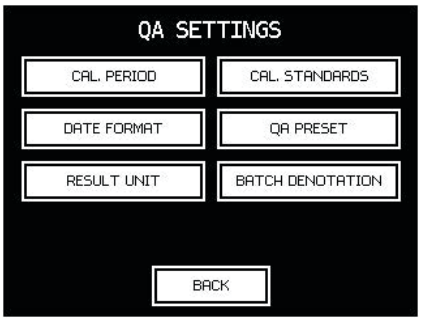


Figure 26 QA Settings menu

2. 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.*

Configure calibration interval

Figure 27 Configure calibration interval

3. Select a calibration interval.
   - When selecting Manual, the device does not prompt you for calibration (not recommended).

Select calibration standards

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.

Figure 28 Select calibration standards

Set up calibration method

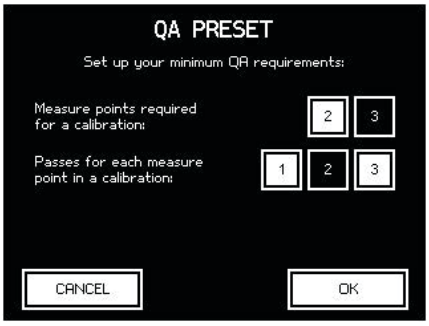


Figure 29 Set up calibration method

4. Select the calibration method:
   - *2-point:* Select 2-point calibration
   - *3-point:* Select 3-point calibration
5. 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.

!

NOTE!

The number of measurements for each calibration point does not affect the repeatability of the result system, but may impact the accuracy of the measurement system. They are only used to arrive at the mean value.

5.4 Date Time

Set date and time

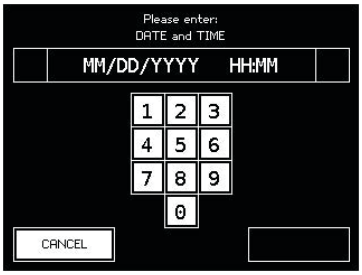


Figure 30 Set date and time

1. Enter date and time as follows:
   DD – Day, two digits [01…31]
   MM – Month, two digits [01…12]
   YYYY – Year, four digits [2020]
   HH – Hour, two digits [00…23]
   MM – Minutes, two digits [00…59]

Set date format

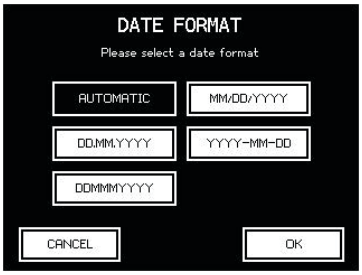


Figure 31 Select date format

2. 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 [2020]

! *NOTE!*

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

5.5 Measurement series name

Set measurement series name

Figure 32 Measurement series name

1. Select the name for your measurement series.

5.6 Result Unit

Set result unit

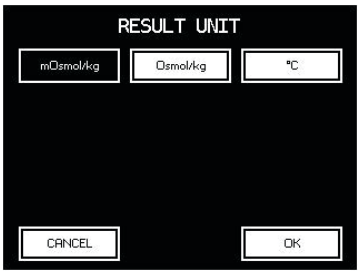


Figure 33 Select Unit

2. Select the unit for the measurement results:
   - ◊ mOsmol/kg
   - ◊ Osmol/kg
   - ◊ °C

Section 6: Operation

6.1 Information before 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.

6.2 Power up device

Personnel: User

Safety gear:

- Disposable lab gloves

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

Figure 34 Power up device

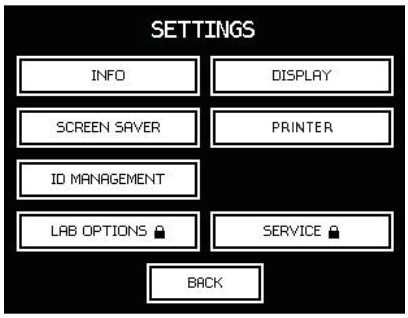
6.3 Modify user preferences

Configure language

Tap Language and select a language.

Figure 35 Select language

Overview



Tapping Settings on the Start menu opens the Settings menu.

The Settings menu lets the user configure the following settings:

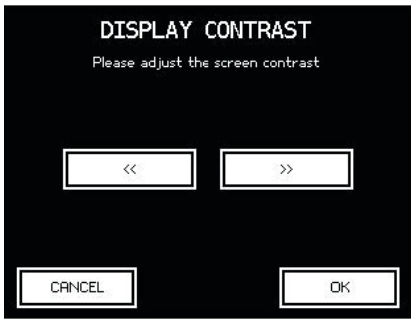
- Info: Shows the version of the device software
- Display: Configure screen contrast
- Screen saver: Configure screen saver
- Printer: Activate paper feed (Model 6000P/SP)
- ID Management: Set ID for sample and series measurements

Figure 36 Overview of user preferences

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

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

Configure screen contrast



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

Figure 37 Configure screen contrast

Configure screen saver

Figure 38 Configure screen saver

1. Select the duration after which the system activates the screen saver. Tapping *OFF* will deactivate the screen saver.

Activate paper feed (Models 6000P/SP)

Figure 39 Activate paper feed

1. Tap *Paper Feed.*
   ⇨ The paper feed of the printer is activated briefly.
   Tap *Back* to exit the menu.

Set sample and batch ID

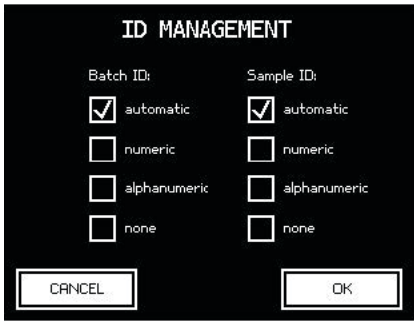


Figure 40 Set sample and batch ID

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 or the optional barcode reader.
- 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.

! ***NOTE!***

Barcode IDs can be composed from the following subset of printable ASCII characters (incl. “space”) as defined in the ANSI X3.4-1986 standard:

!#$%’()+-./0123456789;=?@ABCDEFGHIJKLMNOPQR STUVWXYZ[\]^_`abcdefghijklmnopqrstuvwxyz{|}~*

ID length is up to 32 characters!

Laboratory options

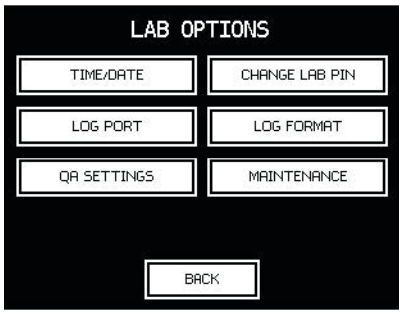


Figure 41 Overview of lab settings

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

The Lab Options option is protected with the lab supervisor pin

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 (“Interface configuration” on page 29)
- *Log Format:* Set log format (“Log formats” on page 30)
- *QA Settings:* Additional configuration settings (“5.3 Set calibration defaults” on page 47)
- *Maintenance:* Options for maintenance and troubleshooting (“7.4 Resolve Errors” on page 73).

6.4 Measure individual/batch samples

Personnel: User

Safety gear:

- Disposable lab gloves

Materials:

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

! ***NOTE!***

Impaired repeatability 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 ELITechGroup.
- 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.*

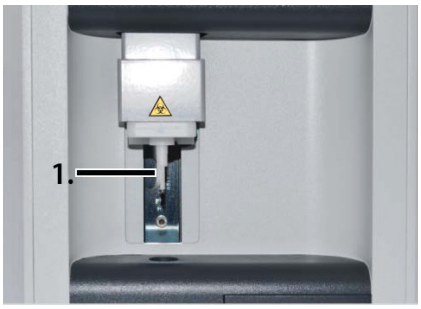


Figure 42 Clean thermistor probe

1. Clean thermistor probe using a soft, dry, lint free paper towel.

Figure 43 Start menu

2. Tap Measure on the Start menu.
   ⇨If the operating time of the device is less than 3 minutes, a wait screen for ice formation is displayed.

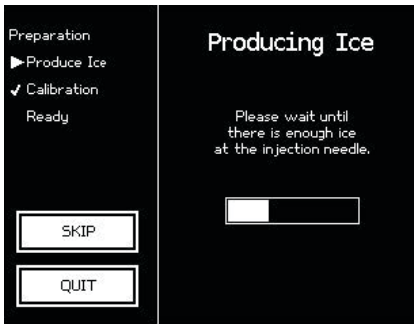


Figure 44 Ice formation

3. Wait until ice forms on the initiation needle.

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

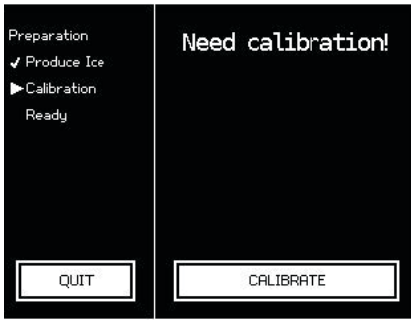


Figure 45 Calibrate device

4. If necessary, calibrate device.
   ”Calibrate device” on page 60.
   ⇨The device is ready.

   Calibration cannot be skipped.
   The calibration interval is defined by the lab supervisor.

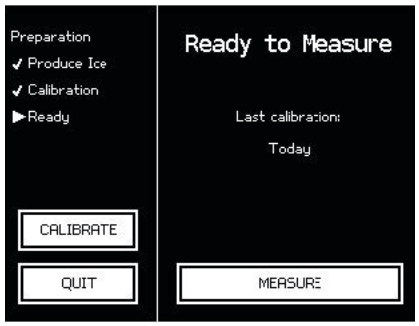


Figure 46 Device is ready for measurement

5. Tap Measure.
   ⇨The measurement menu opens.

Figure 47 Pipette sample

6. Pipette the appropriate sample volume into an unused and clean measurement vessel.
   - Model 6000 / Model 6000P - 15µL
   - Model 6000S / Model 6000SP - 50µL

! *NOTE!*

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

- The sample must be pipetted without air bubbles.

7. Position measurement vessel on thermistor probe with cover facing front (1).

! *NOTE!*

The measurement vessel is securely attached to the thermistor probe when it clicks into place.

Figure 48 Position measurement vessel

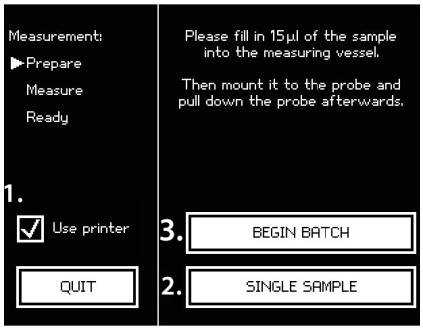


Figure 49 Measurement menu

8. Tap Use printer on the measurement menu to outputthe measurement results to a printer. Make sure that the printer is ready (1).
(Only Model 6000P/Model 6000SP)
9. To start the measurement-
   A. For a single sample, tap “Single Sample” (2).
   If necessary, enter the sample ID using the virtual keyboard.

   OR

   B. To start a series measurement, tap “Begin Batch” (3).
   Enter the batch ID.

! *NOTE!*

The sample/batch ID can be predefined in the user preferences. In this case, the system assigns the sample/batch ID automatically.

Figure 50 Move elevator down

10. Move elevator down.

! *NOTE!*

Moving the elevator up during the measurement will abort the measurement.
Be mindful when lowering the sample that droplets are not formed on the side of the measurement vessel. This can affect the sample reading.

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

Figure 51 Measurement

The measurement result displays on the touchscreen.

On Model 6000P/Model 6000SP the result is printed.

(“10.2 Performance parameters” on page 101)

Figure 52 Clean thermistor probe

11. Move elevator up.

! *NOTE!*

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

Take care when removing the measurement vessel to clear the sample probe to avoid damaging it.

12. Remove measurement vessel from thermistor probe.
Dispose of measurement vessel and sample according to local regulations.

13. Clean thermistor probe using a soft, dry, lint free paper towel.

! ***NOTE!***

Risk of carryover!

- Failure to clean the thermistor probe immediately following measurement can result in carryover and incorrect measurement results.
- Cleaning the probe with a lint free cloth wetted with DI water then wiping and drying the probe, or the use of water blank, may help alleviate this issue. This procedure is recommended to avoid risk of contamination with salt at the thermistor.

14. (If doing series or batch measurements) Start the measurement of the new sample by pressing “Next Sample”, and repeating the work starting with step 9.
To complete the series measurement, tap Complete batch.

- On Model 6000P/Model 6000SP, completing the series measurement also completes the printing operation.

! *NOTE!*

Exiting the measurement menu (by pressing Quit) will also quit the series measurement.

6.5 Calibrate device

Calibration methods

Depending on the predefined calibration interval, opening the measurement menu will automatically show a calibration prompt. Calibration can also be started manually.

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

- 2-point calibration: Calibration using distilled water and another calibration standard (300 mOsmol/kg or 850 mOsmol/kg)

OR

- 3-point calibration: Calibration using distilled water and two other calibration standards (300 mOsmol/kg [SS-276] or 850 mOsmol/kg [SS-277])

The calibration method, the calibration standards used for calibration, and the calibration interval are defined by the lab supervisor during set-up (“5.3 Set calibration defaults” on page 47).

Calibrate device

Personnel: User

Safety gear:

- Disposable lab gloves

Materials:

- Soft, lint free paper tissue
- Pipette
- Distilled water (see “Distilled Water” on page 107)
- Calibration standard(s) (e.g. 300 mOsmol/kg)
- Ampule opener
- Measurement vessels

! *NOTE!*

Impaired repeatability 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 ELITechGroup.
- Never use centrifuge tubes or reaction vessels.
- See “Consumables, Accessories, and Replacement Parts” on page 107

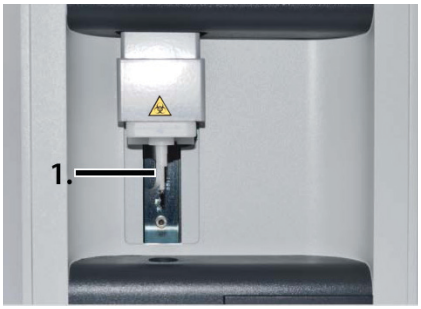


Figure 53 Clean thermistor probe

1. Clean thermistor probe using a soft, dry, lint free paper towel.

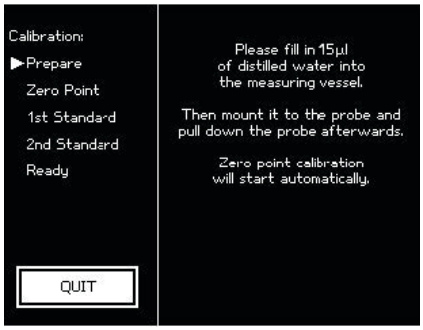


Figure 54 Perform zero point calibration

2. Follow the instructions on the touchscreen.

Figure 55 Pipette distilled water

3. Pipette the appropriate volume of distilled water into an unused and clean measurement vessel.
   - Model 6000 / Model 6000P - 15µL
   - Model 6000S / Model 6000SP - 50µL

! ***NOTE!***

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

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

Figure 56 Position measurement vessel

4. Position measurement vessel on thermistor probe with cover facing front.

! *NOTE!*

The measurement vessel (1) is securely attached to the thermistor probe when it clicks into place.

Perform zero point calibration

Figure 57 Move elevator down

5. Move elevator down.

   ⇨ Zero point calibration starts and is performed automatically.
   Pay attention to the information displayed on the touchscreen.

Figure 58 Move elevator up

6. Move elevator up.
7. Remove measurement vessel from thermistor probe.
   Dispose of measurement vessel and sample according to local regulations.
   Take care when removing the measurement vessel to clear the sample probe to avoid damaging it.
8. Clean thermistor probe using a soft, dry, lint free paper towel.

! ***NOTE!***

Risk of carryover!

- Failure to clean the thermistor probe immediately following measurement can result in carryover and incorrect measurement results.
- Cleaning the probe with a lint free cloth wetted with DI water then wiping and drying the probe, or the use of water blank, may help alleviate this issue. This procedure is recommended to avoid risk of contamination with salt at the thermistor.

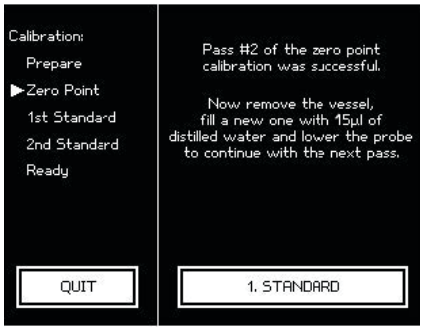


Figure 59 Calibrate device using calibration standard

9. Repeat steps 3 through 8 until the number of measurements per calibration point specified in the calibration defaults (“Set up calibration method” on page 48) (max. 3) is reached.
10. Following successful zero point calibration, tap 1st Standard 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 (“Check reliability of measurements” on page 99).

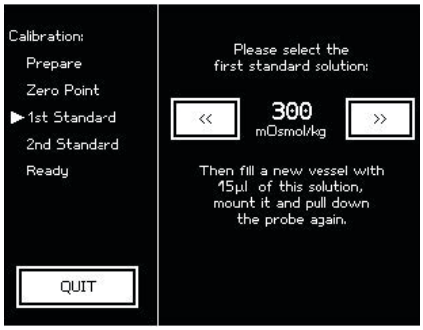
Calibrate device using calibration standard

NOTE!

Impaired reliability 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 ampules twice or mix them together.
- Never freeze opened ampules.
- Do not use the calibration standards past their expiration date.



11. Use the arrow keys << and >> to select the calibration standard to be used.

Figure 60 Select calibration standard

⚠ **WARNING!**

Risk of injury at ampule breaking points!

12. Use the ampule opener to open the ampules containing the calibration standards.

Figure 61 Open ampule

13. Pipette a calibration standard of the appropriate into a clean and unused measurement vessel.
    - Model 6000 / Model 6000P - 15µL
    - Model 6000S / Model 6000SP - 50µL

! ***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 thermistor probe with cover facing front.

! ***NOTE!***

The measurement vessel is securely attached to the thermistor probe when it clicks into place.

Figure 62 Pipette calibration standard

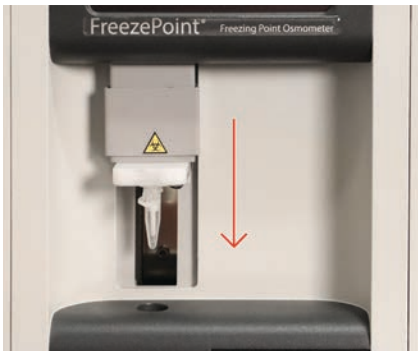


Figure 63 Move elevator down

15. Move elevator down.

    ⇨ Calibration starts automatically.

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

16. Move elevator up

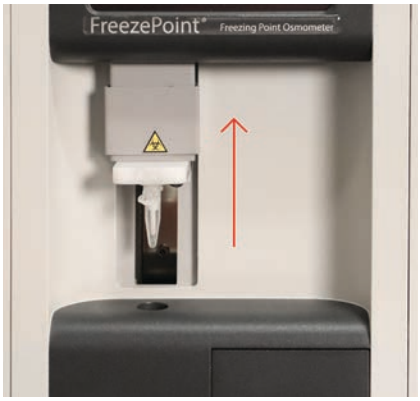


Figure 64 Move elevator up

17. Remove measurement vessel from thermistor probe.

18. Dispose of measurement vessel and sample according to local regulations.

19. Clean thermistor probe using a soft, dry, lint-free paper towel.

! ***NOTE!***

Risk of carryover!

- Failure to clean the thermistor probe immediately following measurement can result in carryover and incorrect measurement results.
- Cleaning the probe with a lint free cloth wetted with DI water then wiping and drying the probe, or the use of water blank, may help alleviate this issue. This procedure is recommended to avoid risk of contamination with salt at the thermistor.

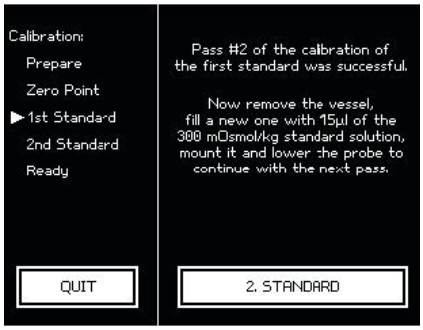


Figure 65 Second calibration standard

20. Repeat steps 13 through 18 until the number of measurements per calibration point specified in the calibration defaults (“5.3 Set calibration defaults” on page 47) (max. 3) is reached.

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

Figure 66 Complete calibration

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

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

This is the result of a 3-point calibration.

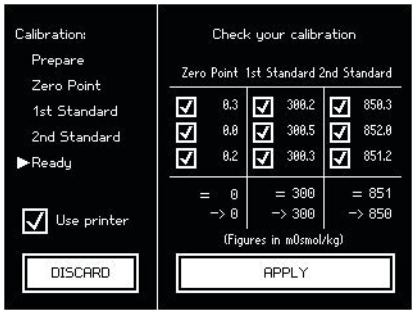


Figure 68 Calibration Results

21. Verify the calibration results.

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

    (“10.2 Performance parameters” on page 101)

22. Tap Apply to complete the calibration.

    ⇨ The device is now calibrated.

23. Verify accuracy (“Check reliability of measurements” on page 99)

    or

    Continue with your measurements (“Measure individual/batch samples” on page 56).

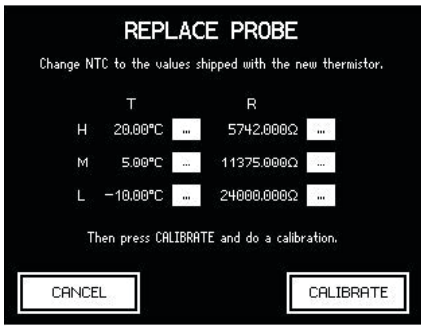


Figure 69 Replace probe

! ***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 (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.

6.6 Power down device

Personnel: User

Safety gear:

- Disposable lab gloves

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

Figure 70 Power down device

2. Position a measurement vessel (1) on the thermistor probe.

! *NOTE!*

The measurement vessel is securely attached to the thermistor probe when it clicks into place.

Figure 71 Position measurement vessel

3. Disinfect device if powered down for an extended period of time. Wipe device using a wipe moistened with disinfectant.
4. Pull protective sleeve included with the delivery over the device.

Figure 72 Device with protective sleeve

Section 7: Troubleshooting

7.1 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, electrical 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 initiation needle!

When installing and removing the initiation needle and the thermistor probe, the tip of the initiation needle is exposed. Movement of the initiation needle can cause needle puncture injuries.

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

7.2 Notes regarding errors

In case of errors that cannot be resolved using the error table on page 69, contact the manufacturer.

Please be prepared when contacting the manufacturer as follows:

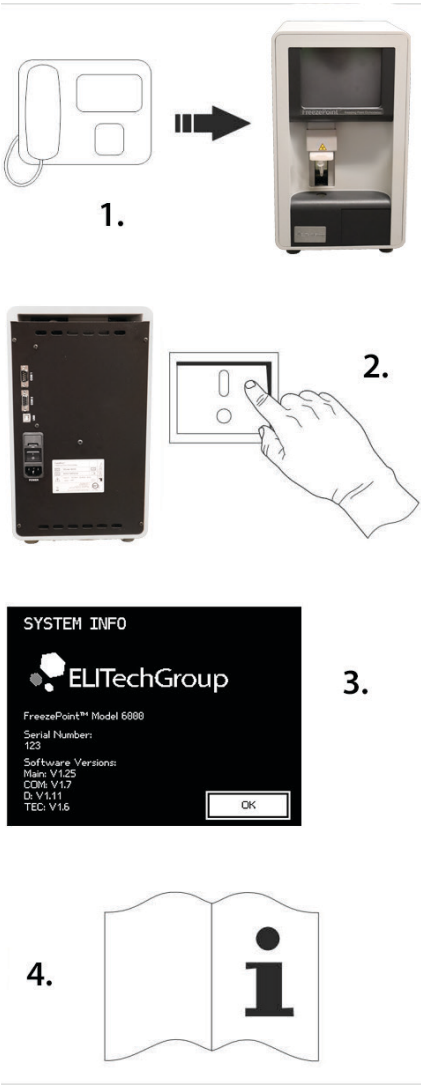


Figure 73 Contact ELITechGroup

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.
Serial number is located on the rear of the device or under *Settings* ➔ *Info*.

4. Have the device documentation available.

Contact information:

ELITechGroup Inc.
370 West 1700 South
Logan, UT 84321-8212 USA

Phone: +1 (435) 752-6011
Fax: +1 (435) 213-2108
E-mail: service.ebs@elitechgroup.com
Web: http://www.elitechgroup.com

7.3 Error table

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

If marked ** please contact ELITechGroup service team for clarification.

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 97)	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 86)	Service technician
	Fan is defective or obstructed	Check if fan is operational and replace if necessary**	
	Peltier element is defective	Replace lower cooling system **	
Motor of initiation needle turns without stopping Or Does not turn one full revolution	Light barrier on motor disk is defective	Replace light barrier **	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 pin using a fiberglass pin (page 81)	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 thermistor probe dirty or blocked by water droplets	Blow out hole using blow-out device	
	Cooling pin dirty	Clean cooling pin using a fiberglass pin (page 81). 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 technician
	Cable connection between cooling system and PCB defective		
	Initiation needle too long or too short	Adjust initiation needle to correct length (page 75)	
	Initiation needle not deburred	Debur initiation needle using fine sandpaper	
	Initiation needle bent	Manually bend initiation needle so that it is vertical, replace if necessary (page 74)	
	Initiation needle does not move Initiation needle disengaged from motor or stuck	Verify free movement of initiation needle (page 76)	
	Error in rotation of motor disk (initiation needle drive)	Align initiation needle (page 75)	Service technician
		Correct length of initiation needle (page 75)	
		Check if light barrier is located properly and replace if necessary **	
		Tighten motor disk	
Printer does not print	Paper roll is used up	Replace paper roll (page 86)	User
	Ribbon is empty	Replace ribbon (page 88)	
Measurement procedure takes longer than usual	Fan is defective or obstructed	Check if fan is operational and remove any foreign objects Replace fan **	Service technician
	Peltier element is defective	Replace lower cooling system **	
Spontaneous crystallization*	Sample not prepared correctly	Use sample according to performance data of device (page 11)	User
	Thermistor probe not aligned correctly	Align thermistor probe (page 82)	Service technician
	Elevator moved up by user	Leave the elevator in the lowered position during the measurement procedure	User

Error description	Possible Cause	Remedy	Personnel
Incorrect measurement results	Lower cooling system not aligned correctly	Align lower cooling system **	Service technician
	Incorrect measurement vessel used	Only use measurement vessels of the correct type supplied by ELITechGroup.	User
	Measurement vessel reused	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 thermistor probe.	
	Thermistor probe defective	Replace thermistor probe (page 77)	Service technician
	Thermistor probe not centered	Align thermistor probe (page 82)	
Negative measurement values	Zero point calibration performed using impure water	Repeat calibration (page 60)	User
Measurement vessel fits too loosely on thermistor probe	Incorrect measurement vessel used Measurement vessel reused	Only use measurement vessels supplied by ELITechGroup.	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 thermistor probe.	User
	Thermistor probe damaged	Replace thermistor probe (page 77)	Service technician
Fan malfunction	Fan is obstructed	Check if fan is operational and remove any foreign objects	Service technician
	Fan is defective	Replace fan **	
Fan makes loud noise	Fan is obstructed	Check if fan is operational and remove any foreign objects	
Error message: Needle stuck*	Needle bar disengaged from motor or stuck due to excessive icing or being bent	If the needle ices up excessively, switch off the device and wait for the defrosting process to complete first. Verify free movement of initiation needle (page 76)	User / Service technician
	Motor slider misaligned	See also: Motor of initiation needle turns without stopping or does not turn one full revolution.	
	Ice formed around needle preventing movement	Turn off the instrument and allow the ice to melt.	User
Micro-fuses trip when powering up device	Device voltage does not match power grid voltage	Check device voltage setting	Service technician

Error description	Possible Cause	Remedy	Personnel
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 85)	
Printer does not print	Paper roll is used up	Replace paper roll (page 86)	User
	Ribbon is empty	Replace ribbon (page 88)	
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
Cannot change lab PIN or calibration/ measurement PIN*	Repeat PIN entry does not match first entry	Repeat PIN change	Lab supervisor
Self-test failed*	A device component is faulty	Contact ELITechGroup and state the error text	User
Illegal Barcode*	Illegal character(s) in scanned barcode	Verify that the barcode only contains allowed characters (page 29)	User
User	Internal system errors	Contact ELITechGroup	User
Battery low—replace immediately*	Battery of system clock is empty	Install a new type CR2032 battery	Service technician

7.4 Resolve Errors

Replace Initiation needle

Personnel: Service technician

Safety gear:

- Disposable lab gloves

Materials:

- Allen key (SW 2.5)
- Precision key file
- Wire cutter

WARNING!

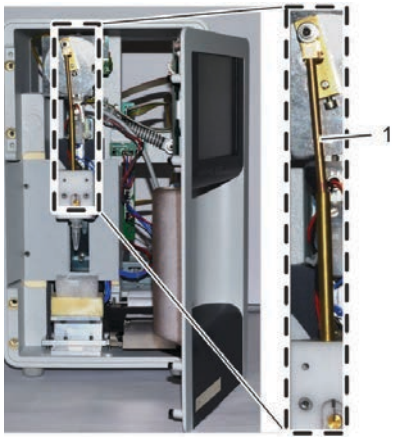
Risk of infection from sample residue!

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

- Wear lab gloves during any kind of work.

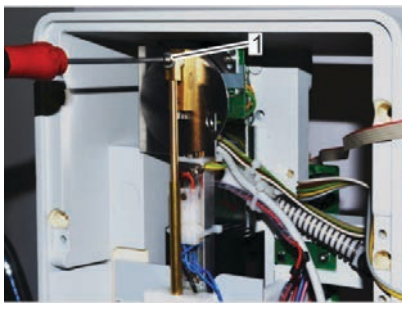
DANGER!

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 (page 93).

Figure 74 Position of initiation needle and details (#1: Initiation needle)



3. Remove mounting screw (1) of initiation needle while holding initiation needle in place.

! *NOTE!*

The mounting screw has a coating of locking paint.

Figure 75 Remove mounting screw

Figure 76 Remove initiation needle

4. Remove initiation needle from motor disk. Hold washer (1) of mounting screw in place.

! ***NOTE!***

Loose washer between initiation needle and motor disk!

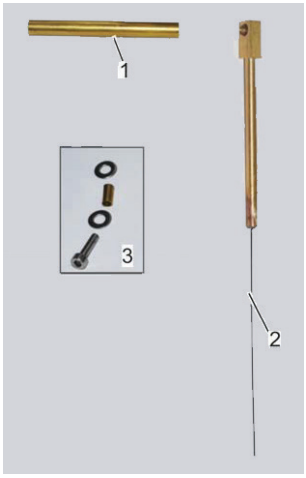


Figure 77 Initiation needle components

5. Remove guide tube (1) and fasteners (3) of initiation needle (2).

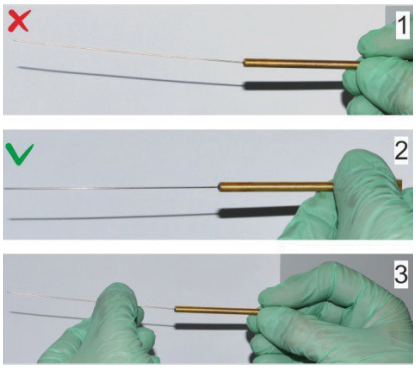
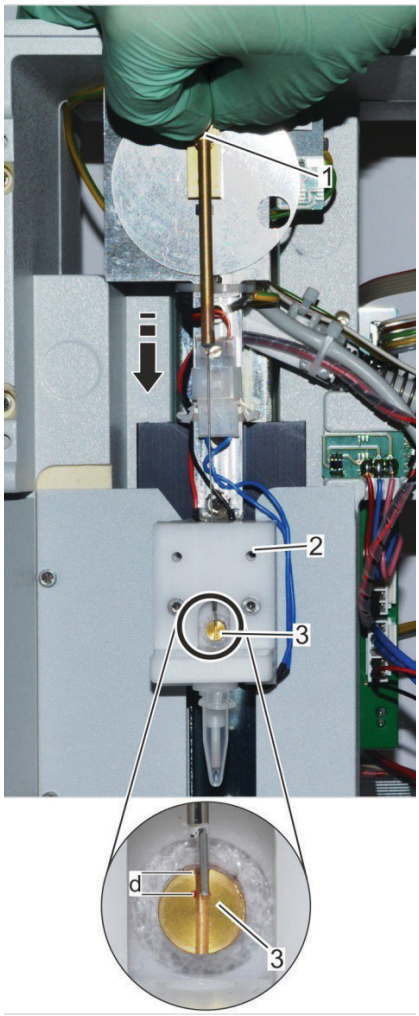


Figure 78 Straighten initiation needle

6. Make sure that the new initiation needle is as straight as possible (1&2).
   1-Incorrect orientation
   2-Correct orientation
   If necessary, bend initiation needle so it is straight (3).
7. Shorten initiation needle to correct length. Proceed as follows.



8. Align motor swipe vertically with upper dead center (1).
   ⇨ The set screw of the motor swipe points down.
9. Move initiation needle through guide tube in upper cooling system (2) onto cooling pin (3).
10. Bolt new needle to motor disk.
11. Align initiation needle with motor swipe and cooling pin.
    The needle end should be located approx. 2mm below the lower edge of the cooling pin (3) (d=2mm).
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.

Figure 79 Adjust length of initiation needle

Figure 80 Install initiation needle

14. Fit initiation needle to motor disk. Assemble fasteners as follows (Reference “Figure 80 Install initiation needle”dle”):
    A. Push washer (2) and fastening tube (3) onto mounting screw (1).
    B. Push mounting screw with washer and fastening screw through head of initiation needle (4).
    C. Secure washer (5) to mounting screw.
    D. Push guide tube (6) onto initiation needle.
    E. Secure initiation needle to motor disk using mounting screw (1).

15. Turn motor disk with attached initiation needle clockwise to check initiation needle for free movement.
    If needle gets jammed, detach needle and check if it is bent. (page 74).
16. Install device front panel (page 96).
17. Power up device on rear side using on/off switch.

Figure 81 Check free movement of initiation needle

18. Verify free movement of initiation needle automatically.
    Open the menu for adjusting the initiation needle (Start menu ➔ Lab Options ➔ Maintenance ➔ Adjust Needle).

CAUTION!

Risk of injury from initiation needle!

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

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

19. Tap Move Needle to test the free movement.
    The needle turns by one revolution.
    Tap Back to exit the menu.

Figure 82 Move needle

Replace the thermistor probe

Personnel: Service technician

Safety gear:

- Disposable lab gloves

Materials:

- Allen key SW 2
- Adjustment tool
- Tweezers
- Fiberglass pin (AC-200)

WARNING!

Risk of injury in case of inadequate hygiene, disinfection, and sterilization procedures!

Contact with the thermistor probe and initiation 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

Figure 83 Position measurement vessel

2. To protect thermistor, cover thermistor probe with a measurement vessel. The cover of the measurement vessel must point forward (1).

CAUTION!

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 thermistor probe.

Figure 84 Move elevator down

3. Move elevator down using handle.

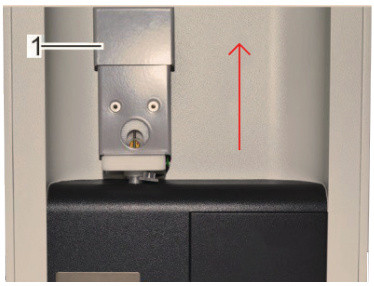


Figure 85 Move elevator cover up

4. Move elevator cover up.

⚠ **CAUTION!**

Do not leave elevator cover up when raising the elevator. Doing so can cause risk of instrument damage!

Figure 86 Remove mounting screws

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

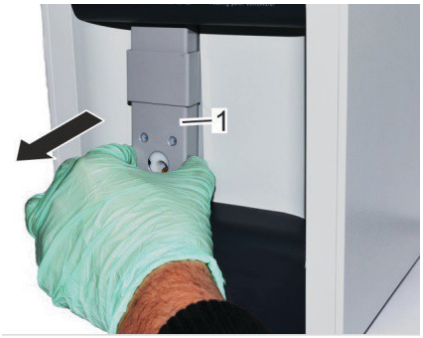


Figure 87 Remove elevator cover

6. Remove the complete elevator cover.

Figure 88 Pull connector

7. Pull connector of thermistor probe.

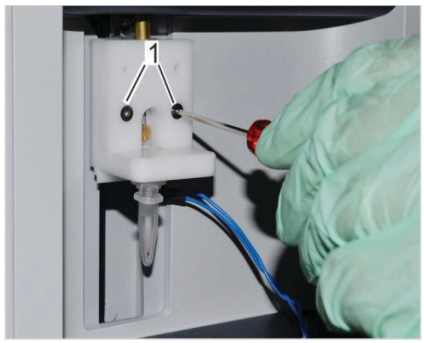


Figure 89 Remove mounting screws

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

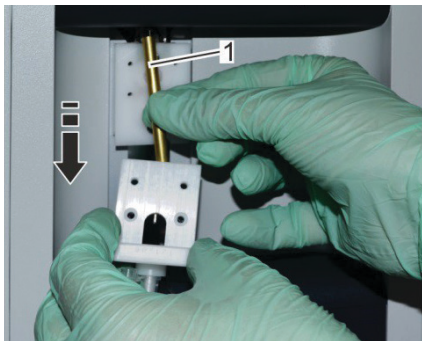


Figure 90 Remove thermistor probe

9. Remove thermistor probe with mounting plate toward the front while holding guide tube of initiation needle (1) in place.
10. If necessary, clean cooling pin.

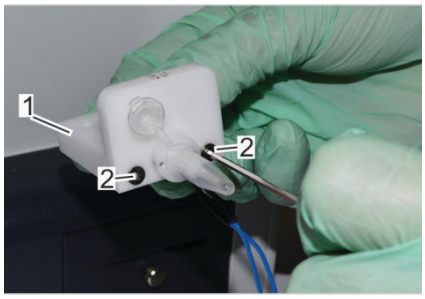


Figure 91 Remove mounting plate

11. Use Allen key (SW 2) (2) to remove thermistor probe from mounting plate (1).

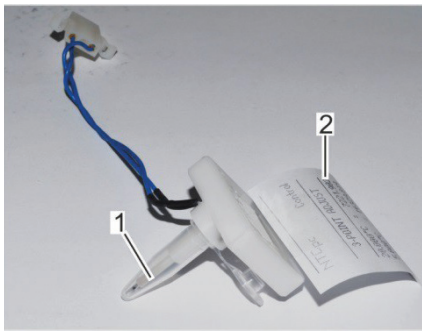


Figure 92 New thermistor probe with data sheet

12. Fit new thermistor probe to mounting plate.

    Keep the data sheet affixed to the thermistor probe (2) in the vicinity of the device.

    To protect thermistor, cover thermistor probe with a measurement vessel (1). The cover of the measurement vessel must point forward.

⚠ ***CAUTION!***

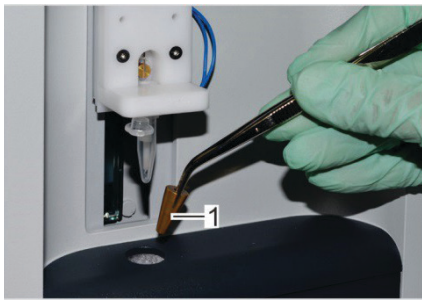
Risk of thermistor damage due to loose position of measurement vessel!

Resistance is felt when sliding on measurement vessel.

When the measurement vessel clicks into place, it is securely positioned on the thermistor probe.

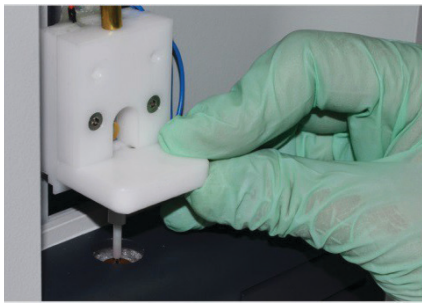
13. Push guide tube onto initiation needle and pass needle through stainless steel tube of mounting plate.

Align the thermistor probe



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

Figure 93 Install adjustment tool



17. Align thermistor probe. Proceed as follows:
    Push thermistor probe **just above** adjustment tool.
18. Position thermistor probe on XY plane so that thermistor is perpendicular to center of hole of adjustment tool (“Figure 95 Thermistor probe (A) Z axis and (B) XY plane”).
19. Tighten the 2 mounting screws on the aligned thermistor probe.

Figure 94 Align the thermistor probe

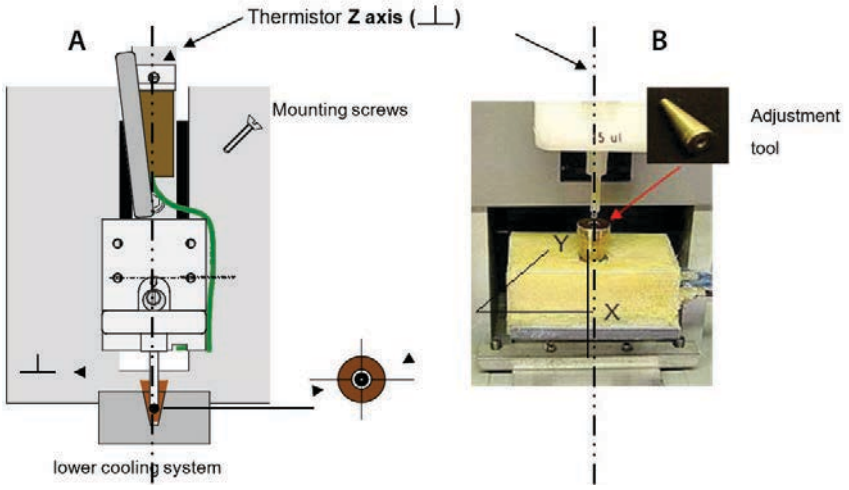


Figure 95 Thermistor probe (A) Z axis and (B) XY plane

Install elevator cover

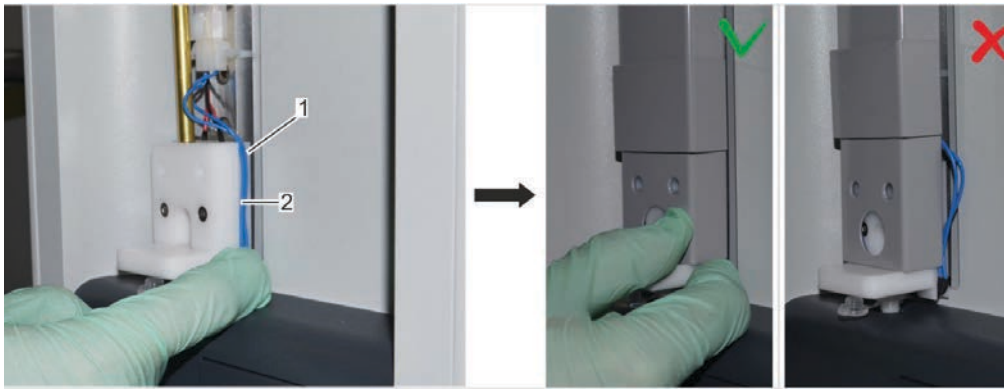


Figure 96 Elevator cover with correct cable routing

⚠ ***CAUTION!***

Risk of cable break!

Figure 97 Tighten mounting screws

20. Place cable (1 Above) on thermistor probe in cable guide (2 Above) and install elevator cover on device.
21. Bolt elevator cover to elevator using the 2 mounting screws (1 Left).
    ⇨ The thermistor probe is now installed.

Clean cooling pin

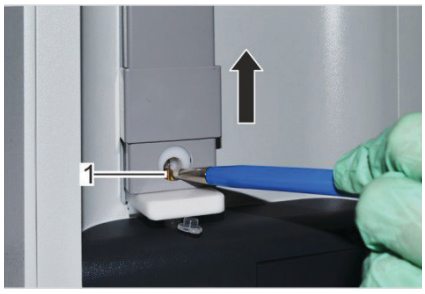


Figure 98 Clean cooling pin

22. Clean cooling pin (1) using a fiberglass pin (AC-200). For this purpose, move elevator cover up.
23. Power up device on rear side using on/off switch.
24. Calibrate the new thermistor probe.

    For this purpose, open the Replace Probe menu (*Start menu* ➔ *Lab Options* ➔ *Maintenance* ➔ *Replace Probe*).
25. Move elevator cover down.

Figure 99 Calibrate thermistor probe

26. 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 (↯ “Calibrate device” on page 60). Use distilled water and the two calibration standards with 300 and 850 mOsm/kg.

Align the Thermistor probe

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 thermistor probe and initiation 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

2. To protect thermistor, cover thermistor probe with a measurement vessel. The cover of the measurement vessel must point forward (1).

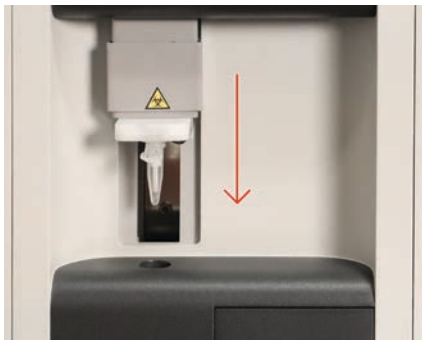
CAUTION!

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 thermistor probe.

Figure 100 Position measurement vessel



3. Move elevator down using handle.

Figure 101 Move elevator down

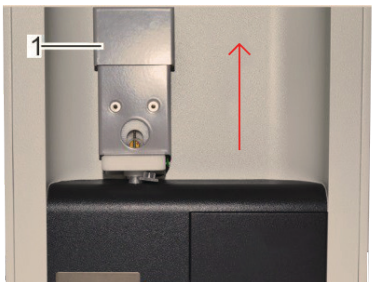


Figure 102 Move elevator cover up

4. Move elevator cover up.

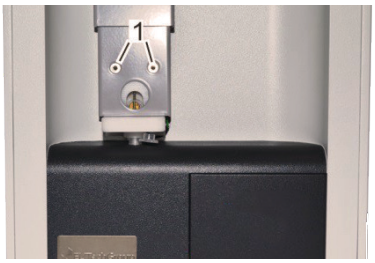


Figure 103 Remove mounting screws

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

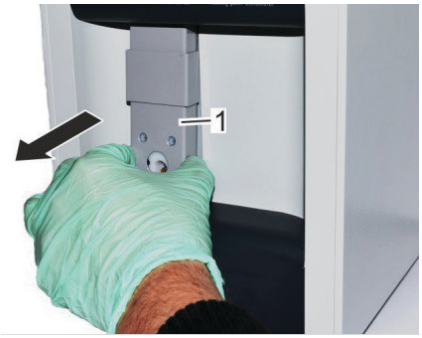


Figure 104 Remove elevator cover

6. Remove the complete elevator cover.
7. Move the elevator up using handle.

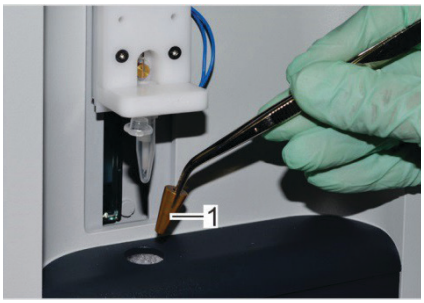


Figure 105 Install adjustment tool

8. Loosen the 2 mounting screws only slightly.
   The thermistor probe must be aligned using the adjustment tool.
9. Install adjustment tool (1) in opening of lower cooling system using tweezers.
10. Remove measurement vessel from thermistor probe.

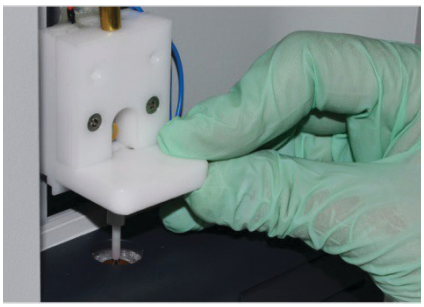


Figure 106 Align the thermistor probe

11. Align thermistor probe. Proceed as follows:
    Push thermistor probe **just above** adjustment tool.
12. Position thermistor probe on XY plane so that thermistor is perpendicular to center of hole of adjustment tool (“Figure 107 Thermistor probe (A) Z axis and (B) XY plane”).
13. Tighten the 2 mounting screws on the aligned thermistor probe.

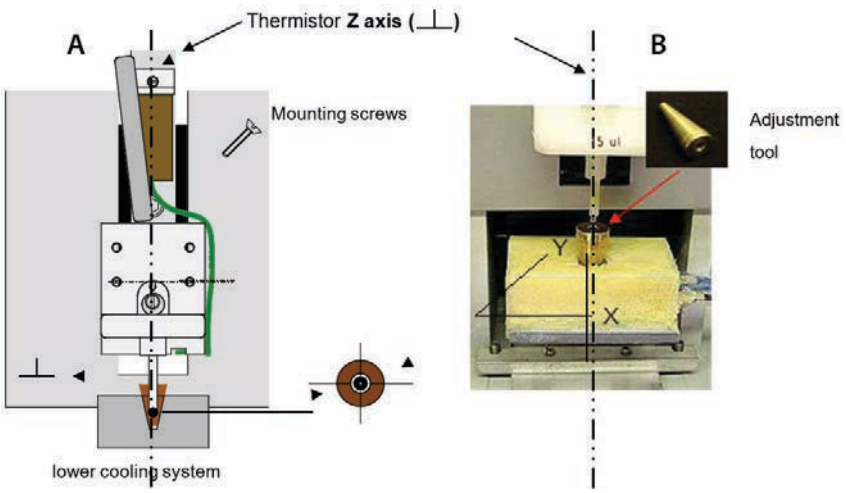


Figure 107 Thermistor probe (A) Z axis and (B) XY plane

Install elevator cover

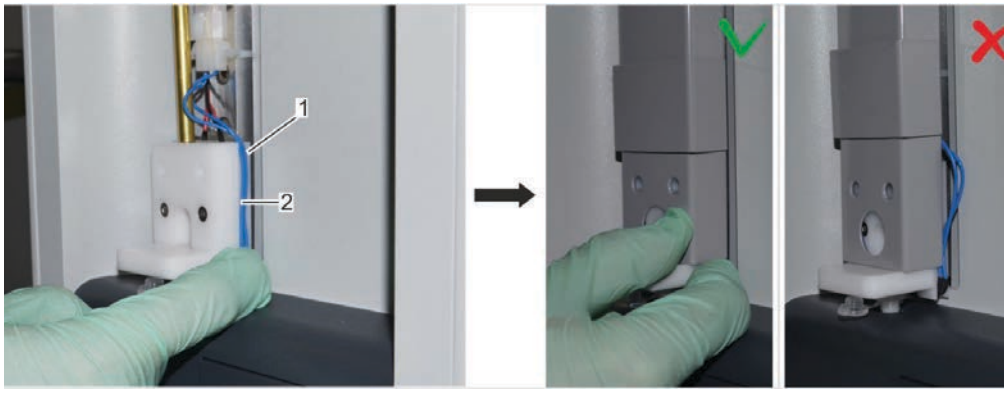


Figure 108 Elevator cover with correct cable routing

⚠ ***CAUTION!***

Risk of cable break!

14. Place cable (1 Above) on thermistor probe in cable guide (2 Above) and install elevator cover on device.
15. Bolt elevator cover to elevator using the 2 mounting screws (1).
    ⇨ The thermistor probe is now aligned.
16. Move elevator cover down.

Figure 109 Tighten mounting screws

❗ ***NOTE!***

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

For this purpose, open the Replace Probe menu (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.

Replace micro-fuses

Safety gear:

- Disposable lab gloves

Materials:

- Flat blade screwdriver
- Micro-fuses (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.

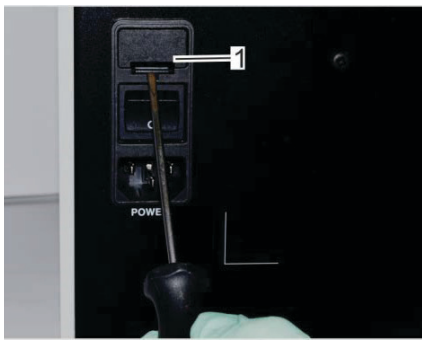


Figure 110 Open micro-fuse cover

2. Open cover (1) using a flat blade screwdriver.
3. Remove micro-fuse attachment.

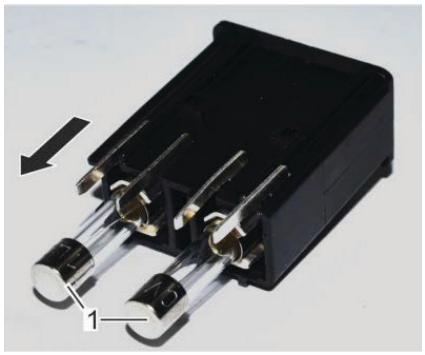


Figure 111 Remove micro-fuses

4. Remove micro-fuses (1) from attachment.

⚠ CAUTION!

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.

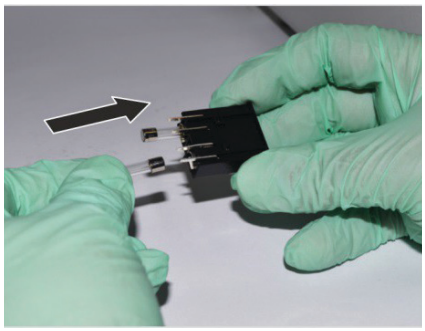


Figure 112 Install micro-fuses

5. Push the micro-fuses included with the delivery into the attachment.

Clean cooling clamp

Personnel: Service technician

Safety gear:

- Disposable lab gloves

Materials:

- Fine sandpaper

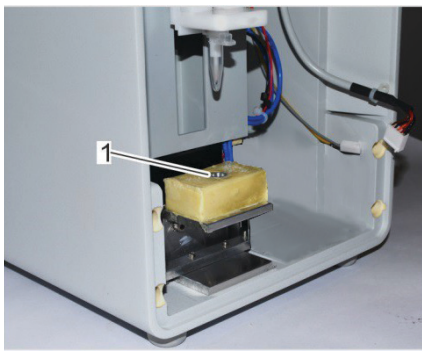


Figure 113 Clean cooling clamp

1. Power down device on rear side using on/off switch.
2. Remove device front panel (“Remove device front panel” on page 93).
3. Clean cooling clamp (1) on lower cooling system using sandpaper.
4. Install device front panel (“8.4 Install device front panel” on page 96).

Replace printer paper (Models 6000P / 6000SP only)

Personnel: User

Safety gear:

- Disposable lab gloves

Materials:

- 1 Paper roll

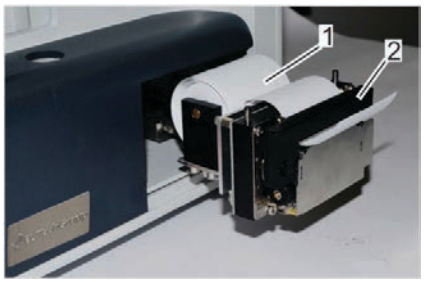


Figure 114 Printer (pulled out)

1. Power down device on rear side using on/off switch.
   1-Paper roll
   2-Ribbon

Figure 115 Pull out printer

2. Pull out printer.

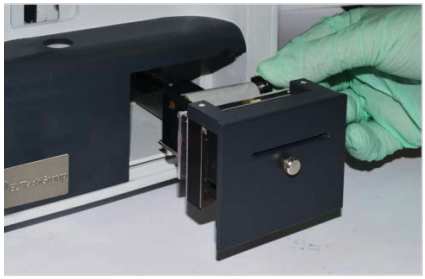
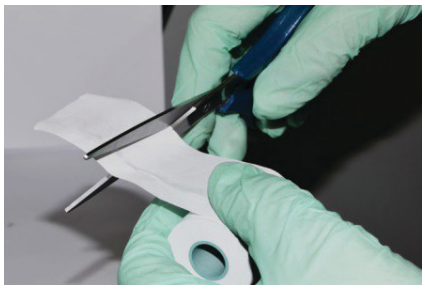


Figure 116 Turn knurled screw

3. Turn knurled screw (1) counter-clockwise.
4. Remove empty paper roll from holder and dispose.



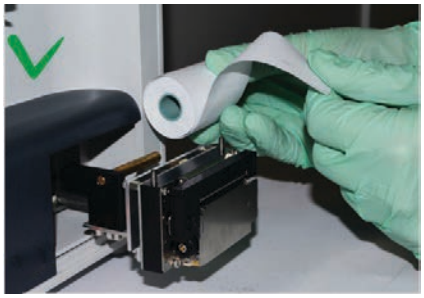


Figure 117 Install Paper Roll

5. Cut off beginning of new paper roll and push onto holder.
   Pay attention to correct feed direction of paper.
6. Position knurled screw and tighten by turning clockwise.
7. Power up device on rear side using on/off switch.

Figure 118 Activate paper feed

8. On the Start menu, select Settings ➔ Printer.
   Tap Paper Feed.
   The paper feed of the printer is activated briefly. (Fig. 121).
   Tap Back to exit the menu.

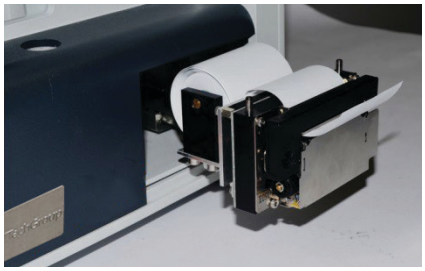


Figure 119 Paper feed

9. Replace printer cover and push printer into casing.

Replace printer ribbon (Models 6000P / 6000SP only)

Personnel: User

Safety gear:

- Disposable lab gloves

Materials:

- 1 Paper roll

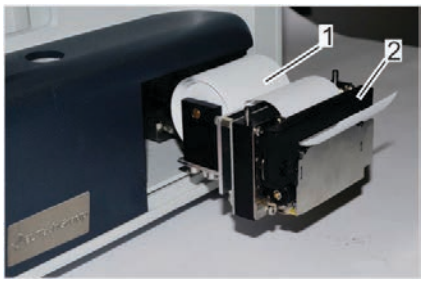


Figure 120 Printer (pulled out)

1. Power down device on rear side using on/off switch.
   1-Paper roll
   2-Ribbon

Figure 121 Pull out printer

2. Pull out printer.

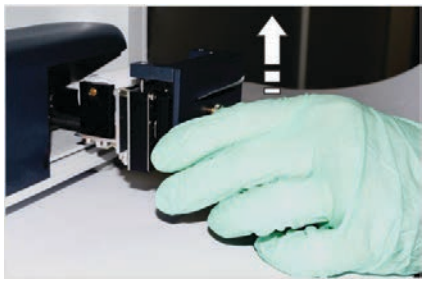


Figure 122 Remove printer cover

3. Remove printer cover.

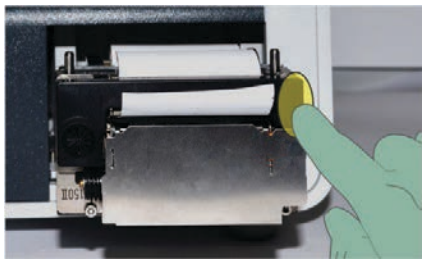


Figure 123 Push out ribbon

4. Push on Push marking on front side of ribbon.
   ⇨ The ribbon is released.
5. Remove the released ribbon.

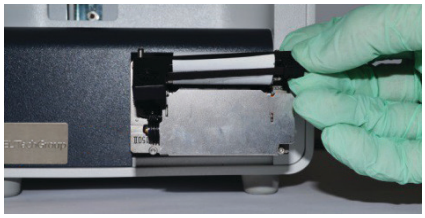


Figure 124 Feed printer paper

6. Feed printer paper through ribbon.
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.

7.5 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:

Figure 125 Reset to Default Settings

1. From the Start menu, select Settings ➔ Lab Options ➔ Maintenance ➔ Default Settings.
2. Tap Reset to Default Settings.
3. Configure the user preferences.
   “6.3 Modify user preferences” on page 53.

   Resetting the device will also purge all existing calibration data.
   Before performing any measurements on the device following the reset, recalibration is mandatory.
   “Figure 107 Thermistor probe (A) Z axis and (B) XY plane” on page 84.

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 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.
- ELITechGroup recommends regular cleaning of the device with water and cleaning-enhancing additives (e.g. detergents or enzymatic products) using the wet wipe or spray wipe method..

8.2 Routine maintenance

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 (“Manufacturer contact information” on page 5).

Interval	Service activity	Personnel
Daily (before use)	Check reliability of measurements “Check reliability of measurements” on page 99	User
Monthly	Check elevator support for ease of movement and lubricate if necessary “8.3 Remove device front panel” on page 93	User
	Perform visual inspection of device “8.6 Perform visual inspection of device” on page 98	User
Yearly	Safety Checks according to relevant national accident prevention guidelines	Lab supervisor
Yearly	All over maintenance	Lab supervisor

8.3 Remove device front panel

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 thermistor probe with a measurement vessel. The cover of the measurement vessel must point forward.

Figure 126 Position measurement vessel

⚠ ***CAUTION!***

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 thermistor probe.

3. Move elevator down.

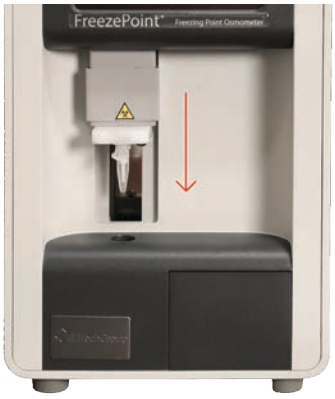
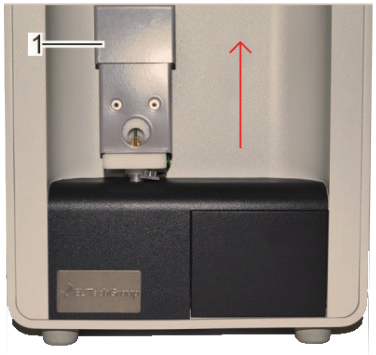


Figure 127 Move elevator down



4. Move elevator cover up (1).

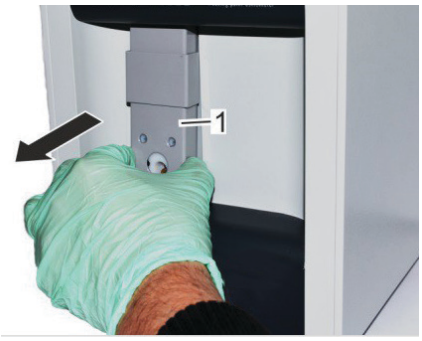
⚠ ***CAUTION!***

Do not leave elevator cover up when raising the elevator. Doing so can cause risk of instrument damage!

Figure 128 Move elevator cover up

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

Figure 129 Remove mounting screws

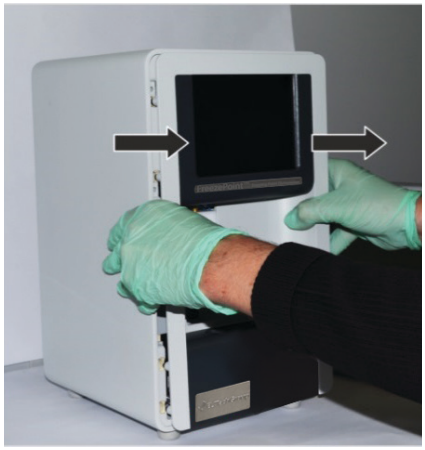


6. Remove complete elevator cover (1).

Figure 130 Remove elevator cover

7. Pull out printer from device. (Model 6000P/Model 6000SP only)

Figure 131 Pull out printer



8. Remove device front panel by pulling forward. The device front panel is secured to the housing by magnets.

CAUTION!

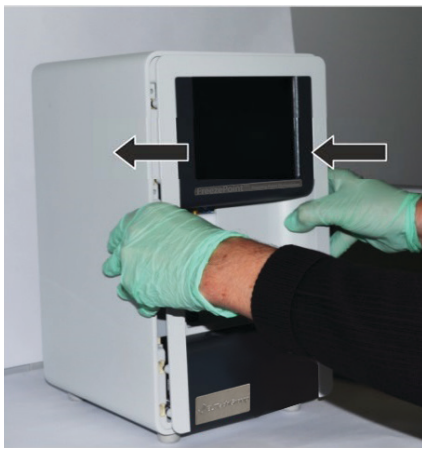
Risk of damage to cables and connectors!

Figure 132 Remove device front panel

9. Carefully place device front panel on its right side.
   ⇨The device front panel is now removed.

Figure 133 Device front panel open

8.4 Install device front panel



1. Install device front panel on device and push into place.
2. Pull out printer from device using handle. (Model 6000P/Model 6000SP only)
3. Install printer cover on printer and push down. (Model 6000P/Model 6000SP only)
   ⇨ The printer cover is now secured.
4. Push printer back into device. (Model 6000P/Model 6000SP only)

Figure 134 Install device front panel

Figure 135 Elevator cover with correct cable routing

1- Cable

2- Cable guide on thermistor probe

✓ Correct cable routing

✗ Incorrect cable routing

⚠ ***CAUTION!***

Risk of cable break!

5. Route cables on thermistor probe through cable guide (2) and install elevator cover on device.
   Pay attention to correct cable routing.

6. Bolt elevator cover to elevator using the 2 mounting screws (1).
   ⇨ The device front panel is now installed.

⚠ ***CAUTION!***

Do not leave elevator cover up when raising the elevator. Doing so can cause risk of instrument damage

Figure 136 Tighten mounting screws

8.5 Lubricate elevator

Personnel: User

Safety gear:

- Disposable lab gloves

Materials:

- Silicone spray

⚠ ***CAUTION!***

Risk of property damage due to wrong lubricant!

The use of lubricating grease can damage the elevator guide.

- Only use silicone spray as lubricant.

Figure 137 Location of elevator guide

1. Power down device on rear side using on/off switch.
2. Remove device front panel (“Remove device front panel” on page 93).

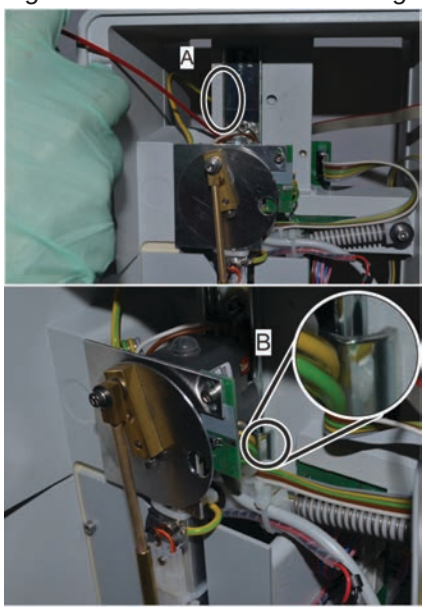


Figure 138 Lubricate elevator guide

3. Lubricate elevator guide on left (A) and right side (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 (A) on the left side of the elevator guide and move the elevator up and down multiple times.

4. Install device front panel (“8.4 Install device front panel” on page 96).

8.6 Perform visual inspection of device

Personnel: User

Safety gear:

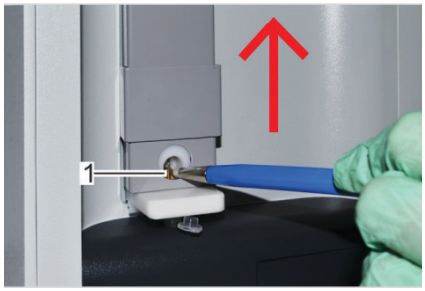
- Disposable lab gloves

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.
2. Check if foreign objects, such as measurement vessels, are located in the openings of the device.

Figure 139 Inspect device for foreign objects



3. Clean cooling pin (1) using the fiberglass pin. For this purpose, move elevator cover up.
4. Wipe off dirt and dust from housing using a soft cloth.
5. Move elevator cover down.

Figure 140 Clean cooling pin

8.7 Check reliability of measurements

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

Sample test protocol measurement check

Mechanical check: Calibration/verification

CAL / mOsmol/kg Sample / mOsmol	ZERO	CAL1	CAL2	REF1	REF2
	Pure Water				
Sample 1					
Sample 2					
Sample 3					
Sample 4					
Sample 5					
Sample 6					
Sample 7					
Sample 8					
Sample 9					
Sample 10					
Statistics					
Mean Value *(mOsmol/kg)*					
SD *(mOsmol/kg)*					
CV (%)					
Record expected range					
Consistent with acceptance criteria? (Yes/No)					

Is the osmolality within limits? ☐ ***yes*** ☐ ***no***

Thermistor no. .....

Responsible: …… (Name) …….. (Date) ……..……..

Note: ……..

(“6.5 Calibrate device” on page 60)

Section 9: 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

WARNING!

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.

- 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.

Section 10: Specifications

10.1 Dimensions

Specification	Value	Unit
Weight	14.3 (6.5)	lbs (kg)
Width	8.1 (205)	inch (mm)
Depth	8.7 (220)	inch (mm)
Height	14.2 (360)	inch (mm)

10.2 Performance parameters

Instrument Specifications	
Measuring range	0 to approx. 3000 mOsmol/kg H_2O
Resolution	1 mOsmol/kg over the entire measuring range
Temperature Effects	Less than 1 mOsmol/kg per 5°C (9°F) ambient temperature change

Precision (within run repeatability)

Models 6000 & 6000P	
Sample Volume	**Repeatability**
0 to ≤ 400 mOsmol/kg	SD ≤ 4 mOsmol/kg
> 400 to ≤ 1500 mOsmol/kg	CV ≤ 1%
> 1500 to ≤ 3000 mOsmol/kg	CV ≤ 2%

Models 6000S & 6000SP	
Range	**Repeatability**
0 to ≤ 400 mOsmol/kg	SD ≤ 2 mOsmol/kg
> 400 to ≤ 1500 mOsmol/kg	CV ≤ 0.5%
> 1500 to ≤ 3000 mOsmol/kg	CV ≤ 1%

SD: standard deviation, CV: coefficient of variation (= relative SD)

Section 10: Specifications

Accuracy (Linearity)*

2-point calibration

Models 6000 & 6000P (15µl) and 6000S & 6000SP (50µl)		
Calibrated Range / mOsmol/kg	0 - 850 mOsmol/kg Cal. (0/850)	0 - 2000 mOsmol/kg Cal. (0/2000)
0 to ≤ 400	≤ ±4 mOsmol/kg	≤ ±10 mOsmol/kg
> 400 to ≤ 1000	≤ ±1.0%	≤ ±3.0%
> 1000 to ≤ 2000	**	≤ ±1.5%

3-point calibration

Models 6000 & 6000P (15µl)		
Calibrated Range / mOsmol/kg	0 - 1000 mOsmol/kg Cal. (0/300/850)	0 - 2000 mOsmol/kg Cal. (0/850/2000)
0 to ≤ 400	≤ ±4 mOsmol/kg	≤ ±10 mOsmol/kg
> 400 to ≤ 1000	≤ ±1.0%	≤ ±3.0%
> 1000 to ≤ 2000	**	≤ ±1.5%

Models 6000S & 6000SP (50µl)		
Calibrated Range / mOsmol/kg	0 - 1000 mOsmol/kg Cal. (0/300/850)	0 - 2000 mOsmol/kg Cal. (0/850/2000)
0 to ≤ 400	≤ ±2 mOsmol/kg	≤ ±6 mOsmol/kg
> 400 to ≤ 1000	≤ ±0.5%	≤ ±1.5%
> 1000 to ≤ 2000	**	≤ ±1.0%

**Performance above 2000 mOsmol/kg dependent on selection of calibration values. For best results, it is recommended to calibrate using values near the intended measuring range. Accuracy (from nominal value, tolerances of reference and calibration solutions excluded) and precision (within run) specifications apply to ELITechGroup standards and reference solutions.*
***Measuring points in this range not recommended for indicated calibration values.*

10.3 Operating Conditions

Environment

Specification	Value	Unit
Temperature range	50-86 (10-30)	°F (°C)
Relative humidity	80 (non-condensing)	%
Maximal operating altitude	6562 (2000)	ft (m)

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
Protection class	IP21	
Protection type	I	
Degree of contamination	2	
Serial Port: RS232	2	
Serial Port: USB	1	

Interfaces

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

Printer (Model 6000P/Model 6000SP only)

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

10.4 Nameplate

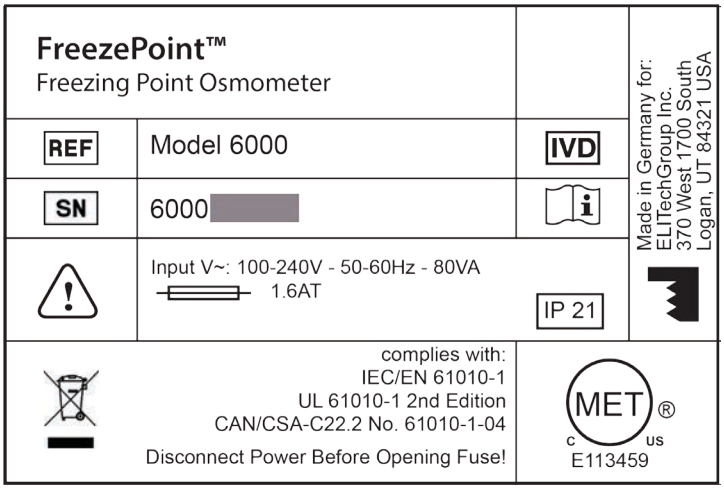


Figure 141 Nameplate

The nameplate is located at the rear of the device.

10.5 Repeatability vs Reproducibility

Repeatability	The ability of the measuring instrument to give constant results (precision) in repeated tests of the same type.
Reproducibility	The ability of the measuring instrument to give repeated results regardless of which operator performs the test (operator error)

Appendix A: Shipping the device

Personnel: User

Safety gear:

- Disposable lab gloves

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

1. Power down device using on/off switch on rear side and disconnect power plug.
2. Clean and disinfect the equipment before returning it to us.

   Warning

   Shipping the device without disinfecting according to instructions is dangerous to service personnel. You will be charged a additional fees 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.

3. Position a measurement vessel (1) on the thermistor probe.

! ***NOTE!***

The measurement vessel is securely attached to the thermistor probe when it clicks into place.

Figure 142 Position measurement vessel

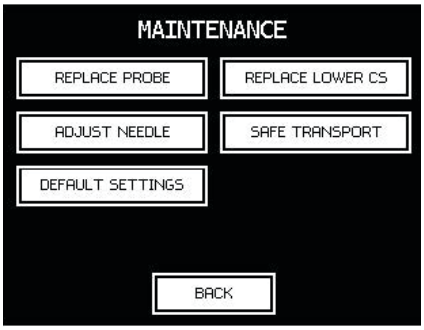


Figure 143 Maintenance menu

4. 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 pin.

Figure 144 Safe Transport menu

5. Tap Park Needle.

   Tap Back to exit the menu.

WARNING!

Risk of infection from sample residue!

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

- Wear lab gloves during any kind of work.

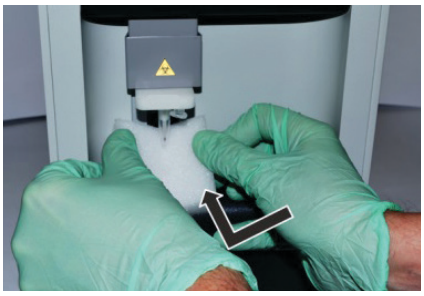


Figure 145 Position transport safety device

6. Tilt transport safety device for thermistor probe and carefully slide behind the thermistor probe.

Figure 146 Device with protective sleeve

7. Pull protective sleeve over device.

8. Ship the equipment in its original packaging. If you no longer have the original packaging, you may purchase replacement packaging from ELITechGroup.

Appendix B: Consumables, Accessories, and Replacement Parts

Accessories

Item no.	Item
SS-283	Calibration Standard, 100 mOsmol/kg, FreezePoint®
SS-284	Reference Solution, 290 mOsmol/kg, FreezePoint®
SS-276	Calibration Standard, 300 mOsmol/kg, FreezePoint®
SS-285	Calibration Standard, 500 mOsmol/kg, FreezePoint®
SS-277	Calibration Standard, 850 mOsmol/kg, FreezePoint®
SS-286	Calibration Standard, 2000 mOsmol/kg, FreezePoint®

Supplies

Item no.	Item
SS-036	Pipettor Tips (1000 ea)
SS-275	Measurement Vessels, 1000 ea., FreezePoint®
SS-279	Measurement Vessels, 100 ea., FreezePoint®
SS-281	Printer Paper, 8 rolls ea, FreezePoint® 6000P/6000SP
SS-282	Endless Ink Ribbon Cassette, FreezePoint® 6000P/6000SP
AC-199	Pipette, 15 µl
AC-201	Pipette, 50 µl
AC-192	Barcode Reader Kit

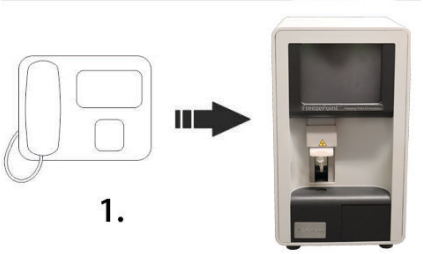
Replacement Parts

Item no.	Item
AC-198	Blow-Out Device 10 ea., FreezePoint®
AC-200	Fiberglass Pin, 1 ea., FreezePoint®
RP-548	USB Cable, FreezePoint®
RP-549	RS232 Cable, FreezePoint®
RP-550	Power Cord, US 120V, FreezePoint®
RP-546	Adjustment Tool, FreezePoint®
RP-547	Micro-Fuse, Slow-Blow 2 ea., 1.6A FreezePoint®
RP-572	Micro-Fuse, Slow-Blow 10 ea., 1.6A FreezePoint®
RP-551	Power Supply, 12V, 6.8A, FreezePoint®
RP-555	Display, FreezePoint®
RP-556	Display Board, FreezePoint®
RP-558	Upper Cooling System, FreezePoint®
RP-559	Lower Cooling System, FreezePoint®
RP-561	Initiation Needle, FreezePoint®
RP-566	Thermistor Probe, 15uL Sample Volume, FreezePoint®6000/P
RP-578	Thermistor Probe, 50uL Sample Volume, FreezePoint® 6000S/SP

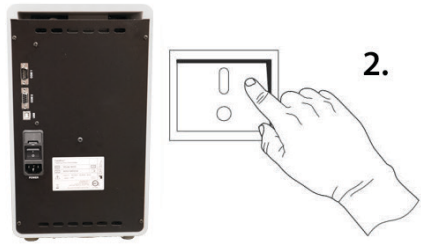
Distilled Water

Standard deionized water has been tested and has no negative effects on the calibration of the device. It is recommended to use water with a resistivity ≥ 200kΩ.

Appendix C: Contacting ELITechGroup



1. Use a telephone located close to the device.



2. Power up device.

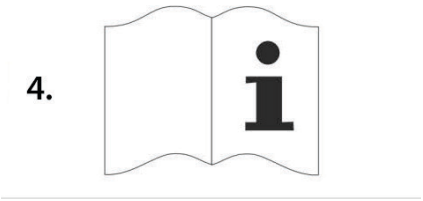
! ***NOTE!***

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.
Serial number is located on the rear of the device or under *Settings* ➔ *Info*.



4. Have the device documentation available.

Figure 147 Contact ELITechGroup

Contact info:

ELITechGroup Inc.
370 West 1700 South
Logan, UT 84321-8212 USA
TOLL Free: +1 (800) 453 2725
Phone: +1 (435) 752 6011

Fax: 1 (435) 213 2108
E-mail: info@elitechgroup.com
Web: http://www.elitechgroup.com

Appendix D: Theory of Operation

The Freezing Point Osmometer is a non-invasive in-vitro diagnostic device used to determine the osmolality of aqueous solutions. The use of the freezing point to determine osmolality is particularly suited for the fields of medicine, industry and research.

The instrument measures the total osmolality of an aqueous solution. The osmolality of a solution is defined as the number 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 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 mole of an ideal non-dissociated substance (6.023 × 1023 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:

$$\mathbf{Cosm = \Delta T / K}$$

Cosm = osmolality [Osmol/kg]

ΔT = freezing point depression [°C]

K = 1.858°C kg/Osmol (cryoscopic constant)

The 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. A sample is pipetted into a measurement vessel. The measurement vessel is placed over the thermistor probe and lowered into the lower cooling system. The sample is cooled to a defined temperature and the crystallization process is initiated by ice crystals produced in the upper cooling system. The osmolality of the unknown sample solutions is determined using the calibration values.

Appendix E: Operational Use

General operating conditions

The FreezePoint® Freezing Point Osmometer is designed exclusively for operation within closed rooms.

To ensure that the systems can be put into operation without trouble and work reliably, the installation site has to be selected so that it is free of dust, dirt, vibration and draft and without indirect heat exposure from sunlight or electric heaters.

In addition, the air inlets and outlets on the system must be unobstructed so that heat and moisture produced by the cooling systems can be removed.

Environment

Specification	Value	Unit
Temperature range	50-86 (10-30)	°F (°C)
Relative humidity	80 (non-condensing)	%
Maximal operating altitude	6562 (2000)	ft (m)

Operational use

The FreezePoint® Freezing Point Osmometer is designed for normal lab analytics with approx. 2500 operating hours per year.

For continuous use in process analytics with up to 8000 operating hours per year, the use of a redundant measuring system for preventive maintenance management is advisable to ensure long life and faultless operation of the systems.

Useful life

Specification	Value	Unit
Operational use	2500	Hours/year
Operating time/overall system	5	years

Operation

The systems feature an advanced electronic measuring system with rules-based cooling systems for the production of ice crystals (required to trigger the crystallization of the sample) and for undercooling the sample solution. Naturally, two key factors affect the measuring procedure: the ambient temperature and humidity.

What effects can conceivably or expectedly occur on the upper and lower cooling systems and what do they mean for measuring operation?

Generally, the systems can be used for continuous or shift operation (24/7). No safety-relevant restrictions exist. However, the metrological effects listed in the table can occur. They prohibit continuous operation and instead require the system to be shut off so that the upper cooling system can defrost. We strongly advise against accelerating the defrosting procedure using a hairdryer or another heat source, both during operation or while shut off. Any residue present in the upper elevator unit could collect and hinder the subsequent formation of ice crystals or block the rotation of the initiation needle. Another conceivable scenario is a shortened overall service life of the upper cooling system.

For reasons of technical work safety and in order not to prematurely shorten the expected service life of the Peltier elements used, we generally recommend shutting the systems off after use. If this is not possible due to the measuring routine, **the system must be shut off at least once every 6 hours for approximately 30 minutes** to prevent the excess formation of ice crystals on the upper cooling system or moisture in the lower cooling system and a possible contamination of the measuring system.

Lower cooling system

Temp./humidity range	Effect on measurement system	Effect on measurement/ sample	Remedy	System operation
10–19°C/10–44% or artificially heated/ climate controlled rooms	none			
20–24°C/45–55%	none			
25–30°C/80%	Excess collection of condensate from the environment, from the sample or due to ice or water droplets dropping down from the upper cooling system	Sample not centered in lower cooling system, which can lead to erroneous or non-reproducible measuring results. Extended cooling procedure delays measuring procedure.	Regularly remove condensate using blow-out device or cotton swab.	No effect

Upper cooling system

Temp./humidity range	Effect on measurement system	Effect on measurement/ sample	Remedy	System operation
10–19°C/10–44% or artificially heated/ climate-controlled rooms	No/insufficient formation of ice crystals	Measurement aborts with message “No crystallization”. Unable to perform serial measurements due to insufficient reformation of ice crystals between measurements.	Open cover of upper cooling system (elevator cover) until you can see ice crystals forming. Breathe on it to add moisture as needed. Repeat procedure at regular intervals.	Shut off once every 6h
20–24°C/45–55%				Shut off once every 6h
25–30°C/80%	Excess formation of ice crystals, possible ice buildup.	Measurement aborts with message “No crystallization”. Stuck ice can block initiation needle. Fluctuating or non-reproducible measuring results, indicating excess ice crystals in the sample.	Seal opening on upper cooling system using tape strip. Regularly remove ice crystals and water droplets using blow-out device.	Shut off every 4-6h

Appendix E: Operational Use

Defrosting procedure

To melt excess ice on the upper cooling system, shut off system.

Place unused measurement vessel onto thermistor probe to collect condensate.

Remove excess water droplets or moisture on upper cooling system using blow-out device. Use cotton swab as needed.

Clean lower cooling system using cotton swab or paper towel.

If no measurement vessel is used for defrosting procedure, make sure to collect condensate using paper towel to prevent it from entering the system.

Depending on the amount of ice buildup on the upper cooling system, the complete defrosting procedure can take up to 30 minutes. This must be taken into account when planning serial measurements.

Safety Testing

Summary of testing:

The product has been tested according to the requirements of:

- IEC 61010-1 :2010, AMD1:2016 (DEKRA report no. 2246514.51A)
- IEC 61010-2-101:2018 (DEKRA report no. 2246514.51B)
- US national differences according UL 61010-1 (3rd ed); Am1 (DEKRA report no.2246514.51C)
- Canada national differences according CAN/CSA C22.2 No. 61010-1+Amd1 (DEKRA report no. 2246514.51D); CAN/CSA C22.2 No. 61010-2-101:15 (DEKRA report no. 2246514.51E)

EMC Tests Fulfilled (EMC TestHaus Dr. Schreiber GmbH, Siegen)

CISPR 11 cl. B:2009 + A1:2010	Emission
IEC 61326-2-6:2012	Immunity
EN 55011 cl. B:2009 + A1:2010	Emission
EN 61326-2-6:2013	Immunity
EN 61000-3-2:2014	Current Harmonics
EN 61000-3-3:2013	Flicker
EN 55032 cl. B:2012	Emission
FCC CFR 47 part 15 subpart B cl. B	Emission
ICES-003 cl. B:2016	Emission

Installation, Operation, and Performance Qualification

Product Information

FreezePoint® Model Number: ☐ ***6000*** ☐ ***6000P*** ☐ ***6000S*** ☐ ***6000SP***

Serial Number: .....

Name of person performing IQOQPQ: .....

Table of Contents

Urgent Safety Information

⚠ **Due to necessary precaution to prevent damage to the measuring system, the initiation needle is in lowered position behind the thermistor probe for transport purposes.**

Do not touch the measuring system – especially the thermistor probe (fitted with or without a measuring vessel) until unit is powered up and self-initialization.

You may risk an injury at the needle.

This may also happen at power loss during measurement. In this case the device may be left in an unknown state and you must follow above instruction.

COMMENTS

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Date .....

Completed by .....

Date .....

Verified by .....

Installation, Operation, and Performance Qualification

Scope

This protocol defines the methods and documentation to be used for evaluating the instrument according to the manufacturer's specifications and intended use. Successful completion of this protocol will verify that the instrumentation operates in accordance with intended usage.

Installation checks will be performed to verify that the Instrumentation has been installed in a proper environmental setting, with proper connections, utilities, and reagents.

Instrument calibration will be verified.

The instrument system will be tested for proper operation of mechanical systems, menu functionality and result reporting (display, serial output, and printer).

Performance claims will be verified (precision (within run repeatability), accuracy (linearity) and stability).

Certification of Conformance will be included.

Functional testing of instrumentation (where appropriate) will be performed to ensure system integrity.

Trained and well informed personnel will perform qualification studies.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and the appropriate course of action determined. All data will be documented.

Instructions

This document is to be completed at the time the instrument is unpacked and set up for operation.

The individual in charge at the end user's location should check the instrument system and perform the various tests as outlined in this Installation, Operation, and Performance Qualification section. Each result will be noted and dated in this section.

All deviations from normal specifications, including any problems with installation, should be noted under COMMENTS. All solutions to such problems will also be noted in the COMMENTS section.

Installation Qualification (IQ) Verification

Item	Date Verified
Instrument and Accessories identified.	.....
Manufacturer's Specifications are included (User's Manual).	.....
Consumables listed.	.....
Purchase Order Sheet.	.....
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COMMENTS

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Date .....

Completed by .....

Date .....

Verified by .....

Supplied Documents		Date Verified
User's Manual	Edition:	.....
Package Insert (Standards)	Comment:	.....

Accessories and Consumables		Date Verified
"Appendix B: Consumables, Accessories, and Replacement Parts" on page 107	Comment:	.....

Certificates	Notes
ELITechGroup provides the following certificates on demand.	
SDS	ELITechGroup Calibration Standards and Reference Solutions (https://ebs.elitechgroup.com/SDS/)
Declaration of Conformity	FreezePoint® Model 6000 / 6000P / 6000S / 6000SP

Integrity		Date Verified
In case of transport damage, especially with the thermistor probe, contact promptly your distributor or the manufacturer	Comment:	.....

COMMENTS

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Date .....

Completed by .....

Date .....

Verified by .....

Provision of Certification / Change Control Procedure

CE compliance requires that the unit is installed and operated in the manner described in the User's Manual. Any departure from the specifications or independent modifications of the unit without the express written consent of ELITechGroup may result in a violation of CE requirements. Such actions invalidate the compliance statement and transfer responsibility to the originator of said actions.

Maintenance

The instrumentation listed in this document will be placed under the control of the purchasing institution with the respect to proper maintenance procedures.

The instrumentation can be easily serviced by individuals whose training or skills provide them with the necessary practical experience. The necessary qualifications may be governed by local or national regulations.

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Date .....

Completed by .....

Date .....

Verified by .....

Installation of the Instrument

Instrument Description

The ELITechGroup FreezePoint® Freezing Point Osmometer is a non-invasive in-vitro diagnostic system according to directive 98/79/EC for the measurement of the total osmolality of aqueous solutions such as human blood, urine, semen, drip solutions and other samples.

It provides a measure of the contribution of the various solutes that are present in a solution to the overall osmotic pressure of the solution.

Instrument Identification		Date Verified
Manufacturer	ELITechGroup Inc.	
Model	.....	.....
Serial Number	.....	.....
Thermistor probe No	.....	.....
Power	100-240 VAC	
Frequency	50-60 Hz	
Power Consumption	80 VA (max)	
Dimension	W 8.1 in (205 mm) x D 8.7 in (220mm) x H 14.2 in (360 mm)	
Weight (Without Printer)	14.3 lbs (6.5 kg)	

Firmware Verification

A microcontroller monitors the unit's functions based on the program flow. The assembly code has been validated prior to the release. Documentation, including source code, will be held for at least 10 years from code release in design history files (DHF). No firmware is offered separately with the instrument.

Firmware			
Display	TEC	Interface	Printer (If Applicable)
Ver:	Ver:	Ver:	Ver: .....

COMMENTS

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Date .....

Completed by .....

Date .....

Verified by .....

Ancillary Information

The following information serves for your safety and the faultless functioning of your Osmometer.

	Comment	Date Verified
While installing the device, the safety-regulations-control is carried out according to the local or on-site regulations.	.....	.....
Is the transport aid for the thermistor probe removed? Caution: remove the transport aid very carefully to avoid damage of the thermistor probe!	.....	.....
Has the thermistor probe been aligned? (Alignment is necessary after shipment)	.....	.....
Does the power supply meet local requirements and instrument specifications?	.....	.....
Does the mains voltage correspond to the one indicated on the back side mounted device label?	.....	.....
Is the power cord properly attached to the rear power terminal and main power supply?	.....	.....
Is the instrument placed away from direct sunlight?	.....	.....
Is the instrument placed away from a heater and air conditioning units?	.....	.....
Is the fan-discharge duct at the device ground free of objects?	.....	.....
RS232 / USB Hint: Only one connection at a time is possible. Is the RS232- or USB cable properly mounted to the Osmometer's COM2 or USB port and the COM or USB port of the computer according to software settings?	.....	.....
Barcode Reader (Optional) Is the Barcode reader properly mounted to the Osmometer's COM1 port?	.....	.....
Printer (Models 6000P / 6000SP) Is enough print-out paper in the printer? Is the paper properly inserted?	.....	.....

COMMENTS

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Date .....

Completed by .....

Date .....

Verified by .....

Device Environment

Environment	Comment	Date Verified
Is a suitable environment given?		
Criteria: • Indoor use • Humidity 80% non-condensing • Ambient temperature 10 – 30°C / 50 – 86 °F • Placed vibration-free • Dust-free	.....	.....

COMMENTS

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Date .....

Completed by .....

Date .....

Verified by .....

Operation (OQ) & Performance Qualification (PQ)

The IQ has to be completed before starting the Operation Qualification. In this phase the process parameters should be challenged to assure that they will result in a product that meets all defined requirements under all anticipated conditions of manufacturing, i.e., worst case testing. During routine production and process control, it is desirable to measure process parameters and/or product characteristics to allow the adjustment of the manufacturing process at various action level(s) and maintain a state of control. These action levels should be evaluated, established and documented during process validation to determine the robustness of the process and to proof the ability to avoid approaching "worst case conditions."

Operation Qualification	Comment	Date Verified
Power ON Functional Tests Is the Display showing the Start Menu?	.....	.....
Initialization phase After pressing the button *measurement* did the screen show a progress bar for producing ice crystals? Progress bar needs less than 3 min to be ready?	.....	.....
Upper Cooling System Raise the cover of the upper cooling system. Is there some frost visible on the cooling pin? Lower the cover of the upper cooling system.	.....	.....
Elevator Raise the elevator up and down. Can the elevator be moved smoothly?	.....	.....
Moved parts Does the fan run free of disturbance?	.....	.....
Motor-control (with initiation needle) Raise the cover of the upper cooling system. Go to Start Menu ➔ Settings ➔ Lab Options ➔ Maintenance ➔ Adjust Needle and follow instructions Did the initiation needle rotate in the cooling pin correctly?	.....	.....

COMMENTS

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Date .....

Completed by .....

Date .....

Verified by .....

Connected to RS232 / USB

	Comment	Date Verified
Device is connected to PC COM-port: USB-Port:	COM2 USB	.....
COM / USB-port specification:		
Baud rate:	9600 bits/s	
Data format:	8 data bits 1 stop bits no parity check	.....

COMMENTS

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Date .....

Completed by .....

Date .....

Verified by .....

Terminal Software / LIMS

If CSV format is selected, during start-up or when closing the menu for log format or log port selection, the device will send the following two lines:

```
FP6000;Main:VX.XX;COM:VX.X;D:VX.XX;TEC:VX.X<CR>
"batch";"sample";date;value;"dimension";"device-no";"check";"message"<CR>
```

The first one is an intro line containing version information, the second one is a header line with column titles for the next result lines.

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

Column	Description
`user`	optional user ID; only present if user login is activated
`batch`	Batch identifier in quotation marks or void if batch ID is disabled in the options (alphanumeric).
`sample`	Sample identifier in quotation marks or void if sample ID is disabled in the options (alphanumeric).
`date`	Date and time in combined ISO 8601 format (e.g. 2018-12-31T13:45).
`value`	Measurement result as integer (in mOsmol/kg) or error identifier.
`device-no`	Serial number of the device in quotation marks (alphanumeric).
`check`	MD5-Checksum
`message`	Human-readable message (always in English) in quotation marks or void.

Perform some measurements, print your received file and attach the print-out to this page to document the proper transmission.

COMMENTS

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Date .....

Completed by .....

Date .....

Verified by .....

Printer (Models 6000P / 6000SP)

Operation Qualification	Comment	Date Verified
Go to Start Menu ➔ Settings ➔ Printer Press button *Paper Feed.* Does the paper move out of the slot as long as the button is pushed?	.....	.....
Go to Start Menu ➔ Measure and measure a sample. A complete protocol for one sample should be printed.	.....	.....
Go to Start Menu ➔ Measure and press Begin Charge and measure at least two samples. Press *End Charge*. A complete protocol for the charge should be printed.	.....	.....
Is the printout legible?	.....	.....
Attach your printouts to this page to document the proper printing.		

COMMENTS

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Date .....

Completed by .....

Date .....

Verified by .....

Ancillary Information

The correct measuring vessel

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

⚠ **When the measuring vessel is placed on the thermistor probe, a soft clicking sound is heard and there is a tangible resistance. If this is not the case and the measuring vessel does not fit securely, it is possible you are using an improper measuring vessel and the measurement results may not be verifiable.**

⚠ **Reused measuring vessels also exhibit these characteristics. This is because their openings are dilated when they are placed on the sensor.**

The customer is expected to use only Gonotec measuring vessels. Gonotec or its representative is not expected to be able to provide application support with the customer measuring vessels.

Using measuring vessel:

Item Number	Description	Date Verified
SS-275	Measurement Vessels, 1000 ea., FreezePoint	.....
SS-279	Measurement Vessels, 100 ea., FreezePoint	.....
Other:	Type:	

COMMENTS

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.....

Date .....

Completed by .....

Date .....

Verified by .....

Ancillary Information

The correct pipette

Repeatability depends on the performance of the pipette, the used tip and execution of pipetting.

	Comment	Date Verified
Pipette type:	.....	.....
S/N:	.....	.....
Calibrated:	.....	
Is the pipette equipped with a disposable tip?	.....	
Has been verified that the pipette delivers a constant sample volume of 15µl or 50µl?*	.....	
Is the personnel trained in using the pipette?	.....	

*Volume depends on FreezePoint® Model

- Model 6000 / Model 6000P - 15µL
- Model 6000S / Model 6000SP - 50µL

Traceability Osmolality Check

Prior to the traceable osmolality check make sure that the thermistor probe has been properly adjusted with the adjustment tool according to the user / service guide – especially after changing thermistor probe or lower cooling system.

The “traceable-check-frequency” has to be carried out in accordance with quality assurance

on site.

COMMENTS

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Date .....

Completed by .....

Date .....

Verified by .....

Performance Specifications

Analytic sensitivity and specificity	Value
Measuring range	0 to approx. 3000 mOsmol/kg H_2O
Resolution	1 mOsmol/kg over the entire measuring range
Temperature Effects	Less than 1 mOsmol/kg per 5°C (9°F) ambient temperature change

Precision (within run repeatability)*

The osmometer works internally with a nearly tenth as high measuring precision related to the measuring value. The measuring value is rounded up from 0.5 onwards. This leads to a total deviation from the expected value. The indication is performed in percentage.

Models 6000 & 6000P	
Sample Volume	**Repeatability**
0 to ≤ 400 mOsmol/kg	SD ≤ 4 mOsmol/kg
> 400 to ≤ 1500 mOsmol/kg	CV ≤ 1%
> 1500 to ≤ 3000 mOsmol/kg	CV ≤ 2%

Models 6000S & 6000SP	
Range	**Repeatability**
0 to ≤ 400 mOsmol/kg	SD ≤ 2 mOsmol/kg
> 400 to ≤ 1500 mOsmol/kg	CV ≤ 0.5%
> 1500 to ≤ 3000 mOsmol/kg	CV ≤ 1%

SD: standard deviation, CV: coefficient of variation (= relative SD)

Accuracy (Linearity)*

2-point calibration

Models 6000 & 6000P (15µl) and 6000S & 6000SP (50µl)		
Calibrated Range / mOsmol/kg	0 - 850 mOsmol/kg Cal. (0/850)	0 - 2000 mOsmol/kg Cal. (0/2000)
0 to ≤ 400	≤ ±4 mOsmol/kg	≤ ±10 mOsmol/kg
> 400 to ≤ 1000	≤ ±1.0%	≤ ±3.0%
> 1000 to ≤ 2000	**	≤ ±1.5%

3-point calibration

Models 6000 & 6000P (15µl)		
Calibrated Range / mOsmol/kg	0 - 1000 mOsmol/kg Cal. (0/300/850)	0 - 2000 mOsmol/kg Cal. (0/850/2000)
0 to ≤ 400	≤ ±4 mOsmol/kg	≤ ±10 mOsmol/kg
> 400 to ≤ 1000	≤ ±1.0%	≤ ±3.0%
> 1000 to ≤ 2000	**	≤ ±1.5%

Models 6000S & 6000SP (50µl)		
Calibrated Range / mOsmol/kg	0 - 1000 mOsmol/kg Cal. (0/300/850)	0 - 2000 mOsmol/kg Cal. (0/850/2000)
0 to ≤ 400	≤ ±2 mOsmol/kg	≤ ±6 mOsmol/kg
> 400 to ≤ 1000	≤ ±0.5%	≤ ±1.5%
> 1000 to ≤ 2000	**	≤ ±1.0%

**Performance above 2000 mOsmol/kg dependent on selection of calibration values. For best results, it is recommended to calibrate using values near the intended measuring range. Accuracy (from nominal value, tolerances of reference and calibration solutions excluded) and precision (within run) specifications apply to ELITechGroup standards and reference solutions.*

***Measuring points in this range not recommended for indicated calibration values.*

COMMENTS

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Date .....

Completed by .....

Date .....

Verified by .....

Calibrators / Reference solutions

It should be noted that there is no generally accepted national or international reference for the traceability of the calibration standards in the field of the freezing point osmometry. Reference solutions for the osmometry, however, should be produced according to the national or international pharmaceutical directives (e.g. USP, JP, PhEur, NIST, etc.).

Measuring Reliability Controls (MRC) in the field of GxP practice.

Measuring reliability controls are used to check whether the medical device is within the maximum measuring deviation (error margin), based on the error limits, which the manufacturer has established in the User's Manual.

Under GxP the MRC is executed by means of Standard Solutions and Procedures stipulated in international Pharmacopoeias (such as current editions of the European Pharmacopeia, USP Monograph <785> OSMOLALITY AND OSMOLARITY, etc.).

For example, the table below can be used to produce reference solutions to be used as measuring reliability controls.

Reference Saline Solutions

Osmolality (mOsmol/kg)	Standard Solutions (Weight in grams of sodium chloride per kg of water)	Molal Osmotic Coefficient (ϕm NaCl)	Freezing Point Depression (°C) ΔT
100	3.087	0.9463	0.186
200	6.260	0.9337	0.372
290*	9.141	0.9270	0.539
300	9.463	0.9264	0.558
400	12.684	0.9215	0.744
500	15.916	0.9180	0.930
600	19.147	0.9157	1.116
700	22.380	0.9140	1.302
850**	27.228	0.9122	1.579
2000**	63.930	0.9142	3.716

Unless otherwise noted reference solutions are based on the European Pharmacopoeia, 4th Edition.
(*) Based on Geigy Scientific Tables, 8th edition.
(**) Determined experimentally using substantially equivalent freezing point osmometer

Quality Control

ELITechGroup calibrators are available for establishing high quality calibration curves for typical clinical ranges. Upon evaluation of control values and the determination of admissible ranges appropriate statistical methods should be used. After calibration reference measurements should be made using solutions with known osmolality to verify the acceptance of the calibration. At least one reference material of known osmolality should be used as control. Deviations to the expected result may be a sign for erroneous use of the device, the calibration and reference material, for contaminated syringes or vessels or a malfunction of the device.

Operation / Performance Qualification

The user is expected to calibrate the system using ELITechGroup calibrators and reference solutions to demonstrate the operation. The service engineer is not expected to be able to provide application support with the customer samples. (See “Accessories” on page 107 for a list of calibrators and reference solutions.)

COMMENTS

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Completed by ..... Date .....

Verified by ..... Date .....

Verification Calibrators / Reference Solutions

Depending on the quality assurance on site, the osmometer is to be calibrated at 2 or 3 points.

Calibrators		Comment	Date Verified
2-Point Calibration			
Deionized Water ZERO		.....	.....
Standard CAL1	mOsmol/kg..... Lot No.	.....	.....
3-Point Calibration			
Deionized Water ZERO		.....	.....
Standard CAL1	mOsmol/kg..... Lot No.	.....	.....
Standard CAL2	mOsmol/kg..... Lot No.	.....	.....

Solutions for comparative measurements / Reference Solutions

One or more reference solutions (“Calibrators / Reference solutions” on page 130) should be measured to ensure that the system is operating properly and the results are within the maximum measuring deviation (margin of error), based on the error limits, which we have established.

Reference Solutions		Comment	Date Verified
Solution REF1	mOsmol/kg..... Lot No.	.....	.....
Solution REF2	mOsmol/kg..... Lot No.	.....	.....

COMMENTS

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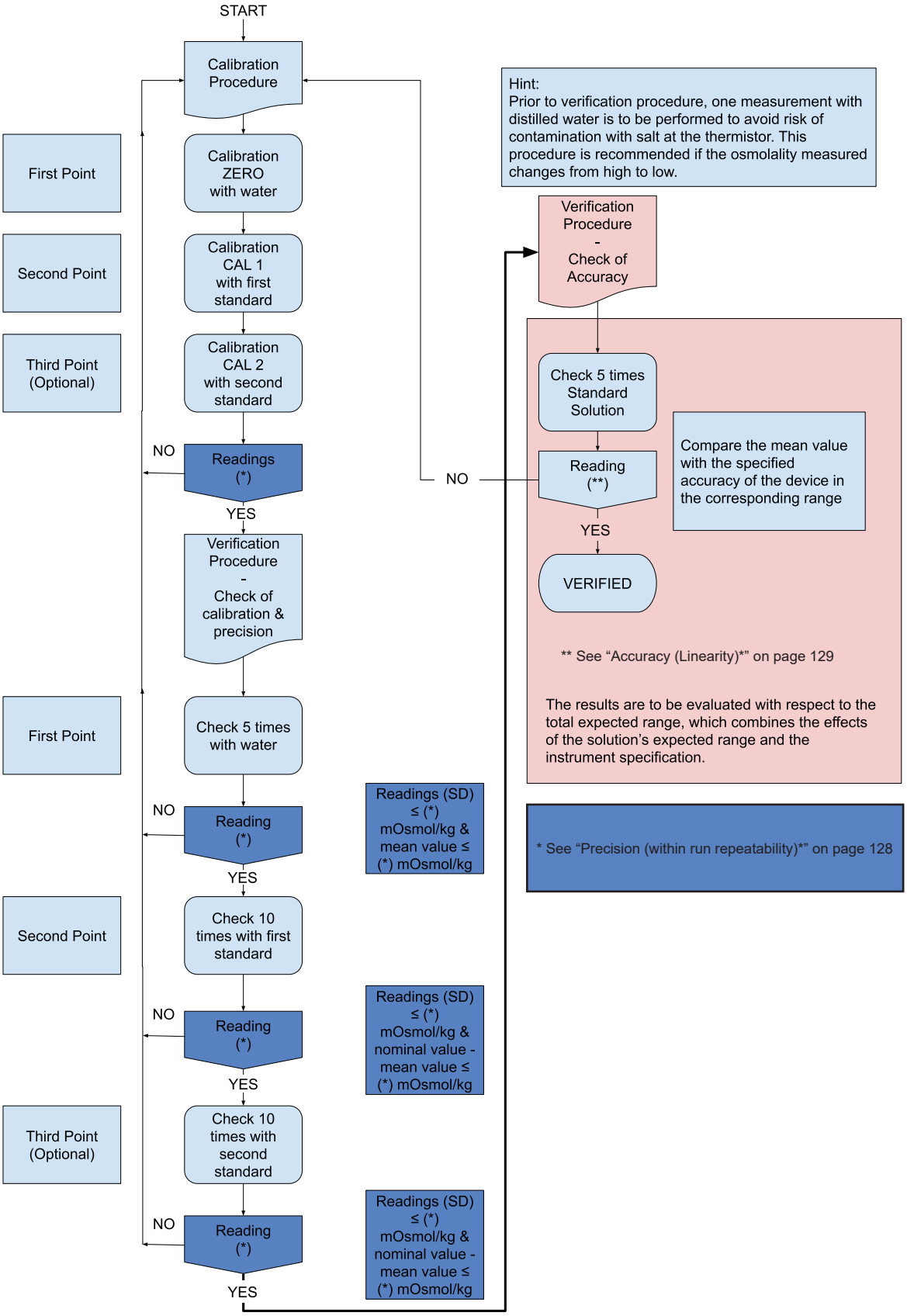
Date .....

Completed by .....

Date .....

Verified by .....

Calibration / Verification Workflow



Performance Check: Calibration / Verification

There are two modes of operation of the FreezePoint® Freezing Point Osmometer:

- Calibrating the system with distilled water and one or two calibration standards.
- Measuring the osmolality of a sample.

The calibration of the FreezePoint® Freezing Point Osmometer consists of two or three single-pass or multi-pass measurements.

This means that the complete calibration (2 or 3 point) is one process. After all required points are measured the results will be displayed and can be accepted, partly disabled or completely discarded.

General Mode of Operation

Method:

1. Choose the operation that should be performed (measure or calibration)
2. Fill a measuring vessel with the appropriate volume of the sample into a dry and clean measuring vessel. Make certain that there are no air bubbles in the sample.
   - ◊ Model 6000 / Model 6000P - 15µL
   - ◊ Model 6000S / Model 6000SP - 50µL
3. Place the measuring vessel **securely** onto the measuring vessel holder (thermistor probe). There will be a slight resistance and you will hear a click when the vessel is in place.
4. Push the vessel holder down into the measuring position. There will be a noticeable resistance. The measuring vessel is immediately cooled by the lower cooling system.
5. A progress bar is showing the cooling process. When the under-cooling temperature is reached, the crystallization is automatically initiated by the injection of ice crystals and a signal will be heard.
6. The resulting ice formation causes the temperature to rise to the freezing point of the solution. A freezing plateau then forms that is measured by the thermistor probe. The osmolality is recorded, saved and presented on the digital display in mOsmol/kg.
7. After the measurement process is finished, regardless of whether it was successful or produced an error message, the elevator will be raised, the measurement system will be automatically switched to standby and the system is ready for the next measurement.
8. After each measurement, the thermistor probe should be thoroughly cleaned with a soft dry paper tissue and a new measuring vessel is to be used for each measurement.

COMMENTS

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Date .....

Completed by .....

Date .....

Verified by .....

Setting the Instrument

1. **Setting the Instrument Zero using water**
   Purpose: Linearization and fixing of instrument's ZERO-point
   Method:
   A. Choose *calibration* from the measurement menu.
   B. Perform the measuring as described as described on the touchscreen and/or the User's Manual.
   C. Depending on the selection in Quality Assurance Preset the user has to run one, two or three passes to confirm the result.
   D. Continues with First Standard Calibration after all required measurements were successful.

2. **Setting the Instrument CAL1 using a calibration solution**
   Purpose: Linearization and fixing of instrument's CAL1-point
   Method:
   A. Choose the osmolality of the standard by pressing the << or >> button until the osmolality of the standard is displayed.
   B. Perform the measuring as described as described on the touchscreen and/or the User's Manual.
   C. Depending on the selection in Quality Assurance Preset the user has to run one, two or three passes to confirm the result.
   D. Continues with Second Standard Calibration after all required measurements were successful.

3. **Setting the Instrument CAL2 using a calibration solution (depending on the selection in Quality Assurance Preset optional or obligatory)**
   Purpose: Linearization and fixing of instrument's CAL2-point
   Method:
   A. Choose the osmolality of the standard by pressing the << or >> button until the osmolality of the standard is displayed.
   B. Perform the measuring as described as described on the touchscreen and/or the User's Manual.
   C. Depending on the selection in Quality Assurance Preset the user has to run one, two or three passes to confirm the result.
   D. If the calibration reveals above average deviations from the linearity, calibrate the internal thermistor in replace probe mode.

4. **Apply calibration values.**
   Purpose: Finalize calibration
   Method:
   A. If necessary, deselect individual results to prevent outliers from distorting the calibration.
   B. Apply to calibration or retry.

5. **Verification Procedure - Check of Precision***
   Purpose: Verification of precision at calibrated points.
   Method: In case of verification fails at one step, re-calibration should be performed first!
   A. Choose measurement from measurement menu.
   B. Verification of Instruments Zero-Point:
      Perform 5 measurements with distilled water.
      Compute mean value and standard deviation.
      Compare the standard deviation (SD) with the specified repeatability of the device at this point.
      If the mean value exceeds the repeatability specification at zero (0), the calibration needs to be repeated.("Precision (within run repeatability)*" on page 128).

C. Verification of Instruments CAL1:
Perform 10 measurements with the previously used calibration solution for CAL1.
Compute either standard deviation (SD) or coefficient of variation (CV) depending if instrument precision specifications ("Precision (within run repeatability)*" on page 128) for the measuring range of the CAL1 solution are based on SD or CV. Also compute the mean value.
Compare the SD (or CV) result with the instrument precision specifications for the measuring range corresponding to the nominal value of the CAL1 solution, confirming that the results meet the specified criterion. Also compare and confirm that the mean value does not differ from the nominal value of CAL1 by more than the same criterion. The calibration needs to be repeated if either comparison does not meet the specified criterion.

D. Verification of Instruments CAL2 (if used for 3-point calibration):
Perform 10 measurements with the previously used calibration solution for CAL2.
Compute either standard deviation (SD) or coefficient of variation (CV) depending if instrument precision specifications ("Precision (within run repeatability)*" on page 128) for the measuring range of the CAL2 solution are based on SD or CV. Also compute the mean value.
Compare the SD (or CV) result with the instrument precision specifications for the measuring range corresponding to the nominal value of the CAL2 solution, confirming that the results meet the specified criterion. Also compare and confirm that the mean value does not differ from the nominal value of CAL2 by more than the same criterion. The calibration needs to be repeated if either comparison does not meet the specified criterion.

6. **Verification Procedure - Check of Accuracy***
Purpose: Verification of Linearity of the Instrument.
Method: Prior to verification procedure, one measurement with distilled water is to be performed to avoid risk of contamination with salt at the thermistor. We recommend this procedure if the osmolality measured changes from high to low!

A. Choose a Standard Solution (e.g. ELITechGroup Calibration Standards or Reference Solutions) or a solution of known osmolality that lies within the calibrated range and close to the expected value of your Sample Solution.

B. Perform 5 measurements. Compute mean value and standard deviation. Compare the mean value with the specified accuracy of the device in the corresponding range. ("Accuracy (Linearity)*" on page 129)**. (Standard deviation is computed for reference purposes only.)

* Both verification procedures presented here – testing for Precision and Accuracy are recommendations from us as manufacturer. Each laboratory should use the materials and expected ranges provided in this document as a guidance to develop a comprehensive Quality Control program exclusive to their laboratory. It may be necessary to observe national or international Pharmacopoeias, Quality Control programs or national Clinical Standards.

** Alternatively, the results can be compared with the total expected result range, which includes contributions of uncertainties due to instrument's accuracy, repeatability, and solutions' expected range (bias).

COMMENTS

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Date .....

Completed by .....

Date .....

Verified by .....

Calibrating Table

Measuring Mode	ZERO	CAL1	CAL2	REF1	REF2
CAL / mOsmol/kg					
Sample / mOsmol/kg	Pure water	.....	.....	.....	.....
Sample 1	.....	.....	.....	.....	.....
Sample 2	.....	.....	.....	.....	.....
Sample 3	.....	.....	.....	.....	.....
Sample 4	.....	.....	.....	.....	.....
Sample 5	.....	.....	.....	.....	.....
Sample 6	.....	.....	.....	.....	.....
Sample 7	.....	.....	.....	.....	.....
Sample 8	.....	.....	.....	.....	.....
Sample 9	.....	.....	.....	.....	.....
Sample 10	.....	.....	.....	.....	.....
Statistics					
Mean value (mOsmol/kg)	.....	.....	.....	.....	.....
SD (mOsmol/kg)	.....	.....	.....	.....	.....
CV (%)	.....	.....	.....	.....	.....
Record expected value	.....	.....	.....	.....	.....
Consistent with acceptance criteria? (Y/N)	.....	.....	.....	.....	.....

Thermistor probe No. .....

COMMENTS

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Date .....

Completed by .....

Date .....

Verified by .....

Revalidation Schedule

The purpose of revalidation is to ensure that already validated instrument systems remain up to date and continue to be fit to operate.

ELITechGroup recommends the IQ, OQ, and PQ on a schedule to maintain qualification of the system, unless instrument malfunction requires significant repair or service prior to the one-year recommendation.

If repair is required, revalidation is recommended. Routine maintenance is not considered repair.

Revalidation timeline depends also on operation conditions of the instrument, may be regulated by local authorities and/or by the internal regulations of the company/institution in which it is installed.

On a routine basis, a daily precision test and a monthly check of the measurement system by means of the adjustment tool is recommended.

A detailed description can be found in this User's Manual, Chapter *Maintenance and Troubleshooting*.

Revalidation determined by (name) ..... (date) .....

Next Servicing as described in the

Service Guide should be performed on (date): .....

COMMENTS

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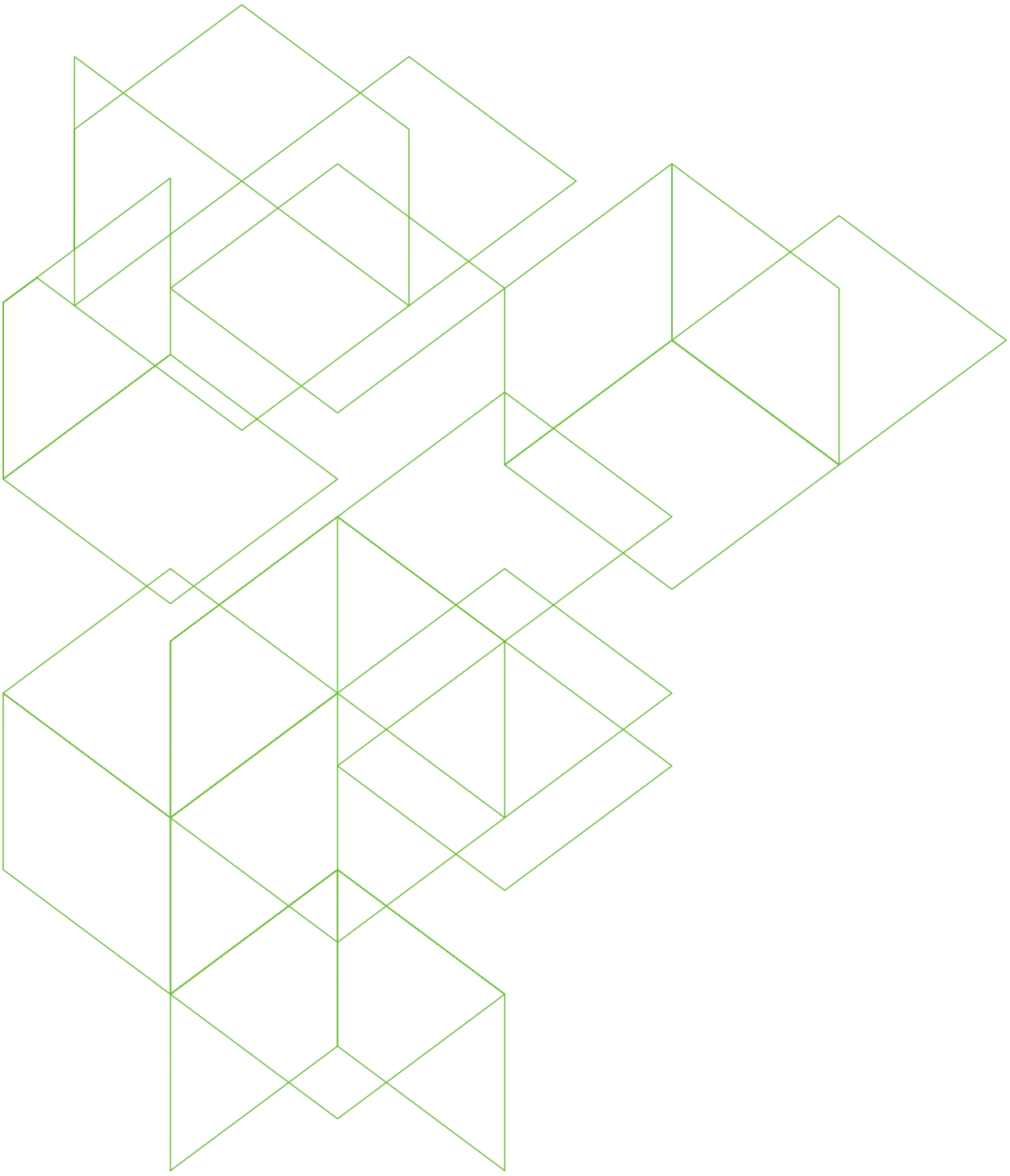
Date .....

Completed by .....

Date .....

Verified by .....



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