# VAPRO®

## Vapor Pressure Osmometer
## MODEL 5600

## USER'S MANUAL


ELITechGroup
EMPOWERING IVD

# VAPRO®
# VAPOR PRESSURE OSMOMETER

## MODEL 5600
## MODEL 5600XR

## USER'S MANUAL

57-0006-03D
Last Revision 26 October 2022

This instrument has been designed and tested to CISPR 11 Class A and FCC Part 15 Class A. In a domestic environment it may cause radio interference, in which case, measures to mitigate the interference may be necessary. This instrument complies with the emission and immunity requirements described in the IEC 61326 series. In an electromagnetic environment, the environment should be evaluated prior to operation of the device.

Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these may interfere with the proper operation.

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## 1.1 Applications Manual Overview

Thank you for purchasing the VAPRO Vapor Pressure Osmometer. You will find it to be a valuable investment and an important partner in the laboratory.

The VAPRO Applications Manual is key to efficiently operating this instrument. ELITechGroup recommends becoming thoroughly familiar with the operation procedures and troubleshooting techniques described in this manual.

Information is generally presented in a systematic format demonstrating the operation and care of the instrument from a first-time user's point of view. Once familiar with the operation of the VAPRO, the manual helps you maintain the instrument in a high state of performance and reliability.

### Intended Purpose

The VAPRO is a bench-top in-vitro diagnostic laboratory instrument for use by trained technical personnel to determine the osmolality concentration of a water-based solution by means of the dew point temperature depression of a specimen sample.

**WARNING!**
**This instrument should be used only by qualified laboratory professionals who are trained in the use of personal protection equipment (PPE) and who observe the safety requirements for handling biohazardous and other potentially dangerous materials. Specimens used with the VAPRO may contain moderately hazardous substances that require care in handling. Always use appropriate safety measures including gloves, eye protection, and other personal protection equipment. In case of use with biohazards, use the instrument in a biological safety hood.**

### Specification of Safe Use

This instrument is designed for indoor use only, between 15 to 37 °C, maximum relative humidity 85%. For use at elevations up to 2000 meters. For use with mains supply voltage of 100 to 240 Volts AC @ 50 to 60 Hz, ±10%. Fuses: All fuses are time-lag (Type T). Transient over-voltage category II. Pollution degree 2 in accordance with IEC 61010-1.

This device conforms to IVD directive 98/79/EC, and is tested to the safety standard 61010-1 at 240 Volts AC.

**WARNING!**
**Using this instrument in a manner not specified by ELITechGroup may impair the safety protection designed into the instrument and may lead to injury.**

SECTION 1
INTRODUCTION

## *1.1 Applications Manual Overview*

### Explanation of Symbols

| Symbol | Symbol Ref. No. | Symbol Title | Symbol Explanation | ISO 7000 Reg. No. |
|---|---|---|---|---|
|  | ISO 15223-1 5.4.4 | Caution | Indicates that caution is necessary when operating the device or control close to where the *symbol* is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences | 0434A |
|  | ISO 15223-1 5.1.6 | Catalogue number | Indicates the manufacturer's catalog number so that the medical device can be identified. | 2493 |
|  | ISO 15223-1 5.1.7 | Serial number | Indicates the manufacturer's serial number so that a specific medical device can be identified | 2498 |
|  | ISO 15223-1 5.1.5 | Batch code | Indicates the manufacturer's batch code so that the batch or lot can be identified. | 2492 |
|  | ISO 15223-1 5.5.1 | In vitro diagnostic medical device | Indicates a medical device that is intended to be used as an in vitro diagnostic medical device | N/A |
|  | ISO 15223-1 5.4.3 | Consult instructions for use | Indicates that need for the user to consult the instructions for use | 1641 |
|  | N/A | European conformity mark | Indicates that the product conforms to the European IVD Directive 98/79/EC | N/A |
|  | N/A | WEEE wheeled bin | This product contains electrical and electronic components that may contain materials which, if disposed with general waste, could be damaging to the environment. Residents of the European Union must follow specific disposal or recycling instructions for this product. Residents outside the European Union must dispose or recycle this product in accordance with local laws or regulations that apply. | N/A |
|  | ISO 15223-1 5.1.1 | Manufacturer | Indicates the medical device manufacturer | 3082 |
|  | ISO 15223-1 5.4.2 | Do not re-use | Indicates a medical device that is intended for one single use only | 1051 |

| | | | | |
|---|---|---|---|---|
|  | ISO 15223-1 5.1.2 | Authorized representative in the European Union | Indicates the authorized representative in the European Union | N/A |
|  | N/A | Warning; biological hazard | Indicates that there is potential biological hazard associated with the medical device | ISO 7010 – W009 |
|  | ISO 15223-1 5.4.1 | Biological risks | Indicates that there are potential biological risks associated with the medical device | 0659 |
|  | N/A | General warning sign | Indicates a general warning | ISO 7010 – W001 |
|  | ISO 15223-1 5.3.2 | Keep away from sunlight | Indicates a medical device that needs protection from light sources | 0624 |
|  | N/A | Environment friendly use period | Indicates the period of time before any RoHS substances are likely to leak out causing harm to the environment. | N/A |
|  | ISO 15223-1 5.3.7 | Temperature limit | Indicates the temperature limits to which the medical device can be safely exposed. | 0632 |
|  | ISO 15223-1 5.1.4 | Use-by date | This symbol shall be accompanied by a date to indicate that the medical device should not be used after the end of the year, month, or day shown. | 2607 |
|  | ISO 15223-1 5.2.8 | Do not use if package is damaged | Indicates that 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. | 2606 |
|  | ISO 15223-1 5.3.1 | Fragile, handle with care | Indicates a medicl device that can be broken or damaged if not handled carefully | 0621 |
|  | IEC 60417 5016 | Fuse | To identify fuse boxes or their location | N/A |
|  | ISO 15223-1 5.3.8 | Humidity limitation | Indicates the range of humidity to which the medical device can be safely exposed | 2620 |
|  | ISO 15223-1 5.5.5 | Contains sufficient for <n> tests | Indicates the total number of tests that can be performed with the medical device | 0518 |

## *1.2 Customer Service*

ELITechGroup is ready to help resolve any difficulty with the operation or performance of the VAPRO. If a problem cannot be solved using the procedures in this manual, please contact us.

Customers within the United States are encouraged to contact their authorized dealer, many offer complete customer service and support. Outside the U.S., many of our authorized dealers offer complete customer service and support. Contact ELITechGroup by email, mail, telephone, or fax at the address and numbers listed below.


**ELITechGroup Inc.**
370 West 1700 South
Logan, Utah 84321 USA

**Telephone:**
435 752 6011
800 453 2725 *(United States & Canada)*
(+1) 435 752 6011 *(International calls)*

**Fax:**
435 752 4127 *(US)*
(+1) 435 752 4127 *(International)*

**Email:**
Service_EBS@elitechgroup.com *(Service)*
Sales_EBS@elitechgroup.com *(Sales)*

**Web Page:**
www.elitechgroup.com


**European Authorized Representative:**
MT Promedt Consulting GmbH
Altenhofstrasse. 80
D-66386 St. Ingbert
Germany

Telephone: +49(0)68 94-58 10 20
Fax: +49(0)68 94-58 10 21
Email: info@mt-procons.com

## *1.3 VAPRO System*

The VAPRO osmometer is an advanced electronic adaptation of the hygrometric method of vapor pressure determination. The sensitive thermocouple and sophisticated electronics provide the means to measure the dew point temperature depression of a specimen with resolution to 0.00031 °C (which equals one mmol/kg).

Vapor pressure and freezing point are among the colligative properties of a solution. Compared with pure solvent, these properties are altered in proportion to the number of solute particles dissolved in each kilogram of solvent (water in the case of biological solutions). Thus, measuring either property is an indirect means of determining solution concentration or osmolality.

The chief advantage of the vapor pressure method is that it does not require alteration of the physical state of the specimen.

### Benefits:

- A 10 µL sample size.
- Routine operation on micro samples of any biological solution, including whole blood, serum, plasma, urine, and sweat, as well as complex specimens such as tissue samples.
- None of the measurement artifacts that arise in freezing point depression measurements due to elevated viscosity, particulate matter, inhomogeneities, or other physical characteristics of the sample.
- Superior reliability because the measurement involves minimal mechanical complexity.

### Features:

- Automated circular sample slide and chamber locking operation, which places all the controls on the front panel.
- Automated self-cleaning thermocouple operation reduces operator maintenance and improves performance by promoting regular cleaning of thermocouple.
- Front panel keys for quick access to calibration, thermocouple cleaning and operation of the sample slide.
- USB (Universal Serial Bus) slave data port for interfacing to computers.
- High resolution display with back lighting.
- Built in clock records and displays a date code for each sample result.
- Universal voltage power supply accepts any line voltage from 100 to 240 volts AC @ 50-60 Hz without making changes to the input module or fuses.
- Advanced self-checking operation to optimize performance, and detect and identify instrument problems.
- Streamlined user interface for quick access to menu items and common functions.
- Four user-selectable languages (English, French, German, Spanish).

## *1. 4 How the VAPRO Works*

A 10-microliter specimen is aspirated into a micropipettor tip. The specimen is then inoculated into a solute-free paper disc in the sample holder. The OPEN/CLOSE key is pressed, which causes the slide to rotate to the closed or measurement position. The measurement starts automatically once the sample chamber seals.

The sensing element is a fine-wire thermocouple hygrometer. This is suspended in a unique, all-metal mount, which when joined with the sample holder, forms a small chamber enclosing the specimen.

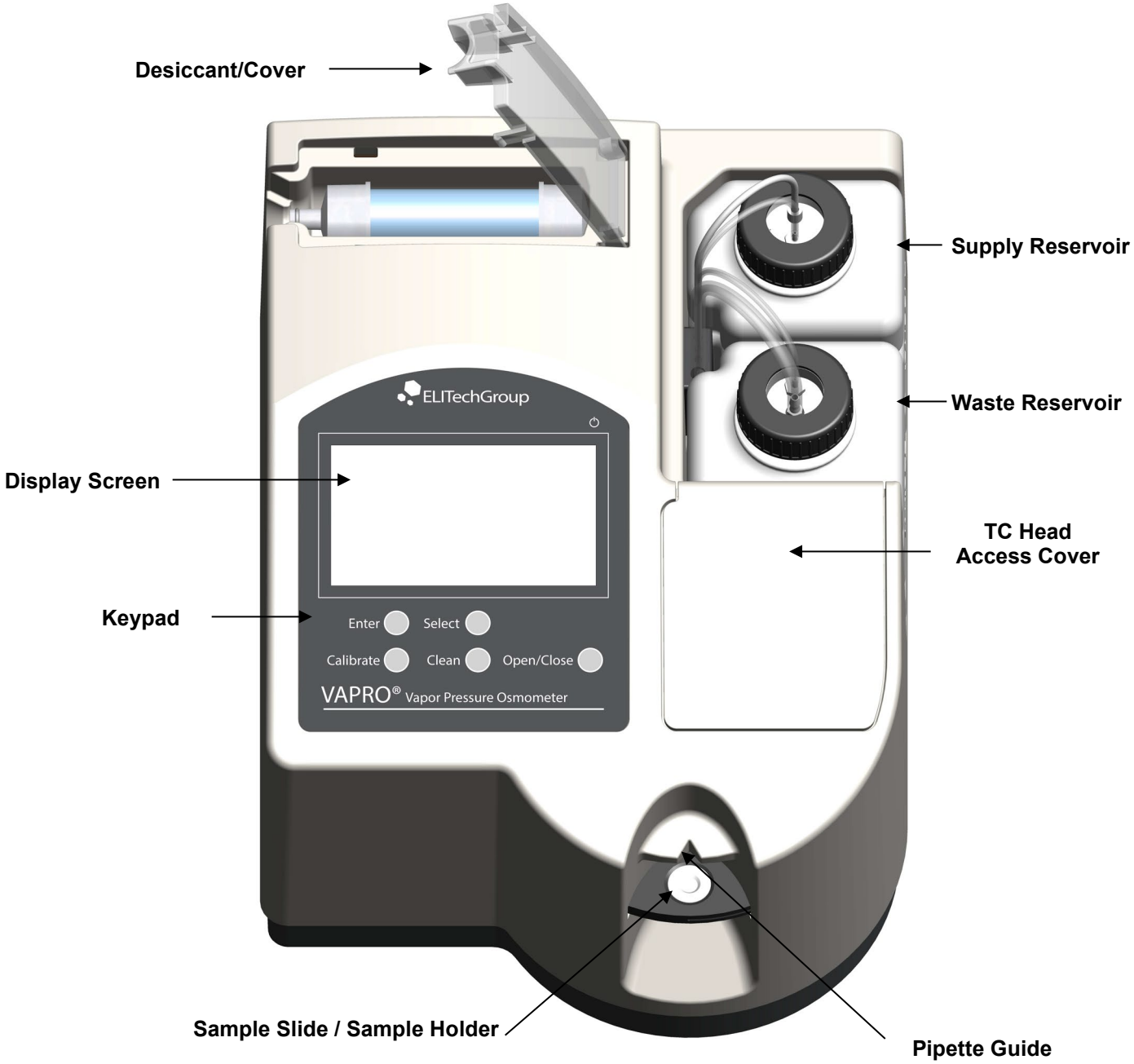
As vapor pressure equilibrates in the chamber airspace, the thermocouple senses the ambient air temperature, thus establishing the reference point for the measurement. Under electronic control, the thermocouple then seeks the dew point temperature within the enclosed space, giving an output proportional to the differential temperature.

The difference between the ambient temperature and the dew point temperature is the dew point temperature depression–an explicit function of solution vapor pressure. Dew point temperature depression is measured with a resolution of 0.00031 °C.

Refer to the Theory of Operation (Appendix A) for additional information.

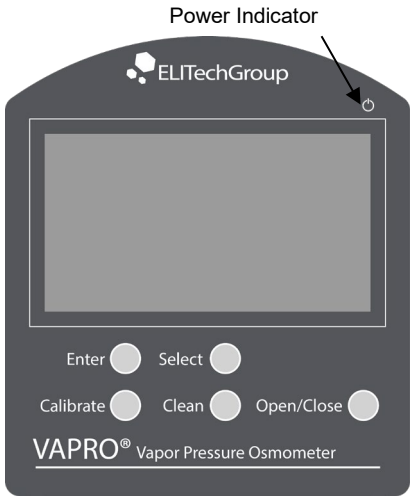
## *1. 5 Controls and Features*

The instrument and all accessories and supplies are clearly identified. The product name is on the top panel of the instrument. The model number is located on a label on the rear of the instrument. Accessories and supplies are labeled with names and product numbers.



## *1. 5 Controls and Features*

# Instrument Top/Front Panel




### Display Screen

240 x 128 pixel high resolution backlit graphic display provides up to 30 characters of text on 16 lines. The screen is used to display menu selections, osmolality readings, progress bar, operating status, fault conditions, and other information.

### Keypad

ENTER – Used to engage a selected menu item or operation mode.

SELECT – Used to call up menus and to select the operation mode.

CALIBRATE – Used to calibrate the instrument.

CLEAN – Used to run an automated thermocouple clean cycle.

OPEN/CLOSE – Used to gain access to the sample slide. The key is a toggle key that either opens (gains access to the sample slide) or closes (places the sample slide in position for taking a measurement).

### Power Indicator

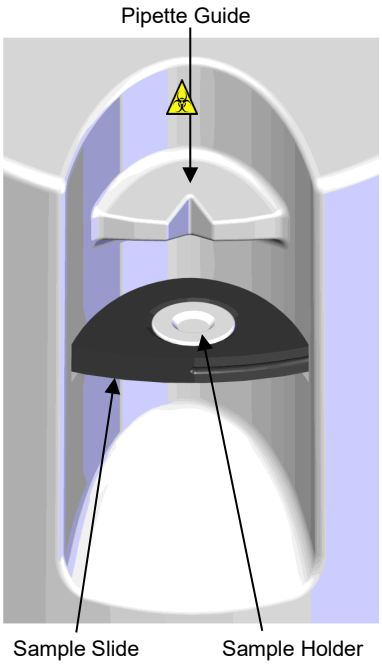
The green light indicates the instrument is on.


### TC Head Access Cover

The TC Head Access Cover provides access to the thermocouple head for manual cleaning and maintenance.

### Desiccant Cartridge/Filter Access Cover

Provides access to the desiccant cartridge/filter for cartridge replacement. The transparent cover allows monitoring the status of the cartridge.




## Pipette Guide

The pipette guide aligns and steadies the pipette for precise application of the specimen onto the sample disc in the sample holder.

## Sample Slide (Automatic – uses OPEN/CLOSE key)

The sample slide holds the sample holder and automatically moves the sample holder from the loading position (under the pipette guide) to the sample chamber by pressing the OPEN/CLOSE key.

## Sample Holder

The sample holder is interchangeable for various volumes of sample specimens. The standard sample holder is for samples up to 10 µL. It requires the use of solute-free paper discs. Other sample holders are available for special applications. Accessory sample volumes include: 2 µL using the AC-063 sample holder, 20 µL using the AC-064 sample holder, and approximately 60 µL using the AC-065 sample holder.

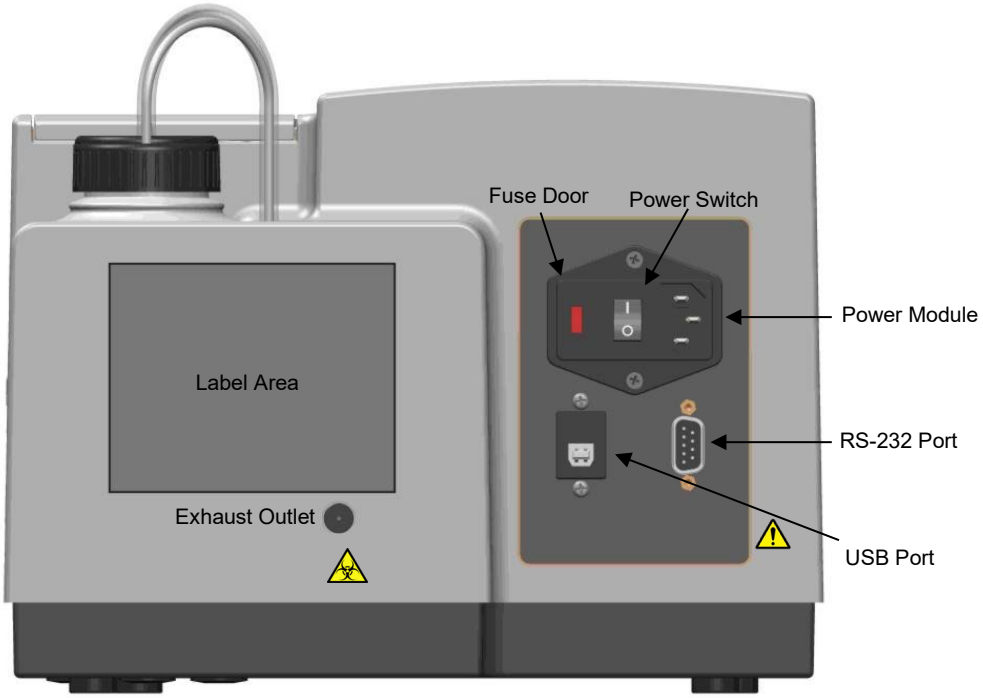
## *Supply and Waste Reservoirs*


Located on the right side of the instrument, the supply reservoir holds the USP purified water used during automated thermocouple cleaning. The waste reservoir collects the wastewater from the thermocouple cleaning process. Reservoir volume levels are visible when using the instrument. The reservoirs have convenient service access for filling the supply reservoir and emptying the waste reservoir.

**WARNING!**
**Whenever filling the supply reservoir, the waste reservoir must be emptied. Failure to empty the waste reservoir can result in damage to the instrument. Depending upon the specimens used, the VAPRO may contain moderately hazardous substances that require care in handling. Always use appropriate safety measures. Dispose of waste material according to prudent laboratory procedures and local regulations.**

## *1. 5 Controls and Features*

# Instrument Rear Panel




### Power Module

The power module accepts a standard IEC 320 type power cord.

### Fuse Door

The fuse door is located on the power entry module and provides access to fuses for replacement.

### Power Switch

Switches power on (**I**) or off (**O**). For best operation, the instrument should remain with power always on except for service operation or extended long periods of non-use.

### Serial Data Ports

**RS-232** – For asynchronous serial communication with a printer or computer. The serial port uses a DB9 connector at RS-232 voltage levels.

**USB** – Slave configuration, uses a USB connector for connecting the instrument to a computer's USB port.

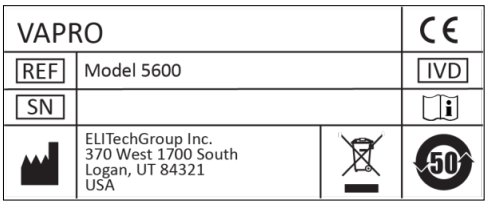
### Exhaust Outlet

The exhaust outlet vents air from the vacuum pump during the clean cycle.

# Instrument Labels

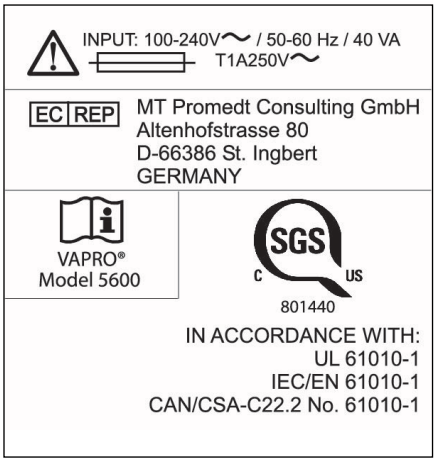
## Model/Serial Number Label

The Model/Serial Number label is located on the back panel of the instrument. The label identifies the VAPRO product, the model and serial number, the manufacturer, and other regulatory information.




## Information Label

The information label is located on the back panel of the instrument and provides additional information about the instrument including the voltage-input requirements, the European Community Representative and safety information.




## Caution Labels

There are two caution labels located on the VAPRO:

1. Located by the waste/supply reservoirs. The installation procedure details how these reservoirs are to be installed.

2. Located on the back of the instrument near the power module and serial data ports. Voltage input ratings must be followed.

## *1. 5 Controls and Features*

### Biological Hazard Labels

There are three biological hazard labels located on the VAPRO:

1. Located by the sample slide on the front of the instrument. The sample slide holder should be cleaned after each specimen is tested.
2. Located by the exhaust outlet on the back of the instrument. The exhaust outlet is used only during the automated clean cycle. This area may be subjected to biological hazardous substances depending upon the type of specimens being tested. In case of use with biohazards, use the instrument in a biological safety hood.
3. Located on the waste reservoir. The waste reservoir is used only during the automated clean cycle.

   If the waste reservoir overfills, fluid will enter the vacuum pump and may exit the exhaust outlet. If a spill occurs, use appropriate safety measures when cleaning. Wipe the spill and surrounding area with a disinfectant.

   If a leak occurs in the instrument, fluid may exit the bottom of the instrument onto the surface where the instrument sits.

## *2. 1 Instrument Setup Procedure*

The following is to help you set the instrument up for operation. These instructions meet Instrument Qualification (IQ) protocols that may be required by various regulatory authorities. Refer to Appendix G, Installation, Operation and Performance Qualification, for a checklist form with signature blocks.

### Accessories and Supplies

Check to make sure the following accessories and supplies were received with the VAPRO and that no damage occurred during shipping:

#### Accessories

- (OA-010) 100 mmol/kg Opti-Mole Osmolality Ampule Standard
- (OA-029) 290 mmol/kg Opti-Mole Osmolality Ampule Standard
- (OA-100) 1000 mmol/kg Opti-Mole Osmolality Ampule Standard
- (SS-273) Osmocoll HNL Osmolality control references six 1-mL vials (2 EA)

#### Supplies

- (AC-062) VAPRO Sample Holder 10 µL
- (57-0006-01) VAPRO Applications Manual
- (AC-037) 10 µL Pipettor
- (SS-036) Micropipettor Disposable Tips
- (AC-036) Forceps
- (SS-033) Paper Sample Discs
- (AC-061) Ampule Organizer
- (AC-011) 9/64-inch Hex Driver
- (SS-238) Desiccant Cartridge/Filter
- (SS-239) Waste Reservoir
- (SS-240) Supply Reservoir
- (AC-176) VAPRO 5600 Lab Report Software
- Thermocouple Head Cleaning Supplies, consisting of:

  (SS-003) Cleaning Solution
  (SS-006) Deionized Water
  (SS-026) Blow Clean™* (U.S. 48 states only)
  (SS-223) Thermocouple Cleaning Solution with Anionic Detergent

** Compressed or liquefied pure gas suitable for blowing dust from delicate surfaces or precision mechanisms. Available under various trade names.*

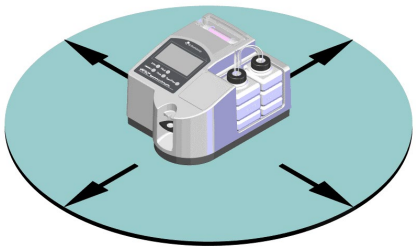
In addition to the above, a supply of lint-free tissue paper or cotton swabs for cleaning the sample holder between specimens and USP purified quality water (< 1 micro-siemens/cm) for use in the supply reservoir for self-cleaning the thermocouple is needed.

**CAUTION**
**Never use facial or other soft tissue to clean the sample holder. Such tissues produce excessive lint residue that contaminates the thermocouple sensor.**

SECTION 2
GETTING STARTED

## *2. 1 Instrument Setup Procedure*

1. Carefully unpack the instrument and check for damage that may have occurred during shipment. Check the packing list to be certain that everything needed for operation is at hand. Inspect accessories and supplies.

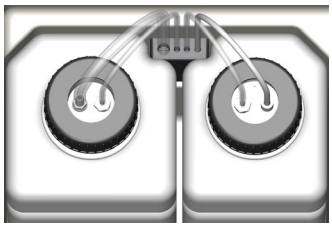


2. The VAPRO is a highly sensitive instrument that takes temperature measurements with a resolution of 0.00031 °C. This requires that the instrument always be located away from anything that could interfere with these measurements, such as: temperature drafts and electrical interference from motors or equipment producing RF emissions such as cell phones.

   Place the instrument on a suitable work surface in an area free from direct exposure to sunlight, heating or air conditioning vents and foot traffic. Avoid locations where instrument precision will be altered by thermal gradients or rapid temperature changes caused by heavy foot traffic, air vents, blowers, heaters, or windows. Leave adequate clearance for access to the supply and waste reservoirs for filling or emptying the reservoirs and for viewing the fluid levels. On the rear of the instrument, leave adequate clearance for access to the power cord and switch.

   **WARNING!**
   **Place the VAPRO in a well-ventilated room with clearance from obstructions or hazardous materials. Do not block access to the power switch or the exhaust outlet on the rear of the instrument. In case of use with biohazards, use the instrument in a biological safety hood.**


Note the location of the tubing in relation to the caps. Do not cross the tubing.



3. To install the supply reservoir, rinse, and then fill the reservoir with USP purified water. Place the filled supply reservoir in the instrument as shown (the waste and supply reservoirs are not interchangeable). Place the supply reservoir cap on the supply reservoir and tighten securely**. Make certain that the supply cap is used; do not cross the tubing and caps.**

   Place the empty waste reservoir in the instrument as shown. Place the waste reservoir cap on the waste reservoir and tighten securely. **Make certain that the waste reservoir cap is used; do not cross the tubing and caps.**

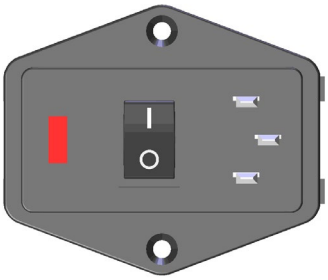
   The pictures at the left show correct installation of the reservoirs, tubing, and caps.

**CAUTION**
**Whenever filling the supply reservoir, the waste reservoir must be emptied. Failure to empty the waste reservoir can result in damage to the instrument. Dispose of waste material according to local regulations.**

4. Remove the blue desiccant cartridge from the sealed bag. Remove the vinyl caps/plugs from the ends of the cartridge. Use the instructions in Section 4.3 to install the new cartridge.

SECTION 2
GETTING STARTED

## *2. 1 Instrument Setup Procedure*



5. Check that the line voltage source is correct (100 to 240 volts AC).

6 Connect the power cord to the VAPRO and the other end to an electrical outlet. Avoid power circuits shared by centrifuges, air conditioners, or other power equipment. Use a power line surge protector to isolate the instrument from spikes and surges.

7 (Optional) If a serial printer is being used, connect the VAPRO printer cable (AC-049 or equivalent) to the serial printer and the other end to the RS-232 9-pin connector on the VAPRO. Refer to the serial printer manual for additional details. The VAPRO cannot be used to interface to a USB printer.

8 (Optional) If the VAPRO Lab Report (AC-176) is being used, connect a USB cable between the Device USB connector on the VAPRO and the USB connector on the computer.

Refer to the VAPRO Lab Report Manual for additional details.

9. Turn the VAPRO ON (**I**). The POWER indicator is green when power is on. Upon power up, the instrument conducts a series of checks and tests before it is ready to accept samples.

**NOTE**

The instrument has an automated thermocouple clean cycle. Run the clean cycle whenever the contamination level rises above 10. During the clean cycle, cleaning water is supplied by the supply reservoir and the resulting waste water collects in a waste reservoir. The waste collected consists primarily of water (99% +) and an extremely small amount of specimen that may have been left in the sample holder when a clean cycle occurs. The waste reservoir must be emptied whenever the supply reservoir is filled.

**CAUTION**

**Dispose of collected waste according to local statute and safety requirements.**

## Relocating the VAPRO

Use the following procedure when locating the VAPRO to a new location:

1. Check the sample holder and make sure that it is empty and clean.
2. Set the VAPRO to an idle state. (If the sample slide is in the open position, press the OPEN/CLOSE key to close the sample slide.)
3. Turn the instrument off and disconnect the power cable and the USB or RS-232 cable if necessary.
4. Remove and/or empty the supply and waste reservoirs before moving.
5. Clean the outside of the instrument.
6. Move the instrument to the new location.
7. Follow the instrument installation procedure to install the instrument.

## *2. 2 Idle or Waiting Periods*

When the instrument is not in use, leave the cleaned sample holder empty and in the measurement (closed) position. If the chamber is left open, every 20 seconds the instrument "chirps" as a reminder that it needs to be closed. Keeping the chamber closed maintains temperature equilibration on the sample holder and keeps it clean.

In the idle mode, the VAPRO monitors and compensates for changing ambient temperatures that would otherwise result in calibration changes. It also maintains a continuous auto-balance in its thermocouple control circuitry to ensure convergence of the thermocouple to the precise dew point temperature during the measurement cycle.

These internal functions are necessary to maintain accurate performance and are why you should leave the instrument powered up when not in use. It is also why long measurement sessions should be interrupted periodically to allow the instrument one full measurement cycle on a dry, empty chamber. **Remember: statistical data is reset when an empty chamber cycle occurs.**

**NOTE**

Occasionally, after a series of measurements, a high osmolality reading can appear on the screen after cycling on an empty chamber. This may be due to residual moisture on the sample holder. If this occurs, open the sample slide and thoroughly clean the sample holder using lint-free tissue. Press the OPEN/CLOSE key to return the slide to the measurement position.

## Power is Turned Off or Lost

When power is turned off to the instrument or there is a power outage, the following conditions occur:

- The instrument always initializes and starts in *Normal Mode*.
- Error messages are stored in non-volatile memory. (The instrument saves the last 18 error messages.)
- Calibration variables are stored in non-volatile memory. (ELITechGroup recommends calibration after the instrument has been turned off or power is lost.)
- The real time clock (RTC) is battery backed and remains powered on all the time.
- The current language setting is stored in non-volatile memory. When power is restored or turned on, the last language setting persists.

## RS-232 Serial Port

The VAPRO RS-232 port uses a DB9 connector on the instrument back panel. This port is for asynchronous serial communication with a printer. When a sample is assayed data outputs to the RS-232 port. Data protocol:

9600 baud
1 Start bit
8 Data bits
No Parity
1 Stop bit

The serial port is configured as Data Communications Equipment (DCE). This requires a null-modem.

Data output is in ASCII characters. Each time a reading displays on the screen, it also is sent to the serial port. Following is an example of the printed data:

```
2009-10-01 13:53 294 mmol/kg
            Samples = 3
            Maximum = 294
            Minimum = 286
            Mean    = 290
Standard Deviation = 4.00
```

.

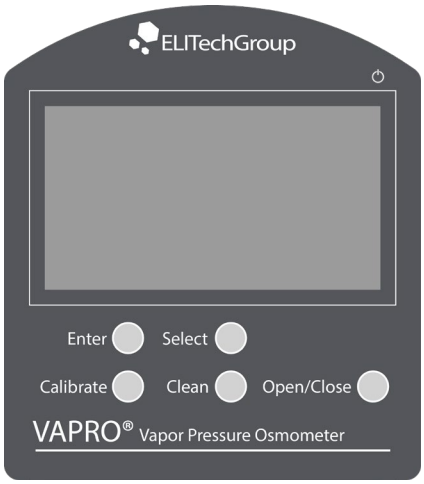
## USB Serial Port

The VAPRO has a Universal Serial Bus (USB), used in conjunction with VAPRO Lab Report (AC-176) software to record data from the VAPRO. The port is configured as a USB device (not a host) and uses a standard USB type receptacle. **This port cannot be used with a USB printer.** Always install the VAPRO Lab Report software before connecting the VAPRO to a computer to allow the computer to correctly recognize the VAPRO when it is connected.

SECTION 3
OPERATING THE VAPRO OSMOMETER

## *3. 1 Operation Overview*

The VAPRO user interface allows the operator to select various functions either from menu selections or from the keypad. Menu and keypad selections are described in this section.




# Keypad Keys

## Calibrate

Use the Calibrate function to calibrate the instrument using the Opti-Mole 290, 1000, and 100 mmol/kg calibration standards. Always begin with the 290 set-point, then follow with the 1000 and 100 mmol/kg.

**NOTE**

Calibration is a critical element of instrument accuracy. While it is not necessary to calibrate the osmometer while familiarizing yourself with it, check calibration before assaying sample material.

## Clean

The automated thermocouple cleaning function greatly reduces the need for removing the thermocouple (TC) head from the instrument in order to clean the thermocouple. This requires no intervention from the operator except to maintain clean water in the supply reservoir, emptying the waste reservoir, and replacing the desiccant cartridge/filter as needed. Upon completing the clean cycle, the instrument returns to the idle state and it is now ready for operation.

Section 4.4 for complete information.

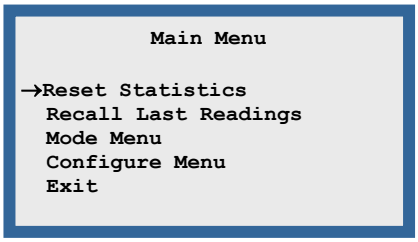
## Select and Enter

Pressing SELECT from the idle state or with the sample slide open brings up the *Main Menu*. From the *Main Menu*, use SELECT and ENTER to choose the desired function or menu item. Pressing SELECT cycles through the items. With the selection arrow in front of the menu item, press ENTER to select that item.

## Open/Close

The OPEN/CLOSE key places the sample slide in either the open (loading) or the closed position. With the slide closed, pressing OPEN/CLOSE aborts the current operation of the instrument and the slide opens to the sample holder position. Pressing OPEN/CLOSE again rotates the slide to the closed or measurement position with the measurement starting automatically once the sample chamber seals.

## Main Menu

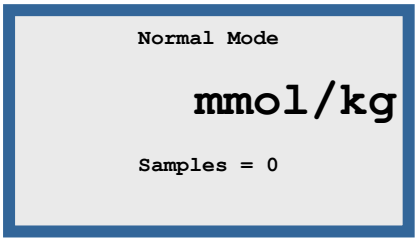



Pressing SELECT from the idle state or with the sample slide open accesses the *Main Menu*. From the *Main Menu*, the SELECT and ENTER keys are used to select from a number of functions or the *Mode Menu* and *Configure Menu*. Pressing SELECT cycles through the items. With the selection arrow in front of the desired menu item, press ENTER to select that menu item.

Selections from the *Main Menu* include:

- Reset Statistics
- Recall Last Readings
- Mode Menu
- Configure Menu
- Exit

## Reset Statistics

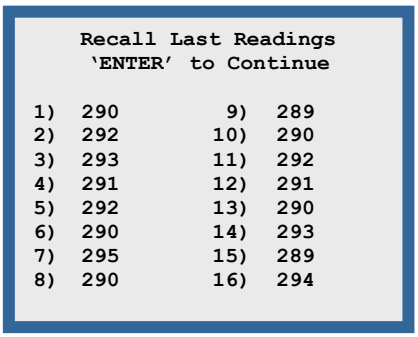



The VAPRO maintains statistical data on up to 16 samples. Using statistical data may improve precision and reduce assay errors. Multiple assays on a sample can be run as needed with the instrument reporting statistical data including: the high reading, low reading, group mean reading and group standard deviation for the assays. Selecting and Entering the *Reset Statistics* from the *Main Menu* resets the data to start a new statistical group and resets the statistics counter to zero. The next measured result becomes the first sample in the statistical stored data. If all 16 data points are filled, the next data point replaces the oldest data point. Calibrating the instrument or allowing the instrument to return to the idle state also resets the data to start a new group. Statistics automatically reset when changing modes of operation or when starting an Auto-Repeat assay on a sample.

The group standard deviation cannot be greater than 45 in order to display the actual value. Values greater than 45 simply display as >45. As long as one of the values in the statistical group produces a result that is greater than 45, the reading displays as >45, even though the total statistical group may be something less than 45. This is because of system limitations.

## *3. 1 Operation Overview*

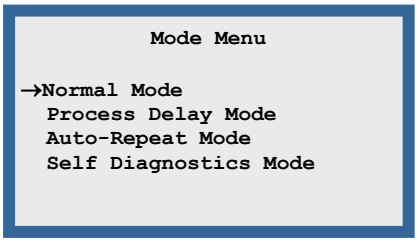
### Recall Last Readings




Selecting the *Recall Last Readings* allows you to recall the last readings. The number of readings since the last time the statistics were reset is displayed (up to 16 readings). The most recent reading is always first, using the example at the left: 1) 290. The oldest reading is always shown last, using the example at the left: 16) 294.

If more than 16 readings are taken without resetting the statistics, the most recent 16 readings are displayed. If no readings are present, the instrument returns to the previous state of operation.

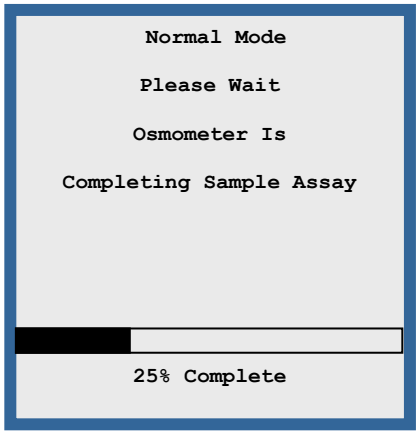
## Mode Menu




The *Mode Menu* selects special modes of operation for the instrument. The current mode displays on the screen. The modes include the following: *Normal Mode, Process Delay Mode, Auto-Repeat Mode*, and *Self Diagnostics Mode*.

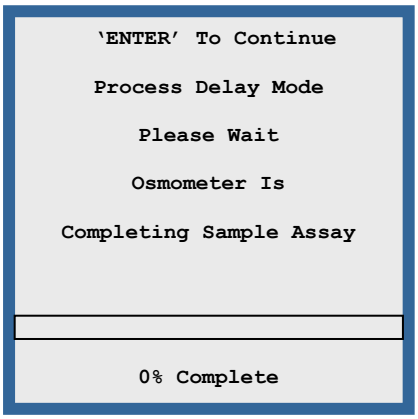
After entering the *Mode Menu*, pressing the SELECT key cycles through the menu items. With the arrow pointing to the desired mode, press ENTER to select that mode of operation. It is possible to change the mode when the instrument is idle or with the sample slide open.

### Normal Mode



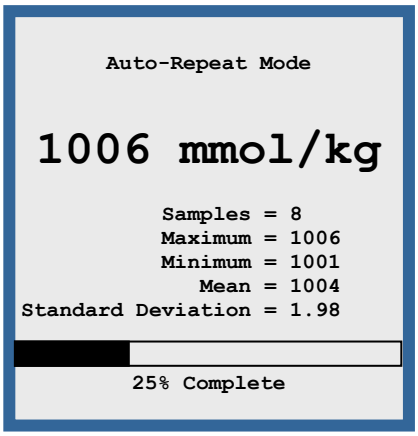

The *Normal Mode* allows osmolality measurement on single samples and is the typical mode (and default setting) of operation Statistical information collects on an on-going basis for up to the latest 16 samples. (Reset the statistics from the *Main Menu*.)

## Process Delay Mode




Complex samples (such as leaf and other semi-solid samples in nature from which water may not readily evaporate) require long periods to reach vapor equilibrium. Entering the *Process Delay Mode* allows the instrument to seal the sample chamber, but not to start the measurement process until the ENTER key is pressed. In research applications, this permits delaying the measurement until achieving vapor equilibrium.

## Auto-Repeat Mode



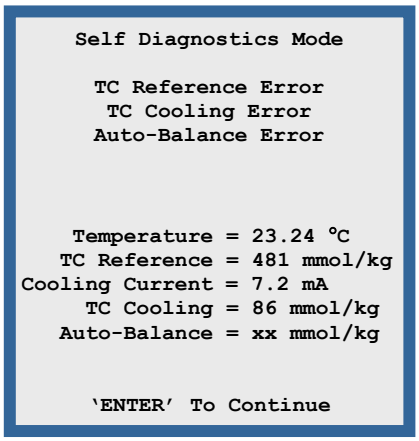

*Auto-Repeat Mode* instructs the instrument to take 10 assays on the same sample. This mode is most useful for checking instrument operation and its ability to repeat assay readings on a given sample. This mode also checks vapor equilibration within the instrument and can be used to see if the sample is reaching equilibration. A non-equilibrated sample continues to give decreased results until reaching equilibration, at which time the results start to repeat. The instrument automatically runs 10 consecutive measurements on the sample, (usually a 1000 mmol/kg Opti-Mole sample) and displays and updates the statistical data after each assay. Since the chamber does not open between measurements as in other modes, a delay occurs while water evaporates from the thermocouple. The message "Drying" displays near the bottom of the display.

Low osmolality samples (below 200 mmol/kg) may show a difference between the first and any subsequent readings if the chamber is contaminated.

The auto-repeat sequence can be interrupted at any point simply by pressing the OPEN/CLOSE key.

Statistics automatically reset when starting an Auto-Repeat assay on a sample.

## *3. 1 Operation Overview*




### Self Diagnostics Mode

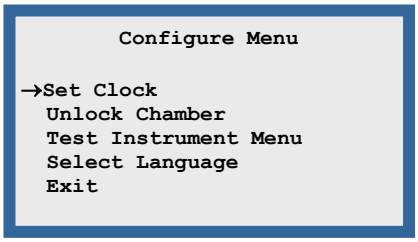
Use the *Self Diagnostics Mode* to diagnose a problem with instrument operation. In this mode, leave the sample holder empty. The instrument takes a series of measurements and displays them to verify the operation of the internal circuits. Error messages display if problems are detected. If errors occur, correct the error conditions and press the ENTER key to continue. Run the self diagnostics once again to make sure that the error conditions have been resolved.

After entering the *Self Diagnostics Mode*, press OPEN/CLOSE to begin the test.

**NOTE**

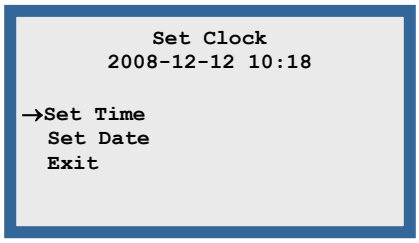
If errors are detected, correct the error condition before using the instrument; otherwise, the results may not be accurate. In most instances, the instrument allows continuation of the process for troubleshooting purposes although the instrument really is not ready to make accurate measurements.

## Configure Menu

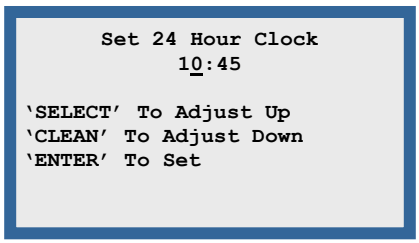



The *Configure Menu* allows you to set the instrument clock, unlock the sample chamber, test the instrument, and to select the language displayed. Press SELECT to scroll to the desired menu item and then press ENTER.

### Set Clock

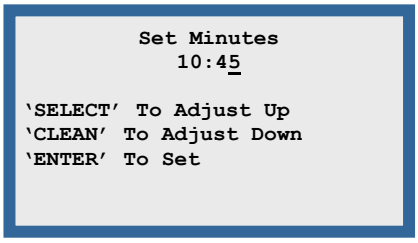



*Set Clock* allows you to set the date (month, day, and year) and the time (hours and minutes in 24-hour format). From the Set Clock menu, SELECT *Set Time* to set the hours and minutes or *Set Date* to set the month, day, and year.




**To set the time,** SELECT the menu item *Set Time* and press ENTER. The *Set 24 Hour Clock* screen appears. A cursor appears under the hours digit.

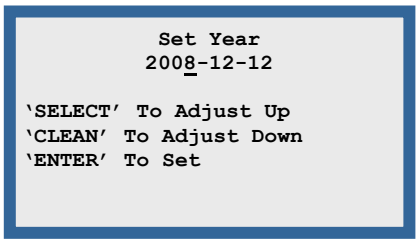
**To set the 24-hour clock,** press SELECT to increase the hours and CLEAN to decrease the hours. After reaching the limits (0 – 23), the hours start over. When the desired hour is displayed, press ENTER to set the hour. The screen automatically advances to the *Set Minutes* screen. A cursor appears under the minute digit.




Press SELECT to increase the minutes and CLEAN to decrease the minutes. After reaching the limits (00 – 59), the minutes start over. When the desired minutes are displayed, press ENTER to set the minutes. The screen returns to the *Set Clock* menu screen with the arrow pointing to *Set Date*.

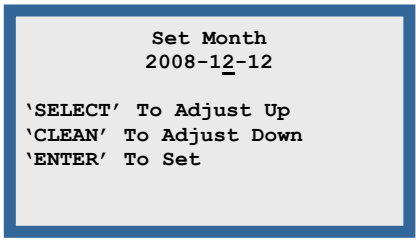
## *3. 1 Operation Overview*

### Setting the Date

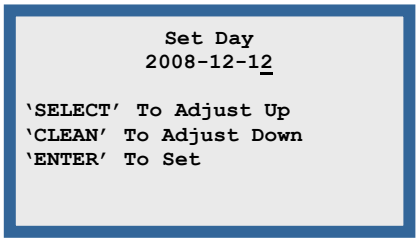



From the *Set Clock* menu, SELECT the menu item *Set Date* and press ENTER. The *Set Year* screen appears. A cursor appears under the year.

**To set the year,** press SELECT to increase the year and CLEAN to decrease the year. After reaching the limits (2000 – 2099), the year starts over. When the desired year is displayed, press ENTER to set the year. The screen automatically advances to the *Set Month* screen. A cursor appears under the month digit.



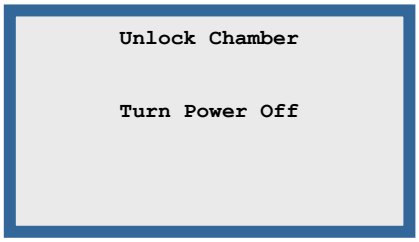

**To set the month,** press SELECT to increase the month and CLEAN to decrease the month. After reaching the limits (1 – 12), the months start over. When the desired month is displayed, press ENTER to set the month. The screen automatically advances to the *Set Day* screen. A cursor appears under the day digit.




**To set the day,** press SELECT to increase the day and CLEAN to decrease the day. After reaching the limits (1 – 31), the day wraps around. When the desired day is displayed, press ENTER to set the day. The screen automatically returns to the *Set Clock* menu screen.

To exit from the *Set Clock* screen, press SELECT to position the arrow so it is pointing to *Exit* and press ENTER.

### Unlocking the Sample Chamber

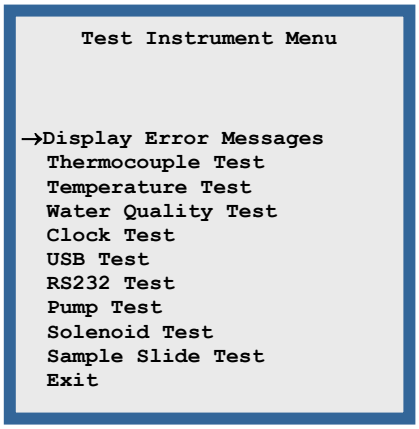



From the *Main Menu* press SELECT until the arrow points to *Configure Menu*, press ENTER. From the *Configure Menu*, press SELECT until the arrow points to Unlock Chamber, press ENTER to unlock the chamber. The display indicates that the chamber is unlocked and to turn the power off.

Under normal operation, the chamber remains sealed under spring pressure either in the cleaning position or in the closed position. Unlocking the chamber removes the spring pressure for manual removal and installation of the thermocouple head. After unlocking the chamber, the keypad is inactive and no other operations can be performed. Power must be turned off to reactivate the keypad.

After unlocking the chamber, always remove power to the VAPRO before disconnecting and removing the thermocouple. When power returns to the instrument, the chamber automatically locks.

## Test Instrument Menu



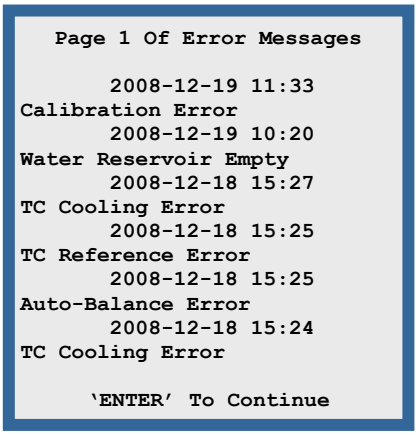

From the *Main Menu* press SELECT until the arrow points to *Configure Menu*, press ENTER. From the *Configure Menu*, press SELECT until the arrow points to *Test Instrument Menu* and press ENTER.

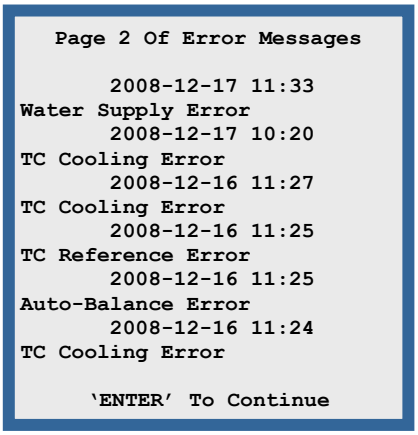
From the *Test Instrument Menu*, use the SELECT key to scroll down to the desired test and press ENTER to select. When exiting from the test, press ENTER and keep the key held down until the test exits.

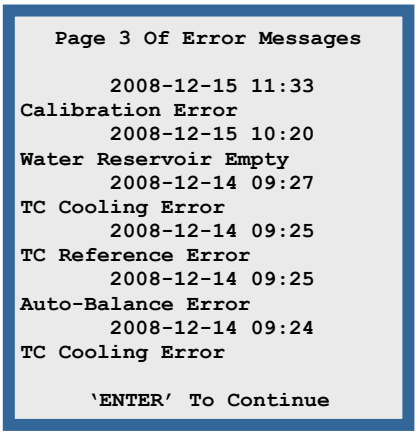
### Display Error Messages

From the *Test Instrument Menu*, press SELECT to scroll to *Display Error Messages* and press ENTER. The Display Error Messages displays the 18 most recent errors along with the date and time of when the error occurred. Upon entering, Page 1 displays the most recent 6 messages (1-6), with the most recent message being on the top.

Press ENTER to continue. If there are more than one page of messages, then the second page of messages displays (messages 7-12) otherwise, control returns to the *Test Instrument Menu*. Press ENTER to continue. If there are more than two pages of messages, the third page of messages displays (messages 13-18) otherwise, control returns to the *Test Instrument Menu*. At the third page of error messages, pressing ENTER one more time returns control to the *Test Instrument Menu*.



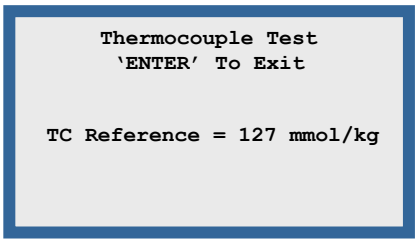



SECTION 3
OPERATING THE VAPRO OSMOMETER

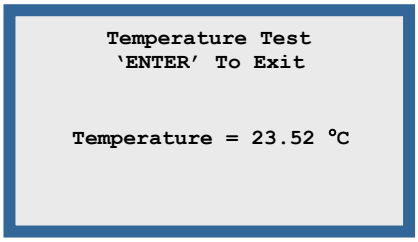
## *3. 1 Operation Overview*

### Thermocouple Test



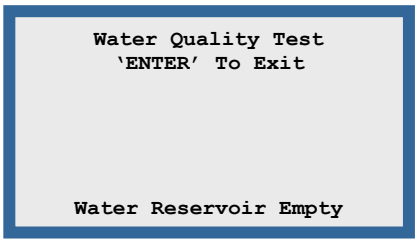

From the *Test Instrument Menu*, press SELECT to scroll to *Thermocouple Test* and press ENTER. Thermocouple Test measures the thermocouple reference and displays the reading in mmol/kg. With an empty chamber, the reading should be less than 200 mmol/kg. Typical readings are about 100 mmol/kg. The test continues to take a reading and update the display until the ENTER key is pressed to exit. When exiting, keep the ENTER key held down until the test exits and control returns to the *Test Instrument Menu*.

### Temperature Test



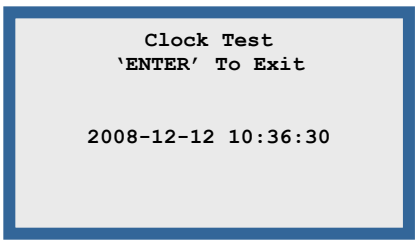

From the *Test Instrument Menu*, press SELECT to scroll to *Temperature Test* and press ENTER. Temperature Test measures the system temperature and displays it in degrees Celsius. The test continues to take a reading and update the display until the ENTER key is pressed to exit the test and control returns to the *Test Instrument Menu*. The temperature from this sensor gets used when displaying the temperature drift of the instrument.

### Water Quality Test



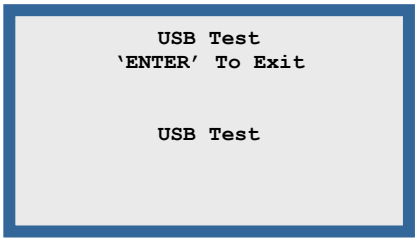

From the *Test Instrument Menu*, press SELECT to scroll to *Water Quality Test* and press ENTER. Water Quality Test measures the quality of the water and displays the result in micro-siemens (µS/cm). The result from this reading either displays the quality of the water or indicates if the supply reservoir is empty. Fresh USP purified water should read less than 1 µS/cm. If the water quality approaches 5 µS/cm, rinse out the supply reservoir and refill it with USP purified water. The test continues to take a reading and update the display until the ENTER key is pressed to exit. Because it takes a few seconds to take a reading; when exiting, press ENTER and keep it held down until the test exits and control returns to the *Test Instrument Menu*.

### Clock Test



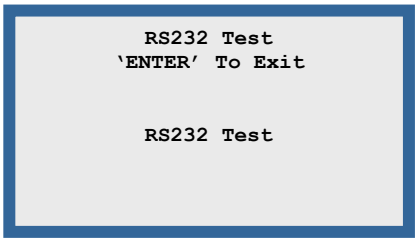

From the *Test Instrument Menu*, press SELECT to scroll to *Clock Test* and press ENTER. Clock Test reads the real time clock and displays the date and time. The test continues to read the real time clock and update the display until the ENTER key is pressed to exit the test and returns control to the *Test Instrument Menu*.

### USB Test



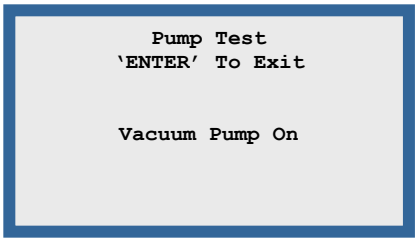

From the *Test Instrument Menu*, press SELECT to scroll to *USB Test* and press ENTER. USB Test sends out data to the USB port and continues to send out data for 32 times or until ENTER is pressed to exit the test and return control to the *Test Instrument Menu*. The message blinks on and off each time it is sent out the port.

### RS232 Test



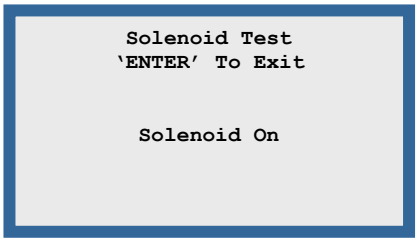

From the *Test Instrument Menu*, press SELECT to scroll to *RS232 Test* and press ENTER. RS232 Test sends out the string of characters 'RS232 Test' to the RS232 port and continues to send out the same message until ENTER is pressed to exit the test and return control to the *Test Instrument Menu*. The message blinks on and off each time it is sent out the port.

### Pump Test




From the *Test Instrument Menu*, press SELECT to scroll to *Pump Test* and press ENTER. Pump Test turns the vacuum pump on. The default position of the pump test pulls air through the desiccant. The pump remains on until ENTER is pressed to exit the test, at which time the vacuum pump turns off and control returns to the *Test Instrument Menu*.

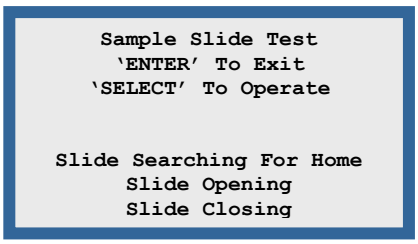
### Solenoid Test




From the *Test Instrument Menu*, press SELECT to scroll to *Solenoid Test* and press ENTER. Solenoid Test actuates the solenoid valve that is used to switch between allowing liquid to be pumped through the chamber for cleaning or for allowing air to be pumped through the chamber for drying. The solenoid is left on until ENTER is pressed to exit the test, at which time the solenoid valve turns off. You should be able to hear the solenoid valve click as it turns on and off. Exiting from the test returns control to the *Test Instrument Menu*.

SECTION 3
OPERATING THE VAPRO OSMOMETER

## 3. 1 Operation Overview



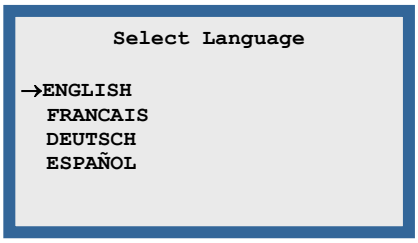

### Sample Slide Test

From the *Test Instrument Menu*, press SELECT to scroll to *Sample Slide Test* and press ENTER. Sample Slide Test positions the sample slide to the open or closed position. After selecting this test, the display shows two options: (1) 'ENTER' To Exit or (2) 'SELECT' To Operate. Pressing SELECT either opens or closes the sample slide, depending upon its current position. Messages that may be displayed include: *Slide Searching For Home, Slide Opening, or Slide Closing*. Press ENTER to exit the test and return control to the *Test Instrument Menu*.

### Exit

From the *Test Instrument Menu*, press SELECT to scroll to *Exit* and press ENTER. The osmometer exits back to the idle state or the sample slide open state.

### *Select Language*

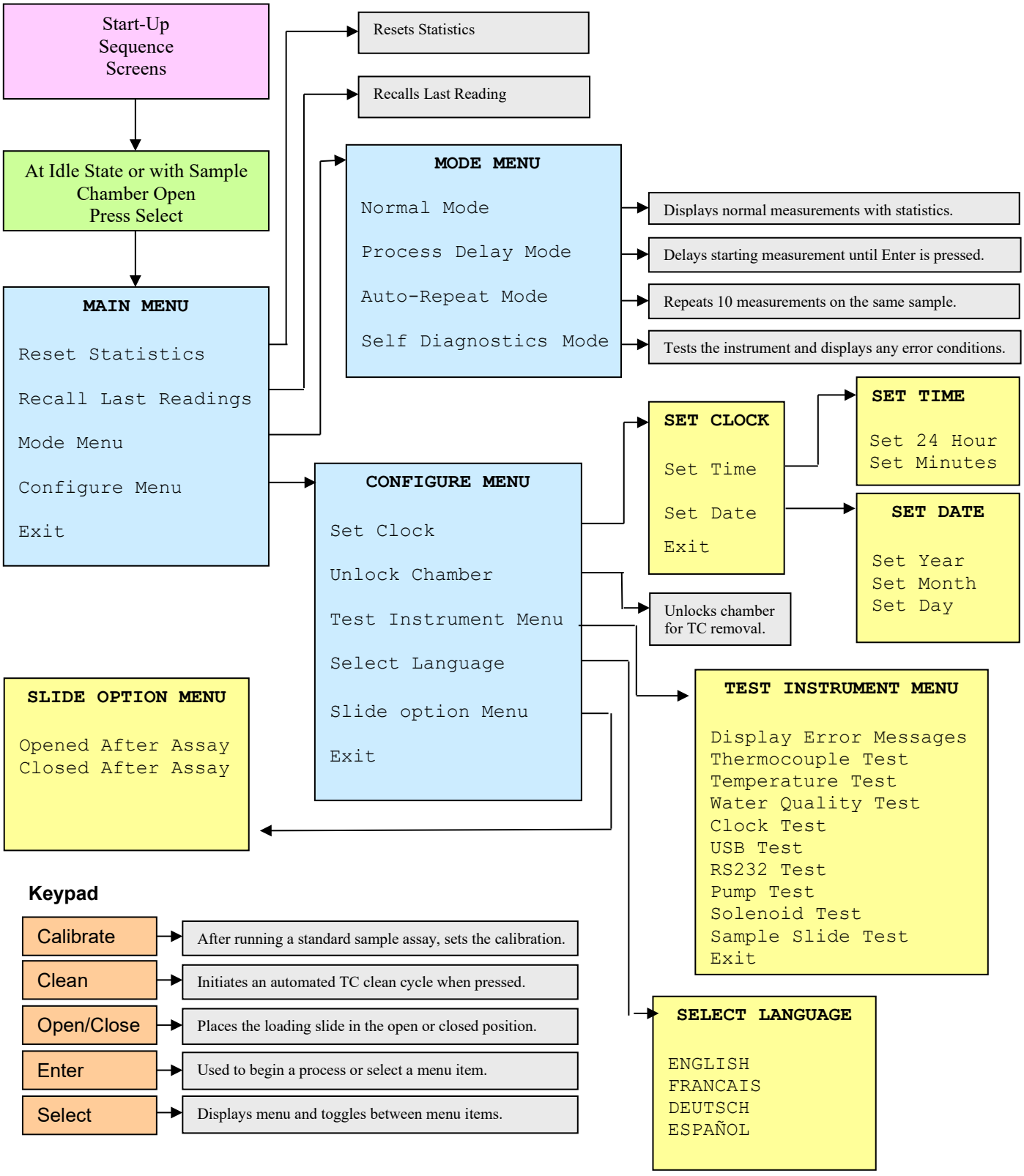



From the *Select Language* menu, use the SELECT and ENTER keys to set the desired language of operation from the selections. Language selections include: ENGLISH (default), FRANCAIS (French), DEUTSCH (German), and ESPAÑOL (Spanish). With the arrow pointing to the desired language, pressing ENTER selects that language and returns control to the idle state or the sample slide open state.

### *Slide Option Menu*

From the *Slide Option Menu,* use the SELECT and ENTER keys to set the desired slide position (*Opened or Closed*) immediately following a sample assay. Using the SELECT key to move the arrow and with the arrow pointing to the desired option, pressing ENTER selects and saves the desired option.

# Table A: Basic Menu Structure Diagram



# Micropipettor Information

The micropipettor furnished with the VAPRO uses a two-step (aspirate/expel) mechanism that dispenses 10 µL of liquid for osmolality assay. This no-maintenance micropipettor works with a wide range of biological solutions and laboratory reagents. Disposable plastic tips eliminate carry-over error from sample to sample. Use the provided micropipettor to assure uniform results among different operators.

ELITechGroup does not recommend three-step pipetting (aspirate/expel/blowout) for loading the osmometer. The blowout step tends to create bubbles in the specimen that can lead to thermocouple contamination.

If bubbles do occur in the specimen, remove the specimen from the sample holder, clean the sample holder and surrounding area, and apply a new specimen.

## Positive Displacement Pipettors

A positive-displacement pipetting device or alternative loading methods may be more suitable for extremely viscous fluids or complex specimens.

**CAUTION**
**Do not use positive displacement pipetting devices for routine operation. Refer to the Appendix F for additional information regarding special applications.**

The sample loading procedure in this manual presumes the use of the ELITechGroup supplied micropipettor.

## Sample Volume Considerations

The VAPRO does not demand a high degree of volumetric accuracy at the 10 µL sample level. Sample volume variations of ± 10% will not noticeably affect the final result.

**CAUTION**
**Significant measurement errors can occur from gross volumetric errors arising from incorrect pipetting technique, micropipettors poorly maintained, or micropipettors not approved by ELITechGroup.**

# Using Opti-Mole Osmolality Standards

Opti-Mole ampule osmolality standards (OA-010, OA-029, and OA-100) provide uncompromising accuracy to satisfy the most stringent quality assurance requirements. Calibration integrity is assured because ampules provide fresh solution for each use. Having the accuracy of reference standards, Opti-Mole standards are ideal for routine osmometer calibration. Ampule standards are manufactured under strict quality control and sealed in glass to preserve accuracy for a minimum storage life of 36 months.

**NOTE**

Once opened, ampule standards should be used or discarded within four hours.

## Instructions

Each ampule contains 0.4 mL of solution. This volume is sufficient to prevent measurable evaporative concentration for four hours after the ampule is opened.

1. Flip the stem of the ampule with your finger, or tap the ampule lightly against a hard surface to dislodge any solution held by capillary action in the stem of the ampule.
2. Place the ampule in the breaker position of the Ampule Organizer (AC-061). Hold the organizer firmly down against the work surface.
3. Slide the provided flexible protection sleeve over the stem of the ampule.
4. Grasp the sleeved stem firmly and snap the neck of the ampule.
5. Aspirate no more than the volume required for measurement directly from the ampule, using a fresh micropipettor tip each time to avoid contamination of the solution.
6. Leave as much solution as possible in the container so as to maintain a low concentration rate.
7. Discard any solution that remains after finishing calibration procedures.

## Assuring Accurate Measurements

The accuracy of reported osmolality is directly linked to the accuracy of the calibrating standard solutions. While these solutions have exact specified osmolality at the time they are opened, osmolality inevitably increases as water evaporates.

Always adhere to the following guidelines when using Opti-Mole ampule standards:

- Since the specified value of osmolality is certain only at the time the ampule is opened, do not rely on any opened ampule if there is an uncertainty of how long its contents have been exposed to evaporation.
- Sample directly from the ampule. Do not transfer the Opti-Mole solution from ampules to other containers.
- Always follow the instructions to calibrate the VAPRO.
- Always verify calibration before running any unknowns.

## Using OSMOCOLL® HNL Serum Control

Osmocoll HNL (SS-273) is a processed, stabilized bovine serum control, which is useful in a quality assurance program for the VAPRO.

For optimum results, always adhere to the following guidelines:

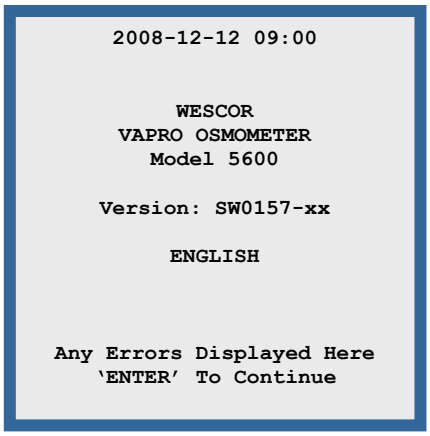
- Upon arrival in your laboratory, refrigerate Osmocoll HNL. Under refrigeration, the serum remains stable until the labeled expiration date.
- Once opened, the maximum stable life is 5 days, if kept refrigerated and tightly capped; however, the solution must be at room temperature before running in the osmometer.
- If the measured osmolality of the Osmocoll serum falls outside of the range listed on the package labeling (each Osmocoll lot is assayed for osmolality), recalibrate the instrument using freshly opened Opti-Mole ampule standards.
- When applying Osmocoll on the disc, bubbles can sometimes form on the sample. If this happens, remove the sample, clean the sample holder, and apply a new disc and sample.

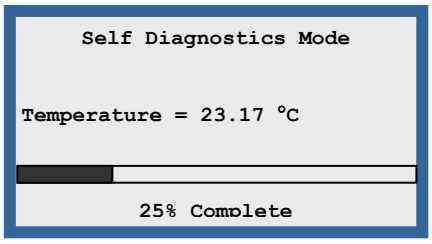
**CAUTION**
**Never calibrate the VAPRO using Osmocoll HNL control solution.**

## Operation Qualification (OQ) Procedure

Operation Qualification is the process of demonstrating that an instrument functions according to its operational specification in the selected environment. The following process provides a method for documented verification. Note that OQ is NOT required to prove that the instrument meets the manufacturer's performance specifications.

For a checklist form with signature blocks of the following procedures, refer to Appendix G.



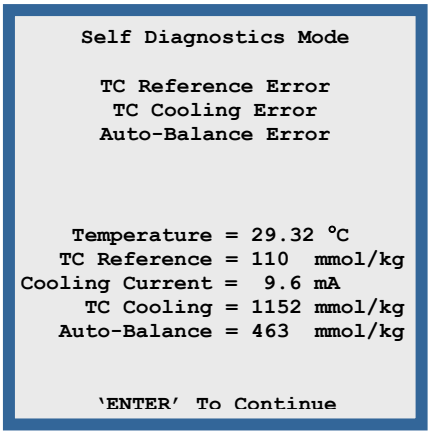

## Initialization and Stabilization

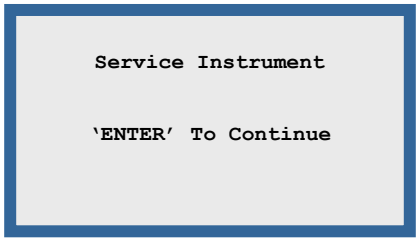
1. Turn the VAPRO ON (**I**). The POWER indicator on the front panel shows green when power is on.

2. Upon power up, the instrument conducts a series of operations before it is ready to accept any samples. These operations include setup of the micro-controller and peripherals and general readiness checks.

3. A sign on screen includes the date, time, and software version. If the instrument senses a condition or state that does not allow it to properly function it does not accept a sample and instead reports the error condition. The instrument may also give a warning if the condition allows operation, but needs attention.

## *3.4 Initialization and Stabilization of the Thermocouple*

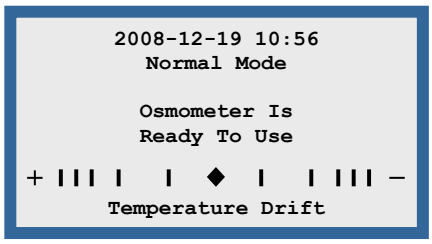



4. The instrument then sequences to the Self Diagnostics Mode where a number of self tests are conducted including:
    a. Reading the temperature sensor and displaying the results.
    b. Reading the TC Reference and displaying the results.
    c. Determining the optimal current to use for cooling the thermocouple and displaying the cooling current.
    d. Reading the TC while cooling and displaying the results.
    e. Determining the initial balance voltage and displaying the results.
    f. Any error conditions that may have occurred during the initialization process are displayed. Correct any errors before continuing to ensure accurate measurements.

    If error messages occur and are displayed, the user must press ENTER to continue. The screen then displays "*Service Instrument*," the sample slide opens, and the user must press ENTER to continue. Pressing the ENTER key allows the instrument to go into the idle state, however the *Self Diagnostics Mode* is the only mode available until the errors are corrected. Access to other menus other than the *Mode Menu* allows further diagnostics if needed. Press OPEN/CLOSE to begin a diagnostics test.

    Running in the *Self Diagnostics Mode* and getting values within the expected range (no errors) allows the user to enter the *Mode Menu* and change the mode back to *Normal Mode*. Powering the instrument off and on and getting valid readings allows the instrument to come up in *Normal Mode*. If errors in the measurement are expected, the instrument will not allow an assay on a sample.



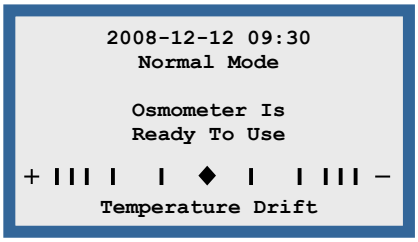

5. When the instrument successfully completes the start-up operations the instrument is in *Normal Mode* and the display reads "*Osmometer is Ready To Use.*" The instrument is now in the idle state, the keyboard becomes active and the instrument accepts a sample introduction. In this idle state the instrument continually runs auto-balancing operations and displays the Temperature Drift scale. This Temperature Drift scale gives indication to the temperature stability of the instrument. The idle screen also displays the mode of operation.

**NOTE**

Although the screen at this point indicates the instrument is ready, calibration will not be stable until the instrument reaches thermal equilibration. Correct any errors to ensure accurate measurements. As a general guideline, once an error has been corrected either run the Self Diagnostics tests or power the instrument off and then back on so that the initialization tests can be performed.

## *3.4 Initialization and Stabilization of the Thermocouple*

### Temperature Drift Scale




Osmolality determination involves the measurement of extremely small temperature differentials. The osmometer is thus sensitive to ambient temperature changes, which induce internal temperature changes.

While the instrument compensates for small changes that occur over time, moving the instrument to a different area or exposing it to too much air circulation shifts the osmometer's readings and calibration points. The Temperature Drift Scale allows you to determine when internal temperature has stabilized.

The Temperature Drift scale appears on the screen whenever the instrument is in the "idle" mode. The instrument is considered stable and ready to operate unless the diamond indicator is against the + or - marks on the scale, indicating a changing internal temperature that can affect instrument calibration.

**CAUTION**
**Do not operate the instrument if the temperature drift scale is not within the operational temperature range.**

Examples of the Temperature Drift scale:


Temperature Drift scale in normal operating temperature range. (The diamond is located in the center.)


Temperature Drift scale with positive temperature gradients that exceed a safe range to take readings. The instrument is not stable to operate. (The diamond is located at the far left of the scale against the '+'.)


Temperature Drift scale with negative temperature gradients that exceed a safe range to take readings. The instrument is not stable to operate. (The diamond is located at the far left of the scale against the '-'.)


Temperature Drift scale within the operating range of the instrument. (The diamond is located to the left of center, but still within the operating range.)

**NOTE**

It is normal for the osmometer to undergo a significant temperature drift during the first few minutes of equilibration. The time required to achieve temperature stability depends on the initial instrument temperature, (typically 10 to 30 minutes) but may be longer if initial temperature varies more than 5 °C from room temperature.

Under normal circumstances, leave power turned on to keep the instrument in a ready state and to maintain stability.

## Loading Samples

When first using the VAPRO system, practice the loading procedure using the micropipettor and the 290 mmol/kg standard. Record the value displayed at the end of the cycle, when the tone sounds. Practice this procedure until obtaining sequential results with a spread of less than 6 mmol/kg. Consistent timing during loading is important for optimum repeatability. This comes naturally after a few samples.

**NOTE**

While practicing, do not be concerned if the instrument readings do not agree with the specified concentration of the solution. When you feel comfortable with the procedure and are able to obtain repeatable results, continue with the procedure.

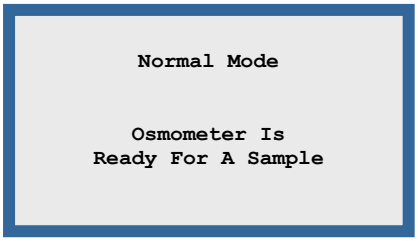
### Sample Volume

The optimum sample volume (10 µL) should fully saturate one of the SS-033 sample discs. The osmometer accommodates variations in sample volume as great as ± 10% (9 µL to 11 µL) without noticeable variation in indicated osmolality.

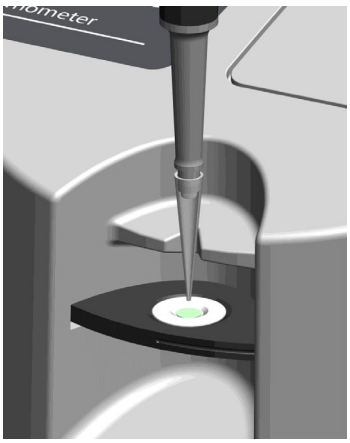
**CAUTION**

**Samples greater than 11 µL can contaminate the thermocouple.**

### Sample Loading Procedure




1. From the idle state, press the OPEN/CLOSE key to bring the sample holder directly under the pipettor guide.



2. Use the forceps supplied with the instrument to place a single sample disc in the central depression of the sample holder. Make sure only a single disc has been picked up. If necessary, use the forceps and a teasing needle to separate the discs. If two discs stick together, the reading will be slightly elevated. Reject imperfect discs or any that do not lie flat.
3. With a clean tip installed, aspirate a sample into the micropipettor by depressing the plunger to the stop, immersing the tip, and gently releasing the plunger.

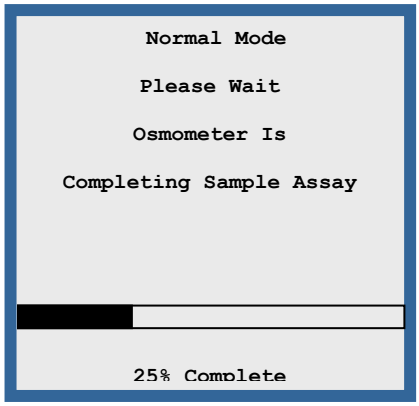
**NOTE**

Normally, sample droplets do not cling to the outside of the tip. If they do, they can usually be removed simply by dragging the tip against the lip of the container while removing it. Occasionally a clinging droplet may have to be removed with a tissue, but be very careful not to wick solution out of the tip.

4. With the pipettor tip resting in the notch of the pipettor guide, position the tip about 5 millimeters above the center of the sample disc.
5. Smoothly depress the micropipettor plunger to the stop. The specimen may drop onto the sample disc. Whether the sample droplet falls onto the disc or clings to the tip, you must complete Step 6.

**CAUTION**
**Never allow the micropipettor tip, sample material, or the wet disc to touch the outer surface of the sample holder. If this occurs, abort the measurement and wipe the sample holder clean before proceeding.**

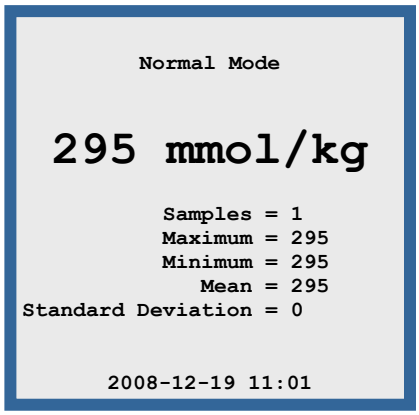
**CAUTION**
**If air bubbles are observed on the sample, remove the sample, clean the sample holder, and introduce a new disc and sample. Breaking bubbles compromises the sample volume and contaminates outer surfaces of the sample holder. A bubble bursting inside the chamber contaminates the thermocouple.**




6. With the plunger still held against the stop, lightly touch the micropipettor tip to the sample disc, and then lift it away. The tip must briefly contact the sample disc to press it flat against the holder. The paper disc should appear fully saturated, with a slight liquid meniscus on its surface.
7. Press the OPEN/CLOSE key to rotate the sample into the measurement position and start the assay.

**NOTE**

Since the sample may concentrate slightly before the chamber seals, perform steps 5 through 8 with consistent timing. A warning chirp sounds every 20 seconds if the chamber is left open.




The progress bar along the bottom of the display shows the assay progress. When the measurement completes the tone sounds and the display screen shows the osmolality of the specimen. The display shows this final reading until the chamber closes again or another function is selected.

**NOTE**

The VAPRO reports osmolality measurements in Standard International (SI) units: mmol/kg.

## *3.5 Running Samples*

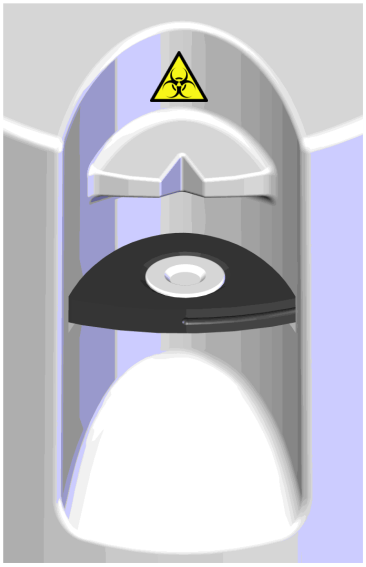
**CAUTION**
**During long uninterrupted measurement periods, occasionally allow the instrument to return to the "idle" mode by initiating an operating cycle on an empty chamber. This allows the instrument to readjust itself to any temperature changes during the interval. Failure to do this can cause unwanted calibration shifts.**

8. Using a lint-free tissue (not facial tissue) or cotton swabs, carefully remove the wet disc and any traces of residual liquid from the sample holder immediately after a measurement. A warning chirp sounds every 20 seconds if the chamber is left open.

9. Repeat the above steps as many times as necessary to become familiar with the loading samples process. Each time an assay occurs statistical information gets updated on the display.

**CAUTION**
**You can severely contaminate the chamber (or the thermocouple) in a single loading by improperly loading the sample or failure to thoroughly clean the sample holder. Severe contamination can make it impossible to calibrate the osmometer.**

## Cleaning the Sample Holder



To clean the sample holder and prepare for another sample:

1. Using a lint-free tissue (not facial tissue) or cotton swabs, carefully remove the wet disc and any traces of residual liquid from the sample holder.

**CAUTION**
**Never use metal forceps to remove wet discs; this can damage the surface of the sample holder.**

2. Leave no visible residue on the holder surface. If needed, use a tissue or swab moistened with deionized water. Always clean the sample holder with a fresh tissue or swab to avoid contamination. Avoid touching the sample holder with bare fingers.

The sample holder should appear bright, shiny, and perfectly dry before loading the next specimen. Using deionized water causes the sample chamber to cool down. If deionized water is used, run an empty chamber between cycles.

## *3.7 Calibrating the VAPRO*

**NOTE**

Regularly perform calibration checks. As a minimum, at the beginning of each shift.

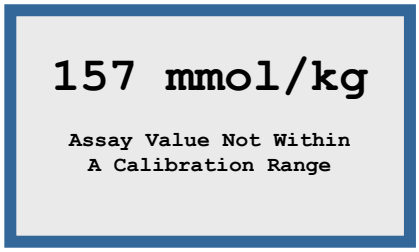
# Calibrating

Calibration accuracy depends upon three main factors:

- Standard solution accuracy
- Thermocouple cleanliness
- Loading technique (repeatability)

Calibration should occur after the initial temperature equilibration period. Thereafter, as a minimum, check calibration before each session of use. Calibration values get saved in non-volatile memory in case power is interrupted.

## Assay Value Not Within a Calibration Range




The VAPRO uses the temperature depression reading taken during a calibration procedure to set the mmol/kg conversion values used for all the readings. This type of calibration eliminates any system errors in the instrument to provide the most accurate results. When the calibration key is pressed, the last assay result is checked to see if the temperature depression value fits within a calibration window. If the value does not fit within any calibration window the message *"Assay Value Not Within A Calibration Range"* displays and calibration is not completed for that assay. The assay result displayed may be very close to an actual calibration value, however that result may be using conversion values that are already near their limits to give that displayed result.

The most common reason for the above message is due to contamination of the thermocouple. The contamination effects the 100 mmol/kg calibration first, but could also affect the 290 mmol/kg calibration. Using the automated cleaning function should resolve this issue. Other causes of this message may be a result of attempting to calibrate on assays that are not proper calibration solutions or Opti-Mole that has been concentrated due to evaporation.

Always calibrate with fresh Opti-Mole solutions and discard any old solution.

## Instrument Response Characteristics

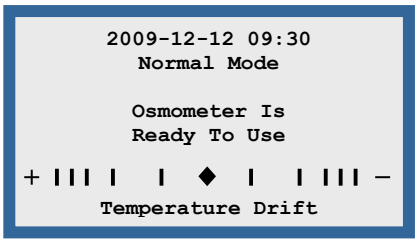
Most clinical osmolality determinations range from 200 mmol/kg to 1000 mmol/kg. The inherent linearity of the vapor pressure method results in an extremely linear instrument response from 100 mmol/kg to 1800 mmol/kg.

**NOTE**

Use Opti-Mole glass-encapsulated ampule 290 mmol/kg, 1000 mmol/kg, and 100 mmol/kg standards for calibration.

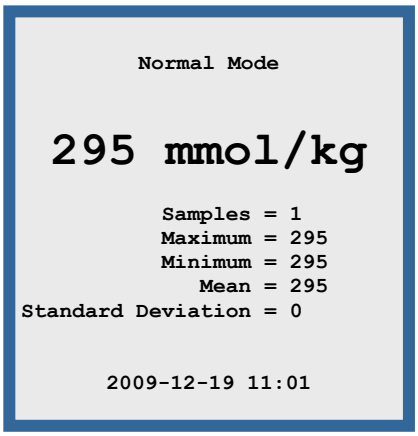
## *3.7 Calibrating the VAPRO*

### Initial or Routine Calibration



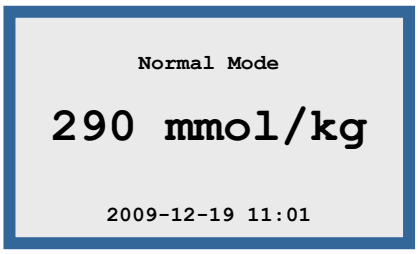

1. With the osmometer in Normal Mode and in an idle state, press the OPEN/CLOSE key to position the sample holder below the pipette guide.

2. Place a single sample disc in the central depression of the sample holder.




3. Pipette 10 µL from an Opti-Mole 290 mmol/kg standard onto the disc.

4. Press the OPEN/CLOSE key to position the sample holder to the closed or measurement position. Once the sample chamber seals the measurement automatically begins. After completion of the measurement, the slide rotates to the Open position and the assayed value displays.




5. Remove the specimen from the sample holder immediately after a measurement. If the osmometer reading is not within ± 3 mmol/kg of the standard (287 to 293), press the CALIBRATE key to calibrate the instrument to the standard; otherwise, continue with the calibration process. When the CALIBRATE key is pressed, statistical data gets reset with the calibrated reading being the first reading of the new statistical group.

6. Repeat Steps 2-5 using an Opti-Mole 1000 mmol/kg standard. In Step 5, if the reading is not within ± 5 mmol/kg of the 1000 mmol/kg standard (995 to 1005), press the CALIBRATE key to calibrate the instrument to the standard; otherwise, continue with the calibration process. Disregard the statistical data.

7. Repeat Steps 2-5 using an Opti-Mole 100 mmol/kg standard. In Step 5, if the reading is not within ± 2 mmol/kg of the 100 mmol/kg standard (98 to 102), press the CALIBRATE key to calibrate the instrument to the standard; otherwise, the calibration process is completed. Disregard the statistical data.

**NOTE**

A thermocouple contamination level reading automatically occurs whenever a calibration at 100 mmol/kg occurs. If the displayed contamination level is greater than 10, perform the automated thermocouple clean cycle. After the clean cycle, calibrate the instrument.

## Running Test Samples Using Osmolality Standards

The following procedure is for Operation Qualification where multiple assays of a calibration standard are taken to ensure proper operation of the instrument.

1. If not already completed, calibrate the osmometer using the Opti-Mole 290 mmol/kg, 1000 mmol/kg, and 100 mmol/kg standards. Record the calibration readings.
2. In *Normal Mode*, run three assays using the Opti-Mole 100 mmol/kg standard. Record the readings, including the mean and standard deviation. The mean should be within ± 4 mmol/kg for the 100 mmol/kg standard.
    - With the osmometer in an idle state, press the OPEN/CLOSE key to position the sample holder below the pipette guide.
    - Place a single sample disc in the central depression of the sample holder. Pipette 10 µL from an Opti-Mole 100 mmol/kg standard onto the disc.
    - Press the OPEN/CLOSE key to position the sample holder to the closed or measurement position.
    - Remove the specimen from the sample holder immediately after the measurement.
    - Record the readings, including the mean and standard deviation.
    - Repeat the process for the remaining two assays.
    - After running the three assays, from the *Main Menu*, reset the statistics before running the next set of assays.
3. In *Normal Mode*, run three assays using the Opti-Mole 290 mmol/kg standard. Record the readings, including the mean and standard deviation. The mean should be within ± 6 mmol/kg for the 290 mmol/kg standard. From the *Main Menu*, reset the statistics before running the next set of assays.
4. In *Normal Mode*, run three assays using the Opti-Mole 1000 mmol/kg standard. Record the readings, including the mean and standard deviation. The mean should be within ± 10 mmol/kg for the 1000 mmol/kg standard. From the *Main Menu*, reset the statistics before running the next set of assays.

## Performance Qualification

Performance Qualification is a formal protocol that tests that the system performs as intended for the selected application. The following process provides a method for documented verification. For a checklist form with signature blocks of the following procedures, refer to Appendix G, VAPRO Performance Qualification Checklist.

## General Performance Checks

Check the following instrument performance.

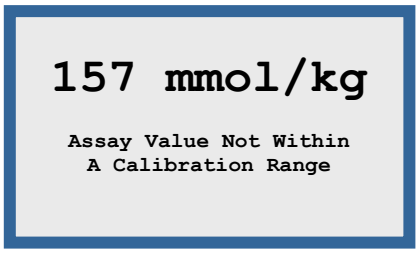
1. Verify the power switch operates properly.
2. Turn power off, wait 10 seconds, and turn power on. Let the osmometer complete the system initialization sequence.
3. Verify that when power turns on, the power indicator light comes on.
4. Verify that the instrument can reach system temperature equilibration.
5. Press the OPEN/CLOSE key and verify that the slide chamber rotates to the open position.
6. Pipette a 10 µL Opti-Mole 100 mmol/kg standard sample on the sample holder. Verify that the system accepts a 10 µL sample.
7. Press the OPEN/CLOSE key and verify that the slide chamber rotates to the closed position and that an assay begins.
8. Assay a sample and verify that the cycle time is 90 seconds or less.
9. Verify that 100 mmol/kg ± 4 mmol/kg displays on the screen. (It may be necessary to perform an entire calibration process.)
10. Verify that the contamination level is less than 10. If greater than 10, perform the automated thermocouple clean cycle.

## Calibrating

You should calibrate the VAPRO after the initial temperature equilibration period, and as a minimum, check calibration before each session of use. Calibration values are saved in non-volatile memory in case power is interrupted.

**NOTE**

Use Opti-Mole glass-encapsulated ampule 290 mmol/kg, 1000 mmol/kg, and 100 mmol/kg standards for calibration.




## Assay Value Not Within a Calibration Range

If the assay value is not in the correct range see Section 3.7 for instructions.

**Turn the instrument OFF before conducting maintenance.**

The VAPRO requires minimal routine maintenance:

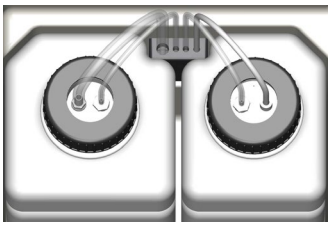
- Monitoring the supply and waste reservoirs and refilling or emptying them as needed.
- Replacing the desiccant cartridge/filter used in the thermocouple clean cycle.
- Cleaning the thermocouple (TC) head using the automated self-cleaning feature.
- Cleaning the exterior of the instrument.

**CAUTION**

**Clean the exterior of the instrument regularly, (at least once per shift). Cleaning includes wiping down the exterior surfaces with a mild detergent and water, or a 10% chlorine disinfectant solution. For decontamination refer to Section 4.10.**

## *4.2 Filling the Supply Reservoir*


Note the location of the tubing in relation to the caps. Do not cross the tubing.



The supply and waste reservoirs allow for at least 20 cleaning cycles before the supply reservoir needs to be refilled and the waste reservoir emptied. These reservoir fluid levels are visible and should be checked frequently (at least once per shift). When the supply reservoir is almost empty, refill the supply reservoir and empty the waste reservoir. The water quality sensor also senses if the supply reservoir is empty and the VAPRO displays a "Water Reservoir Empty" message and prompts to "Please Empty Waste Reservoir." **Always service both reservoirs together.**

1. The reservoirs are visible to the operator and should be checked frequently, at least once per shift. When the supply reservoir is almost empty, refill it.
2. Turn the VAPRO OFF.
3. Remove the reservoir cap assembly from the supply reservoir.
4. Clean the supply reservoir with a disinfectant solution of 10% chlorine or equivalent. Thoroughly rinse out the supply reservoir with, and then refill it with **USP purified water**.
5. Reposition the supply reservoir cap assembly, securely tightening the cap.
6. Remove the reservoir cap assembly from the waste reservoir.
7. Remove the waste reservoir and empty it according to local regulations.
8. Clean the waste reservoir with a disinfectant solution (10% chlorine or equivalent).
9. Reposition the waste reservoir cap assembly, securely tightening the cap. The pictures at left show the proper installation of the reservoirs, tubing, can caps.
10. Turn the VAPRO ON and allow it to reach temperature equilibrium.

**WARNING!**
**Always wear appropriate personal protection equipment when performing preventative maintenance on this instrument. Dispose of waste material according to local regulations.**

**Not emptying the waste reservoir can result in damage to the instrument. Always empty the waste reservoir when filling the supply reservoir.**

## *4.3 Replacing the Desiccant Cartridge/Filter*

The drying mechanism for the thermocouple self-cleaning is a desiccant cartridge/filter that dries the air during the clean cycle in less than 15 minutes (typically 5 to 6 minutes) under normal operating conditions. The minimum life of the cartridge is 20 clean cycles under these conditions (less when operating at higher temperature and humidity environments). The desiccant is blue in a new cartridge and gradually turns to a lighter blue and then to purple/pink as it approaches its useful life. When the entire desiccant turns to a purple/pink color, replace the desiccant cartridge/filter.

To replace or rotate the desiccant cartridge/filter:

1. Turn the power switch off.

**Pink Desiccant Needs Replacing**

2. Open the desiccant access cover from the top of the osmometer. There is a slot on the left side of the cover to use when opening the cover. The cover hinges from the right side.

3. To remove the desiccant cartridge/filter, grasp the cartridge from the left side and pull it straight out and then up.

4. To replace the desiccant cartridge/filter with a new one, grasp the cartridge at one end. Position the cartridge at a slight angle so that it fits into the opening on the right side of the holder. Set the cartridge down into the holder and push the cartridge in until it stops. You can feel the friction from the O-ring as it seats in place.

**Blue Desiccant Good Cartridge**

5. Close the desiccant access cover, if the cover does not close completely, the cartridge is incorrectly seated.

6. Turn power ON and allow the instrument to reach temperature equilibrium.

## *4.4 Automated Cleaning of the TC Head*

**WARNING!**
**Specimens used with the VAPRO may contain moderately hazardous substances that require care in handling. Always use appropriate safety measures including gloves, eye protection, and other personal protection equipment. In case of use with biohazards, use the instrument in a biological safety hood (including during the automated cleaning of the TC head).**

During normal use, dust or lint particles gradually accumulate in the sample chamber. Reasonable care in loading and removing sample material from the sample holder usually makes it possible to run 50-100 assays before cleaning becomes necessary, depending upon the type of sample solutions. Certain sample solutions can cause oxidation of the TC and rapid contamination, which results in cleaning the TC head more frequently. As a minimum, ELITechGroup recommends running a Clean cycle at the end of each shift.

Gross contamination usually results from incorrect sample loading or not completely removing sample material from the sample holder following an assay. When correctly operated, sample material never contacts internal chamber parts.

Under heavy use, run a 100 mmol/kg calibration when the osmometer has assayed 50-100 samples. By running a calibration at 100 mmol/kg a thermocouple contamination level reading automatically occurs. Record the results of this reading. When the reading shows moderate contamination (reading of around 10) try running the automated Clean cycle. If this fails to correct the problem, perform the full manual cleaning procedure.

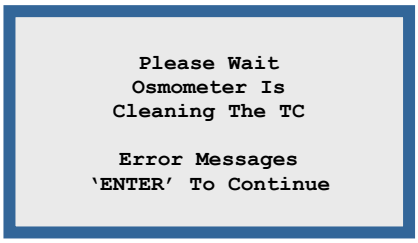
Running a Clean cycle as soon as moderate levels of contamination are measured saves time. Cleaning is much more difficult if left until contamination interferes with normal calibration settings.

The thermocouple cleaning function eliminates the need for removing the thermocouple head from the instrument in order to clean the thermocouple. This function is fully automated and self-contained requiring no intervention from the operator except to maintain clean water in the supply reservoir, emptying the waste reservoir when filling the supply reservoir, and replacing the desiccant cartridge/filter as needed. Once the Clean cycle completes, the instrument returns to the IDLE state and is ready for operation. Thermocouple cleaning can be initiated from the instruments IDLE state or from the SLIDE OPEN state.

**NOTE**

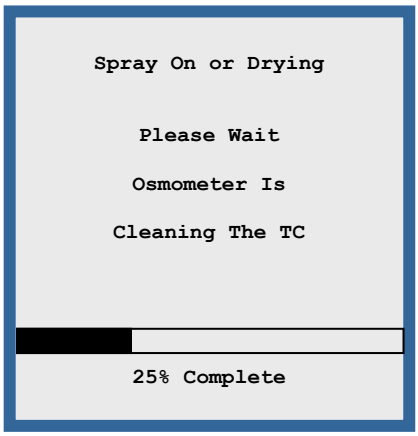
Always remove any sample from the sample holder before starting a Clean cycle.

## *4.4 Automated Cleaning of the TC Head*




1. Press CLEAN to start the TC cleaning cycle.

2. If the slide is in the closed position, it rotates to the open position and seals the thermocouple onto the cleaning position. In the open position, the slide always seals to the cleaning position. If an error occurs, a message displays and the ENTER key must be pressed to continue.




3. The cleaning cycle sprays pure water onto the TC to clean it. The instrument monitors supply water conductivity. Ideally, the conductivity is less than 1 micro-siemens/cm. If the conductivity level exceeds five micro-siemens/cm, the message "*Water Quality is > 5 uS*" displays and prompts the user to press ENTER. When ENTER is pressed, the instrument checks the water quality level. The water quality level must be < 5 µS/cm before the instrument allows a Clean cycle to occur. Water quality levels > 5 µS/cm can contaminate the TC. The message "*Spray On*" displays while the thermocouple is being sprayed with water.

4. A vacuum pump then evaporates the water from the TC to dry it. The desiccant cartridge/filter used on the intake side removes particles and water vapor from the incoming air. The message "*Drying*" displays during this time.

5. As the desiccant cartridge/filter becomes saturated its effectiveness declines, requiring longer drying times. If the thermocouple is not dry after the first attempt, the instrument enters an extended drying period. If the thermocouple fails to dry after this extended drying period, an error message: "*TC Is Not Dry"* appears. The user is prompted to press ENTER to continue. Before proceeding, inspect the inlet to the desiccant cartridge/filter to make sure it is not blocked. Replace the desiccant cartridge/filter if the color has changed to pink. Press ENTER to start a new clean cycle.

6. When the TC cleaning operation completes and the instrument determines that the thermocouple is dry, the slide moves to the closed position and an auto-balance cycle begins. If an error condition occurs during the auto-balance cycle the instrument will enter the Self Test mode until the error is resolved and the instrument is functional.

**CAUTION**
**Whenever refilling the supply reservoir always empty the waste reservoir at the same time. Failing to do so could cause damage or flooding of the instrument. Only fill the supply reservoir with USP grade or equivalent purified water.**

## *4.5 Manually Cleaning the TC Head*

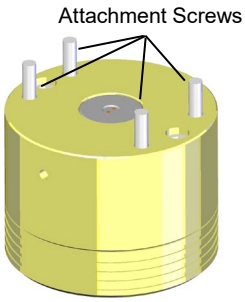
Typically, cleaning the TC head is performed using the automated self-cleaning feature of the instrument on a regular basis. Manual cleaning of the TC head requires removing it from the instrument. Carefully follow directions to safeguard the thermocouple and ensure successful completion of the manual cleaning process.

**CAUTION**
**Manual cleaning should only occur if the automated cleaning cycle does not adequately clean the TC head.**

### *Causes of Contamination*

While there are many potential causes of contamination, the following are the most common:

- A severely contaminated thermocouple with visible accumulations of organic matter or salt deposits is evidence of incorrect or careless loading procedures.
- Careless loading of greasy or waxy specimens.
- Failure to clean fingerprints or other deposits from the sample holder.
- Oily residue from compressed air lines when an air jet is used to blow water droplets from the thermocouple after cleaning.
- Improper use of Blow Clean. Liquid discharged from the can onto the thermocouple mount leaves an oily deposit that is difficult to remove.

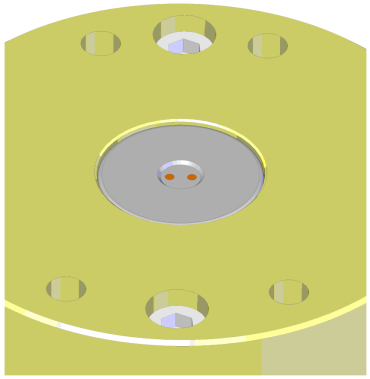



### Instructions for Removing the TC Head

1. From the idle state, press SELECT to access the *Main Menu*. SELECT the *Configure Menu* and press ENTER. From the *Configure Menu*, SELECT *Unlock Chamber* and press ENTER. The chamber unlocks.
2. Turn the power switch off.
3. Remove the TC head access cover from the top of the osmometer by lifting up from the top of the cover.
4. Remove the TC head connector by squeezing the locking tab and lifting.
5. Using the 9/64-inch hex driver, completely loosen (but do not remove from the TC head) the four attachment screws.
6. Grasp the top of the TC head (with the loose attachment screws still in the head) and lift it straight up and out of the instrument. Replace the access cover while the TC head is out of the instrument.

7. Remove the attachment screws from the head.

**CAUTION**
**To avoid thermocouple damage, invert the TC head with the thermocouple facing up, before setting it down.**



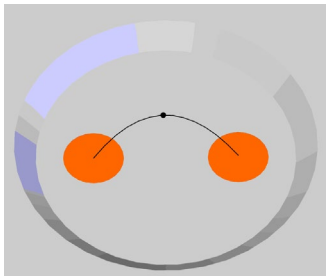
## TC Head Cleaning Instructions

Materials needed to clean the TC head:

- ELITechGroup Cleaning Solution, (SS-003)
- Thermocouple Cleaning Solution with Anionic Detergent (SS- 223)
- Purified Water
- Blow Clean Liquefied Propellant or Equivalent. (Pressure limited to 20 PSIG.)

**NOTE**

To remove significant contamination, use both the cleaning solutions (SS-003 and SS-223) followed by numerous successive rinses with pure water. ELITechGroup's cleaning solution (SS-003) is approximately 8% ammonium hydroxide. Concentrated ammonium hydroxide can be used to remove particularly stubborn contamination. The Thermocouple Cleaning Solution with Anionic Detergent (SS-223) removes oily, waxy, or greasy contaminants. Lint or dust particles can usually be removed by simply rinsing with DI water a number of times.



1. Place a waste container close by on the floor. Use a cotton swab to remove residue from the surface of the mount surrounding the thermocouple.

**CAUTION**
**Do not contact the thermocouple with the swab.**

2. Release SS-003 cleaning solution onto the thermocouple mount using the dropper bottle.
3. Immerse the thermocouple and the entire surface of the mount in cleaning solution. Let stand at least one minute.
4. Hold the TC head over the waste container with the TC pointing down.
5. Quickly move the TC head straight down and then back up and away from the droplet of liquid, allowing the liquid to fall into the waste container directly below.

## *4.5 Manually Cleaning the TC Head*

6. Immediately apply rinse water to the thermocouple and the entire surface of the mount before evaporation can occur. Use purified water with one micro-siemens (µS /cm) or lower for rinsing. Water of lesser quality contaminates the thermocouple.

**CAUTION**
**Do not contaminate the rinse water by touching the tip of the dropper bottle (or the water drop) to the water standing on the mount.**

7. Dilute any remaining droplets of cleaning solution with purified water.
8. Repeat the rinsing process ten times and then continue.
9. Place the Blow Clean upright and level on the bench. Clear the nozzle with a slight stream of gas. Hold the TC mount about 2 inches from the nozzle, then aim the nozzle directly at the thermocouple and release a slight stream of gas to blow away any remaining droplets.

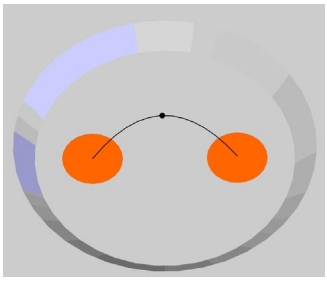
**CAUTION**
**Shaking or tipping the can of Blow Clean severely contaminates the thermocouple. The can must remain flat on the bench.**

10. Repeat Steps 1 through 10 using ELITechGroup's Thermocouple Cleaning Solution with Anionic Detergent (SS-223).
11. Inspect the TC mount for any residual contamination. If foreign material cannot be removed using this procedure, refer to the next section, Removing Severe or Stubborn Contamination.

**NOTE**

Inspection can reveal many types of contamination. However, some contamination is invisible, even under the microscope. The contamination reading that occurs when running a 100 mmol/kg calibration should also be considered for overall cleanliness of the TC.

## *4.6 Removing Severe or Stubborn Contamination of the TC Head*



If a contamination reading (from the 100 mmol/kg calibration) indicates residual contamination in spite of a clean appearance:

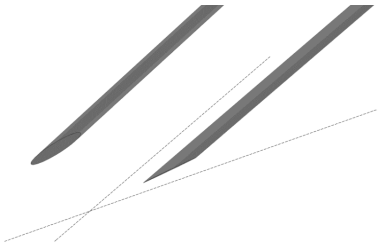
1. Repeat the manual cleaning procedure. Calibrate the instrument using the 290 mmol/kg, 1000 mmol/kg, and 100 mmol/kg standards. If there is significant improvement in the contamination level when calibrating at 100 mmol/kg, contamination can likely be removed by repeated manual cleaning.
2. You can often successfully remove the contaminant simply by applying a droplet of purified water to the thermocouple, allowing it to stand for 30 to 60 minutes, and then rinsing it thoroughly.
3. Many contaminants can be detected and removed under microscopic examination. If cleaning fails to produce an acceptable contamination level, examine the thermocouple head under a microscope at 30X to 60X power.

   Gross contamination can usually be removed by repeated manual cleanings, although mechanical scrubbing, as described below, may expedite the process.

**NOTE**

Concentrated ammonium hydroxide (from local stores) can be used to remove stubborn contaminants; however, it may not be effective on oily, greasy, or waxy materials. For these more difficult situations, try cleaning agents such as acetone or a laboratory detergent such as ELITechGroup's Thermocouple Cleaning Solution with Anionic Detergent (SS-223) or Alconox®.

**To remove deposits:**



1. Apply cleaning agents using the methods described earlier.
2. Cut a wooden swab stick on a sharp angle to form a fine point.
3. Scrub the surface of the mount with the swab stick and rinse.

Performed under the microscope, this procedure is unlikely to cause damage to the thermocouple itself. With patience, and repeated use of cleaning agents, even the most severely contaminated thermocouple can be cleaned.

## *4.6 Removing Severe or Stubborn Contamination of the TC Head*

### To clean dark or corroded copper connection points:

1. Apply a droplet of concentrated ammonium hydroxide ($NH_4OH$, 28 to 30%) or household lime remover to the TC mount. Soaking with this solution for a few minutes reduces oxidation and restores the bright copper color.
2. Rinse the thermocouple with pure water at least 10 times.
3. Place the Blow Clean upright and level on the bench. Clear the nozzle with a slight stream of gas. Hold the TC mount about 2 inches from the nozzle, then aim the nozzle directly at the thermocouple and release a slight stream of gas to blow away any remaining droplets.

## Reinstalling the TC Head

1. Open the TC head access cover.
2. By aligning the attachment screws, carefully position the TC head inside the instrument. Note that the TC head has a specific orientation.

**CAUTION**
**The instrument will not hold calibration if the chamber screws are loose.**

3. Start each screw into the threads, and then tighten each screw progressively with the 9/64-inch hex driver, until all four are firmly tightened.
4. Reinstall the TC head connector.
5. Reposition the access cover.
6. Turn on the power. Allow the instrument to complete the initialization sequence and reach thermal equilibrium before attempting to calibrate.
7. Calibrate using the 290-mmol/kg, 1000-mmol/kg, and then 100-mmol/kg standards.
8. If the 100-mmol/kg calibration reveals contamination, run the automated Clean cycle. If contamination levels are still present, try manually cleaning the thermocouple one more time.

## Equilibration After Cleaning

Manually cleaning the thermocouple mount changes the thermal equilibrium of the instrument and causes a temporary shift in calibration after the TC head is reinstalled. After reinstalling the thermocouple head, allow the instrument to regain thermal equilibrium.

The Temperature Drift indicator will be near center when the osmometer temperature is stable. Calibrate the instrument before taking any assays.

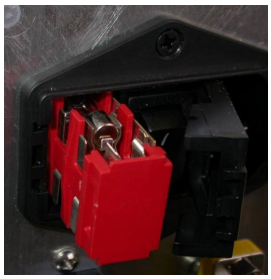
## *4.8 Fuse and Battery Replacement*

### Changing Fuses

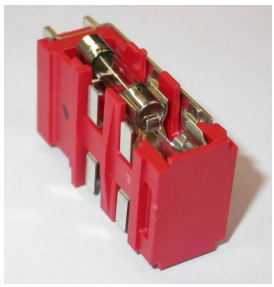
To access the main fuses.


1. Turn power off and disconnect the power cord.

2. Use a small screwdriver to open the fuse door by prying it from the inside edge of the power module.



3. Pull the fuse holder out (you may need to use the small screw driver to pry it out).



4. Replace both fuses with new fuses of the correct rating (5 x 20 mm time-delayed type 1A @ 250V).

5. Reposition the fuse holder and push it into the holder making sure it seats all the way in. (The door will not close if it is not seated properly.)

6. Close the fuse door.

7. Connect the power cord and turn on the instrument.

**WARNING!**
**For continued protection against fire hazard, only use fuses of the correct type and rating.**

### Fuse Specifications

5 x 20 mm time-delay type 1 ampere at 250 volts.

## Replacing the Backup Battery

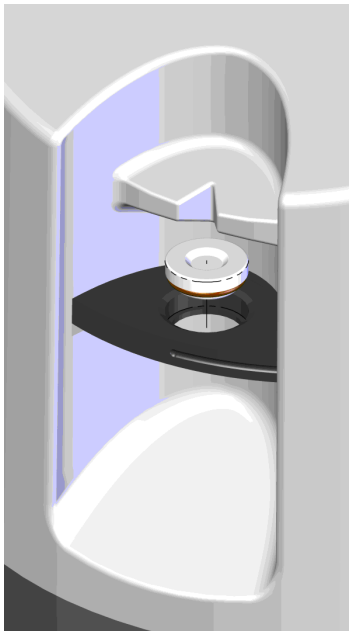
The VAPRO has an internal lithium coin cell backup battery used to power the real real-time clock in the event of power loss to the instrument. The battery is not accessible to the user and should only be replaced by qualified service personnel. Use only the RP-238 replacement battery. Ensure proper polarity when installing a new battery. Dispose of the old battery according to local statute and safety requirements.

## *4.9 Changing Sample Holders*

ELITechGroup offers the following sample holders for different applications:

- AC-062 Sample Holder, 10 µL, 7 mm diameter x 1.25 mm deep (standard)
- AC-063 Sample Holder*, 2 µL, 4.25 mm diameter X 1.2 mm deep
- AC-064 Sample Holder*, 20 µL, 7 mm diameter x 2.5 mm deep
- AC-065 Sample Holder*, 60 µL, 9.5 mm diameter x 4.5 mm deep

* The 10 µL AC-062 (standard) is provided with the device. AC-063, AC-064, and AC-065 are available upon request however, all device testing was performed using the 10 µL standard sample holder.



### To change a sample holder:

1. Press the OPEN/CLOSE key to open the slide and position the sample holder under the pipette guide.
2. From underneath the sample holder, (wearing gloves) gently push straight up on the sample holder. It should pop out of the sample slide. The sample holder is held in place by using a friction fit with an O-ring. It should not require very much pressure on the sample holder to pop it out.
3. Remove the sample holder and replace it with the new sample holder.
4. Make sure the sample holder is lined up with the hole in the slide. Gently push the sample holder straight down so that it is positioned inside the sample slide. Verify that the O-ring is properly seated in the groove.
5. Make sure the top surface of the sample holder is flush with the sample slide.
6. Press the OPEN/CLOSE key to close the slide. Allow the instrument time to reach temperature equilibration.
7. Always calibrate the instrument using equivalent solution to match sample holder and sample volume.
8. Follow any special instructions that may be supplied with the sample holder.

**CAUTION**
**Use gloves when handling the sample holders to avoid contamination from oils on skin and to protect the skin from potential biohazards.**

## *4.10 Decontamination Procedures*

Under normal clinical use, the VAPRO poses very little risk of biological infection to laboratory workers. The osmometer is essentially an environmental surface, which should be kept clean. Only low-level disinfection is required.

**WARNING!**
**The user is responsible for performing appropriate decontamination procedures when the instrument interior or exterior is contaminated with biohazardous materials. Always use appropriate safety measures including gloves, eye protection, and other personal protection equipment.**

Biological contamination occurs primarily when specimens slide off the sample holder. These tend to be removed by normal cleaning conditions. The TC assembly is self-cleaning under normal use, but cannot be considered decontaminated. The osmometer exterior can also be contaminated by touching with contaminated gloves and requires routine surface cleaning.

**If the osmometer is contaminated by biohazardous materials or disinfection resistant organisms, further treatment with appropriate procedures may be necessary.** If you are returning the osmometer for service or repair, you must contact ELITechGroup for current decontamination and shipping instructions.

### Decontaminating Instructions

1. With the instrument powered, press OPEN/CLOSE to open the slide. Decontaminate the sample holder by wiping it and the surrounding area of the slide with a disinfectant. Press OPEN/CLOSE to position the slide to the closed position. Use of any of the following:

- A freshly prepared (less than 24 hours) 10% bleach in water solution.
- A disinfecting laboratory wipe such as DisCide™.
- Isopropyl alcohol or alcohol wipes.
- A 1-part T.B.Q. / 64-parts deionized water solution. (2 oz./gallon. T.B.Q. is a product of Calgon Vestal™ Division of Steris® Corporation. Follow their container directions.)
- ELITechGroup Decontamination Solution Concentrate (SS-133, 3.75 mL vial dilutes to 244 mL).

## *4.10 Decontamination Procedures*

2. With the instrument powered off, clean any residue, dried blood, etc. from the exterior case and pipette guide with the same disinfectant.
3. Remove the supply reservoir cap assembly from the supply reservoir. Empty the reservoir, wash it out using a 10% bleach solution in water, and thoroughly rinse it using USP purified water. Replace the supply reservoir cap assembly securely tightening the cap.
4. Remove the waste reservoir cap assembly from the waste reservoir. Empty the reservoir, wash it out using a 10% bleach solution in water, and replace the waste reservoir cap assembly securely tightening the cap.

**CAUTION**
**Contact ELITechGroup before using any decontamination methods or cleaning agents other than those shown in this manual. Other methods can damage the instrument and void the VAPRO warranty.**

## *5.1 Diagnosing and Solving Common Problems*

This section describes problems you might encounter in using the VAPRO with suggested solutions. The suggestions listed here are intended to help solve routine problems. If you have tried all these suggestions and still need help, contact your dealer or ELITechGroup for assistance.

# Using Error Messages to Solve Common Problems

Following are some common error messages with the resulting problem that needs to be corrected:

| Error Message | Problem to Correct |
|---|---|
| Temperature Sensor Error with other TC Errors | If the Temperature Sensor error is received in conjunction with TC errors and Auto-Balance errors, then turn off the instrument and remove the thermocouple access cover. Check that the thermocouple connector is fully engaged into the thermocouple head.<br>If that does not fix the problem, try swapping the TC head with a known good one if one is available. That will help determine if the problem is with the TC head or the instrument PCB.<br>The other potential problems could be with the cable or connectors.<br>If the temperature sensor error is the only error being received, then the problem is probably with the temperature sensor PCB. The thermocouple head may need to be replaced. |

## *5.1 Diagnosing and Solving Common Problems*

| Error Message | Problem to Correct |
|---|---|
| TC Reference Error<br>TC Cooling Error<br>Auto-Balance Error | If the TC Reference Error is received in conjunction with the TC Cooling Error and Auto-Balance Error, then the thermocouple may be broken and the TC head may need to be replaced.<br>Also check and make sure the sample holder is clean. (A sample may have been left in the sample holder.)<br>If a sample has been left in the holder, remove the sample and clean the holder. Turn the VAPRO off and then back on. Make sure the self diagnostic tests pass before performing an assay. |
| Water Reservoir Empty | Fill the supply reservoir with fresh USP purified water. If the supply reservoir is full and the error still occurs, the problem could be related to the sensor or related circuitry on the PCB. If necessary, empty the waste reservoir. |
| Assay Value Not Within Calibration Range | Be sure the correct calibration standard is being used.<br>Run the automated Clean cycle. If the calibration standard is 100 mmol/kg and other calibration solutions read normal, a contaminated TC is likely.<br>Manually clean the thermocouple.<br>Check the TC head connector for faulty connection and for loose TC head screws. |

### Common Problems and Solutions

Following are common problems that may occur and possible solutions to the problem:

| Problem | Solution |
|---|---|
| There is a large shift in calibration. | Check the Temperature Drift Scale on the display. If the scale indicates that ambient temperature is outside acceptable levels, take steps to stabilize the temperature.<br>Check the freshness of the calibration standards and replace if needed.<br>Calibrate the instrument using the 100 mmol/kg standard. If the contamination reading is greater than 10, clean the thermocouple by running a Clean cycle. If the contamination is less than 10, recalibrate the instrument using each of the calibration standards. |
| There is poor linearity in the low range (below 200 mmol/kg). | Check the Temperature Drift Scale on the display to see if the temperature is stable. If necessary, allow the instrument to stabilize.<br>Verify the use of fresh calibration standards.<br>Calibrate the instrument using the 100 mmol/kg standard. If contamination reading is greater than 10, clean the thermocouple by using the automated Clean cycle.<br>If the contamination is still greater than 10 after running an automated Clean cycle, then clean the thermocouple using the manual method.<br>If, after taking the above steps, the error message again appears after running the 100 mmol/kg calibration, check the TC mount for gross (visible) contamination. A grossly contaminated TC mount requires extensive cleaning and may require replacement. If additional cleaning fails to resolve the problem, contact a dealer or ELITechGroup or assistance. |

## *5.1 Diagnosing and Solving Common Problems*

| Problem | Solution |
|---|---|
| Erratic reading on the display or poor repeatability. | Run a 1000 mmol/kg standard in *Auto Repeat Mode*, then check the standard deviation shown on the display. If less than 2.0, assess your sample loading technique for possible loading errors.<br>If the standard deviation is greater than 2.0, check for loose TC head screws. If this is not the problem, check the TC mount for gross contamination.<br>If these steps fail to resolve the problem, contact a dealer or ELITechGroup for assistance. |
| Display is blank. | Reset the instrument by turning off power for 3 seconds. Then turn power back on.<br>Check to see if the power indicator is on.<br>Check to see if the instrument is plugged in.<br>Check the fuses.<br>Check the display and keyboard connections.<br>**WARNING!**<br>**To avoid the risk of serious injury, the display and keyboard connections should only be checked by qualified service personnel.** |

## *5.2 Instrument System Checks*

**WARNING!**
**Always correct any instrument error conditions before attempting to calibrate or use the instrument to assay unknown samples.**

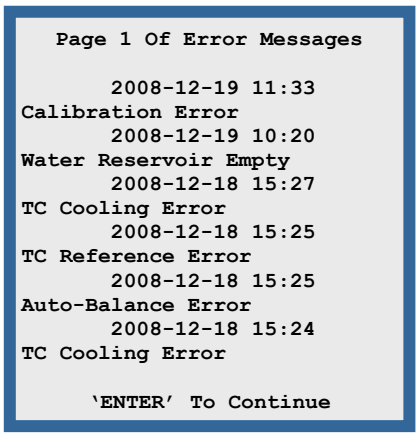
# Instrument System Checks

During the normal power on sequence of the VAPRO the instrument runs a series of operations that are required to initialize the internal circuitry and includes system checks. If errors or fault conditions occur during these operations, the error condition is shown on the display and operator is prompted to press the ENTER key before the instrument proceeds with the next operation. In addition, whenever any errors or faults occur, an error message is saved in non-volatile memory. This error message can be recalled to assist with trouble-shooting instrument problems.

Once the initialization has completed, the instrument conducts a Self-Diagnostics Check. During this important operation, the cooling current optimizes for the installed thermocouple and an auto-balance cycle initializes the circuitry to ensure convergence of the thermocouple to the precise dew point temperature during the measurement cycle. The instrument checks that the thermocouple values are within an expected range for proper operation. This operation can take several minutes to complete and reports a series of errors if they occur. The reported errors can be very useful in diagnosing problems with the instrument. If errors are encountered, the error conditions are stored and the user prompted to press ENTER before the instrument operation continues.

Once the user proceeds past the error screen message, the following occurs:

1. The screen clears and displays "*Service Instrument*." The sample slide opens and the display shows *'ENTER' To Continue*.
2. Pressing the ENTER key allows the instrument to go into the idle state, however the *Self Diagnostics Mode* is the only mode available. Attempting to enter the *Mode Menu* returns you back out. Access to other menus is available so that further diagnostics and troubleshooting can be performed, such as running the clean cycle.
3. Running in the Self Diagnostics Mode and getting values within the expected range (no errors) permits access to the Mode Menu where the operational mode can be changed back to Normal Mode. Powering the instrument off and on and getting valid readings allows the instrument to come up on the Normal Mode.
4. The instrument does not allow the user to run an assay on a sample if errors in the measurement will be expected because of some error condition.




## Display Error Messages

The error messages that get stored in the instrument can be useful with trouble-shooting instrument problems. To access the *Display Error Message* function, from the *Main Menu* SELECT *Configure Menu* and press ENTER. From the *Configure Menu* SELECT *Test Instrument* and press ENTER. The Display Error Message feature allows the operator to display the last 16 instrument error messages. These error messages are stored in non-volatile memory in order of most recent to oldest message. The messages are displayed in two pages with eight messages per page. If there are less than 16 error messages, the display shows No Error for the unrecorded memory locations.

The stored history of error messages can be useful in resolving problems with the instrument. The operator should be ready to access and provide the list of error messages when contacting the manufacturer for assistance in solving problems with the instrument.

**NOTE**

It is common to have the error messages listed multiple times if the error condition was encountered more than once.

Following is a listing of possible error messages that can get stored and a possible solution to the problem:

| Error Message | Problem / Solution |
|---|---|
| ADC Error | If an ADC Error occurs (Analog-to-Digital Converter Error) there is probably a problem with the A/D circuitry on the PCB. Try turning the instrument off for a couple of minutes and then turning it back on. If the problem persists, the instrument may need to be returned for repair. Contact your dealer or ELITechGroup for assistance. |
| Auto-Balance Error | If the Auto-Balance Error occurs in conjunction with the TC Cooling Error and TC Reference Error, the thermocouple may be broken and the TC head may need to be replaced.<br>If the Auto-Balance Error occurs in conjunction with the TC Cooling Error, the TC may be smashed. It may be possible to fix the problem without replacing the TC head.<br>Check and make sure the sample holder is clean. (A sample may have been left in the sample holder.)<br>The problem could also be with the instrument PCB. |

## *5.3 Error Messages*

| Error Message | Problem / Solution |
|---|---|
| Clock Failure | The replaceable back-up coin cell battery on the main PCB may be dead and may need to be replaced by qualified service personnel. When replacing the battery, observe proper polarity (see section 4.8). If the back-up battery is not dead, the problem may be related to the clock circuitry on the PCB.<br>To check to see if the back-up battery is dead, do the following:<br>Set the clock to the current time. Go to the Test Instrument menu and then to Test Clock. Verify that the clock is running and set to the current time. If the clock is working then the problem probably is not with the PCB.<br>Turn power off and allow the instrument to sit for a couple of minutes.<br>Power the instrument back on and go to Test Clock. If the clock was reset or at a different time, then the back-up coin cell battery on the main PCB needs to be replaced. (When the instrument is on, the main power supply powers the clock. When turned off, the back-up battery powers the clock.) |
| IIC Failure | This is an indication of a problem with the PCB, typically with the microprocessor. Contact your dealer or ELITechGroup for assistance. The instrument needs to be returned for repair. |
| Power Failure | A Power Failure is either an indication of a power related problem with a power supply on the PCB or other circuitry related to powering the instrument. The instrument needs to be returned for repair. Contact your dealer or ELITechGroup for assistance. |
| RS232 Failure | Check the RS-232 cable and the connections between the RS-232 connector on the VAPRO and the RS-232 connector on the computer or printer.<br>Make sure the communication parameters are set correctly on the computer or printer (9600 baud, 8 data bits, 1 stop bit, no parity).<br>Try going into the Test Instrument menu and running the RS232 Test. The message “RS232 Test” is continually sent out the port. The message flashes each time it is sent to the port.<br>If the error still occurs then the problem could be with the instrument PCB. |
| Sample Slide Error | Check and make sure that there is nothing interfering with or blocking the movement of the slide from the outside of the instrument. Open the TC head cover and check and make sure that there is nothing interfering with or blocking the movement of the slide from inside the instrument.<br>Manually test the sample slide movement by going to the Test Instrument menu and running the Sample Slide Test.<br>An alternative method of manually testing the slide movement is to try and position the slide to the Open position (sample holder is visible). Go to the Unlock Chamber menu item and unlock the chamber. Try moving the slide holder with your hand. This might give indications as to the location of the problem. |
| SPI Failure | This is an indication of a problem with the PCB. Contact your dealer or ELITechGroup for assistance. The instrument may need to be returned for repair. |

| Error Message | Problem / Solution |
|---|---|
| TC Cooling Error | If the TC Cooling Error occurs in conjunction with the TC Reference Error and Auto-Balance Error, then the thermocouple may be broken and the TC head may need to be replaced.<br>If the TC Cooling Error occurs in conjunction with the Auto-Balance Error, the TC may be smashed. It may be possible to fix the problem without replacing the TC head.<br>Check and make sure the sample holder is clean. (A sample may have been left in the sample holder.) The problem may also be with the PCB. |
| TC Is Not Dry | The TC Is Not Dry error occurs when the auto-balance function is performed during the cleaning cycle and the chamber does not dry sufficiently.<br>Check the desiccant cartridge/filter and replace as necessary. Run another Clean cycle to see if the problem can be corrected.<br>Verify that the vacuum pump is turning on and pulling air through the cartridge.<br>Another check is to verify that there are no water droplets on the sample holder. Make this check when the slide rotates to the Open/Loading position the first time after performing a clean cycle. If the TC mount has water droplets on it, there may be problems with the chamber when it is in the locked position. This could result from gross contamination or a possible mechanical problem.<br>Another possibility is if a Self Diagnostics is run, the error messages returned are TC Cooling Error and Auto-Balance Error. |
| TC Reference Error | If the TC Reference Error is received in conjunction with the TC Cooling Error and Auto-Balance Error, then the thermocouple may be broken and the TC head may need to be replaced.<br>Check and make sure the sample holder is clean. (A sample may have been left in the sample holder.)<br>The problem may also be with the TC or pre-amp board in the TC head. |
| Temperature Sensor Error | If the Temperature Sensor error is received in conjunction with TC errors and Auto-Balance errors, then turn off the instrument and remove the thermocouple access cover. Check that the thermocouple connector is fully engaged into the thermocouple head.<br>If that does not fix the problem, try swapping the TC head with a known good one if one is available. That will help determine if the problem is with the TC head or the instrument PCB.<br>Other potential problems could be with the cable or connectors.<br>If the temperature sensor error is the only error being received, then the problem is probably with the temperature sensor PCB. The thermocouple head may need to be replaced. |

## *5.3 Error Messages*

| Error Message | Problem / Solution |
|---|---|
| USB Failure | Check the USB cable and the connections between the USB connector on the VAPRO and the USB connector on the computer. Make sure the cable is connected properly.<br>On the computer side, make sure that the communication protocols are set properly. (115200 baud, 8 data bits, 1 stop bit, no parity).<br>Try going into the Test Instrument menu and running the USB Test. The message "USB Test" is continually sent out the port. The message flashes each time it is sent to the port.<br>If the error still occurs then the problem could be with the instrument PCB. |
| Water Quality > 5 µS/cm | Empty and wash the supply reservoir and then fill the supply reservoir with fresh USP purified water.<br>After replacing the water if the error still occurs, the problem could be related to the water quality sensor or related circuitry on the PCB.<br>Going to the Test Instrument menu and running the Water Quality Test can manually test the water quality. Ideally, the water quality reading would be less than 1 µS/cm. When the water quality level is greater than 5 µS/cm, the instrument will not allow an automated clean cycle to occur because of the potential of contaminating the TC. The water quality level must be less than 5 µS/cm. |
| Water Reservoir Empty | Fill the supply reservoir with fresh USP purified water.<br>If the supply reservoir is full and the error still occurs, the problem could be related to the sensor or related circuitry on the PCB. |

## *5.4 Testing Instrument Functions*

Another useful tool when troubleshooting is the ability to manually test many of the instrument's functions. From the *Main Menu*, SELECT *Configure Menu* and press ENTER. From the *Configure Menu* SELECT *Test Instrument* and press ENTER to access the *Test Instrument Menu*. Following is a brief description of each of the Instrument Tests and how to use each for troubleshooting.

| Instrument Test | Description / Problem / Solution |
|---|---|
| Thermocouple Test | The Thermocouple Test measures the thermocouple reference and displays the reading in mmol/kg. The test continues to take a reading and update the display until the ENTER key is pressed to exit.<br>With an empty sample holder and everything working properly, the reading should be less than 200 mmol/kg.<br>If the reading is > 200 mmol/kg, check if a sample has been left in the sample holder. Make sure the sample holder is clean. Check for water vapor in the sample holder area, especially after a clean cycle. If there is moisture in the sample holder, this might indicate the pump not working properly or the desiccant needs changing.<br>A reading > 2000 mmol/kg typically indicates that the TC is broken. The problem could also be with the pre-amp in the TC head or the connections. |
| Temperature Test | The Temperature Test measures the system temperature and displays it in degrees Celsius. The test continues to take a reading and update the display until the ENTER key is pressed to exit. The temperature from this sensor is used when displaying the Temperature Drift.<br>The temperature reading will be slightly higher than room temperature, but should not be greater than 40 °C or less than 15 °C. If the reading jumps around or reads too high or too low, the problem could be related to the sensor or the connection between the TC head and the main PCB. |
| Water Quality Test | The Water Quality Test measures the quality of the water and displays the result. The result from this reading either displays the quality of the water or indicates if the supply reservoir is empty. The test continues to take a reading and update the display until the ENTER key is pressed to exit.<br>If the supply reservoir is empty, a message displays that the reservoir is empty. Fill the reservoir with USP purified water. A good reading is < 1 µS/cm.<br>When the water quality level is greater than 5 µS/cm, the instrument will not allow an automated clean cycle to occur because of the potential of contaminating the TC. The water quality level must be less than 5 µS/cm. Wash out the supply reservoir and refill it with fresh USP purified water.<br>If the reading is still above 5 µS/cm, the problem may be with the sensor or circuitry related to the sensor. |

## *5.4 Testing Instrument Functions*

| Instrument Test | Description / Problem / Solution |
|---|---|
| Clock Test | The Clock Test reads the real time clock and displays the date and time. The display continues to get updated until the ENTER key is pressed to exit.<br>If the correct date and time are not displayed, try resetting the clock from the *Configure Menu \ Set Clock*. If the clock cannot be set, the problem may be with the electronics.<br>To check if the back-up battery is dead, do the following:<br>Set the clock to the current time. Go to the *Test Instrument* menu and then to *Test Clock*. Verify that the clock is running and set to the current time. If the clock is working then the problem probably is not with the electronics.<br>Turn power off and allow the instrument to sit for a couple of minutes.<br>Power the instrument back on and go to *Test Clock*. If the clock was reset or at a different time, then the back-up coin-cell battery on the main PCB needs to be replaced by qualified service personnel. When replacing the battery, observe proper polarity. (When the instrument is on, the main power supply powers the clock. When turned off, the back-up battery powers the clock.) If after replacing the battery, the clock still does not work, the problem is probably the circuitry related to the real time clock and the instrument may need to be returned for repair. |
| USB Test | VAPRO Lab Report software should always be installed before connecting the VAPRO to a computer via the USB cable to ensure computer recognition of the VAPRO. The USB Test sends out a string of characters to the USB port and repeats the string until either ENTER is pressed to exit the test or the string has been sent 32 times. The character strings sent out by the VAPRO test the USB connection by entering data in the VAPRO Lab Report without running actual samples in the instrument. |
| RS232 Test | The RS232 Test sends out the string of characters “RS232 Test” to the RS-232 port and continues to send out the same message until ENTER is pressed to exit the test.<br>If the message is not being received on the printer, check the RS-232 cable and the connections between the RS-232 connector on the VAPRO and the RS-232 connector on the printer. Make sure that the printer communication protocols are set properly. (9600 baud, 8 data bits, 1 stop bit, no parity). |
| Pump Test | The Pump Test turns the vacuum pump on. The pump remains on until ENTER is pressed to exit the test, at which time the vacuum pump turns off. You should be able to hear the pump when it is on. If the vacuum pump does not turn on then the problem could be with the pump, the connections to the pump, or the circuitry related to the pump on the PCB.<br>When the pump is on, air is pulled through the desiccant (assuming that the solenoid valve is working properly). Check this by placing a finger over the inlet to the desiccant cartridge. You should be able to feel the suction on your finger. If water can be seen flowing through the tubes from the supply reservoir, there is a problem with the solenoid. |

| Instrument Test | Description / Problem / Solution |
|---|---|
| Sample Slide Test | Sample Slide Test positions the sample slide to the open or closed position. After selecting this test, the display shows two options: (1) 'ENTER' To Exit or (2) 'SELECT' To Operate. Pressing SELECT either opens or closes the sample slide, depending upon its current position.<br>There are two motors that are used when moving the sample slide to either the open or closed positions. The sequence is as follows:<br>1. The chamber motor turns on and unlatches the chamber so that the sample slide can move. The chamber motor then turns off.<br>2. The sample slide motor turns on and rotates the sample slide to either the open or closed position and then turns off.<br>3. The chamber motor turns on and latches the chamber (sample slide cannot move).<br>Each motor has a unique sound that can be heard while on. If you cannot hear the motors, then there is a problem with either the motor, connections to the motor, or related circuitry on the PCB.<br>Check and make sure that there is nothing interfering with or blocking the movement of the slide from the outside of the instrument. Open the TC head cover and make sure that there is nothing interfering with or blocking the movement of the slide from inside the instrument.<br>If there is nothing blocking or interfering with the slide movement then the problem could be with the motor, the mechanical interaction between the various parts, connections to the motor or related circuitry on the PCB. |
| Solenoid Test | The Solenoid Test actuates the solenoid valve that is used to switch between allowing liquid to be pumped through the chamber for cleaning or for allowing air to be pumped through the chamber for drying. The default position of the solenoid is to air. The solenoid is left on until ENTER is pressed to exit the test, at which time the solenoid valve turns off.<br>A clicking sound can be heard when the solenoid turns on and off. If a clicking sound cannot be heard, the solenoid is sticking or there is a problem with the PCB. |

## *5.5 Common TC Head Problems*

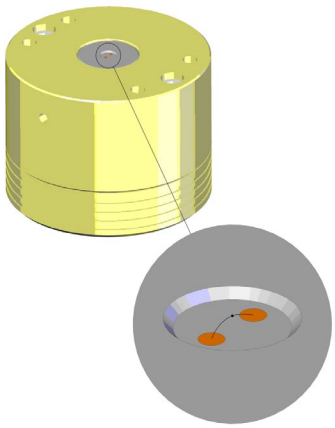
Many years of field experience have shown that the majority of problems encountered with the osmometer are with the thermocouple sensor. It is suspended from the thermocouple mount, which forms the upper half of the sample chamber. The thermocouple mount is part of the thermocouple head assembly, referred to simply as the 'TC head.'

Common thermocouple problems affect instrument performance in distinctive ways, providing significant clues that are evident in the behavior of the instrument. These are summarized below in order of most likely occurrence.

### COMMON TC HEAD PROBLEMS

| Problem | Symptom(s) |
|---|---|
| Thermocouple Contamination | A shift in calibration. Error during calibration. |
| Deformed or Flattened Thermocouple | Loss of high range readings or precision. |
| Broken Thermocouple | ERROR message on display or wildly erratic behavior if the connection is intermittent. |
| Disconnected TC Head Connector | ERROR message on the display. |
| Loose TC Head Screws | Unstable calibration and erratic readings. ERROR message during calibration. |

## Inspecting and Cleaning the TC Head



1. Follow the instructions in Section 4.5 to remove the TC Head.

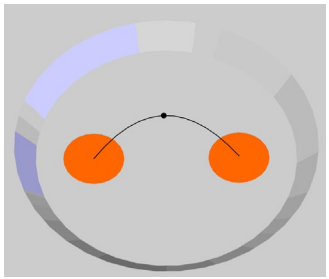
**NOTE**

To improve temperature stability inside the osmometer, leave the access cover in place while the TC head is out of the instrument.

2. Carefully inspect the TC head under a microscope. Check for any gross contamination on the thermocouple or thermocouple mount.

   Contamination is a natural consequence of normal use of the osmometer. It may also occur inadvertently during shipping or set-up. Contamination changes the linearity of the instrument response, first detectable in the lower ranges of osmolality.

   Contamination does not generally degrade precision, but, depending upon the nature of the contaminating substance, this can occur. See Section 4.5 for complete instructions to detect and remove contamination.



**NOTE**

Contamination can be invisible to the eye; even if the thermocouple appears to be clean, it may not give an acceptable contamination level reading. In this case, follow the instructions in Section 4.5.

3. Check if the thermocouple has been deformed or broken. Refer to "Restoring a Deformed Thermocouple" in this section for information on identifying thermocouple deformation and how to restore it to normal shape.

4. Inspect the TC head connector and the mating pins for distortion or misalignment.

**NOTE**

Always switch power OFF before connecting or disconnecting the TC head.

If the connector is damaged, electrical connection may be compromised or fail altogether. A failed connection produces an ERROR message on the display, as with a broken thermocouple. A poor connection can cause erratic performance.

If the source of difficulty is still unknown, at least the most frequently occurring problems have been eliminated.

## Testing Osmometer Performance

1. Reinstall the TC head to continue troubleshooting.
2. Set the instrument up using the performance procedure outline in Section 4.1.
3. Allow 30 minutes for thermal equilibrium.
4. If you have a problem performing any of the steps of the performance procedure, a malfunctioning electronic module is likely. Contact ELITechGroup or your dealer for assistance. Some replacement parts are available for user installation, or return the instrument for repair.

Problems with instrument precision have a number of possible sources. Often, poor reproducibility is caused by external factors that are entirely independent of the instrument itself. The following are some of these factors:

## Incorrect Use of Calibration Standards

Instrument accuracy and linearity depend upon the correct use of osmolality calibration standards. Do not use calibration standards other than Opti-Mole. Make sure the standards have not expired or have been left sitting very long so that the concentration levels have changed.

## Sampling Error

Sampling errors will be amplified when dealing with small volume specimens. Prevent errors by using consistent technique and appropriate methods of transferring samples. The specimen could cause an error if separation occurs.

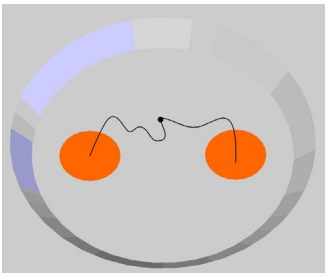
## Micropipettor-Caused Errors

Unlike the maintenance-free micropipettor supplied by ELITechGroup, many micropipetting devices require routine maintenance. Without proper maintenance, micropipetting devices can exhibit significant volumetric error (more than 50%) and cause corresponding variations in indicated osmolality. Positive displacement micropipettors are not recommended as an alternative to the ELITechGroup micropipettor, except when dealing with samples of very high viscosity.

## Poor Precision

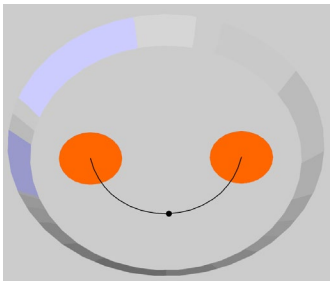
1. Determine whether the problem is with the instrument or is caused by external factors, such as the micropipettor.
2. Check the location of the osmometer for possible sources of thermal disturbance.
3. Best instrument performance requires a dedicated operator. If the sample holder is left in the open position it may cool, causing a shift in precision. If an operator cannot be in constant attendance to the instrument, the select the Slide Option Closed option to ensure the sample holder remains at instrument temperature. With this option selected, the slide does not open automatically and the operator must press the Open/Closed key to clean out the sample.
4. Use the *Auto Repeat Mode* to evaluate the precision of the osmometer.
5. Run the instrument with 1000 mmol/kg standard in *Auto Repeat Mode* to determine if the instrument can repeatedly measure the same results. If it does, consider the possibility of loading errors causing poor repeatability.
6. A grossly contaminated TC gives poor precision. Check the calibration and contamination level by running a 100 mmol/kg sample.

## *5.5 Common TC Head Problems*



The thermocouple is well protected while the TC head is in the instrument. Cleaning procedures detailed in this manual should not harm the thermocouple; however, it can be deformed or broken if contacted by any object while it is out of the instrument.

- If the thermo thermocouple is only slightly deformed, the instrument automatically adjusts for the deformed thermocouple and functions normally.
- A badly deformed thermocouple still functions, but shows a noticeable loss of measurement precision.

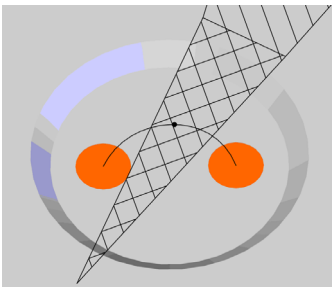


- A deformed or flattened thermocouple with its bead lying close to or touching the surface of the mount will not cool to normal temperature depression during the measurement cycle. Therefore, the instrument may display an error. This is one of the reasons why it is important to run calibration checks on a regular basis. Refer to the Troubleshooting Section.

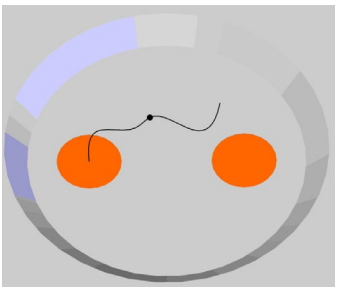
### Restoring a Deformed Thermocouple

Even a severely deformed thermocouple can be salvaged by very carefully lifting it into normal position. Although the thermocouple wires are only 0.025 mm in diameter, they are quite malleable and are generally amenable to straightening and reshaping.

Because of the delicate nature of the task, you will need steady hands and a microscope, preferably stereoscopic, having magnification in the range of 30X to 60X.



1. Make a tool by cutting a thin sliver or wedge from a sheet of ordinary paper.
2. Work the pointed end of the paper sliver under the thermocouple wire.
3. Use the paper sliver to lift and reshape the thermocouple. The paper sliver is sufficiently flexible to avoid undue stress on the thermocouple wires. Shape the thermocouple to a rounded arch that is perpendicular to the surface of the TC mount, as illustrated. The junction (bead) should be at the high point of the arc.
4. Thoroughly clean the thermocouple (Section 4) before reinstalling the TC head.



## Broken Thermocouple

Usually, a broken thermocouple is readily evident, especially under a microscope. On rare occasions, the thermocouple may have an intermittent electrical connection that causes highly erratic behavior in the osmometer. A break at either of the thermocouple connection points may require meticulous inspection to discover. A broken thermocouple requires replacement of the TC head. Contact your dealer or ELITechGroup for assistance.

APPENDIX
A

# *Theory of Operation*

Osmolality is an expression of the total concentration of dissolved particles in a solution without regard for particle size, density, configuration, or electrical charge. Indirect means for the measurement of osmolality are afforded by the fact that the addition of solute particles to a solvent changes the free energy of the solvent molecules. This results in a modification of the cardinal properties of the solvent, i.e., vapor pressure, freezing point, and boiling point. Compared with pure solvent, the vapor pressure and freezing point of a solution are lowered, while its boiling point is elevated, provided that a single solvent is present in the solution. Solutions containing more than one solvent generally behave in ways that are more complex.

In single-solvent solutions, the relative changes in solution properties are linearly related to the number of particles added to the solvent, although not necessarily linearly related to the weight of solute, since solute molecules may dissociate into two or more ionic components. Since these properties all change linearly in proportion to the concentration of solute particles, they are known as “colligative” properties.

Osmotic pressure is also a colligative property of a solution, but unlike the other three, it is not a cardinal property of the solvent. Solution osmotic pressure can be measured directly using a semipermeable membrane apparatus, but only with respect to those solute particles that are impermeable, since smaller solute particles freely transude the membrane and do not directly contribute to osmotic pressure. Such a measurement is referred to as “colloid osmotic pressure” or “oncotic pressure.” It is expressed in terms of pressure, in mmHg or kPa. Total osmotic pressure, i.e., that which can be calculated on the basis of total solute concentration, is a theoretical concept only.

The measurement of total solution concentration, or osmolality, can only be made indirectly by comparing one of the solution colligative properties with the corresponding cardinal property of the pure solvent. The first practical laboratory instruments developed for routine measurement of osmolality were based upon depression of the freezing point and, until recent years, all osmometers for large-scale testing were based on this methodology.

The VAPRO embodies newer technology. It is based upon a measurement of vapor pressure depression made possible by thermocouple hygrometry. The vapor pressure method enjoys a significant intrinsic advantage over the measurement of either freezing point depression or boiling point elevation in that it can be performed without the necessity for a change in the physical state of the specimen. It is thus a passive technique of measurement that is free from measurement artifacts that often occur when the specimen to be tested must be altered physically. This fundamental difference in methodology gives rise to the many advantages of the vapor pressure osmometer over the older method.

In the VAPRO, a sample of the solution to be tested is pipetted onto a small, solute-free paper disc, which is then inserted into a sample chamber and sealed. A thermocouple hygrometer is incorporated integrally within the chamber. This sensitive temperature sensor operates on the basis of a unique thermal energy balancing principle to measure the dew point temperature depression within the chamber. This parameter, in itself a colligative property of the solution, is an explicit function of solution vapor pressure.

## Program Step 1, Equilibration and Zero Set

To introduce a sample for assay measurement, start by preparing all needed supplies and samples. With the slide in the closed position, pressing the OPEN/CLOSE key causes the instruments current operation to abort and the slide to OPEN to the sample position.

A specimen is aspirated into a micropipettor tip. The specimen is then inoculated into a solute-free paper disc in the sample holder. The OPEN/CLOSE key is pressed, which causes the slide to rotate to the closed or measurement position and the measurement starts automatically once the sample chamber seals. A progress bar and percent completed displays and updates until the end of sequence at Program Step 4.

The sensing element is a fine-wire thermocouple hygrometer. This is suspended in a unique, all metal mount, which when joined with the sample holder, forms a small chamber enclosing the specimen.

At this point, there will generally be some difference between the temperature of the specimen and the temperature of the sample chamber. Temperature equilibrium occurs within a few seconds. The equilibration time is sufficient to allow most samples to reach vapor pressure equilibration.

## Program Step 2, Cooling

An electrical current passes through the thermocouple, cooling it by means of thermo-electric cooling to a temperature below the dew point. Water condenses from the air in the chamber to form microscopic droplets upon the surface of the thermocouple.

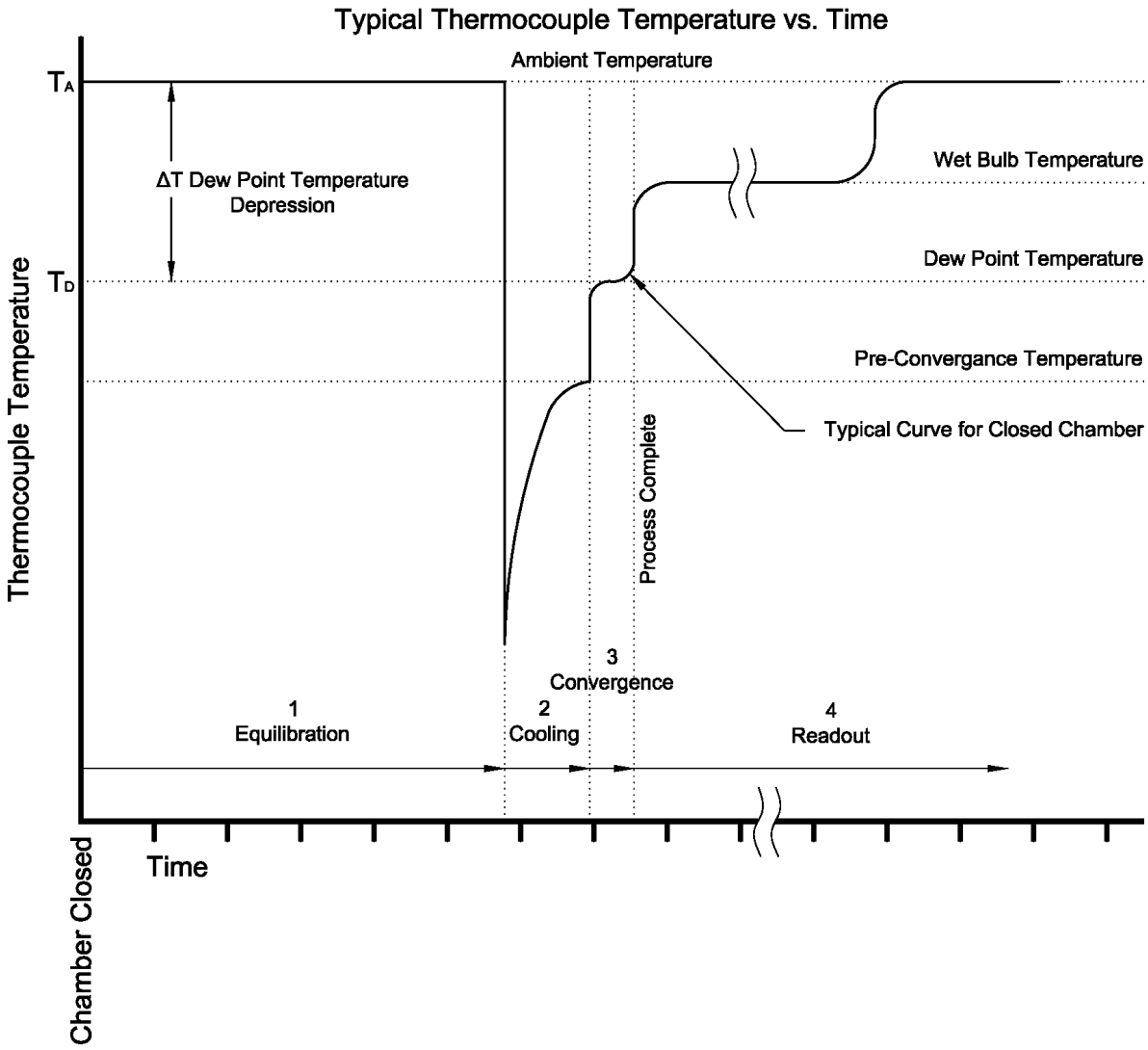
## Program Step 3, Dew Point Convergence

Electronics control the thermo-electric cooling to act as a solid-state heat pump in such a way as to cancel out heat influx to the thermocouple by conduction, convection, and radiation. Given this, the temperature of the thermocouple is controlled exclusively by the water condensing upon its surface. Thermocouple temperature, depressed below the dew point in Step 2, rises asymptotically toward the dew point as water continues to condense. When the temperature of the thermocouple reaches the dew point, condensation ceases, causing the thermocouple temperature to stabilize.

## Program Step 4, End of Sequence and Readout

The difference between the ambient temperature and the dew point temperature is the dew point temperature depression – an explicit function of solution vapor pressure. Dew point temperature depression is measured with a resolution of 0.00031 °C. When this final reading is reached, the slide automatically rotates to the OPEN position, a tone sounds, and the final result is displayed. The reading on the display is proportional to the vapor pressure of the solution.

The result is displayed in SI units of osmolality—mmol/kg.




## Temperature versus Osmolality

The above graph is a plot of thermocouple temperature versus time as the instrument cycles through the measurement, beginning with chamber closure. The graph depicts the excursion of thermocouple temperature that typically occurs during each of the program steps outlined above. $T_A$ is the ambient temperature in the chamber. $T_D$ is the dew point temperature, and ΔT is the dew point temperature depression. The output is proportional to ΔT.

APPENDIX
A

## *Theory of Operation*

Assuming that the chamber remains closed while the osmometer displays the final reading at Step 4, the thermocouple temperature returns to $T_A$ after all of the water has evaporated from the thermocouple. If the chamber is opened, the water evaporates almost instantly and the thermocouple temperature quickly returns to near ambient.

The relationship between sample osmolality and the reading obtained by the osmometer is governed by fundamental considerations. Vapor pressure depression, a linear function of osmolality, has been identified as one of the colligative properties of a solution. The relationship between vapor pressure depression and dew point temperature depression is given by:

$$\Delta T = \Delta e / S$$

where $\Delta T$ is the dew point temperature depression in degrees Celsius, $\Delta e$ is the difference between saturation and chamber vapor pressure and $S$ is the slope of the vapor pressure temperature function at ambient temperature. The Clausius-Clapeyron equation gives $S$ as a function of temperature ($T$), saturation vapor pressure ($e_o$,) and latent heat of vaporization ($\lambda$):

$$S = \frac{e_o \lambda}{RT^2}$$

where $R$ is the universal gas constant.

The dew point temperature depression, $\Delta T$, is measured as a voltage signal from the thermocouple. This voltage is equal to $\Delta T$ multiplied by the thermocouple responsivity, which is approximately 62 microvolts per degree Celsius. After voltage amplification by a preamplifier, the microprocessor processes the voltage signal to provide calibration and compensation functions and then displays the reading in mmol/kg.

APPENDIX
B

# *Specifications*

| | |
|---|---|
| **Sample Volume** | 10 µL nominal (Other accessory sample volumes: 2 µL using AC-063, 20 µL using AC-064 sample holder, and approximately 60 µL using AC-065 sample holder.) |
| **Measurement Range** | Typically 20 to 3200 mmol/kg* (to 3500 mmol/kg with extended range osmometer) @ 25 °C ambient. |
| **Measurement Time** | 90 seconds. |
| **Resolution**** | 1 mmol/kg. |
| **Repeatability**** | 2 mmol/kg Standard Deviation. |
| **Linearity**** | ± 1% of reading over calibrated range (100 mmol/kg-1000 mmol/kg.<br>± 5% < 100 mmol/kg and > 1000 mmol/kg up to 3200 mmol/kg.<br>±10% > 3200 mmol/kg for XR units while operating between 20 and 25 °C. |
| **Calibration** | Automatic using Opti-Mole osmolality standards. |
| **Readout** | 240 x 128 pixel backlit LCD. |
| **Operating Temperature** | This device has been designed for indoor use only between 15 and 37 °C with a maximum relative humidity of 85%. For use at altitudes up to 2000 meters. (Instrument should be at stable temperature before calibrating.) |
| **Storage Temperature** | 0 to 60 °C. |
| **Serial Outputs** | **RS-232** (ASCII format).<br>Data Protocol: 9600 Baud, 1 Start Bit, 8 Data Bits, No Parity, 1 Stop Bit.<br>9-Pin Sub-D Connector:<br>**USB** – Device.<br>Type-B Receptacle.<br>Data Protocol: 115200 Baud, 1 Start Bit, 8 Data Bits, No Parity, 1 Stop Bit. |
| **Electrical** | |
| **Line Voltage** | 100 to 240 Volts AC @ 50-60 Hz. |
| **Power** | 40 Watts maximum. |
| **Fuses** | (2 required) 5 x 20 mm time-delay type T – 1 ampere at 250 volts. Manufactured by Littlefuse Part # 218001 or Bussman Part # GDC-1A. |
| **Size (H x W x D)** | 20 cm (8”) x 28 cm (11”) x 36 cm (14”). |
| **Weight** | 6.8 kg (15 lbs.). |

*mmol/kg is the Standard International (SI) unit of osmolality.
**Specifications established using 10 µL sample size.

APPENDIX
C

# *Accessories, Supplies, and Replacement Parts*

**STANDARD SAMPLE HOLDERS (for solution osmolality)**

AC-062 Sample Holder, 7 mm diameter x 1.25 mm deep, 10 µL (supplied with instrument)

AC-063 Sample Holder, 4.25 mm diameter x 1.2 mm deep, 2 µL (low sample volume)

**SPECIAL PURPOSE SAMPLE HOLDERS (gross samples)**

AC-064 Sample Holder, 7 mm diameter x 2.5 mm deep, approximately 20 µL

AC-065 Sample Holder, 9.5 mm diameter x 4.5 mm deep, approximately 60 µL

**OSMOMETRY STANDARDS/CONTROLS**

**OPTI-MOLE AMPULE STANDARDS, 0.4 mL vial (package of 60)**

OA-010 Opti-Mole Osmolality Standard Solution, 100 mmol/kg

OA-029 Opti-Mole Osmolality Standard Solution, 290 mmol/kg

OA-100 Opti-Mole Osmolality Standard Solution, 1000 mmol/kg

**OSMOLALITY CONTROLS**

SS-273 Osmocoll HNL (High, Normal, and Low level) Osmolality Control References (package of 6, 1 mL vials, 2 High, 2 Normal, and 2 Low)
High: Approximately 330 mmol/kg (each Osmocoll lot has a specific osmolality)
Normal: Approximately 290 mmol/kg (each Osmocoll lot has a specific osmolality)
Low: Approximately 270 mmol/kg (each Osmocoll lot has a specific osmolality)

# *Accessories, Supplies, and Replacement Parts*

## SUPPLIES

| | |
|---|---|
| AC-037 | Micropipettor, 10 µL |
| AC-061 | Ampule Organizer |
| AC-011 | Hex Driver, 9/64 (screwdriver handle) |
| AC-036 | Forceps, 5-inch, stainless steel |
| AC-177 | Seiko Printer (9600 baud) Power Supply and Cable |
| 121006 | Power Cord (115V) |
| 121175 | Power Cord (230V) |
| AC-176 | VAPRO Lab Report Software |
| SS-003 | Cleaning Solution, for manual cleaning (2 oz dropper bottle) |
| SS-006 | Deionized Water (2 oz dropper bottle) |
| SS-223 | Thermocouple Cleaning Solution with Anionic Detergent (60 mL dropper bottle) |
| SS-026 | Blow Clean |
| SS-033 | Sample Discs (vial of 5000) |
| SS-036 | Micropipettor Disposable Tips for AC-037 (package of 1000) |
| SS-238 | Desiccant Cartridge/Filter |
| SS-239 | Waste Reservoir |
| SS-240 | Supply Reservoir |

## REPLACEMENT PARTS

**Only replacement parts supplied by ELITechGroup should be used in this instrument. Use of non-approved parts may affect the performance and safety features of this product.**

### CIRCUIT MODULES and ASSEMBLIES

| | |
|---|---|
| RP-429 | Power Supply |
| RP-430 | Electronic Module |
| RP-488 | TC Head 0-3200 mmol/kg |
| RP-432 | TC Head Cable Assembly |
| RP-238 | Battery, Lithium CR2025 3V |

### FACTORY SERVICE

| | |
|---|---|
| FS-255 | Thermocouple Clean and Check Service |

### MANUALS and INSTRUCTIONAL MATERIALS

| | |
|---|---|
| RP-445 | Manual, application, for VAPRO 5600/5600XR |
| RP-403 | Thermocouple Cleaning DVD, Format: NTSC |
| RP-404 | Thermocouple Cleaning DVD, Format: PAL |

APPENDIX
D

## *Critical Components*

| OA-010 100 mmol/kg Opti-Mole Osmolality Standard | |
|---|---|
| Hazard Pictogram | None |
| Single Word | None |
| Hazard Statements | None |
| Precautionary Statements | None |

| OA-029 290 mmol/kg Opti-Mole Osmolality Standard | |
|---|---|
| Hazard Pictogram | None |
| Single Word | None |
| Hazard Statements | None |
| Precautionary Statements | None |

| OA-100 1000 mmol/kg Opti-Mole Osmolality Standard | |
|---|---|
| Hazard Pictogram | None |
| Single Word | None |
| Hazard Statements | None |
| Precautionary Statements | None |

| **SS-003 Cleaning Solution for Cleaning VAPRO® Thermocouples** | |
|---|---|
| Hazard Pictogram |  |
| Single Word | Danger |
| Hazard Statements | H314 – Causes severe skin burns and eye damage<br>H335 – May cause respiratory irritation |
| Precautionary Statements | P260 – Do not breathe vapors.<br>P264 – Wash hands thoroughly after handling.<br>P280 – Wear protective gloves.<br>P301+P312 – If swallowed: Call a doctor, a POISON CENTER if you feel unwell.<br>P303+P351+P353 – If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.<br>P304+P340 – If inhaled: Remove person to fresh air and keep comfortable for breathing.<br>P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P403+P233 – Store in a well-ventilated place. Keep container tightly closed.<br>P501 – Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national, and/or international regulation. |

| **SS-026 Blow Clean Inert Dusting Gas** | |
|---|---|
| Hazard Pictogram |  |
| Single Word | Warning |
| Hazard Statements | H280 – Contains gas under pressure; may explode if heated |
| Precautionary Statements | P410+P403 – Protect from sunlight. Store in a well-ventilated place. |

| **SS-273 OSMOCOLL®** | |
|---|---|
| Hazard Pictogram | None |
| Single Word | None |
| Hazard Statements | None |
| Precautionary Statements | None |

APPENDIX
D

## *Critical Components*

| SS-223 Cleaning Solution with Anionic Detergent | |
|---|---|
| Hazard Pictogram |  |
| Single Word | Warning |
| Hazard Statements | H319 – Causes serious eye irritation |
| Precautionary Statements | P264 – Wash hands thoroughly after handling.<br>P280 – Wear protective gloves, eye protection.<br>P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P337+P313 – If eye irritation persists: Get medical advice/attention. |

| SS-238 Desiccant Cartridge / Filter | |
|---|---|
| Hazard Pictogram |  |
| Single Word | Danger |
| Hazard Statements | H317 – May cause an allergic skin reaction<br>H334 – May cause an allergy or asthma symptoms or breathing difficulties if inhaled<br>H350 – May cause cancer (Inhalation)<br>H360 – May damage fertility or the unborn child (Inhalation)<br>H412 – Toxic to aquatic life with long lasting effects |
| Precautionary Statements | P201 – Obtain special instructions before use.<br>P261– Avoid breathing dust, fume, vapors.<br>P273 – Avoid release to the environment.<br>P280 – Wear protective gloves.<br>P302+P352 – If on skin: Wash with plenty of soap and water.<br>P304+P341 – If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.<br>P308+P313 – If exposed or concerned; Get medical advice/attention.<br>P501 – Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national, and /or international regulation. |

| SS-006 Deionized Water for Cleaning VAPRO® Thermocouples | |
|---|---|
| Hazard Pictogram | None |
| Single Word | None |
| Hazard Statements | None |
| Precautionary Statements | None |

## Storing the Instrument

Before storing the osmometer do the following:

1. Purge the automated cleaning system of residual water.
    a. Remove the supply reservoir cap assembly from the supply reservoir. Remove the water take-up tube from the reservoir, leaving the water sensor tube in the container. Press the CLEAN key to initiate the cleaning function. This process will draw water from the tubing and internal cleaning system.
    b. When the cleaning process is complete, remove the desiccant cartridge/filter from the instrument. Place the provided sealing caps over both ends of the cartridge to prevent moisture from being absorbed into the cartridge while not in use.
2. Decontaminate the instrument.
    a. With the instrument powered, press the OPEN/CLOSE key to open the slide. Decontaminate the sample holder by wiping it and the surrounding area of the slide with a disinfectant. Press the OPEN/CLOSE key to position the slide to the closed position. Use of any of the following:
        - A freshly prepared (less than 24 hours) 10% bleach in water solution.
        - A disinfecting laboratory wipe such as DisCide™.
        - Isopropyl alcohol or alcohol wipes.
        - ELITechGroup Decontamination Solution Concentrate (SS-133, 2 mL vial dilutes to 500 mL).
    b. With the instrument powered off, clean any residue, dried blood, etc. from the exterior case and pipette guide with the same disinfectant.
3. Remove the supply reservoir cap assembly from the supply reservoir. Empty the reservoir, wash it out using a 10% bleach solution in water, and thoroughly rinse it using USP purified water. Replace the supply reservoir cap assembly securely tightening the cap.
4. Remove the waste reservoir cap assembly from the waste reservoir. Empty the reservoir, wash it out using a 10% bleach solution in water, and replace the waste reservoir cap assembly securely tightening the cap.
5. If storing for an extended period of time, place the instrument in a plastic bag or other type of container to keep dust or other particles from collecting on the instrument.
6. Store the instrument in a location within the storage temperature range of 0 to 60 °C and less than 85% non-condensing humidity.

APPENDIX
E

# *Instrument Storage, Transport and Disposal Instructions*

## Shipping an Instrument

Instruments must be cleaned and decontaminated before returning them to an authorized service center. A charge is assessed if an instrument has to be cleaned or decontaminated at the service center.

**NOTE**

It is not necessary to include the power cord with instruments returning for repair.

1. Purge the automated cleaning system of residual water.
   a. Remove the supply reservoir cap assembly from the supply reservoir. Remove the water take-up tube from the reservoir, leaving the water sensor tube in the container. Press the CLEAN key to initiate the cleaning function. This process will draw water from the tubing and internal cleaning system.
   b. When the cleaning process is complete, remove the desiccant cartridge/filter from the instrument. Place the provided sealing caps over both ends of the cartridge to prevent moisture from being absorbed into the cartridge while not in use.
2. Decontaminate the instrument.
   a. With the instrument powered, press the OPEN/CLOSE key to open the slide. Decontaminate the sample holder by wiping it and the surrounding area of the slide with a disinfectant. Press the OPEN/CLOSE key to position the slide to the closed position. The service center requires the use of any of the following for cleaning purposes:
      - A freshly prepared (less than 24 hours) 10% bleach in water solution.
      - A disinfecting laboratory wipe such as DisCide™.
      - Isopropyl alcohol or alcohol wipes.
      - ELITechGroup Decontamination Solution Concentrate (SS-133, 2 mL vial dilutes to 500 mL).
3. With the instrument powered off, clean any residue, dried blood, etc. from the exterior case and pipette guide with the same disinfectant.

4. Remove the supply reservoir cap assembly from the supply reservoir. Empty the reservoir, wash it out using a 10% bleach solution in water, and thoroughly rinse it using USP purified water. Replace the supply reservoir cap assembly securely tightening the cap. Remove the waste reservoir cap assembly from the waste reservoir, empty the reservoir, rinse the reservoir using a 10% bleach in water solution, and replace the waste reservoir cap assembly securely tightening the cap.
5. Complete the HAZARD FREE CERTIFICATION FORM. Make sure an RMA (Return Maintenance Authorization) number appears in the upper right corner. Make a copy for your records.
6. Enclose the instrument in a container comparable to its original packaging. You may use the packaging from the loaner instrument if you received one or request a new shipping container from the service center. Include the completed HAZARD FREE CERTIFICATION FORM with the shipment. With a black marker, boldly write the RMA number on at least two sides of the container.
7. Shipping Conditions: Temperature – 0 to 40 °C, Humidity < 85% Non-condensing. (Water in the supply lines could cause problems if frozen.)
8. Return the instrument to ELITechGroup Inc, Logan, UT. The customer is responsible for the cost of shipping and insurance covering the value of the device.

## Disposal of the Instrument

This device should be completely decontaminated and disposed of as follows:

Under Directive 2012/19/EU (WEEE), this instrument cannot be disposed of in a normal landfill. Instead, the instrument must be disposed of either by:

1. Routing to an authorized local facility approved for handling hazardous materials, or
2. Returning the instrument to ELITechGroup or an authorized service center.

APPENDIX
F



## Clinical and General Research

The VAPRO has unique advantages in many aspects of clinical chemistry due to its very small sample requirement. This is particularly true in pediatric practice. For example, the amount of sample collected for sweat, fecal, sputum, duodenal, and gastric analysis is frequently too small to allow osmolality assay by older macro methods, especially since other analytical parameters are very often simultaneously requested on such specimens.

An equally important advantage is that the vapor pressure osmometer does not physically change the sample. Where biological specimens or medications are multiphasic, or highly viscous, vapor pressure osmometry becomes the only reliable method of measurement. For example, feces, sputum, and gastrointestinal aspirate specimens usually contain variable amounts of mucous material that interferes with or prevents freezing point depression measurements, but does not affect vapor pressure osmometry. Neither does the presence of finely suspended insoluble material, a feature of radio-opaque media, which are often examined to detect grossly high osmolality values likely to produce rapid dehydration when given to small infants.

In general research, the potential applications are too numerous to list. However, the vapor pressure osmometer is of value to a wide range of biologists and microbiologists concerned with fluid and electrolyte balance in all forms of life, especially where specimens are necessarily very limited in size, and may exhibit unusual viscosity.

The instrument is capable of vapor pressure determinations (expressed as osmolality) even on complex specimens such as tissue sections. Such specimens should be cut to approximately the diameter and thickness of the paper sample disc, if possible.

For experimental purposes, large-volume sample holders are available. These sample holders accommodate gross specimens that are not amenable to testing with the standard shallow sample holder. Contact ELITechGroup for more information.

## Procedure for Very Small Samples

Measure samples with very low volumes (under 4 µL) using the following procedures.

Sample discs must be hand made from high-grade filter paper (Whatman #1 or equivalent) using a high-precision 1/8-inch diameter paper punch to produce discs with a very clean edge.

Required Equipment

- ELITechGroup low-volume sample holder (AC-063)
- High quality round hole paper punch, 1/8" diameter (Mieth or equivalent)
- High quality 2 µL pipette, which delivers precisely 2 µL or less
- Pipette tips (short)
- Tweezers
- Teasing needle
- Whatman #1 Filter Paper or equivalent
- Lint-free tissue paper
- Cotton-tipped applicators

**NOTE**

Maintain a stable ambient temperature. Heat, cold, air currents and temperature fluctuations that vary more than approximately 0.3 °C within a 10-to-15-minute time frame, generally result in poor quality data. Monitor the Temperature Drift Scale for ambient temperature fluctuations, which interfere with instrument accuracy.

Technique, including timing, is vitally important to obtaining good data while conducting very low volume tests.

# Special Low-Volume Procedure

## Preparing Paper Discs

1. Use a (Mieth or equivalent) 1/8-inch diameter punch to create a supply of paper discs. Punch only one thickness of paper stock at a time, to prevent paper discs from sticking together. That, along with static electricity make it difficult to pick up a single disc with the tweezers.
2. After punching, remove paper discs from the retainer of the punch. Store discs in a clean, static-free container. As stated before, very low volume tests require careful and consistent technique to achieve reliable results. The following are important to consider when running samples with very low volumes:
   - Use only single sample discs. Because of their small size, be careful not to load more than one.
   - Discs must be punched cleanly – no ragged edges.
   - The sample holder must be kept very clean.
   - Do not exceed 4 µL of sample in the special sample holder. Using too much sample fluid can severely contaminate the thermocouple.
   - The paper disc must be completely saturated by sample fluid. If not fully saturated the disc may appear patchy. In this condition, data is inconsistent and repeatability is poor.

**NOTE**

Very small samples of less than 2 µL can be successfully measured using lighter paper for the discs. Experiment with various papers. Be cautious that some papers contain electrolytes that make them unsuitable. Successful results have been achieved using standard laboratory lint-free tissue.

## Instructions

Before running the 2 µL samples, calibrate the instrument using 10 µL samples at the 290, 1000, and 100 mmol/kg calibration set points.

1. Press the OPEN/CLOSE key to position the sample holder under the pipette guide.
2. From underneath the sample holder, gently push straight up on the sample holder. It should pop out of the sample slide. It is held in place by using a friction fit with an o-ring. Remove the 10 µL sample holder.

3. Insert the 2 µL sample holder (AC-063). Line up the sample holder with the hole in the sample slide. Gently push the sample holder straight down so that it positions inside the sample slide. Make sure the top surface of the sample holder is flush with the sample slide.
4. Press the OPEN/CLOSE key to close the slide. Allow the instrument time to reach temperature equilibration. Always calibrate the instrument using the equivalent solution volume to match the sample holder, in this instance 2 µL. Calibrate using the 290 mmol/kg standard. If the osmolality of the samples is close to the 290 calibration set point it is not necessary to calibrate at the 1000 mmol/kg level.
5. Load a single paper disc into the center of the special sample holder. If necessary, use the teasing needle and the tweezers to separate discs that are stuck together.
6. Place the sample into the center of the paper disc. Be sure to touch the pipette onto the disc as in the regular procedure. Be sure the disc is completely saturated.
7. Press the OPEN/CLOSE key to close the sample chamber to begin the measurement cycle.
8. When the measurement is complete, retract the sample from the sample holder.
9. Thoroughly clean the sample holder of all sample material using lint-free tissue and a cotton-tipped applicator.

APPENDIX
F

# *Special Application Notes*

## Measuring Large Samples

Measuring large samples requires consideration of the nature and size of the sample. Experiment with these procedures to find the best approach for your particular application.

Samples such as leaf discs, tissues, and other solids often require considerable time to reach equilibrium. The *Process Delay Mode* allows the user to delay the measurement indefinitely or to take successive readings without opening the chamber.

The time required to achieve equilibration can be determined by taking measurements until the readings no longer decrease. Once familiar with the required equilibration time for a particular type of sample, simply leave the chamber closed for the required time and then press ENTER to begin the osmolality measurement.

The standard sample holder (AC-062) has a diameter of 7 mm and a depth of 1.25 mm (10 µL). Two optional sample holders are available from ELITechGroup for measuring samples that are too large for the standard sample holder.

AC-064 sample holder is 7 mm diameter x 2.5 mm deep (approximately 20 µL).

AC-065 sample holder is 9.5 mm diameter x 4.5 mm deep (approximately 60 µL).

### Instructions

1. For best precision, use the smallest holder that can accommodate the sample volume without danger of contaminating the thermocouple.

**CAUTION**
**Never load any sample that extends above the lip of the sample holder. Solid sample material extending above the lip of the sample holder can severely contaminate or even break the thermocouple.**

2. Calibrate the instrument. Use the same size sample holder as will be used for the assayed sample. Match the volume and shape of the subject sample and the calibration solution as closely as possible. Several filter paper discs saturated with standard solution should be used for calibration to dampen the motion of the solution and to approximate the size and shape of the sample material.

3. Select *Process Delay Mode*. This allows you to delay the measurement cycle after closing the chamber until pressing ENTER.
4. Place the sample in the sample holder. Press the OPEN/CLOSE key. Solid (or some viscous) samples require extended periods to reach equilibration inside the chamber. On such samples you may want to make repeated measurements without opening the chamber to determine the time required to achieve equilibrium. Osmolality values trend downward until they stabilize. If the required time is known, simply defer the measurement for that period.
5. Press ENTER to make a measurement. Osmolality displays when the measurement is complete.

## Sampling Viscous and/or Nonhomogeneous Specimens

The broad range of specimen materials amenable to testing in the vapor pressure osmometer may require you to adapt your sampling technique to suit the physical characteristics of unusual samples. Using the micropipettor assures the application of uniform volumes of both test specimen and calibrating solutions, but if the viscosity of the sample is extremely high, a positive-displacement micropipettor may be preferable for sampling. These devices are not recommended for routine use, however, due to their propensity toward carry-over error.

If the sample material does not readily saturate the paper sample disc or does not spread out over the whole disc naturally, it may be preferable to eliminate the sample disc and use the pipettor tip to apply the material as uniformly as possible over the central depression of the sample holder.

In other situations, materials can be sampled successfully by immersing the paper sample disc, which is held in the forceps, into the specimen to be tested, then carefully transferring the wet disc to the central depression of the sample holder. Caution must be exercised when using this “disc immersion” technique to avoid any contact of the wet sample disc with the outer portion of the sample holder, since this would result in solute material being transferred to the thermocouple mount and would rapidly contaminate the sample chamber.

In any event, when working with unusual specimens, make certain the sample occupies the full diameter of the central depression in the sample holder, as it would if saturated into a paper sample disc. The thickness of the specimen should be as small as possible.

APPENDIX
F

*Special Application Notes*

## Osmometry With Multi-Solvent Solutions

Biological solutions, in general, are aqueous in nature. Most specimens submitted to the clinical laboratory for testing, both pathologic and normal, exhibit characteristic properties that are essentially attributable to the cardinal properties of water, as modified by the dissolved solute particles. Such solutions, which can be represented by a simple model, i.e., water as solvent with nonvolatile solutes, have a linear, uniform relationship among all of the colligative properties (vapor pressure, freezing point, boiling point, etc.). In addition, most of these same solutions can be uniformly frozen with few artifacts arising from the freezing process. Thus, one can expect to obtain very similar results, if not exact duplication, between freezing point and vapor pressure measurements on the vast majority of clinical specimens.

Aside from this broad category of solutions, there is a small but important class of solutions that may be encountered in clinical work where the colligative relationships do not necessarily hold. These are solutions in which non-physiological volatile solutes–actually solvents–are present. In such cases, the interactions among the various molecules cause the properties of such solutions to be more complex. They generally do not follow linear relationships, as in solutions having only a single solvent. It must be remembered that osmometers for clinical applications, whether based on freezing point or vapor pressure methodology, determine the osmolality of solutions by indirect means. When complex solutions are encountered, the results obtained by either of these instruments may not faithfully represent the osmolality of the solution. Each instrument responds to the parameter it is designed to measure, and the resultant indications must be interpreted accordingly.

You must be aware of this phenomenon to correctly interpret results. To illustrate, the table below depicts the results of solution osmolality measurements made by both vapor pressure and freezing point osmometers for varying amounts of ethanol in human blood serum. Note that in the vapor pressure instrument, concentrations of ethanol anywhere within the clinically significant range do not appreciably affect the indication of osmolality. This is because the vapor pressure of a water-ethanol solution does not change measurably with small concentrations of ethanol. On the other hand, the freezing point osmometer tends to overestimate the actual number of ethanol particles in the solution, as the freezing point falls disproportionately with increasing amounts of ethanol. Thus, neither instrument faithfully reports osmolality in the case of water-ethanol mixtures. In clinical practice, the unique response of the vapor pressure osmometer is usually an advantage inasmuch as it allows the clinician or attending physician to monitor the patient's serum metabolites (other than alcohol) independently of the patient's blood alcohol level.

## Ethanol in Human Blood Serum Vapor Pressure Versus Freezing Point Osmolality Determination

| (1) Serum Osmolality (mmol/kg) | (2) Ethanol Added / kg (µL) | (2) Ethanol (mg) | (2) Ethanol Added / kg (mmol) | Calculated Total Osmolality (mmol/kg) | Measured F.P. Osmolality (mmol/kg) | Measured V.P. Osmolality (mmol/kg) |
|---|---|---|---|---|---|---|
| 289 | 2500 | 1953 | 42 | 331 | 340 | 287 |
| 289 | 5000 | 3905 | 85 | 374 | 392 | 285 |
| 289 | 10000 | 7810 | 170 | 459 | 501 | 282 |
| 289 | 25000 | 19525 | 424 | 713 | 798 | 277 |
| 289 | 50000 | 39050 | 849 | 1138 | 1400 (out of cal) | 250 |

(1) Instruments gave identical results on serum alone.
(2) Assuming 100% ethanol, with a relative gravity of 0.78.

APPENDIX
F



## Standard International (SI) Units of Osmolality

Osmolality, by definition, is an expression of the total number of solute particles dissolved in one kilogram of solvent without regard for particle size, density, configuration, or electrical charge.

Traditionally, osmolality has been expressed as milliosmols per kilogram, with various abbreviations such as mOs/kg, mOsm/kg, and mOsmol/kg. The letters "Os" signify that osmolality is defined as the concentration, expressed on a molal basis, of the osmotically active particles in true solution. Thus, one mole (1000 mmol) of sodium chloride dissolved in a kilogram of water has an ideal osmolality of 2000 mOsm/kg, since a molecule of sodium chloride dissociates in solution to produce two ions, that is, two osmotically active particles.

In fact, a molal solution of sodium chloride has an osmolality value slightly less than the ideal because the residual mutual attraction of the hydrated ions reduces their mutual independence due to the osmotic coefficient. Since this coefficient varies with the solute concentration, the relation between osmolality and concentration of solute is not linear. For this reason, measurements of osmolality made on laboratory-diluted specimens, with subsequent multiplication by the dilution factor to calculate the original solution osmolality, does not give valid results.

With complex solutions, such as biological fluids, analytical variables are universally expressed as the concentration of specific ions and of undissociated solute particles. It follows that a molal solution of NaCl can be analytically expressed as a combination of a molal solution of sodium ions and a molal solution of chloride ions. The total concentration of solute particles (the osmolality) is therefore 2000 millimolal. Osmolality can best be expressed simply as 2000 mmol/kg without the necessity of introducing the "osmole" concept.

The commissions on Clinical Chemistry of the International Union of Pure and Applied Chemistry (IUPAC) and the International Federation of Clinical Chemistry (IFCC) have recommended that the unit of osmolality be mmol/kg. This has been adopted by the American Journal Clinical Chemistry as part of its general acceptance of Standard International units. Wescor Inc (Now ELITechGroup Inc) led the industry as the first osmometer manufacturer to adopt Standard International (SI) units for osmolality.

## Quality Assurance

ELITechGroup manufactures calibration solutions using reference data on the concentrative properties of sodium chloride in water from the Handbook of Physics and Chemistry, CRC Press. For quality assurance, each lot is compared by replicate osmolality measurements to reference solutions prepared from dried, high-purity sodium chloride obtained from the National Institute of Standards and Technology (NIST).

ELITechGroup guarantees the accuracy of its calibration solutions within the combined overall accuracy of the reference solution formulations and the control measurements: 100 ± 2 mmol/kg; 290 ± 3 mmol/kg; 1000 ± 5 mmol/kg, under nominal conditions.

APPENDIX
G



# VAPRO Installation Qualification Checklist

| | |
|---|---|
| **Product Name:** | VAPRO 5600/5600XR |
| **Product Manufacturer:** | ELITechGroup Inc. |
| **Address:** | _____<br>_____ |
| **Serial Number:** | |
| **Location of Installation (Asset Number):**<br>(Indicate if it is a mobile unit) | |

| Check | Accessories and Supplies Check List |
|---|---|
| | 57-0006-XX User's Manual for VAPRO 5600/5600XR |
| | AC-037 10 µL Pipettor |
| | SS-036 Micropipettor Disposable Tips |
| | AC-036 Forceps |
| | SS-033 Paper Sample Discs |
| | OA-010 100 mmol/kg Opti-Mole Osmolality Ampule Standard |
| | OA-029 290 mmol/kg Opti-Mole Osmolality Ampule Standard |
| | OA-100 1000 mmol/kg Opti-Mole Osmolality Ampule Standard |
| | AC-061 Ampule Organizer |
| | AC-011 9/64-inch Hex Driver |
| | SS-238 Desiccant Cartridge/Filter |
| | Thermocouple Head Cleaning Supplies, consisting of: |
| | SS-003 Cleaning Solution |
| | SS-006 Deionized Water |
| | SS-026 Blow Clean (U.S. 48 States only) |
| | SS-223 Thermocouple Cleaning Solution with Anionic Detergent |
| | Power Cord (115V or 230 V) |
| | * In addition, you will need a supply of lint-free tissue paper (Kimwipes) for cleaning the sample holder between specimens. (Not supplied with the osmometer.) |

| Check | Installation Qualification Procedure |
|---|---|
| | 1. Carefully unpack the instrument and compare the contents with the packing list to be certain that everything needed for operation is at hand. Inspect accessories and supplies. |
| | 2. Place the instrument on a suitable work surface in an area free from drafts or direct sunlight.<br>***Avoid locations where instrument precision will be altered by thermal gradients or rapid temperature changes caused by heavy foot traffic, air vents, blowers, heaters, or windows.*** |
| | 3. Fill the supply reservoir with USP purified water and install the supply and waste reservoirs. |
| | 4. Install the desiccant cartridge/filter. Verify the cartridge is blue in color. |
| | 5. Check that the laboratory line voltage source falls within the range specified on the instrument voltage label (100 to 240 volts AC). |

| | |
|---|---|
| | 6. Connect the power cord to an electrical outlet that matches the voltage selected on the rear panel. Avoid power circuits that are shared by centrifuges, air conditioners, or other power equipment. ELITechGroup recommends that you use a power line surge protector to isolate the osmometer from spikes and surges. |
| | 7. (Optional) If a serial printer is being used, connect the AC-049 VAPRO printer cable between the printer and the VAPRO. |
| | 8. (Optional) If the VAPRO Lab Report software is being used, connect an RS-232 cable or a USB cable between the VAPRO and the serial port of the computer. |
| | 9. Turn the osmometer on (**I**). The POWER indicator on the front panel shows green when power is on. |
| **Check** | **Relocating the VAPRO** |
| | 1. Check the sample holder and make sure that it is empty and clean. |
| | 2. Set the VAPRO to an idle state. (If the sample slide is in the open position, press the OPEN/CLOSE key.) |
| | 3. Turn the instrument off and disconnect the power cable and the USB or RS-232 cable if necessary. |
| | 4. Remove and/or empty the supply and waste reservoirs. |
| | 5. Clean the outside of the instrument. |
| | 6. Move the instrument to the new location. |
| | 7. Follow the instrument installation procedure to install the instrument. |
| | |
| **Check** | **Maintenance Review Tasks** |
| | Verify that there is a plan for spare/replacement parts. |
| | Verify that there is a preventive maintenance program for the VAPRO. |
| | Verify that there is a calibration procedure and it details when calibration should occur. |
| | Verify that there is a training program in place. (Operators to be trained before using the instrument.) |

The VAPRO 5600/5600XR was installed and powered on as expected / not as expected. (Circle appropriate answer)

| | |
|---|---|
| Performed By: _____ | Date: _____ |
| Approved By: _____ | Date: _____ |

Notes or Comments:

# VAPRO Operation Qualification Checklist

| | |
|---|---|
| **Product Name:** | VAPRO 5600/5600XR |
| **Product Manufacturer:** | ELITechGroup Inc. |
| **Serial Number:** | |
| **Location of Installation (Asset Number):**<br>(Indicate if it is a mobile unit) | |

| Check | Operation Qualification Checklist |
|---|---|
| __Pass<br>__Fail | **Initialization and Stabilization**<br>1. Turn the osmometer on. Verify that the initialization process passes and no errors occur.<br>2. Allow the osmometer to reach temperature stability (typically 10 to 30 minutes). |
| __Pass<br>__Fail | **Loading Samples**<br>1. Press the OPEN/CLOSE key to bring the sample holder directly under the pipettor guide.<br>2. Use the forceps supplied with the instrument to place a single sample disc in the central depression of the sample holder.<br>3. With a clean tip installed, aspirate a sample into the micropipettor.<br>4. Position the tip about 5 millimeters above the center of the sample disc.<br>5. Smoothly depress the micropipettor plunger to the stop.<br>6. Lightly touch the micropipettor tip to the sample disc, and then lift it away. The paper disc should appear fully saturated, with a slight liquid meniscus on its surface.<br>7. Press the OPEN/CLOSE key to rotate the sample into the measurement position and start the assay. Allow the measurement to complete.<br>8. Using a lint-free tissue (not facial tissue) or cotton swabs, carefully remove the wet disc and any traces of residual liquid from the sample holder immediately after a measurement.<br>9. Repeat the above process as many times as needed to become familiar with loading samples. |
| __Pass<br>__Fail | **Cleaning the Sample Holder**<br>1. Using a lint-free tissue (not facial tissue) or cotton swabs, carefully remove the web disc and any traces of residual liquid from the sample holder.<br>2. Leave no visible residue on the holder surface. If needed, use a tissue or swab moistened with deionized water. Always clean the sample holder with a fresh tissue or swab to avoid contamination. Avoid touching the sample holder with bare fingers. |
| __Pass<br>__Fail | **Calibrating**<br>1. With the osmometer in an idle state, press the OPEN/CLOSE key to position the sample chamber below the pipette guide.<br>2. Place a single disc in the central depression of the sample holder.<br>3. Pipette 10 µL from an Opti-Mole 290 mmol/kg standard onto the disc.<br>4. Press the OPEN/CLOSE key to position the sample chamber to the closed or measurement position. Once the sample chamber seals the measurement automatically begins. After completion of the measurement, the slide rotates to the Open position and the assayed value displays. Repeat steps 2 through 4 two more times. On the third sample, press the Calibrate key when the slide rotates to the Open position.<br>5. Remove the specimen from the sample chamber and repeat steps 2 through 4 using the Opti-Mol 1000 mmol/kg standard. Press the Calibrate key after the third sample value has displayed.<br>6. Remove the specimen from the sample chamber and repeat steps 2 through 4 using the Opti-Mol 100 mmol/kg standard. Press the Calibrate key after the third sample value has displayed.<br>A thermocouple contamination level reading automatically occurs whenever a calibration at 100 mmol/kg occurs. Record the contamination level. If the displayed contamination level is greater than 2, perform the automated thermocouple clean cycle. |

| | Calibrated on the 3rd Sample | Standard | | Notes |
|---|---|---|---|---|
| | | 290-mmol/kg | Yes/No | |
| | | 1000-mmol/kg | Yes/No | |
| | | 100-mmol/kg | Yes/No | |
| | | Contamination Level | | |

__Pass
__Fail

**Running Test Samples using Osmolality Standards**

1. If not already completed, calibrate the osmometer using the 290-mmol/kg, 1000-mmol/kg, and 100-mmol/kg standards. Record the calibration readings in the space provided below. (Copy the readings from the Calibrating process previously performed.)
2. In *Normal Mode*, run three assays using the Opti-Mole 100-mmol/kg standard. Record the readings, including the mean and standard deviation in the space provided below. The mean reading should be within ± 4-mmol/kg for the 100-mmol/kg standard. From the *Main Menu*, reset the statistics before running the next set of assays.
3. In *Normal Mode*, run three assays using the Opti-Mole 290-mmol/kg standard. Record the readings, including the mean and standard deviation in the space provide below. The mean reading should be within ± 6-mmol/kg for the 290-mmol/kg standard. From the *Main Menu*, reset the statistics before running the next set of assays.
4. In *Normal Mode*, run three assays using the Opti-Mole 1000 mmol/kg standard. Record the readings, including the mean and standard deviation. The mean reading should be within ± 10 mmol/kg for the 1000 mmol/kg standard. From the *Main Menu*, reset the statistics before running the next set of assays.

| Standard | 100-mmol/kg | 290-mmol/kg | 1000-mmol/kg |
|---|---|---|---|
| **Assay 1** | | | |
| **Assay 2** | | | |
| **Assay 3** | | | |
| **Mean** | | | |
| **Standard Deviation** | | | |

The VAPRO operated as expected / not as expected. (Circle appropriate answer)

Performed By: _____ Date: _____

Approved By: _____ Date: _____

# VAPRO Performance Qualification Checklist

| | |
|---|---|
| **Product Name:** | VAPRO 5600/5600XR |
| **Product Manufacturer:** | ELITechGroup Inc. |
| **Serial Number:** | |
| **Location of Installation (Asset Number):**<br>(Indicate if it is a mobile unit) | |

| Check | Performance Qualification Task |
|---|---|
| __Pass<br>__Fail | **General Performance Checks**<br>1. Verify the power switch operates properly.<br>2. Turn power off, wait 10 seconds, and turn power on – Let the osmometer complete the system initialization sequence.<br>3. Verify that the power indicator light comes on.<br>4. Verify that the instrument has reached system temperature equilibration (typically 2 to 4 hours).<br>5. Press the OPEN/CLOSE key and verify that the slide chamber rotates to the open position.<br>6. Pipette a 10 µL Opti-Mole 100 mmol/kg standard sample on the sample holder. Verify that the instrument accepts 10 µL sample.<br>7. Press the OPEN/CLOSE key and verify that the slide chamber rotates to the closed position and that an assay begins.<br>8. Assay a sample and verify that the system meets the 90 second cycle time.<br>9. Verify that 100 mmol/kg ± 4 mmol/kg displays on the screen. (May need to calibrate first.)<br>10. Verify that the contamination level is less than 10. If greater than 10, perform the automated thermocouple clean cycle. |
| __Pass<br>__Fail | **Calibrating**<br>1. With the osmometer in an idle state, press the OPEN/CLOSE key to position the sample chamber below the pipette guide.<br>2. Place a single disc in the central depression of the sample holder.<br>3. Pipette 10 µL from an Opti-Mole 290 mmol/kg standard onto the disc.<br>4. Press the OPEN/CLOSE key to position the sample chamber to the closed or measurement position. Once the sample chamber seals the measurement automatically begins. After completion of the measurement, the slide rotates to the Open position and the assayed value displays.<br>5. Remove the specimen from the sample chamber immediately after a measurement. If the osmometer reading is not within ± 3 mmol/kg of the standard (287 to 293), press the CALIBRATE key to calibrate the instrument to the standard; otherwise, continue with the calibration process.<br>6. Repeat Steps 2-5 using an Opti-Mole 1000 mmol/kg standard. In Step 5, if the reading is not within ± 5 mmol/kg of the 1000 mmol/kg standard (995 to 1005), press the CALIBRATE key to calibrate the instrument to the standard; otherwise, continue with the calibration process. Record the readings in the space provided below.<br>7. Repeat Steps 2-5 using an Opti-Mole 100 mmol/kg standard. In Step 5, if the reading is not within ± 2 mmol/kg of the 100 mmol/kg standard (98 to 102), press the CALIBRATE key to calibrate the instrument to the standard; otherwise, the calibration process is completed.<br>A thermocouple contamination level reading automatically occurs whenever a calibration at 100 mmol/kg occurs. Record the contamination level. If the displayed contamination level is greater than 2, perform the automated thermocouple clean cycle. |

| Preventative Maintenance | |
|---|---|
| __Pass<br>__Fail | **Filling the Supply Reservoir**<br>1. Check the level of the supply reservoir, if the reservoir is almost empty, then do the following:<br>**2. Turn the VAPRO off.**<br>3. Remove the reservoir cap assembly from the supply reservoir.<br>4. Wash out the supply reservoir with a disinfectant solution with 10% chlorine or equivalent, thoroughly rinse, and refill it with USP purified water.<br>5. Reposition the supply reservoir cap assembly, securely tightening the cap.<br>6. Remove the reservoir cap assembly from the waste reservoir.<br>7. Remove the waste reservoir and empty it according to local regulations.<br>8. Wash out the waste reservoir with a disinfectant solution with 10% chlorine or equivalent.<br>9. Reposition the waste reservoir cap assembly, securely tightening the cap.<br>10. Turn the VAPRO on and allow it to reach temperature equilibrium. |
| __Pass<br>__Fail | **Replacing the Desiccant Cartridge/Filter**<br>**1. Turn the power switch off.**<br>2. Open the desiccant access cover from the top of the osmometer.<br>3. Remove the desiccant cartridge/filter (desiccant is pink/purple in color). If replacement is not necessary, grasp the cartridge and rotate it ½ turn – 180°.<br>4. Replace the desiccant cartridge/filter with a new one (desiccant is blue in color).<br>5. Close the desiccant access cover on the top of the osmometer.<br>6. Turn power on and allow the instrument to reach temperature equilibrium. |
| _ Pass<br>_ Fail | **Automated Cleaning of the TC Head**<br>Always remove any sample from the sample holder before starting a Clean cycle.<br>1. Press the CLEAN key and allow the clean process to complete.<br>2. If an error occurs, press ENTER to continue.<br>3. Message “Spray On” displays while the TC is being sprayed with water.<br>4. Vacuum pump evaporates the water from the TC to dry it. Message “Drying” displays.<br>5. Conductivity is ideally less than one micro-siemens/cm. If it exceeds five, an error message displays and the clean cycle aborts.<br>6. After the cleaning operation completes, an auto-balance function occurs.<br>7. Run an assay using an Opti-Mole 100 mmol/kg standard.<br>8. Verify the contamination level 10 or less. If greater than 10, repeat this process. If the contamination level is still greater than 10, try manually cleaning the TC head. |

**Manual Cleaning of the TC Head (Only use if the Automated Clean Does NOT reduce the contamination level.)**

__Pass
__Fail

### Removing the TC Head

1. SELECT and ENTER *Unlock Chamber* menu item from the *Configure Menu*.
2. **Turn the power switch off.**
3. Remove the TC head access cover from the top of the osmometer.
4. Remove the TC head connector by squeezing the locking tab and lifting.
5. Using the 9/64-inch hex driver, completely loosen (but do not remove from the TC head) the attachment screws.
6. Grasp the top of the TC head (with the loose attachment screws still in the head) and lift it straight up and out of the instrument. Replace the access cover while the TC head is out of the instrument.
7. Remove the attachment screws from the head.

__Pass
__Fail

### Cleaning the Head

1. Place a waste container close by on the floor. Use a cotton swab to remove residue from the surface of the mount surrounding the thermocouple. Do not contact the thermocouple with the swab.
2. With the dropper, release cleaning solution onto the thermocouple mount.
3. Immerse the thermocouple and the entire surface of the mount in cleaning solution. Let stand at least 1 minute.
4. Hold the TC head over the waste container.
5. Quickly pull the TC head straight down and away from the droplet of liquid, allowing liquid to fall into the waste container directly below.
6. Immediately apply rinse water before evaporation can occur. Use purified water with resistivity of 1 Megohm/$cm^3$ or higher for rinsing. Water of lesser quality contaminates the thermocouple.
7. Dilute any remaining droplets of cleaning solution with purified water.
8. Repeat the rinsing process ten times and then continue.
9. Place the Blow Clean upright and level on the bench. Clear the nozzle with a slight stream of gas. Hold the TC mount about 2 inches from the nozzle, then aim the nozzle directly at the thermocouple and release a slight stream of gas to blow away any remaining droplets.
10. Repeat Steps 1 through 10 using ELITechGroup's Thermocouple Cleaning Solution with Anionic Detergent (SS-223).
11. Inspect the TC mount for any residual contamination. If foreign material cannot be removed using this procedure, refer to the Removing Difficult Contamination section.

__Pass
__Fail

### Severe or Stubborn Contamination

If the contamination reading (from the 100 mmol/kg calibration) indicates residual contamination in spite of a clean appearance:

1. Repeat the cleaning procedure. Calibrate the instrument using the 290-mmol/kg, 1000-mmol/kg, and 100-mmol/kg standards. If there is significant improvement, contamination can likely be removed by repeated manual cleaning.
2. You can often successfully remove the contaminant simply by applying a droplet of purified water to the thermocouple and allowing it to stand for 30 to 60 minutes.
3. Many contaminants can be detected and removed under microscopic examination. If cleaning fails to produce an acceptable contamination level, examine the thermocouple head under a microscope at 30X to 60X power. Gross contamination can usually be removed by repeated manual cleaning, although mechanical scrubbing, as described below, may expedite the process.

To Remove Deposits:

1. Apply cleaning agents using the methods described earlier.
2. Cut a wooden swab stick on a sharp angle to form a fine point.
3. Scrub the surface of the mount with the swab stick and rinse. Performed under the microscope, this procedure is unlikely to damage to the thermocouple itself. With patience, and repeated use of cleaning agents, even the most severely contaminated thermocouple can be cleaned.

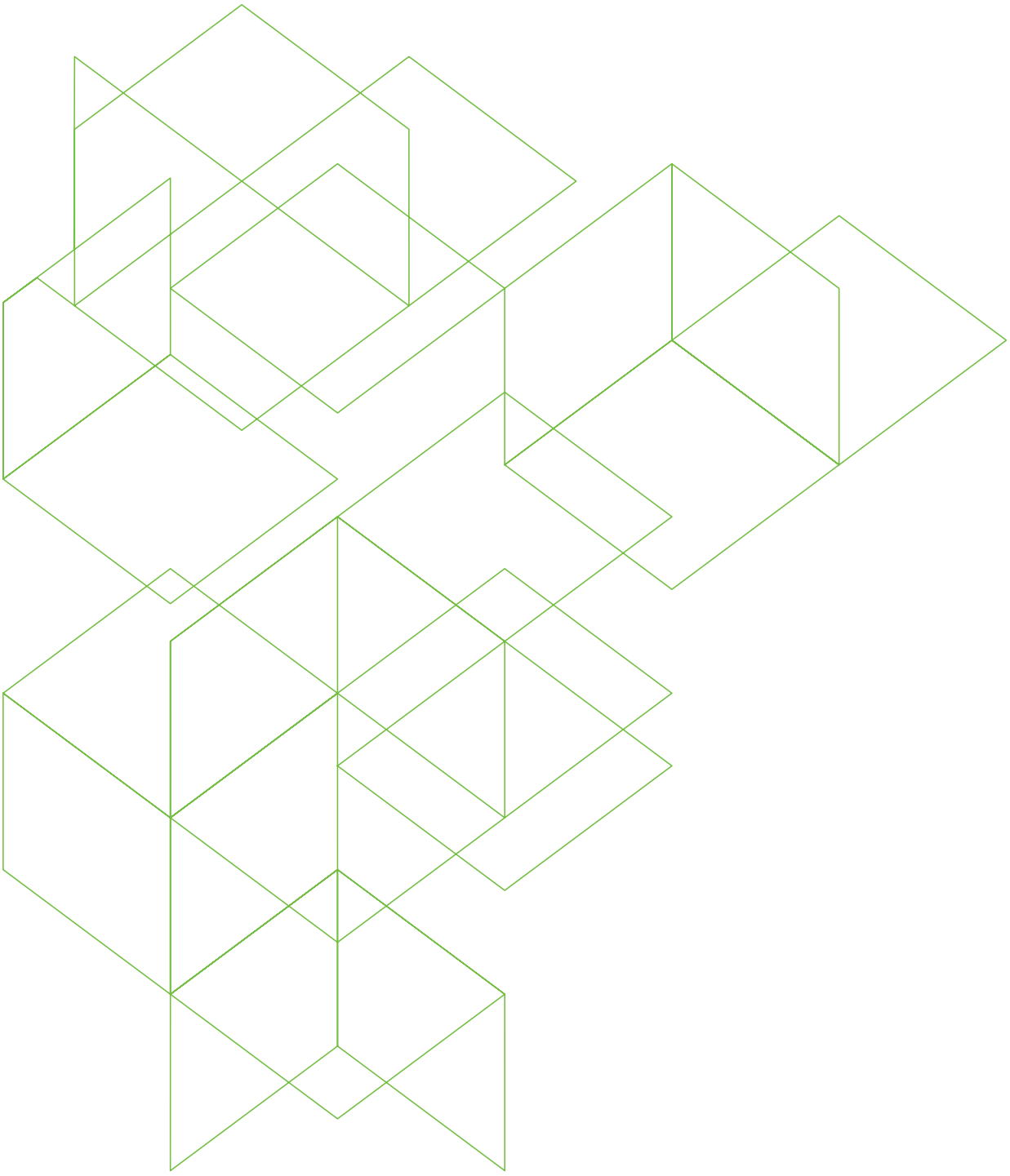
To clean dark or corroded copper connection points:

| | |
|---|---|
| | 1. Apply a droplet of concentrated ammonium hydroxide (NH4OH, 28 to 30%) or household lime remover to the TC mount. Soaking with this solution for a few minutes reduces oxidation and restores the bright copper color.<br>2. Rinse the thermocouple with pure water at least 10 times. |
| __Pass<br>__Fail | **Reinstalling the TC Head**<br>1. Open the TC head access cover.<br>2. By aligning the attachment screws, carefully position the TC head inside the instrument.<br>3. Start each screw into the threads, and then tighten each screw progressively with the 9/64-inch hex driver, until all four are firmly tightened.<br>4. Reinstall the TC head connector.<br>5. Reposition the access cover.<br>6. Turn on the power. Allow the instrument to complete the initialization sequence and reach thermal equilibrium before attempting to calibrate the osmometer.<br>7. Calibrate using the 290 mmol/kg, 1000 mmol/kg, and then 100 mmol/kg standards.<br>8. If the 100-mmol/kg calibration reveals contamination, run the automated Clean cycle. If contamination levels are still present, try manual cleaning the thermocouple one more time. |
| __Pass<br>__Fail | **Equilibration After Cleaning**<br>1. Manual cleaning the thermocouple mount changes the thermal equilibrium of the instrument and causes a temporary shift in calibration after the TC head is reinstalled. After reinstalling the thermocouple head, allow the instrument to regain thermal equilibrium.<br>2. The Temperature Drift indicator will be near center when the osmometer temperature is stable. |

The VAPRO 5600/5600XR operated as expected / not as expected. (Circle appropriate answer)

| | |
|---|---|
| Performed By: _____ | Date: _____ |
| Approved By: _____ | Date: _____ |

Notes or Comments:



**ELITechGroup Inc.**

370 West 1700 South
Logan Utah 84321-8212
800 453 2725
+1 435 752 6011

REF 57-0006-03D

ELITechGroup
EMPOWERING IVD

**www.elitechgroup.com**
**info@elitechgroup.com**