

User Manual

HALIMETER® PLUS PN. 120-00011

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Section 1 - Introduction

Congratulations on your purchase of the INTERSCAN Halimeter[®] PLUS! The Halimeter[®] PLUS is a complete reimagining of the world's most trusted and widely used instrument for the analysis and treatment of chronic halitosis.

Your instrument combines field-proven electrochemical sensing technology with an allnew electronics package, intuitive controls, and a real-time graphics display. Key features include:

- Real time continuous sampling and monitoring.
- Automatic data logging downloadable in a .csv (commas separated value) file.
- SD Card data storage.
- User adjustable flow rate with auto blockage detection.
- Rechargeable Li-ion battery providing 5-8 hours of monitoring in the field.
- Instantaneous and accumulated measurement display (Monitor and Graph views).
- Quick connect sampling ports.
- Mini USB charging port.
- Rear panel terminals for analog outputs.

1.1 PRECAUTIONS

Read this manual fully and carefully before using your instrument. This manual should be read by anyone who will be operating the Halimeter[®] PLUS to ensure accurate measurement and long life.

NOTE 1: It is a good idea to charge the batteries in your instrument before initial operation. Connect the battery charger and run the instrument for 24 hours in OFF MODE to allow the batteries to fully charge and the sensor to fully stabilize. See section 3 for details on battery charging and navigating operation modes.

NOTE 2: It is recommended that the Halimeter[®] PLUS be connected to the power supply/battery charger during long term storage. See section 3.5 for battery charging information.

WARNING: ALCOHOL OR CHLORINATED MOUTHWASH RESIDUE REMAINING IN THE MOUTH OF A SAMPLE SUBJECT WILL RESULT IN ERRONEOUS HALIMETER[®] PLUS READINGS AND SERIOUSLY LIMIT SENSOR LIFE. IF MOUTHWASH HAS BEEN USED PRIOR TO TAKING A HALIMETER[®] PLUS READING, RINSE OUT THE MOUTH THOROUGHLY WITH WATER AT LEAST 30 MINUTES PRIOR TO SAMPLING.

IT IS ALSO RECOMMENDED THAT THE PATIENT SHOULD REFRAIN FROM EATING, SMOKING, DRINKING (WATER IS ALLOWED) AND ORAL HYGIENE ACTIVITIES FOR 3-4 HOURS BEFORE TESTING.

THE SENSOR WARRANTY WILL BE VOIDED IF THE SENSOR IS CONTAMINATED BY MOUTHWASH VAPOR OR THAT OF OTHER CONTAIMNANT LIQUIDS.

1.2 HALIMETER[®] PLUS PACKING CONTENTS

Carefully remove the Halimeter[®] PLUS from it's packing container along with the accessories. Inspect the instrument for any damage. Check that all accessories are included according to the contents list shown below:

Halimeter[®] PLUS Mini USB Wall Charger/Charging Cable Sample Tubing / tube connector Sample Straws (20 ea.) Halimeter[®] PLUS User Manual

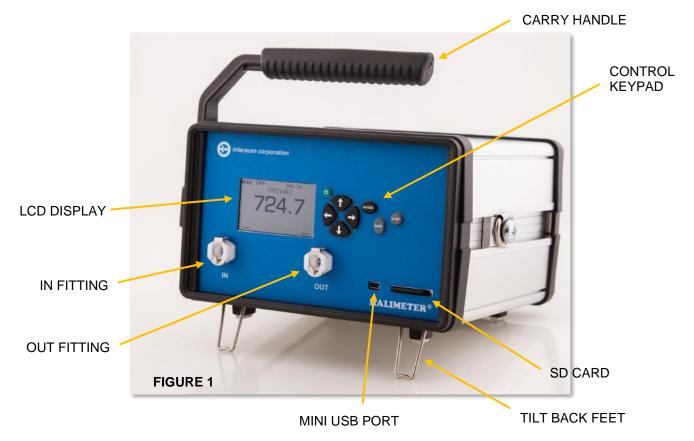
Contact the Interscan Service Dept. immediately (see section 11) to report any damaged or missing items.

Any items reported damaged or missing after 30 days from delivery will not be covered by INTERSCAN and the customer will be responsible for any replacement or repair expense.

Section 2 – Instrument Description

2.1 CONTROLS & FEATURES

Figure 1 below shows the Halimeter[®] PLUS case and front panel features which are described in the table and sections that follow.



LDC DISPLAY – Displays all relevant numeric and text information related to sampling and menu navigation. Breath sample values can be displayed numerically or graphically. See section 2.1.1 for display details.

IN FITTING – Quick connect socket for introduction of sample via sample inlet tubing. See section 2.2 for connection details.

OUT FITTING – Exhaust port for sample stream. No connection is necessary. *DO NOT BLOCK THIS PORT!*

MINI USB PORT – USB connector for battery charging and powered operation. See section 3.5

TILT-BACK FEET – Provides a slight tilt angle for table-top use. Feet are shipped in the collapsed or "flat use" position but can be engaged by simply rotating them forward until they lock in place.

SD CARD – Slot for data storage memory card. See section 6 for details on data storage and accessing data.

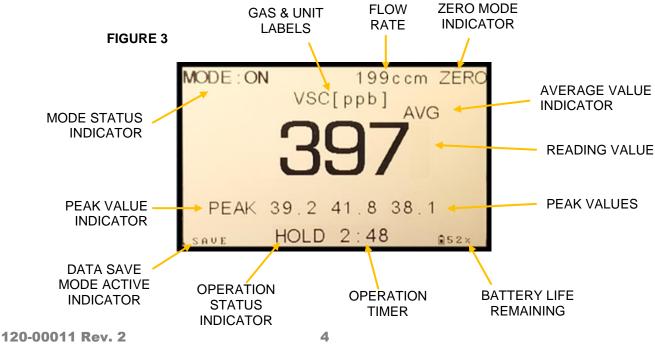
CONTROL KEYPAD – Button cluster for unit operation. See section 2.1.2 for control details. **CARRY HANDLE** – Enables easy carrying of the instrument between sampling locations. The handle can also be rotated 180° to the underside of instrument case for deeper angled tilt during table-top use as shown in Figure 2. To rotate handle, pull out on the handle mount on the left side of case and rotate handle towards the front of the instrument. It will lock into place when at the 180° position. Be sure to collapse the tilt back feet before rotating the handle.



FIGURE 2

2.1.1 DISPLAY FIELDS AND INDICATORS

The Halimeter[®] PLUS display screen offers a variety of information as detailed in Figure 3 below. Elements will be visible depending on the active mode and operation being performed.



2.1.2 CONTROL KEYPAD

The Halimeter[®] PLUS control keypad is detailed in Figure 4 below. Each button is described in the table that follows.

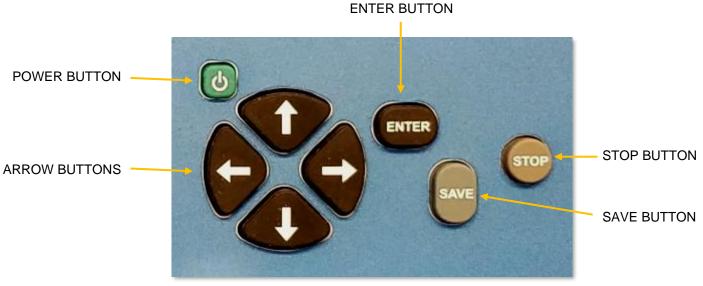


FIGURE 4

POWER BUTTON – Press to turn power to instrument ON. Press from the MAIN MENU to turn power OFF.

ARROW BUTTONS – Used to navigate through the instrument's menus and enter values during numeric and text entry. Proper use is indicated in specific function descriptions.

ENTER BUTTON – Used to advance through the sequential menus and finalize certain functions.

STOP BUTTON – Used to back up in sequential menus or end a particular function.

SAVE BUTTON – Press at any point during sampling to save current data to memory card.

2.2 SAMPLE INLET TUBING AND COUPLING CONNECTOR

The provided sample tubing connects to the SAMPLE INLET fitting via a "push-in" style tube adapter shown to the right. To connect, first push down on the metal locking tab then plug the adapter into the "IN" connector until you hear the locking mechanism click into place.



To remove the tube adapter, press down on the metal locking tab on the top of the connector while pulling out on the tubing.

The tube coupling connector fitted to the other end of the sample tubing shown below is provided as an interface for the sample straw. This connector should always be left in place.





2.3 SAMPLE STRAW

The Sample Straw is the means of sample delivery for the patient. Your instrument comes with 10 straws for connection fo the tube coupling connector during sampling.

To connect the straw to the tube coupling connector, simply press the straw in to the connector port until you feel it hit the tube stop. The straw can easily be removed from the connector merely by pulling it away from the connector.

NOTE: For proper sanitation, always use a new straw when taking samples from a new patient. DO NOT RE-USE STRAWS WITH DIFFERENT PATIENTS.

When replacing straws, Interscan recommends the use of the Dixie JW7 which is of the proper diameter, wall thickness and material makeup for optimal air seal when interfaced with the coupling connector. Specifications are noted below.

Replacement straw specifications (Dixie JW7 recommended):

- Outside diameter 0.217 in. (5.512 mm)
- Wall thickness 0.007 in. (0.1778 mm)
- Material Translucent polypropylene

2.4 ANALOG OUTPUT CONNECTIONS

The Halimeter[®] PLUS is equipped with 0-2.5 V and 4-20 mA output signals available at the 10 pin rear panel terminal block as shown below. Each signal range corresponds to the full scale range of the instrument from 0 - max range.

Connect to the terminal block by inserting wire conductor into the desired terminal and tightening the terminal's screw. The terminal block can be removed from the rear panel for ease of wiring by gently pulling the block away from the panel. Re-connect the block by gently pressing it back into the receptacle.

Use the VCC output (Pin 3) as the positive reference for the 4-20 mA output (AOUT1 – Pin 8) and the device ground (Pin 1 or 2) as the negative reference for the 2.5 V output (AOUT2 – Pin 7).



| PIN | NAME | TYPE | DESCRIPTION |
|-----|-------|-----------------------|---------------------------------|
| 1 | GND | Reference | Local Device Ground |
| 2 | GND | Reference | Local Device Ground |
| 3 | VCC | Reference | +5 Volts |
| 4 | - | N/C | - |
| 5 | - | N/C | - |
| 6 | - | N/C | - |
| 7 | AOUT2 | Analog Voltage Output | Breath Measurement in volts |
| 8 | AOUT1 | Analog Current Output | Breath Measurement in milliamps |
| 9 | - | N/C | - |
| 10 | - | N/C | - |

Section 3 – Halimeter[®] PLUS Operation

3.1 POWERING THE HALIMETER® PLUS

To turn the instrument on, press the green power button. The MAIN MENU screen showed on the right will be displayed.

Check the battery life indicator in the lower right corner of the display and confirm that adequate battery life remains for use. Expected battery life is 5-8 hours on a full charge depending on



nature of use. See section 3.5 for details on charging the batteries.

To power the unit down, navigate to the MAIN MENU screen shown on the right and press the green power button. The screen will prompt you to confirm power down as shown. Press the **RIGHT ARROW** button to confirm power down.

| Cor | nfirmation |
|------|-------------------|
| | Power Off Device? |
| | |
| v1.0 | 18 <u></u> 35% |

NOTE: Normal power down only works from the MAIN MENU screen. Access the main menu screen from any of the operating modes or sub-menus by successively pressing the **STOP** button until the MAIN MENU is displayed.

3.2 MAIN MENU NAVIGATION

To navigate through the MAIN MENU, use the *UP* or *DOWN ARROW* buttons to highlight the desired menu selection then use the *RIGHT ARROW* button to open the highlighted sub-menu. This is the procedure for navigating any sub-menu in the Halimeter[®] PLUS.

The MAIN MENU offers 3 sub-menu selections that are detailed below:

MEASURE – Sequential sub-menu of primary operating modes as follows:

- STARUP MODE > OFF MODE > ON MODE > SAMPLE MODE.

See section 3.3 for details on the MEASURE sub-menu.

SETUP – Sub-menu of user adjustable parameters and functions including:

- FLOW RATE
- SAMPLING MODE
- DATE/TIME
- BREATH CALIBRATION
- DIGITAL CALIBRATION
- FACTORY SETTINGS

See section 3.6 for details on the SETUP sub-menu.

FILES – Sub-menu of data storage parameters as follows:

- Create (create and name new data file)
- Delete (delete any existing data file)
- Select (select any existing data file for next sample storage)
- Recent Measurements (list of 10 most recent samples taken)

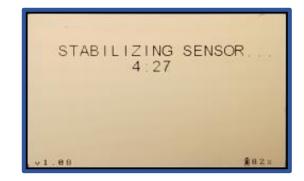
See section 6 for details on the FILES menu and accessing data.

3.3 MEASURE MODE

MEASURE MODE is the primary operating mode for the Halimeter[®] PLUS. It is comprised of a sequence of 4 separate modes as detailed below.

SENSOR STABILIZING MODE

Upon selecting MEASURE from the main menu, the unit will automatically advance to SENSOR STABILIZING mode. A 5-minute timer will count down while the sensor is allowed to stabilize following power up. The screen shown to the right will be displayed



during SENSOR STABILIZING mode. When the startup timer elapses, the instrument will automatically enter OFF MODE.

OFF MODE

In OFF MODE, the pump is turned off and the screen showed on the right will be displayed. This is the mode the Halimeter[®] PLUS should be kept in when powered but not in use. To advance to ON MODE from OFF MODE, press the **ENTER** button. To return to the main menu from OFF MODE, press the **STOP** button.



ON MODE

In ON MODE, the pump is turned on and the sensor is allowed to stabilize to ambient air flow. The screen shown on the right will be displayed. Zeroing of the display is accomplished from ON MODE (See section 5.1 for more on zeroing). To advance to SAMPLE MODE from ON MODE, press the



ENTER button. To return to OFF MODE from ON MODE, press the STOP button.

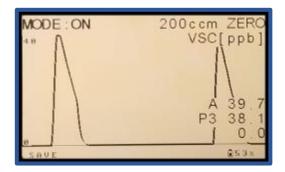
SAMPLE MODE

In SAMPLE MODE, breath samples are taken and data is stored. Upon entering SAMPLE MODE, the first of 3 separate breath sample cycles will begin automatically. Each cycle consists of a 3-minute stabilization or "HOLD" period followed by a 35-second breath sampling period. Peak ppb values are



displayed at the end of each breath sample period and the average peak value is displayed at the end of the 3 complete cycles.

A graphical display of the continuous reading is also accessible during the breath sampling periods by pressing the *RIGHT ARROW* button. See section 5 for details on operating in SAMPLE MODE and taking samples.



Any mode can be entered from the preceding mode by pressing the *ENTER* button or exited to the preceding mode by pressing the *STOP* button. Pressing the *STOP* button successively will return the display to the MAIN MENU where the SETUP and FILE menus can be accessed.

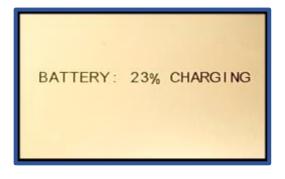
3.5 CHARGING THE BATTERIES

The Halimeter[®] PLUS includes a wall charger that can be used to recharge the Halimeter[®] PLUS batteries, as well as power the instrument during extended use. **The expected battery capacity on a full charge is 5-8 hours depending on nature of use.**

When the battery charge drops below 10%, the display will indicate "Low Battery!" at the bottom of the screen. Follow the procedure below to re-charge the batteries:

- 1. Select the desired plug type on the multi-region charger plug unit.
- 2. Plug the large USB connector end of the supplied charger cable into one of the charger's USB ports.
- 3. Connect the mini-USB connector into the mini USB port on the front panel of the instrument.
- 4. Plug the charger into the wall.
- 5. Charge until the battery life indicator on the instrument display reads "100%".

If charged with the power off, the Halimeter[®] PLUS will automatically power up to the MAIN MENU as soon as the charger is connected to the USB port. If the instrument is then powered down the display will show a charging percentage



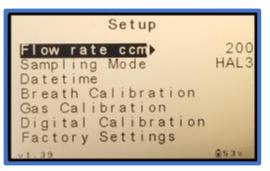
indicator as shown on the right. The instrument can be charged with power on or off.

For fastest charging of the Halimeter[®] PLUS do not connect any other USB devices to the charger.

NOTE: The internal batteries must have a charge to maintain the sensor bias voltage and minimize sensor warmup time. <u>It is recommended you keep the instrument</u> <u>connected to the power supply for long term storage or extended use.</u>

3.6 SETUP MENU

The Setup Menu shown on the right offers access to parameters that may need to be changed for the user's particular application as well as maintenance functions. This menu is detailed below.



Flow rate – cc / min – Nominal setting = 200 cc / min. Do not change this setting.

Sampling Mode – Nominal setting = **HAL3**. This setting controls the SAMPLE MODE procedure with 4 options as follows:

- **Continuous** Sample is drawn continuously.
- **HAL1** Sample is drawn in a single cycle of 3-minute hold followed by a 35 second breath sample.
- HAL2 Sample is drawn in 2 sample cycles as noted in HAL1.
- HAL3 Sample is drawn in 3 sample cycles as noted in HAL1. This is the default Halimeter[®] PLUS sampling mode.

Datetime – Set the date and time according to the user's time zone.

Breath Calibration – Provides for user calibration using a NORMAL BREATH sample. See section 7 for details on calibration.

Gas Calibration – Allows for calibration using a calibration gas standard. Typically used for calibration at the factory and not the recommended method for user calibration.

Digital Calibration – This feature is intended for non-Halimeter applications and will not be used on the Halimeter[®] PLUS.

Factory Setup – A password protected setup sub-menu for factory setup only.

Section 4 – Breath Sampling Considerations

The Halimeter[®] PLUS is designed to reliably measure VSC (Volatile Sulfur Compound) concentrations as part of a total program for the treatment of halitosis. Along with a thorough history and physical examination of the patient, the quantitative nature of Halimeter[®] PLUS data can serve as an excellent tool for following the progress of treatment and for archiving hard copy records.

A "normal" Halimeter[®] PLUS reading is defined as a reading measured with a subject who does not present with an apparent bad breath problem. Based on a statistical study of several thousand individual Halimeter[®] PLUS readings taken at INTERSCAN using multiple subjects not presenting apparent breath problems, <u>more than 90%</u> of the readings occur within a range of <u>80 to 120 ppb</u>. The following scale can be used as a guide for interpreting Halimeter[®] PLUS readings.

- Normal readings, for subjects with no oral malodor, are generally in the range of 80-120 parts per billion (ppb). Readings lower than this range are still indicative of no oral malodor, and are otherwise clinically inconsequential.
- 2) At levels of 200-300 ppb, oral malodor is noticeable by an observer standing close to the patient.
- 3) At 350-400 ppb, the odor is noticeable by an observer standing several feet away from the patient.
- 4) At 500-700 ppb the odor is more noticeable not because it is "stronger," but because it is more foul.
- 5) At over 1000 ppb, the odor will linger for several minutes after the patient leaves the room. In many of these cases, odor will continue to emanate from the tongue during the entire sampling process, and the Halimeter reading will keep climbing, and may not truly peak, as the sample pump seems to draw more VSC's off the tongue surface. Removal of the tongue coating should eliminate this phenomenon.

NOTE: Halimeter[®] PLUS data by itself cannot affirm whether a breath problem exists. The dental practitioner is required to include the assessment of other diagnostic procedures prior to making a positive conclusion.

4.1 SAMPLE INTERFERENCES

Part of ensuring accurate sample readings is minimizing sensor interferences that may result in false readings. One of the most common interferences to the Halimeter® PLUS sensor are vapors present in MOUTHWASH. The presence of residual mouthwash in the mouth will produce a false Halimeter® PLUS reading and can <u>seriously limit</u> <u>sensor life</u>.

If mouthwash is used prior to taking a Halimeter® PLUS reading, the mouth must be rinsed thoroughly with water to clear out residual mouthwash solution. This must be done at least <u>30 minutes prior</u> to using the Halimeter® PLUS.

It is also recommended that the patient should refrain from eating, smoking, drinking (water is allowed) and any oral hygiene activity for 3-4 hours prior to testing.

WARNING: THE SENSOR WARRANTY WILL BE VOIDED IF THE SENSOR IS CONTAMINATED BY MOUTHWASH VAPOR OR THAT OF OTHER CONTAMINANT LIQUIDS.

Other possible interference conditions include handling the sample tube connector while the sensor is stabilizing. This should be avoided as substances on the hands may cause false reactions and inhibit proper sensor stabilization.

4.2 PROPER SAMPLING TECHNIQUE

The manner in which the sample is collected is critical to obtaining accurate readings. The proper sampling technique is described in detail below.

 Ensure that the sample straw is inserted FULLY into the sample tube connector until it reaches the tube stop. If not fully inserted, sample may be lost to leakage at the connector.

- The patient's mouth should remain closed prior to sampling to allow a full build up of any VSCs present in the breath sample.
- 3) When ready to collect sample, the end of the sample straw should be inserted into the patient's mouth at a depth of approximately 1-2 inches (25-50mm) resting on the back of the tongue. The lips should be almost closed allowing for a slight gap between the lips and the sample straw. DO NOT PRESS THE LIPS OR TEETH DOWN ON THE SAMPLE STRAW.
- 4) Breathing should continue THROUGH THE NOSE during sampling allowing sample to be drawn from the mouth by the Halimeter[®] PLUS pump rather than forced in by the lungs.
- 5) DO NOT BLOW INTO THE SAMPLE STRAW AS THIS WILL AFFECT SAMPLE ACCURACY. The flow indicator should be monitored by the individual supervising the breath test to ensure that the flow rate stays at approximately 200 ml/min and that it is not increasing or fluctuating as a result of the patient breathing or blowing into the sample straw.
- 6) Typically, the ppb level will rise during the sample period and reach a peak value after which the value will begin to fall. When the sample ppb value begins to decrease, the sample straw should be removed from the mouth and set down until the next sample period at which point the sequence will be repeated.

Section 5 – Taking Breath Samples

After powering up the Halimeter[®] PLUS, select MEASURE from the MAIN MENU by pressing the *RIGHT ARROW* button. This will open SENSOR STABILIZING MODE and a 5-minute timer will elapse. Upon the timer elapsing, the instrument will automatically enter OFF MODE.

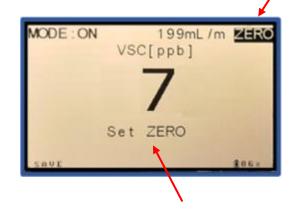
From OFF MODE, press the *ENTER* button to advance to ON MODE. The pump will now turn on. Allow the sensor several minutes to stabilize to ambient flow. You may notice the flow rate reading fluctuates for several seconds before stabilizing at 200 mL/m. This fluctuation is normal.

Once the reading has stabilized, the instrument is ready to be zeroed.

5.1 ZEROING THE HALIMETER® PLUS

It is always a good idea to zero the Halimeter[®] PLUS prior to sampling. To accomplish this, ensure the unit is in ON MODE and has been allowed to stabilize in this mode for several minutes. Confirm that the flow rate has settled at 200 mL/m and the PPB display is not rising or falling significantly. Zero the instrument as follows:

- Press the UP ARROW button. The ZERO indicator will now be highlighted indicating ZERO MODE is active.
- Press the *ENTER* button. "Set ZERO" will display under the PPB display for 3 seconds indicating the display is being zeroed.
- Press the **DOWN ARROW** button after zeroing is complete to exit ZERO MODE.

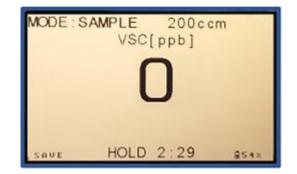


The instrument is now ready for sampling.

5.2 TAKING SAMPLES

After zeroing the display, the instrument is ready for sampling. The following steps detail the sample procedure:

1) From ON MODE, press the **ENTER** button. This will advance the instrument to SAMPLE MODE starting a series of 3 sample cycles where 3 separate breath samples will be taken. The screen shown to the right will be displayed which shows a "HOLD" countdown timer at the bottom of the display. During this 3-minute time period, the



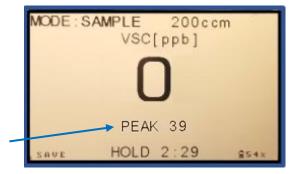
patient should wait with his/her mouth closed to allow a proper breath sample to accumulate. The patient should breath through the nose and refrain from talking.

2) When the countdown timer fully elapses, there will be 3 rapid "beeps" indicating the start of the first 35-second sample period. The timer label will indicate "SAMPLING" as shown on the right and the timer will begin it's 35 second countdown. There will be a "beep" every 3 seconds during the SAMPLE cycle. At this point, the patient should



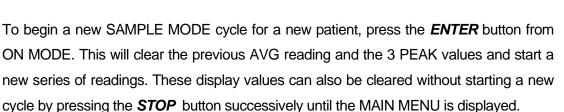
put the sample straw into his/her mouth as detailed previously in section 4.2. As sample is drawn from the mouth, the displayed value will begin to rise until it hits a peak value after which it will begin to decline. At this point the patient may remove the straw from his/her mouth and wait until the next SAMPLE cycle with mouth closed.

4) At the end of the SAMPLE cycle, there will again be 3 rapid "beeps" indicating the beginning of the next HOLD cycle. The timer label will indicate "HOLD" and the 3-minute timer will begin again. The PEAK value from the SAMPLE cycle just completed will be displayed above the timer display. The patient should again wait with mouth closed as in step 1.



5) This HOLD/SAMPLING cycle will repeat for 3 total samples. A new PEAK value will be added for each completed SAMPLE cycle above the timer field. At the end of the third SAMPLE cycle, the instrument will return to ON mode and the breath value display will show the average of the 3 PEAK sample values as indicated by "AVG" above and to the right of the numeric display as shown to the right.

Throughout the SAMPLE MODE cycles, the display can be toggled between a numeric value and a graphical value by pressing the *RIGHT ARROW* button to show graph display and the *LEFT ARROW* button to return to numeric display. The graphical display is shown to the right.



MODE : ON

PEAK 392

SAMPLE

5.3 AUTO BLOCKAGE DETECTION

The Halimeter[®] PLUS is equipped with flow rate detection to protect against unwanted blockages in the inlet line. In the event of a sudden drop in flowrate in ON or SAMPLE modes, the screen shown to the right will be displayed. This indicates a blockage of the inlet tube that must be addressed before sampling can resume.

| Tube blocked | |
|------------------|----|
| Please clear tub | е. |
| ENTER D | |

Should this message appear, check the tubing for any blockages or kinks that might restrict flow. Clear this blockage then press the *ENTER* button to proceed.



P2 4

C

199ccm ZER

381

200ccm

VSC[ppb

AVG

VSC[ppb]

418

Section 6 – Data Storage And Access

Sample data can be stored on standard SD card media (a 32 GB card is provided with the instrument). Data is saved to the SD card automatically in ON mode and SAMPLE mode at a rate of one sample per second when AUTO SAVE is enabled (this is the default status on power up).

"SAVE" will be displayed in the lower left corner of the display in ON and SAMPLE modes indicating that the AUTO SAVE feature is active. AUTO SAVE mode can be disabled by pressing the SAVE button in any mode. When disabled, "SAVE" will NOT appear on the display in ON and SAMPLE modes.

Leaving the instrument in AUTO SAVE mode is the surest way to ensure data storage is completed. The tradeoff is the potential for storing long strings of unnecessary data every second in ON mode. For this reason the option is provided to disable AUTO SAVE when the instrument is idle and data storage is known to be unnecessary.

6.1 FILES MENU

Data is stored in user created files. The user must create a file for storage and then select the desired file as the data location for future data collection. All file management is executed from the FILES menu as detailed below.

File management is accessed from the MAIN MENU by selecting FILES and then pressing the *RIGHT ARROW* button to open the FILES submenu shown on the right. Highlight the desired option using the *DOWN and UP* ARROW buttons and select the desired option using the *RIGHT ARROW* button. FILES options are shown below.

| Files | | |
|--------|--------------|------|
| Create | file |) |
| Delete | | |
| Select | file | |
| Recent | Measurements | |
| S | elected File | |
| | data.csv | |
| | | 028× |

Create file – Shown on the right. Use the *RIGHT ARROW* button to highlight the name field then use the *UP/DOWN* arrow buttons to change the character as desired and the *RIGHT/LEFT* arrow buttons to move the character position as desired. Press the **SAVE** button when finished to save the new file.

Delete file – Shown on the right. Delete existing files and their content. Highlight the desired file using the *UP/DOWN* arrows then press the *RIGHT ARROW* button to delete. You will be prompted to confirm deletion with the *RIGHT ARROW* button.

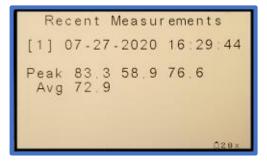
Select file – Shown on the right. Select the desired file in which to store the data for the next sample cycle(s). Highlight the desired file using the *UP/DOWN* arrows then press the *RIGHT ARROW* button to select. The currently selected file will be shown on the FILES screen.

Recent measurements – Shown on the right. Display recent individual SAMPLE cycle results including date/time, PEAK values and AVG PEAK value. Use the UP & DOWN ARROW buttons to scroll through a list of recent results. Press the LEFT ARROW button to return to the FILES menu.









6.2 ACCESSING AND SAVING DATA

Data can be accessed and exported by removing the SD card and inserting it into an SD card slot on any computer. To remove the SD card, push the edge of the card into the slot

until you hear a "click" and the card will eject. To re-insert, press the card all the way into the slot until you hear the "click".

The data files can be opened in Microsoft Excel or Notepad. Always save data files to a computer and perform any editing of the file to the saved version. **Do not edit files directly on the SD card as this may corrupt the file when read by the instrument!**

NOTE: It is always a good idea to power the instrument down before removing or reinserting the SD card from the SD card slot.

NOTE: If the SD card is not inserted into the instrument's SD card slot on power up, "**NO SD Card**!" will be displayed in the lower left corner of the LCD display and AUTO SAVE will be disabled.

WARNING: DO NOT CONNECT THE USB CABLE BETWEEN THE INSTRUMENT AND THE COMPUTER WHILE PERFORMING MEASUREMENTS AS THIS CAN LEAD TO DATA ERRORS AND FILE CORRUPTION.

Section 7 - Calibration

Periodic calibration of the Halimeter[®] PLUS is required to compensate for decreased sensor sensitivity and maintain accuracy of readings. The frequency of calibration is a function of instrument use and the concentrations of volatile sulfur compounds (VSC) to which the sensor is exposed. As such, no exact schedule of calibration can be recommended but a good rule of thumb is to calibrate at least once per year with regular use.

Lower than normal readings often are an indication that the instrument is in need of calibration. A "normal" Halimeter[®] PLUS reading is defined as a reading measured with a subject who does not present with an apparent bad breath problem. After extensive testing, INTERSCAN CORP has determined this to be a within a range of 80 to 120 ppb (see section 4). As you use the instrument, take note of where normal patient readings tend to fall. If you notice the baseline values are tending to decrease over time, calibration may be indicated.

The most convenient method of calibration in the field is to present known "NORMAL BREATH" sample as the calibration standard. To facilitate this, a BREATH CALIBRATION mode is provided in the SETUP menu. This procedure is detailed in the section 7.1 below.

For users who have access to and prefer using a calibration gas standard, a GAS CALIBRATION mode is also available and is detailed in sections 7.2 and 7.3 below.

7.1 BREATH CALIBRATION PROCEDURE

The procedure that follows details how to accomplish calibration of the Halimeter[®] PLUS using the BREATH CALIBRATION MODE. As noted above, a NORMAL BREATH subject should be used to provide the sample standard for this calibration. The sample technique detailed in section 4.2 should be followed in the same manner as with normal sampling. In particular, the subject should keep his/her mouth closed up until the point where sample is delivered.

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- value of 100 ppb. Use the RIGHT and LEFT ARROW buttons to move the cursor and the UP & DOWN ARROW buttons to change the value of the desired characters as needed. (The unit will not allow an entry of all zeros. Change digit values from right to left). NOTE: BE SURE THIS VALUE IS CORRECT BEFORE ADVANCING AS AN **INCORRECT VALUE WILL RESULT IN INACCURATE CALIBRATION SCALING.**
 - Breath Calibration Step 2: SENSITIVITY Enter Breath ppb level **\$0**00100 then Press ENTER
- 652 5) When the zero timer fully elapses, the screen shown below right will be displayed. In the field indicated by the red arrow, enter the NORMAL BREATH SAMPLE baseline
- for this step).
- 4) The screen shown to the right will be displayed where the unit will first be zeroed. Press the ENTER button to proceed. (zeroing will draw ambient air. No zero gas is re quired

1) Navigate to the MAIN MENU by pressing the

MENU shown to the right is displayed.

SETUP MENU.

STOP button successively until the MAIN

Flow rate ccm 3) Use the DOWN ARROW button to move the Sampling Mode cursor and highlight "Breath Calibration" as Datetime shown to the right and press the RIGHT **ARROW** button to begin the calibration routine.

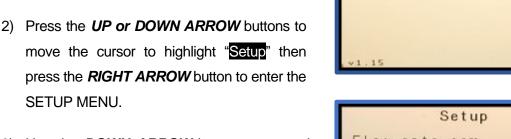


200

HAL

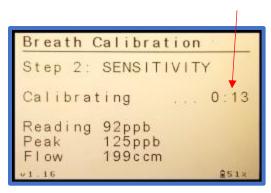
Halimeter PLUS

| Breath Calibration Gas Calibration Digital Calibration Factory Settings |
|--|
| Breath Calibration Step 1: ZERO |
| Zeroing 1:45 |
| Reading Oppb Flow 204ccm |



When the value is correct, press the ENTER button to begin calibration sampling.

6) The screen shown on the right will now open showing the CAL timer (red arrow), the active ppb reading value and the peak ppb value. At this point, the breath subject should place the sample straw in his/her mouth and present a sample in the manner described in section 4.2. The CAL timer will elapse from 60 seconds to



0 seconds. At some point during the 60 second sample period, the reading value will peak and begin falling. After the peak value is established the subject may remove the straw from the mouth.

7) At the end of the calibration sample period the screen shown to the right will be displayed. The "Sample peak" value is displayed as is the "Target peak" reference value (the value entered in step 5). Press the SAVE button to lock in the scaling adjustment and complete the calibration. Press the STOP button to cancel the calibration scaling if desired.

| Breath Calibration |
|--|
| Confirm Calibration |
| Sample peak 125ppb Target peak 100ppb |
| Press SAVE to re-scale |
| or STOP to Cancel |
| v1.16 @52z |

7.2 GAS CALIBRATION

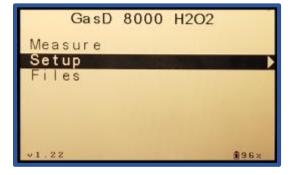
Gas Calibration entails the introduction of a certified calibration gas standard taken from a gas cylinder or a permeation device. Besides being essential for calibration, having a known certified gas standard on hand allows the user to test the analyzer at any time to confirm proper functionality.

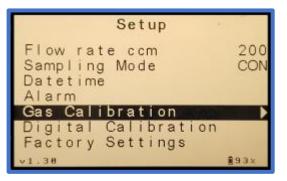
Whatever the source of calibration gas, the recommended delivery method is via a proper sample bag which is attached to the analyzer INLET. The calibration gas is drawn from the proper sample bag through the sensor. **USE AT LEAST A 2 LITER BAG TO ENSURE ADEQUATE CAL GAS SAMPLE VOLUME.** Teflon® or Tedlar® bags are suitable for H₂S. Alternatively, a regulated pressurized certified gas cylinder fitted with a tee-manifold and unrestricted vent is a viable source of calibration gas.

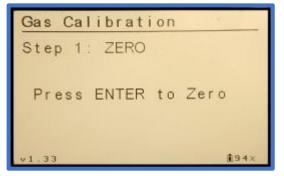
NOTE: PRESSURIZED SAMPLE MUST BE REGULATED TO <u>4 PSI OR LOWER</u>. OVER-PRESSURIZATION CAN DAMAGE THE SENSOR AND VOID THE WARRANTY!

7.3 GAS CALIBRATION PROCEDURE

- Navigate to the MAIN MENU by pressing the *STOP* button successively until the MAIN MENU shown to the right is displayed.
- Press the UP or DOWN ARROW buttons to move the cursor to highlight "Setup" then press the RIGHT ARROW button to enter the SETUP MENU.
- 3) Use the DOWN ARROW button to move the cursor and highlight "Gas Calibration" as shown to the right and press the RIGHT ARROW button to enter the Gas Calibration Menu.
- You will now be prompted to carry out zeroing as shown to the right. With the analyzer <u>drawing</u> <u>clean ambient</u> air, press the **ENTER** button to initiate zeroing.





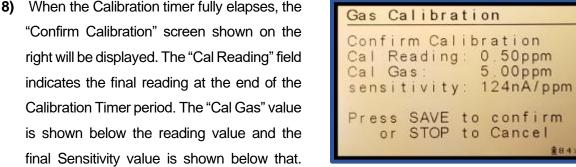


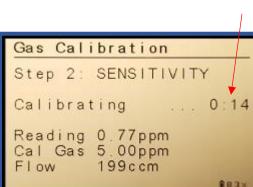
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calibration.

- right will be displayed. The "Cal Reading" field indicates the final reading at the end of the Calibration Timer period. The "Cal Gas" value is shown below the reading value and the final Sensitivity value is shown below that. Press the SAVE button to confirm calibration or press the STOP button to cancel

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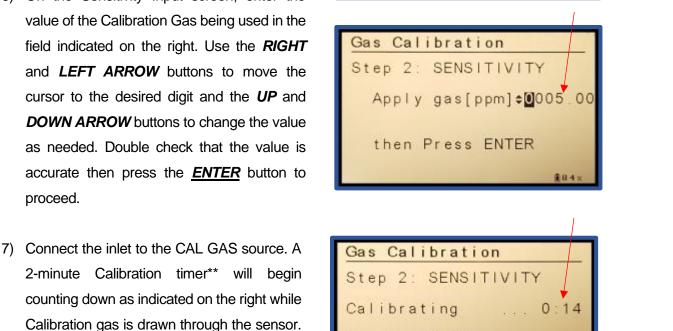
6) On the Sensitivity Input screen, enter the value of the Calibration Gas being used in the field indicated on the right. Use the **RIGHT** and LEFT ARROW buttons to move the cursor to the desired digit and the UP and **DOWN ARROW** buttons to change the value as needed. Double check that the value is accurate then press the ENTER button to proceed.

The "Reading" indication shows the real time

sensor response which can be compared to

the "Cal Gas" value. ** Calibration timer value may vary depending on gas application.

5) A 2-minute Zero timer will begin counting down as shown on the right after which the unit will automatically zero itself and jump to the Sensitivity input screen.



... 1:33

185

Gas Calibration

Reading 0.05ppm

200ccm

Step 1: ZERO

Zeroing

Flow

Section 8 – Sensor Replacement Procedure

The procedure detailed below addresses removing and replacing the Halimeter[®] PLUS sensor. USE CARE WHEN WORKING INSIDE THE INSTRUMENT TO AVOID CONTACT WITH CIRCUIT BOARDS AND SURFACE MOUNT COMPONENTS!

8.1 SENSOR REMOVAL

1) Power the unit OFF.



2) Using your thumb and finger as shown in Figure 8-1, gently pry the right side of the rear bezel away from the side of the instrument case while pulling the bezel toward you. The bezel will pivot away from the case as shown in figure 8-2.





 Slowly continue pivoting the right side of the bezel away from the case until the left side is freed as shown in Figure 8-3. Set the bezel aside.



4) Firmly grasp the rear terminal block as shown in Figure 8-4 below and gently pull the left side out away from the panel until it is freed from its mating connector as shown in Figure 8-5. Set the terminal block aside.



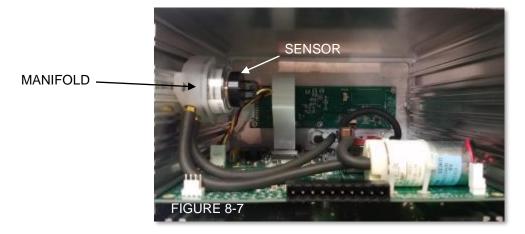


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5) Remove the 4 screws from the corners of the rear panel as shown in Figure 8-6 below and set aside. Use care not to lose screws or plastic washers! Pull the panel away from the instrument case and set aside.



6) The sensor is held in a manifold that is attached to the left side of the instrument case (looking from the rear) as shown below in Figure 8-7.



7) Reaching carefully into the instrument case, grasp the black sensor connector attached to the top of the sensor as shown in Figure 8-8 below. Gently rock the connector from side to side and pull the connector away from the sensor as shown in Figure 8-9 below.





8) Firmly grasping the sensor body as shown in Figure 8-10 below, slowly tilt the furthest edge of the sensor body away from the manifold and toward you as shown in Fig 8-10. Don't attempt to pull the sensor straight out or rotate the sensor in the manifold. The senor should release from the manifold as shown in figure 8-11.

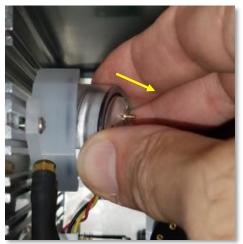


FIGURE 8-10



FIGURE 8-11

8.1 SENSOR INSTALLATION

 Press the new sensor firmly into the manifold until you feel it snap into place. Orient with the terminal pins positioned to align with the connector sockets as shown below in figure 8-12. Carefully re-connect the black connector to the top of the sensor as shown in Figure 8-13. The bottom of the connector should be flush with the top of the sensor.



FIGURE 8-12



FIGURE 8-13

2) Position the rear panel so the top and side edges are aligned with the instrument case as shown below in Figure 8-14. Secure with the panel screws. NOTE: The screws should thread easily into the screw holes. If there is any significant resistance when threading the screws, STOP, back the screw out and re-align the panel holes with the threaded holes. Forcing a mis-aligned screw into the threaded hole will strip the threads.



- Re-connect the terminal block to the connector socket (terminal screws on the top). Press firmly into place.
- 4) Align the bezel with the rear of the instrument case and press the bezel back onto the rear of the case as shown in Figure 8-15 below. Confirm that the bezel has fully snapped into place on both sides by pressing firmly with the palm of your hand on each side.



Section 9 - Troubleshooting

The chart below addresses common troubleshooting issues and provides probable causes and corrective actions to take. Always consult with the *INTERSCAN service department* for problems not on this list or if suggested corrective actions fail to address the problem.

| Symptom | Probably cause / Corrective action |
|---|--|
| Erroneous low readings | Sample straw is too shallow in the patient's mouth. Straw should be inserted at a depth of 1-2 inches at the back of the tongue. |
| | • Lips or teeth are pinching the straw. Me sure patient's lips/teeth are not contacting the straw. |
| | • Patient is speaking or has mouth open during the 3-minute pre-sample countdown. Be sure patient's mouth remains closed during this period to ensure adequate buildup of Volatile Sulfur Compounds (VSC). |
| | Instrument may require calibration. If patient is executing proper sample technique and low readings are still occurring, perform instrument calibration. See section 7. |
| Erroneous high readings | Patent is blowing or breathing into the straw. Be sure the patient is breathing through the nose and not blowing into the straw. |
| Unit will not power up | • Eject the SD card and/or remove the mini USB cable from the USB port and re-attempt power up. Re-insert the SD card or re-connect the USB cable after successful power up. |
| Trouble with menu navigation or powering down | • Should the instrument "lock up" or if menu navigation functionality is compromised, the user can perform an emergency shutdown by pressing and holding the POWER button for 10 seconds to power the unit down from any screen. <i>This should only be done if normal MAIN MENU screen power down is not possible.</i> |

Section 10 - Warranty

INTERSCAN CORPORATION warrants any Halimeter[®] PLUS of its manufacture to be free from defects in material and workmanship for a period of one year from date of shipment. Exceptions to this are sensors, fuses, lamps, tubing, and fittings. *INTERSCAN CORPORATION* further warrants sensors of its manufacture to be free from defects in material and workmanship for a period of six months from date of shipment.

INTERSCAN CORPORATION's sole obligation under this warranty is limited to repairing or replacing, at its option, any item covered under this warranty, when such item is returned intact, prepaid to the Factory (or designated service center).

This warranty does not apply to any of our products which have been repaired or altered by unauthorized persons, or which have been subject to misuse, negligence, or accident, incorrect wiring by others, installation or use not in accordance with instructions furnished by the manufacturer, or which have had the serial numbers altered, effaced, or removed. This warranty is in lieu of all other warranties whether expressed or implied.

This warranty does not apply to any of our products, that have had any program and/or software changes incurred, without written authorization from *INTERSCAN CORPORATION*.

Additionally, warranty on any component shall not exceed the manufacturer's warranty given to *INTERSCAN CORPORATION*.

Section 11 - Customer Service

The INTERSCAN Customer Service Department can be reached at the numbers listed below:

Toll-Free **800-458-6153 x121 818-882-2331 x121** FAX **818-341-0642** e-mail: service@gasdetection.com

11.1 RETURN AUTHORIZATION

All units being returned for repair or service require a RETURN AUTHORIZATION NUMBER issued by the INTERSCAN Customer Service Department upon request. This is required to ensure the problem truly needs factory service.

In many cases, problems can be resolved in the field by the user. As such, before contacting Interscan with service questions, consult the TROUBLESHOOTING section of this manual (section 9, page 29) as this may help you to resolve any problems without returning the unit.

Should consulting the TROUBLESHOOTING section of the manual not address your problem, contact the INTERSCAN Customer Service Department as noted below to acquire a RETURN AUTHORIZATION NUMBER. The RMA will expedite prompt return of the repaired unit.

The RMA request form can be found at the following link on line...

http://www.gasdetection.com/contact-interscan/rma-request/

11.2 SPARE PARTS

Contact the Interscan Customer Service Department for inquiries regarding consumable spare parts for your monitor. Have your monitor's serial number at hand when calling.