HALIMETER®

Instruction Manual

PN 120-00005

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PRECAUTIONS:

ALCOHOL OR CHLORINATED MOUTHWASH RESIDUE REMAINING IN THE MOUTH WHEN TAKING BREATH SAMPLES, WILL RESULT IN ERRONEOUS HALIMETER® READINGS AND SERIOUSLY LIMIT SENSOR LIFE. IF MOUTHWASH HAS BEEN USED PRIOR TO TAKING A HALIMETER® READING, RINSE OUT THE MOUTH THOROUGHLY WITH WATER AT LEAST 30 MINUTES PRIOR TO SAMPLING.

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

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

Section 1 - Unpacking The Halimeter®

Carefully remove the Halimeter® from its packing container along with the accessories. Inspect the HALIMETER® for any damage. Check that all accessories are included according to the contents list shown below:

HALIMETER®

A/C POWER CORD

HALIMETER® MANUAL

SAMPLE STRAWS (20 ea.)

Contact **Interscan** to report any damage or missing items immediately. Any items reported damaged or missing after 30 days from delivery will not be covered by **Interscan** and the customer will be responsible for replacement or repair expense.

Section 2 - Halimeter® Description

2.1 Halimeter® Controls & Components

Figure 1 below shows the Halimeter® front panel controls and components which are described in the table that follows.

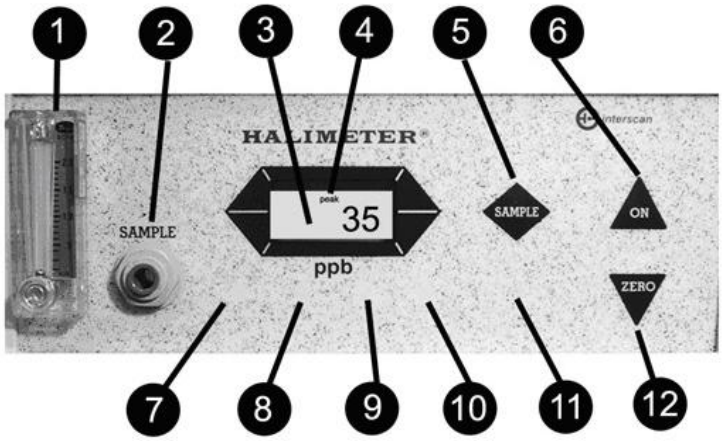


FIGURE 1

Front Panel Controls/Components

(1) Flow meter – Indicates the rate of sample flow through the sensor.

(2) SAMPLE INLET – Connection point for the sample inlet tube.

(3) Digital display – Display area for numeric ppb values and text indications.

(4) PEAK display – Indicates that the current display value is the peak value for the sample just taken.

(5) SAMPLE control – Pushbutton control for initiating SAMPLE mode.

(6) ON/OFF control – Pushbutton control for ON and OFF modes..

(7,8,9) Numeric Breath Sample LED's – When lit, indicates which of the 3 breath samples are currently being taken.

(10) Average LED "A" – When lit, indicates that the peak value displayed is the 3 sample average.

(11) Sampling LED "S" – Lights when sampling is to commence and user is to present sample.

(12) ZERO control – Pushbutton control used to zero the digital display once sensor has stabilized to ambient air flow.

Figure 2 below shows the Halimeter® rear panel connections and components described in the table that follows:

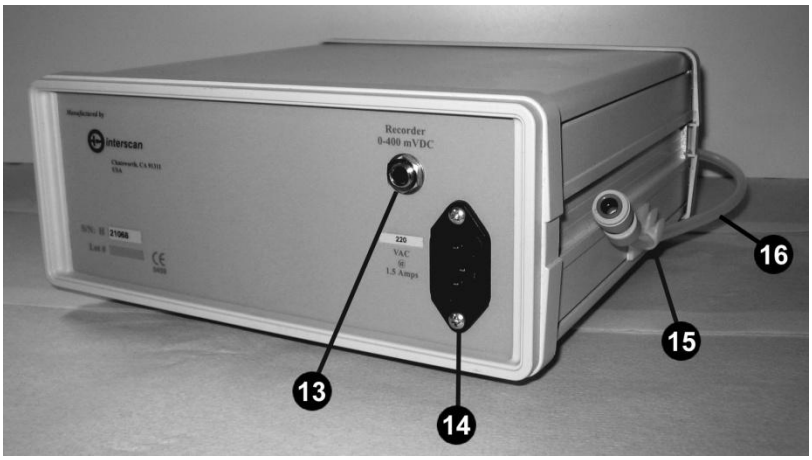


FIGURE 2

Rear Panel Connectors/Components

(13) 0-400mVdc recorder output – ¼" mono phone plug output for connection to recorder device.

(14) A/C power connector – Receptacle for A/C power cord supplied with Halimeter®.

(15) Inlet tube clamp – Clamp for holding inlet tube in place during transport and storage.

(16) Sample Inlet Tube/Connector – Connects to sample straw for delivery of breath sample.

WARNING

TO AVOID ELECTRICAL HAZARD, DO NOT OPEN THE HALIMETER®! THERE ARE NO USER SERVICEABLE PARTS INSIDE THE HALIMETER® ENCLOSURE.

2.2 Sample Tube And Connector

The sampling tube connects to the SAMPLE INLET fitting via a “push-in” style connector that provides a leak-proof seal when connected properly. The tube is shipped already connected to the SAMPLE INLET with the tube connector on the opposite end for connection to the sample straw. The factory tube length is 12-13 inches. Longer tube lengths can be used if needed but **DO NOT EXCEED 20 INCHES IN SAMPLE TUBE LENGTH AS THIS MAY RESULT IN SAMPLE LOSS.**

Should you ever need to remove the sample tube from the Halimeter®, do so by pressing in on the dark grey collet ring with one hand WHILE pulling the tube outward firmly with the other hand. When done properly, the tube should release easily from the collet.

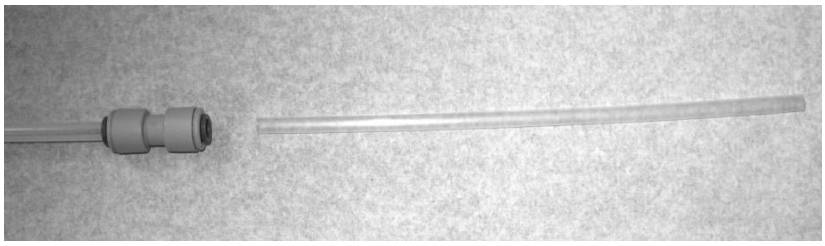
To reconnect the tube, push the tube into the collet ring until you feel it hit the tube stop, then pull back on the tube gently to ensure a solid seal.

2.3 Sample Straw

The length is not the critical specification. The diameter and wall thickness are critical. The diameter specified below produces an optimal sealing surface (between the straw and coupling), while the thickness provides structural integrity to prevent crimping. The diameter and wall thickness work in conjunction to achieve an optimum seal, thus preventing dilution due to air leaks.

Testing of lab samples recommends the use of the **Dixie JW7**. This is a 7.75 inch (196.85 mm) translucent polypropylene straw. Outside diameter is 0.217 in. (5.512 mm), with a wall thickness of 0.007 in. (0.1778 mm). No active chloride is present. The recommended straw assures no absorption of sulfur containing gases, (as would be expected in breath samples).

Connect the straw to the tube connector by pushing the straw gently into the end of the connector until it reaches the tube stop. Since the straw is more flexible than the inlet tubing, it can easily be removed from the connector merely by pulling gently on the straw. As such it is not necessary to pull on the straw to seal a connection.



NOTE: ALWAYS USE A NEW STRAW WHEN TAKING SAMPLES FROM A NEW PATIENT. DO NOT RE-USE STRAWS WITH PATIENTS.

Section 3 - Halimeter® Basic Operation

3.1 Halimeter® Operation Modes

The operation of the Halimeter® can be divided into 4 basic "modes" as follows:

STARTUP MODE – When the Halimeter® is first connected to AC power, it will enter STARTUP MODE in which the pump will automatically turn on and the digital display will commence a 30 minute countdown allowing for sensor stabilization. When the countdown is finished, the instrument will automatically enter OFF MODE.

OFF MODE – In this mode, the pump is off and the sensor is "on bias" or "charging". This is the mode the Halimeter® should be in when not in use. (pg 5 (#6)

ON MODE – In this mode, the pump is running and the sensor is allowed to stabilize to ambient air flow. This mode is used prior to zeroing and taking samples and is entered from OFF mode by pressing the ON control. (pg 5 (#6)

SAMPLE MODE – This is the mode used for taking actual breath samples and is accessed from ON MODE by pressing the SAMPLE control (pg 5 (#5). In SAMPLE MODE, a series of 3 separate 30 second samples are collected. The **peak** (pg 5 (#4) ppb values are displayed at the end of each sample period after which an **average** (pg 5 (#10) peak ppb value for all 3 samples is displayed. There is a 3 minute re-stabilization period before each sample is taken.

NOTE: To preserve sensor and pump life, always switch the instrument to OFF MODE when not in use.

3.2 Powering Up The Halimeter®

To prepare the Halimeter® for use, connect the female end of the power cord into the receptacle in the back of the Halimeter®. Connect the male end to an **UNSWITCHED AC POWER SOURCE**. Once connected to AC power, the instrument will default to STARTUP MODE during which the pump will automatically turn on and the digital display (pg 5 (#3) will first flash **"oFF 2"** then **"oFF 1"** and then commence a 30 minute countdown. The 5 panel L.E.D.s will light continuously in succession indicating STARTUP MODE is active. This mode provides for initial sensor stabilization which is required anytime the instrument is un-powered for any length of time.

When the countdown is complete, the pump will turn off and the digital display will read "**oFF**" (OFF MODE) (pg 5 (#3). When powering up for the first time or after lengthy periods of not being connected to AC power, **allow the Halimeter® sensor 24 hours to fully charge and stabilize in OFF MODE prior operation of the instrument.** In cases where the instrument is briefly disconnected from AC power (less than 5 minutes) such as to move to another treatment room, STARTUP MODE can be bypassed after reconnecting to AC power by pressing the ON control (pg 5 (#6). This will switch the unit to OFF mode where the pump will shut off and display will read "**oFF**".

NOTE: IT IS IMPORTANT THAT THE HALIMETER® ALWAYS BE CONNECTED TO <u>UNSWITCHED</u> AC POWER WHEN NOT IN USE SO THAT THE SENSOR IS ALWAYS "ON BIAS". This helps eliminate the need for long stabilization periods between use.

Section 4 – Breath Sample Considerations

The function of the Halimeter® is to serve as a reliable monitor for the measurement of VSC (Volatile Sulfur Compound) concentrations.

The Halimeter® can be utilized as part of a total program encompassing a thorough history and physical examination of the patient. Along with an organoleptic assessment, the quantitative nature of Halimeter® data can serve as an excellent tool for following the progress of treating halitosis, and for archiving hard copy records.

Halimeter® 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.

Many practitioners have developed their own sampling techniques, some of which do not incubate the sample for as long as we recommend, and some of which might be more prone to dilution from the ambient air.

Are these sampling techniques "wrong"?

They are only "wrong" if one wishes to produce VSC readings conforming to the interpretations discussed below. However, if alternative sampling techniques are practiced with consistency, good results can be obtained, and will conform in a RELATIVE sense with our numerical scale. ***It is noted that alternative sampling techniques will usually produce lower readings***

1) Normal readings, for subjects with no oral malodor, are generally in the range of 80-140 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.

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® sensor are vapors present in MOUTHWASH. **The presence of residual mouthwash in the mouth will produce a false Halimeter® reading and can seriously limit sensor life. *If mouthwash is used prior to taking a the Halimeter® reading, the mouth must be rinsed thoroughly with water to clear out residual mouthwash solution. This must be done at least 30 minutes prior to using the Halimeter®* .**

NOTE: 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.

1) 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.

2) 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.** Breathing should continue THROUGH THE NOSE during sampling allowing sample to be drawn from the mouth into the Halimeter® by the pump rather than forced in by the lungs.

4) **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 steady and that it is not increasing or fluctuating as a result of the patient breathing or blowing into the sample straw.

5) 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® and allowing ample time for sensor stabilization, the instrument is ready for sampling.

5.1 Zeroing The Halimeter®

From OFF MODE, press the ON control (pg 5 (#6). The pump will turn on and the display will show the sensor's current output value. Confirm that the flowmeter shows a steady flow (pg 5 (#1). Allow the sensor several minutes to stabilize to ambient air flow. Once the display value settles and does not change significantly for at least 10 seconds, you may proceed.

If the PPB reading settles at a value above +10 PPB or below -10 PPB, the display should be zeroed. Press the ZERO control (pg 5 (#12) and hold until the display value changes to a value near zero. Do not expect an exact zero reading. Readings within ±10 PPB are acceptable. If the display value does not stay within ±10 PPB and continues to rise or fall, the instrument requires more time to stabilize and should be re-zeroed after stabilization has been confirmed.

5.2 Sample Mode

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

1) Enter sample mode by pressing the SAMPLE control (pg 5 (#5). The number **1** L.E.D. will light indicating that the 1st sample period has commenced. The display will count down from 180 seconds (3 minutes) and will alternate between **"Hold"** and the time remaining in the countdown. During this time, the patient should keep their mouth closed to accumulate the sample. The patient should not hold the sample straw or tube during the countdown.

2) When the countdown reaches "**0**", the SAMPLE L.E.D. **S** (pg 5 (#11) will light and you will hear a series of 3 rapid tones followed by a less rapid continuous sequence of tones as the sample period counts down (approx 35 seconds). The sample straw should now be inserted into the patient's mouth as described in section 4.2 and with the patient breathing through their nose. This condition should be held until the display reading reaches its highest value and then begins to decrease. At this point the sample straw may be removed and set down for the remaining sample time.

When the 1st sample cycle is complete, you will hear 3 rapid tones after which the PEAK indicator (pg 5 (#4) will light and the display will briefly show the peak PPB value for the sample just taken.

The Halimeter® will then enter the 2nd countdown period (SAMPLE L.E.D. **2** will light) where the 2 steps above will repeat. This will be followed by the 3rd sample period after which the AVERAGE L.E.D. **"A"** (pg 5 (#10) and the **"PEAK"** (pg 5 (#4) indicators will light and the display will show the **average** peak PPB value for the 3 samples just taken. This completes the full sample cycle.

To begin a new cycle for a different patient, press the ZERO control (pg 5 (#12) momentarily to return the instrument to the ON mode. Allow the instrument time to return to **0** on it's own (or within the ±10 PPB range mentioned in section 5.1). It is not necessary to manually re-zero the instrument between patients. Press the SAMPLE control to begin a new sample sequence.

Sampling can be interrupted at any time by pressing the ZERO control (pg 5 (#12) , returning the instrument to the ON mode.

When finished sampling, press the ZERO control (pg 5 (#12) to enter ON mode, then press the ON control (pg 5 (#6) to enter the OFF mode. The display should read **"oFF"** and the pump should not be running. The Halimeter® should be left in this mode when not in use.

Section 6 – Calibration

Periodic calibration of the Halimeter® is required to adjust for decreased sensor sensitivity. Frequency of calibration is a function of Halimeter® use and the concentration of volatile sulfur compounds (VSC) to which the sensor is exposed.

Calibration is done by introducing a known concentration of gas to the Halimeter® and adjusting the Halimeter® according to the known concentration of gas. Typically, the Halimeter® will need to be returned to the factory for this function to be performed.

No exact schedule of calibration can be suggested, since use and VSC level exposure cannot be predicted. However, if the Halimeter® is used on a regular basis, it should be calibrated at least every year. Consistently lower than expected readings are an indication that the Halimeter® is in need of calibration.

6.1 User "Quick Span" Adjustment

Occasionally, a user may wish to increase the span setting on the Halimeter® to compensate for loss of sensor sensitivity without doing a full calibration. This can be done by following the procedure detailed below. Read this procedure in full before performing:

1) Confirm that the Halimeter® has been connected to AC power and that the sensor has fully stabilized.
2) If the pump is currently not running, press the ON button (pg 5 (#6). If the pump is already running, proceed to the next step.
3) If the stabilized reading is above +10 PPB or below -10 PPB, the Halimeter® should be zeroed. In this case, press and hold the ZERO control (pg 5 (#12) until the display value changes to a value near zero. (do not expect an exact zero reading. Readings within $\pm$ 10 PPB continues to rise or fall, the instrument requires more time to stabilize and should be re-zeroed after stabilization has been confirmed.)
4) Press and hold the SAMPLE control (pg 5 (#5) for 3 seconds. This will initiate a single sample cycle during which a breath sample should be taken from an individual known to exhibit "normal" breath conditions.
5) Upon completion of the sample, the peak value will be displayed at which point the user can increase or decrease this value as necessary to reflect a typical "normal" sample reading. Repeatedly press the ON control (pg 5 (#6) to increase the value or press the ZERO control (pg 5 (#12) to decrease the value. (Holding either button will accelerate the incrementing of the value).
6) Once the desired value is attained, press and release the SAMPLE control (pg 5 (#5). The display should now ready "**y n**". Press the ON control (pg 5 (#6) to save the new value or press the ZERO (pg 5 (#12) control to exit the quick span function without saving the new value.

Section 7 – Troubleshooting

7.1 Erroneous Low Readings

Lower than expected PPB readings taken from a patient exhibiting an obvious breath problem can result from the following:

Undersized straws: Testing in our lab recommends the use of the **Dixie JW7**. This is a 7.75 inch (196.85 mm) translucent polypropylene straw. Outside diameter is 0.217 in. (5.512 mm), with a wall thickness of 0.007 in. (0.1778 mm). No active chloride is present. The recommended straw assures no absorption of sulfur containing gases, such as would be expected in breath samples.

Improper Sampling Techniques: Some sampling techniques may result in low PPB readings (see section 4.2). These include:

Shallow straw depth in the mouth -Insertion of the straw into the mouth should be at the back of the tongue at a depth of approximately 1 to 2 inches (25 - 50mm) , with the mouth **slightly open.**

Lips fully closed on the sample straw like sipping a drink – The lips and teeth should not touch the sample straw nor should the straw be pinched or squeezed as this will restrict the sample flow.

Talking immediately prior to sample collection – The mouth should remain closed throughout the 3 minute countdown that precedes the sample period.

Instrument out of calibration: As the Halimeter® sensor ages, it loses sensitivity requiring the instrument to be returned to the factory for calibration. If the low readings are accompanied by a sluggish response, the sensor may be close to the end of its normal life expectancy (2 to 3 years). Contact the *INTERSCAN SERVICE DEPT* if you suspect sensor related problems.

7.2 Erroneous High Readings

High readings can also be produced by interfering compounds, such as flavoring agents in mouth rinses, mints, and herbal teas. The Halimeter® is measuring in the parts-per-billion range, and some of these flavoring agents can be present at oral concentrations several orders of magnitude higher. This is one reason why we recommend that the patient should refrain from food, smoking, drinking (water is allowed), and oral hygiene for 3-4 hours before the testing.

Higher than expected readings can be caused by the following:

Blowing into the sampling straw - This causes an increase in sample flow rate which will result in increased sensor response.

Section 8 – Warranty

INTERSCAN CORPORATION warrants Halimeters® 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. The sensors are factory-sealed and must not be opened or modified in the field for the warranty to remain in effect. This warranty is in lieu of all other warranties whether expressed or implied.

Section 9 – Return Authorization Service

All returns for repairs require a "RETURN AUTHORIZATION NUMBER" issued by the Interscan Service Department upon request. Below is the link to the RMA request form:

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

INTERSCAN CORPORATION

Service Department

(800) 458-6153 ext. 121

(818) 882-2331 ext. 121

FAX (818) 341-0642

E-mail: service@gasdetection.com