A Personal Note to all Halimeter Users

The Halimeter is designed to quantify breath measurements in parts-per-billion of volatile sulfur compounds (VSC). This instrument has been thoroughly checked out by our technicians immediately prior to shipment. Checkout consists of carefully calibrating the Halimeter with an accurately known sulfide gas standard, followed by breath measurements taken from INTERSCAN employees. Haligram records are tabulated and stored for future reference. Readings are logged into a computer.

You can save yourself a lot of time by reading this Manual carefully once through. Keep it handy for future reference.

The greatest source of error is improper sampling. The oral cavity itself is not an ideal sampling chamber, because of its small size and dynamic changes in VSC level. Despite this, reliable readings can be obtained if instructions are followed closely.

Most important! DO NOT BLOW INTO or SUCK FROM the drinking straw oral probe. HOLD YOUR BREATH for the several seconds required to attain a peak reading. DO NOT close your mouth around the straw. Leave the mouth slightly OPEN. Take several readings at a sitting for a more reliable average.

Should you have any questions, please give us a call at 1-800-458-6153 x121, or fax us at 818-341-0642. INTERSCAN'S Service Department will be glad to help you. If you want more Halimeter details and background, I'd be pleased to talk with you.

Manny Shaw, President

INTERSCAN CORPORATION

Model RH-17K Halimeter

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RINSE OUT THE MOUTH THOROUGHLY WITH WATER FOLLOWING A MOUTHWASH TREATMENT BEFORE TAKING A HALIMETER READING.

SENSOR WARRANTY IS VOID IF THE SENSOR IS CONTAMINATED BY MOUTHWASH VAPOR OR THAT OF OTHER LIQUIDS.

INSTRUCTION MANUAL FOR INTERSCAN HALIMETER
Model RH-17K

1.0 Introduction

INTERSCAN is a manufacturer of toxic gas measuring instruments designed to monitor the workplace for specific pollutant gases and vapors. Using INTERSCAN-developed sensor technology, INTERSCAN instruments have been in international use since 1975 to monitor air pollutants.

The connection between bad breath (halitosis) and certain volatile sulfur compounds (VSC) was first established by Tonzetich[1]. He determined that certain anaerobes were the source of these compounds, primarily methyl mercaptan, hydrogen sulfide, and to a lesser extent, dimethyl sulfide.

Industrial INTERSCAN monitors for these sulfur gases have been sold since the company's inception. Because of their ability to quantify VSC concentrations at the parts-per-billion (ppb) level, these INTERSCAN instruments eventually were used in academic studies of bad breath.

The Halimeter gives a digital readout in parts-per-billion (ppb) VSC, which is not only quantitative, but is more accurate than the very subjective organoleptic method. Using a recorder, in conjunction with the Halimeter, offers a hard-copy record for both the dentist and patient. Optional recording devices include an Interscan data logger and computer interface enabling record storage and retrieval by computer (see section 6.0).

[1] Tonzetich, J. (1977). Production and Origin of Oral Malodor. A review. J. Periodont. **48:** 13-20

1.1 Applying the Halimeter to Bad Breath Measurements

The only function of the Halimeter is to serve as a reliable monitor for the measurement of VSC concentrations. If other chemical agents cause bad breath, and might exist in the breath sample, they may or may not respond in the Halimeter.

The Halimeter is intended to 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. VSC levels can change with the time of day. The dental practitioner is required to include the assessment of other diagnostic procedures prior to making a positive conclusion.

1.2 Halimeter Description

The Model RH-17K Halimeter has a digital display readout in ppb, two controls labeled ZERO and CAL, a power switch, and an inlet connection for the oral sample. There are two test points on the circuit board inside of the Halimeter, S and G (ground) used for calibrating the instrument. A recorder output is also located on the rear panel. Contained within the monitor are the sensor, electronic circuitry, and a pump to draw the oral sample through the sensor. The sensing device is a highly sensitive IINTERSCAN patented electrochemical voltametric sensor, which generates a signal when exposed to sulfide and mercaptan gases.

1.3 Typical Halimeter Measurements

Dental practitioners and researchers generally consider peak values less than approximately 150 ppb as normal levels of VSC not constituting a bad breath problem. It has been reported that based on Halimeter data of several hundred patients, the average range of bad breath readings is 300 to 500 ppb, although levels as high as 1000 ppb have been encountered.

2.0 Operating Instructions

Note: Your INTERSCAN Halimeter has been calibrated at the Factory

Insert the inlet sampling tube into the Halimeter and firmly push in. Upon initially plugging in the Halimeter, it should be allowed to stand for *at least* 12 hours prior to use. The power switch need not be on until measurements are to be taken. As long as the Halimeter remains connected to the a/c power (whether switched on or off) no warm up time is required. To preserve sensor and pump life, switch off the unit when not in use.

Note: Where the Halimeter may be moved between treatment rooms, no warm-up time is required if the Halimeter can be re-connected within 5 minutes.

2.1 Sampling Procedure

Sampling procedure is highly important and if not properly done will lead to erroneous readings. A drinking straw is inserted into the hard plastic connector of the sampling tube. The connector permits easy insertion of the straw **but the straw must be pushed deep** into the tip to ensure a tight fit.

Prior to taking the first reading, instruct the patient to keep their mouth closed for 2 or 3 minutes, and to refrain from talking. This is necessary to allow sufficient build-up of VSC.

Proper procedure is to insert the straw about 1 to 2 inches into a slightly open mouth. The mouth should be open about 1/2 inch. **DO NOT CLOSE LIPS AROUND THE STRAW! DO NOT BLOW! DO NOT SUCK ON STRAW!** The Halimeter pump draws the oral sample into the instrument at a set flow rate, which must not be interfered with.

With the POWER on, adjust the ZERO control to get as close to a zero (000) reading on the meter as possible. Do not expect a steady reading. The best one can expect is several ppb on either side of the zero. Zero readings within ±10 ppb are acceptable.

When the lowest possible zero reading is obtained, insert the straw probe into the oral cavity.

While the subject holds their breath, monitor the digital readout until a **maximum** reading is reached, at which time **the probe is removed. Note the peak reading.**

On removal of the probe, the readings will decrease, then drop sharply to a negative value, after which they will return more slowly to an approximate zero value. The instrument will return to zero on its own. Do not re-zero the instrument.

After the zero is restored, and in not less than 1 to 2 minutes since the first reading, reinsert the probe for a second reading.

Repeat with a third reading. Take the average of the 3 readings and accept this average value as the breath content of the VSC for that patient at that time of measurement.

DO NOT RELY ON ONE READING ONLY. The mouth environment is not that consistent. Take a minimum of 3 or 4 readings, and calculate the average.

2.2 Variance of Halimeter Readings

INTERSCAN has several hundred sets of computerized Halimeter readings, along with the corresponding Haligram's (recorded peaks). Even with proper sampling procedure, there can be fairly large differences in readings of a given subject at a given time. There can also be significant variance in readings taken for a given subject at different times throughout the day.

Significant difference of readings in a given set (when taken at the same time) is more likely due to inadvertent placing of the probe in different regions of the mouth, closer or farther away from sources of VSC generation. As an example, try placing the probe at the back of the tongue, resting it on the tongue surface. Take care not to block the end of the straw.

Significant difference in comparing readings of a given subject at different times of the day simply reflect anaerobic activity based on a number of factors including availability of protein sources.

2.3 Average Values and Standard Deviation

As stated above, a minimum of 3 separate readings should always be taken when examining a patient for bad breath. Even more than 3 readings are required

when large discrepancies are found, in order to arrive at a more meaningful average value.

Standard deviation, a statistical parameter, is a convenient method of measuring the scatter (variance) in a set of readings. This parameter roughly relates to the plus or minus ppb deviation from the average value. Use of standard deviation also allows one to determine if two sets of readings (*e.g.* before-and-after use of a mouthwash) are significantly different. Standard deviations are directly readable from an inexpensive pocket calculator.

Table I shows the distribution of standard deviations for 711 sets of Haligram's, each set representing the average of 3 readings.

TABLE I Distribution of Standard Deviation

Std dev'n (ppb)	No. of Sets	% of Total
1-5	307	43
6-10	220	31
11-15	107	15
16-20	52	8
21-25	16	2
>25	9	1

Approximately 90% of the readings are repeatable within ±15 ppb, a spread of 30 ppb. About 75% of readings are repeatable within ±10 ppb, a spread of 20 ppb.

2.4 Range of Normal Halimeter Readings

We define a "normal" Halimeter reading as one measured with an individual not having an apparent bad breath problem. Based on a statistical study of several thousand individual Halimeter readings taken at INTERSCAN using two or three subjects not having an apparent breath problem, more than 90% occur within a range of 50 to 170 ppb.

Chronic bad breath problems lie in the range of 300 to 500 ppb, which INTERSCAN has also observed. Some doctors have reported readings well in excess of 500 ppb, and in rare cases as high as 1000 ppb.

685 sets of mostly 3 readings each were taken over a period of six months. Results are shown in Table II.

TABLE II Distribution of Normal Breath Readings

ppb	No. of sets	%
50-70	11	1
71-90	38	6
91-110	114	17
111-130	213	31
131-150	198	29
151-170	111	16

Of a total of 685 average values, representing in excess of 2055 readings, 93% occur within a range of 90 to 170 ppb. The single largest block of readings comprises 77% of the total, and lies between 110 and 150 ppb. Of this block the majority of readings lie within 130 and 140 ppb.

2.5 Validity of Halimeter Readings

Some Halimeter users may wonder whether their readings are too low or too high. This is a legitimate concern. Unfortunately, there is no such thing as a "standard breath". The only logical approach is to take a large population of Halimeter readings, using subjects having apparently normal breath (where normal is defined as not having an obvious breath problem), and subject this data to a statistical analysis.

Using this statistical approach, Table II can now serve as a standard for normal breath readings. As an example, if a Halimeter shows a high percentage of readings in the 50-70 ppb range, it is obvious the instrument needs adjustment since our standard data shows that readings in this range ppb account for only 8% of the total population.

2.6 Minor Halimeter Adjustment versus Calibration

Minor adjustment is user-friendly, It is only necessary to contact INTERSCAN for simple instructions for ZERO and CAL adjustment. No voltmeter is needed. Minor adjustment is a compensation for sensor speed of response. Calibration is a compensation for sensor sensitivity, and is done by returning the Halimeter to the Factory, or by using the ECS program as described in section 3.2

Extensive usage of the Halimeter, along with frequent exposure to high VSC levels, will eventually require sensor replacement, because minor adjustment or calibration will not be able to compensate for excessive sensor sluggishness.

2.7 Regarding Mouthwash Readings

The presence of residual mouthwash in the mouth will itself give a signal in the Halimeter. It is **IMPORTANT TO RINSE THE MOUTH WITH WATER FOLLOWING A MOUTHWASH RINSE** to clear out any residual mouthwash solution. Any alcohol based mouthwash or rinse will eventually kill the sensing electrode and damage the sensor.

3.0 Calibration

No gas-measuring instrument gives an absolute reading. It is necessary to calibrate it against an accurately known concentration of the gas. Special techniques are required for preparing ppb levels of standards. These are used on a daily basis at INTERSCAN, and each Halimeter is so calibrated prior to shipment.

Periodic calibration of the Halimeter is required. This is for the purpose of compensating any possible decrease in sensor sensitivity by increasing the amplification proportionately. Frequency of calibration is a function of Halimeter usage and the concentration of volatile sulfur compounds to which the sensor is exposed.

Accordingly, no exact schedule of calibration can be suggested, since usage 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. An indication that the Halimeter is in need of calibration is when lower-than-normally expected readings are consistently obtained.

3.1 INTERSCAN ECS Program (Electronic Calibration Service)

The Halimeter user has the option of returning the instrument to the Factory for calibration, or subscribing to the ECS program that permits the user to calibrate the monitor themselves in a simple procedure involving a digital voltmeter only.

Although there is no more than a week turn-around in returning the Halimeter to the Factory, this may be unacceptable to those using the instrument on a regular basis. ECS is a procedure by which the user replaces the sensor with a spare, and returns the original to the Factory for re-certification. The ECS certificate permits the user to perform the calibration themselves without the need of a special gas standard, using a voltmeter purchased at any electronic supply outlet.

Using the special gas standard and appropriate procedure, the Factory measures the existing sensitivity (output signal/ppb) of the sensor. The sensor is then returned to the user, along with a certificate denoting the voltage value to which the CAL control is adjusted to effect the instrument calibration. This sensor then becomes the spare to be installed when the active sensor is returned for certification.

3.2 Procedure for ECS Calibration

NOTE: As a precaution, do not open the bag containing the sensor, if any liquid is observed. Return the package to the Factory

Do the calibration prior to reconnecting the sensor.

Refer to the ECS Certificate accompanying the returned sensor.

Select DC volts on the digital voltmeter. Connect the positive lead (red) to test point S, and the negative lead (black) to test point G. These are located on the circuit board identified as HM6-1 next to the pump.

Adjust the ZERO control to read the positive (+) millivolt reading indicated on the certificate.

Adjust the CAL control so that the Halimeter display panel meter reads the ppb level indicated on the certificate.

Readjust the ZERO control to read zero on the Halimeter display panel meter.

The Halimeter is now calibrated.

3.3 Reconnecting the sensor

Make the gas and electrical connections to the sensor ***before*** returning it to the Halimeter. Orient the sensor over the Halimeter with the banana jack towards the rear of the instrument, and the gas fittings tight and pointing down.

Connect the shorter length tubing (inlet) to the *left* gas fitting on the sensor. Connect the longer length tubing (outlet) to the *right* gas fitting.

Connect the blue wire connector to its final position on the sensor.

Insert the banana plug into the banana jack on the sensor. These are low voltage connections and can be safely handled with bare fingers.

Orient the sensor so that the banana jack is in the approximate “11:00 o’clock” position, so that the two holes in the bottom of the sensor align with the two positioning rods in the base of the instrument. Push the sensor into position.

3.4 Removal of Sensor from Halimeter

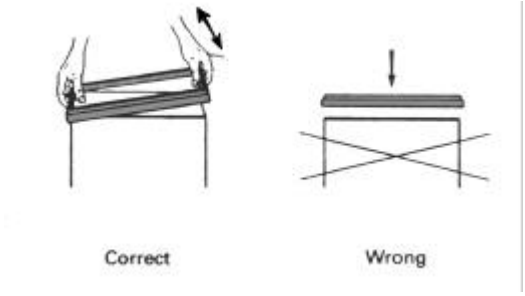

Figure 2

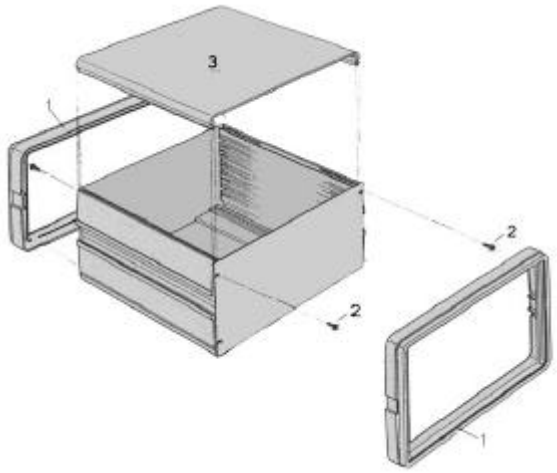

Figure 3

To gain access to the sensor, the top of the Model RH-17K Halimeter must be removed.

See Figure 2. Remove the plastic bezels (1) from around the front and rear of the Halimeter, by pulling the right side of each bezel outward and toward you.

See Figure 3. Remove the two sheet metal screws (2) from the top of the front and rear panels. Do **not** remove the screws from the bottom of the front and rear panels.

Lift top panel (3) off Halimeter. NOTE: It may be necessary to spread side panels apart slightly to remove top panel.

Lift out the sensor, and disconnect the banana plug and pin connectors. These are very low voltage connections, and can be safely handled with bare fingers.

Remove the sensor inlet and outlet tubing by a twisting and pulling motion.

4.0 Erroneous Readings

Use of the Halimeter requires the proper sampling technique in order to avoid erroneous readings.

Low readings, when there's an obvious breath problem, are normally caused by dilution of the sample by air being pulled into. This can occur as a result of the following:

Undersized straws. The correct straw's to be used are a standard 7 ¼" drinking straw. INTERSCAN stocks the proper straws to avoid this problem. Insufficient depth of straw, insertion of the straw should be about 1-2 inches, with the mouth **slightly open.**

If accompanied by a sluggish response, the sensor may be close to its normal expected life (1 to 3 years).

Other Improper Sampling Methods Resulting in Erroneous Readings

Lips fully closed, like sipping a drink.

Talking immediately prior to measurement. Actually, the best procedure is to take a sample following mouth closure for about 3 minutes.

Blowing into the sampling tube can result in false higher readings.

Unwarranted re-adjustment of the CAL pot will give erroneous readings. In very rare cases, bad breath may be due to something other than volatile sulfur compounds, and therefore not show up in the Halimeter reading. Squeezing the straw, or otherwise restricting sample flow, will give a wrong reading.

5.0 Flow Indicator

The flow indicator is located on the front panel immediately left of the inlet. This should be monitored by the individual supervising the breath test to assure that the patient is not either blowing into the straw, or having the lips closed around the straw. Blowing into the straw will force the ball upwards. Lips closed over the straw will cause the ball to jump up and down tending towards zero flow as the pump struggles to operate.

6.0 Optional Equipment

Permanent records of breath measurements can be achieved by use of recording equipment, such as a pen-and-ink recorder. Using a flatbed recorder, the peak value of the reading can be written on the strip chart. The recorded trace is called a **Haligram.**

Such recording devices serve to create hard copy records, and in the case of the data logger/computer interface combination, can supply diskette storage capability with instant computer retrieval.

Contact the INTERSCAN Sales Department for more information.

7.0 Shipping Instructions

The Halimeter should packaged in its original packing material. If this is no longer available, be sure to package the Halimeter so that the monitor is not loose in the box. Proper packaging will avoid any damage during shipment. The sensor should be placed in a lock-type plastic bag, wrapped securely in some packaging material, and sealed in a carton ready for shipment. In order to expedite prompt return, a **Return Authorization Number** is required. Refer to section 8.0.

8.0 Return Authorization Service

Halimeter's being returned for repair, or sensors being returned as part of the ECS program of calibration, must have a RETURN AUTHORIZATION NUMBER issued by the INTERSCAN Service Department. This is done for the purpose of having a more orderly handling of the instrument or sensor, assuring prompt return.

Please contact the Service Department at INTERSCAN.

Toll-Free 800-458-6153 x121

Alternate 818-882-2331

FAX 818-341-0642

e-mail: service@gasdetection.com

9.0 Warranty

INTERSCAN CORPORATION warrants Halimeter's 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.