



HISTORY OF QUINTRON HISTORY OF BREATH-TESTING PRINCIPALS OF BREATH-TESTING INSTRUMENTATION COLLECTION SYSTEM INFORMATION BREATH-TESTING COMMON QUESTIONS GENERAL CARE FOR REUSABLE PARTS INTERPRETING HELP FOR DOCTORS PRODUCT ORDERING INFORMATION

CATALOG AND INFORMATION



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## History of Breath-Testing

Breath trace-gases were first used as an indicator that complex sugars (disaccharides) were not broken down (hydrolyzed) and absorbed in the small intestine during the digestion of foods. Hydrogen  $(H_2)$  was measured in the breath after administering a dose of the sugar to be studied. The widest application of the test was for **lactose malabsorption** or **lactose intolerance**, which is related to milk intolerance in a majority of adults world-wide. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the NIH (USA) estimates that between 30 and 50 million Americans are lactose intolerant. The hydrogen breath-test (often referred to as the HBT) replaced a blood-test which was based on the absence of a blood glucose response following lactose ingestion. The test is not as reliable as the breath hydrogen test since it produces a greater proportion of false negative and false positive tests.

The incidence of lactose malabsorption throughout the world is surprising to most people. Adults who cannot digest milk sugar make up the majority of the world's population. Those who can drink milk without getting sick are likely to be North Americans, Australians or Northern Europeans. The ability to digest milk beyond the age of 3-5 years is genetically determined, and is a dominant trait.

When the reliability and simplicity of the breath- $H_2$  test was demonstrated with lactose, it was soon applied to other complex sugars like fructose (from fruits), maltose (from some starches), and sucrose (common table sugar, which is rarely absorbed). It has also been used to indicate that some people are unusually sensitive to sorbitol, an artificial sweetener used in dietetic candy, sugar-free chewing gum, and other dietetic foods.

Recent studies have shown that methane has been added as a useful trace-gas for the study of digestive problems. Methane  $(CH_4)$  is an important intestinal gas and it should also be measured in studies of carbohydrate malabsorption in order to provide the most information to the physician. Clinicians who are leaders in their medical community are beginning to work with methane and will continue to be well ahead of the field as  $CH_4$  become more widely understood. QuinTron manufactures breath-testing instrumentation for trace-gas analysis that encompasses both  $H_2$  and  $CH_4$  in a single instrument for clinicians that wish to take advantage of the opportunity that  $CH_4$  provides to the patient studies.

References available for history of breath-testing can be found in the <u>Breath-Tests and Gastroenterology, 1998</u> <u>edition</u> written by Dr. Lyle Hamilton, Ph.D. or from QuinTron directly if requested.



## History of QuinTron

QuinTron Instrument Company, Inc., was incorporated in 1961 as a small manufacturer of specialized gas analyzers and gas-handling equipment for the fields of pulmonary function and exercise physiology. Its major effort was directed toward the development and marketing of unique instruments, affordable enough to be used by small-volume laboratories for pulmonary function testing.

Because of the success of their gas chromatographs for complex gas mixtures, the company was asked to develop methods to measure trace concentrations of breath-hydrogen. The technique could be used by specialists in digestive diseases to diagnose lactose intolerance, detect bacterial overgrowth and measure intestinal transit time in a non-invasive manner. QuinTron successfully met this challenge and, in the process, entered a different field with an analytical system which performed the measurement faster and better than any other available system. The Model 12 MicroLyzer, introduced in 1981, made breath-hydrogen testing practical, and helped popularize its use in the field of gastroenterology. In 1982, QuinTron introduced the Model CM MicroLyzer, which competed effectively in the foreign market and broadened the application of the test. The Model DP MicroLyzer was introduced in 1985 for the measurement of breath-methane, in addition to hydrogen.

In more recent times, QuinTron redesigned the entire MicroLyzer instruments to meet customer demands for a more simple, accurate and reliable instrument for breath-testing. For those reasons and many others, QuinTron introduced the BreathTracker Series. The BreathTracker Series released in 2007 has replaced the MicroLyzer instruments being manufactured and has continued QuinTron's reputation for providing the best in breath-testing instrumentation and supplies since the company was incorporated. The BreathTrackers are dimensionally smaller and lighter weight, faster and easier to operate than previous MicroLyzer instrumentation. QuinTron instrumentation is considered to be the world's gold-standard in the breath-testing field for carbohydrate malabsorption and small intestinal bacterial overgrowth detection.

Wherever the market leads it, QuinTron's imaginative leadership will be at the forefront of the field, providing innovative instruments and knowledgeable assistance for medical gas analysis.



## **Breath-Tests and Digestive Problems**

"...improved analytical instrumentation and a greater understanding of its limitation have transformed the H2 breath test from an investigative curiosity to a mainline clinical tool."

- Noel W. Solomons, M.D., Current Concepts in Gastroenterology, Vol. 8/1: 30-34 and 37-40, 1983

#### WHAT DO BREATH-TESTS HAVE TO DO WITH DIGESTIVE PROBLEMS?

When some bacteria digest (or ferment) food substances, they produce acids, water and gases. The major gases which are produced by bacteria include, primarily, carbon dioxide (CO<sub>2</sub>), hydrogen (H<sub>2</sub>), methane (CH<sub>4</sub>) and small concentrations of aromatic gases. Carbon dioxide is produced by all cells during metabolism, but only bacteria can produce H<sub>2</sub> and CH<sub>4</sub> as metabolic by-products, and this is accomplished primarily by bacteria which thrive in the absence of oxygen (called anaerobic bacteria). So, if either H<sub>2</sub> or CH<sub>4</sub> are



produced biologically, it tells us that some food substance is exposed to bacterial fermentation.

In the digestive tract, bacteria are normally limited to the colon. Most of the bacteria contained in food are killed by the acidity of the stomach, so the small intestine usually has few bacteria. In some conditions, called "bacterial overgrowth", bacteria exist in high concentrations in the small intestine. Their presence in that area can interfere with the absorption of some vitamins and other essential foodstuffs, so it is important to diagnose the condition.

The colon is concerned with conserving water and salt by reabsorbing them from the lumenal contents. However, the colon is involved in other functions, some of which depend on having a high bacterial-count.



Fiber, very popular in breakfast cereals, is not digested in the small intestine, so it undergoes bacterial fermentation in the colon. Short-chain fatty acids (SCFA) produced by that process are absorbed in the colon, and are beneficial to health. It is becoming apparent that substantial amounts of starch (10-20% of foods like legumes) escape digestion in the small intestine and are broken down in the colon, thus, adding to the efficiency of energy production by such food-stuffs.

In addition, colonic bacteria contribute to fecal bulk, and the shortchain fatty acids mentioned above reduce colonic pH. These factors may reduce the likelihood of diarrhea, confer some degree of protection against other severe colon problems, and enhance the colonic absorption of metal ions like calcium, magnesium and zinc. Thus, fermentation in the colon

is normal, and it is important.

Gases which are produced in the colon are reabsorbed and equilibrated with the

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blood leaving that area. They appear in the lung and cross the capillary membrane into the alveoli, from which they are expired during breathing. The alveolar air can be collected with QuinTron collection devices and analyzed on BreathTracker or MicroLyzer instrumentation.





## Basics Of Hydrogen/Methane Breath Tests

Hydrogen and methane are produced in the digestive system *primarily* only by the bacterial fermentation of carbohydrates (sugars, starches or vegetable fibers), so if either of these gases appear in the expired air, it is usually a signal that carbohydrates or carbohydrate fragments have been exposed to bacteria, permitting such fermentation to take place<sup>2</sup>. The generation of H<sub>2</sub> and/or CH<sub>4</sub> will result in the reabsorption of some of these gases into the blood stream from the site of their digestion, and they will appear in the expired air.

Bacteria are ordinarily not present in significant numbers in the small intestine, where digestion and absorption of sugars take place. Therefore, when a challenge dose (eg. lactose) is ingested, the level of hydrogen in alveolar air will rise significantly within one to two hours (depending on the intestinal transit time) only if the sugar is not digested and, therefore reaches the colon.

The breath-H<sub>2</sub> test is a simple non-invasive procedure which is readily accepted by patients and staff<sup>3</sup>, and which has greater reliability and acceptability than the blood test, according to many reports.<sup>1,4-8</sup> The lower dose of lactose usually does not cause the discomfort and explosive diarrhea frequently seen by malabsorbers who are given the larger dose required for the blood test<sup>9</sup>.

A study<sup>10</sup> with over 300 patients showed that G-I symptoms after a lactose challenge are strongly associated with the amount of  $H_2$  excreted; the relationship between blood glucose change and symptom-severity was less evident.

False-positive breath-tests are rare, and when they occur they are usually caused by improperly doing the test - allowing the subject to smoke, sleep or eat shortly before or during the test<sup>11</sup>. Bacterial overgrowth (from the colon retrograde into the small intestine) can also produce a false-positive breath-test, but it is usually preceded by an elevated fasting breath- $H_2$  level and the response is seen soon after the sugar is ingested (within 20-30 minutes).

The incidence of false-negative results with the breath-test is well below that seen with the blood test <sup>1,4,5</sup>. False-negative results are reported to be from 5-15% of all lactose malabsorbers,<sup>12-14</sup> due to a variety of causes. Many of the false-negative reports can be avoided by measuring methane in addition to hydrogen<sup>15</sup> because some methanogenic flora convert colonic  $H_2$  to  $CH_4$ .

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## Product Compatibility Issues

All products sold by QuinTron are either manufactured by QuinTron or tested thoroughly with our instrumentation to ensure that the product does not interfere with patient samples. Many products not supplied by QuinTron use materials/solvents/lubricants in the manufacturing process that adversely affect both patient samples and the sensors in the QuinTron instrumentation; it is highly recommended to use only products offered by QuinTron. This awareness of product compatibility should be strongly adhered to and applies to the science of breath-testing, not just QuinTron instrumentation.

Many products may seem similar to QuinTron's (e.g. calibration gas, syringes, stopcocks, evacuated glass tubes, etc.) but have not been tested with our instrumentation and can cause problems affecting your patient samples and/or cause damage to your instrumentation.

Please <u>do not</u> develop or modify any collection techniques or devices without consulting QuinTron's Customer Service Department. QuinTron shall not be held responsible for any patient samples that have been jeopardized or damage to your instrumentation by use of products not supplied by QuinTron.

We know for certain that:

- Syringes manufactured by "BD" are NOT compatible with MicroLyzer or BreathTracker instrumentation.
- Glass evacuated tubes (Exetainer<sup>®</sup>) from Labco Limited are NOT compatible with BreathTracker instrumentation. In addition, the vacuum in the tubes supplied by Labco Limited may be inconsistent causing varying degrees of sample contamination and/or improper Hydrogen readings which cannot be detected by end-users. Therefore, it is not recommended to use evacuated tubes for any breath-testing samples which are to be analyzed on MicroLyzer or BreathTracker instrumentation from any other vendor other than QuinTron to ensure sample collection and analysis are not compromised.

When using products other than those supplied by QuinTron, it is very difficult for the end-user to detect if the resulting sample is inadequate. If users are found to be using products not supplied by QuinTron (i.e. stopcocks, syringes, glass evacuated tubes or collection supplies), QuinTron cannot provide any interpretation help, servicing assistance, or technical support until all supplies are proven to be from QuinTron.

For an updated list of products that have been discovered to be incompatible with our instrumentation, please visit our web site: <u>www.QuinTron-USA.com</u>.

Please review all the information provided for collection and analysis of patient samples prior to attempting the collection or analysis of actual patient samples to minimize potential error.





## BreathTracker Comparison

# Simple.

Breath testing with QuinTron's instrumentation and collection devices provides economic and safe alternatives compared to more invasive procedures such as biopsies and/or obtaining aspirate for culturing.

# Accurate.

QuinTron instrumentation are the only devices available with the ability to measure hydrogen and methane in a single sample of alveolar air, increasing the accuracy of the breath test. All instruments are easily upgradable as new SensorPaks<sup>TM</sup> become available, allowing additional trace gases to be measured.

# Reliable.

QuinTron offers the only instrumentation available using solid-state sensors that will never need regular replacement, unlike fuel sensors that may need to be replaced periodically. All instruments have an internal pump that flushes out the previous patient sample. Since the patients never come in contact with the instrument, you can be certain that residual gas and cross contamination will never be an issue.



Simple. Accurate. Reliable	SC	DP	H2+	H2
Breath Hydrogen Analysis	٢	0	0	
Breath Methane Analysis	٢	0		
Sample Correction	0		0	
Automatic Flow Monitoring	0	0	0	0
Simple Push Button Control	٢	0	0	
Upgradable SensorPaks™	٢	0		0
Three-Year Warranty	٢	0		0
DataTracker <sup>™</sup> Compatible	0	0	$\bigcirc$	0
Available Take Home Kits	0		0	
Results in less than 50sec.	٢	0	0	0
Solid-State Sensor	0	0	0	0
Single Alphanumeric Data Display	٥	0	0	

Key Benefits:

- ► EASY TO USE!
- ► 2-STEP CALIBRATION.
- ► FREE, UNLIMITED TELEPHONE SUPPORT.
- ► 3-YEAR FULL PARTS AND LABOR WARRANTY.
- ► SAMPLE RESULTS IN LESS THAN 50 SECONDS.
- ► EASILY UPGRADABLE FOR ADDITIONAL CAPABILITIES.
- ► SOLID-STATE SENSORS NEVER NEED REGULAR REPLACEMENT UNLIKE FUEL SENSORS.
- ▶ INTERNAL PUMP FLUSHES OUT PREVIOUS SAMPLE ASSURING NO INTER-PATIENT CONTAMINATION OR RESIDUAL GAS.

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## Choosing the Right BreathTracker

The correct choice of BreathTracker for a laboratory or office should be made on the basis of the individual facility. Considerations should include the kind of practice engaged in by the physicians and the expected number of patients which will need breath-tests. The CLIA regulations have exempted breath-testing from their certification for now (since 1996), so the test can be done in a laboratory or office not certified by the HHS. Additional information on the BreathTrackers is located in the "BreathTracker Comparison" section.

#### **Selecting and Instrument for H2 Analysis Only**

If the customer selects an instrument only for the measurement of  $H_2$  (usually based on an expected low workload or for a specific research application), a choice can be made between the BreathTracker H2 or BreathTracker H2+ (Plus). These less expensive BreathTrackers will detect hydrogen ( $H_2$ ) as well as the other QuinTron analyzers, but they will allow a small percentage of lactose malabsorbers to avoid detection due to conversion of  $H_2$  to Methane (CH<sub>4</sub>). This principle is not limited to only QuinTron instrumentation; all other manufacturer analyzers which are limited to only  $H_2$  analysis also have this limitation.

The main difference between the BreathTracker H2 and H2+ model is the additional  $CO_2$  sensor installed into the BreathTracker H2+. The BreathTracker H2 and H2+ models were designed as clinical instruments and are recommended only if cost is the determining factor. The BreathTracker H2 can be as accurate and reliable as the other instruments if attention is paid to its analytical technique, and if it is operated properly.

### WHY CH4 ANALYSIS SHOULD BE INCLUDED IN THE TEST

Two models are available for the measurement of  $H_2$  and  $CH_4$ ; the BreathTracker DP and BreathTracker SC.

As described earlier above, some malabsorbers who have negative  $H_2$  breath-tests may generate  $CH_4$  instead. These patients will be recognized if  $CH_4$  is measured as part of the routine test. If the malabsorber generates neither  $H_2$  nor  $CH_4$  following ingestion of a nonabsorbed sugar, the patient must be a "non-producer", either as a result of having a sterile gut or of having rapid-transit diarrhea and/or a hostile pH (acidity too severe for the existence of hydrogen-producing bacteria).

There is overwhelming evidence in field-literature that most patients who fail to produce significant increases in  $H_2$  after the administration of lactulose excrete increased levels of  $CH_4$ . In one study a linear relationship was found between the amount of a disaccharide mixture ingested and  $H_2$  produced over a 10-hour period. If  $CH_4$  was formed, the sum of <u>both</u> gases followed a linear dose-effect relationship, indicating an interaction between the two components. Others have demonstrated an effect of  $CH_4$ -production on fasting  $H_2$  baseline values, breath- $H_2$  area under the curve following lactulose and orocecal transit time, suggesting that knowledge of  $CH_4$  status is necessary for the proper interpretation of the  $H_2$  breath-test.

The BreathTracker DP has the same  $H_2$  analysis specifications and features as the BreathTracker H2 and H2+ models, with the additional feature of detecting  $CH_4$  in the same alveolar air sample.

The BreathTracker SC, analyzer of choice for breath trace-gas studies, measures  $H_2$  and  $CH_4$ , and uses carbon dioxide (CO<sub>2</sub>) to correct for any dilution of the alveolar sample by dead space air or sampling error.

### WHY CO2 MEASUREMENTS SHOULD BE UTILIZED

The BreathTracker SC and H2+ models have a unique feature for detecting and correcting samples for contamination with room air or dead space air during the collection procedure. Such contaminations result from improper sample collection, in which some of the respiratory dead space air is captured with the sample, or the technician inadvertently contaminates the sample with room air during handling. These two BreathTracker models measure the  $CO_2$  in the sample, then compare it with what the alveolar  $CO_2$  should be, then corrects each samples H<sub>2</sub> and/or  $CH_4$  values for the contamination.

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## Principle Behind the CO<sub>2</sub> Correction Factor

The BreathTrackers SC and H2+ utilize a  $CO_2$  correction factor technique to minimize error caused by improper sampling techniques. The  $CO_2$  correction factor is based on the concept that carbon dioxide is present in alveolar (lung) air at a virtually constant concentration; while  $CO_2$  in room air is virtually zero (in fact it is present, but in extremely trace concentrations). Therefore, if an alveolar air sample is accidentally contaminated (mixed) with room air, the  $CO_2$  concentration in the sample will be reduced, as will any other trace gases in the sample (in our case H<sub>2</sub> and/or CH<sub>4</sub>). By knowing the degree to which the  $CO_2$  is diluted, it is possible to apply a correction to the analysis of each trace gas of interest (again in our case H<sub>2</sub> and/or CH<sub>4</sub>), and be able to estimate the "true alveolar" concentration of these trace gases. The sample concentrations of H<sub>2</sub> and/or CH<sub>4</sub> are multiplied by the factor calculated from:

#### FACTOR = Alveolar $CO_2$ concentration/Sample $CO_2$ concentration

 $CO_2$  is the physiological regulator of breathing, and the whole breathing system is dedicated to keeping the alveolar  $CO_2$ -pressure (PACO<sub>2</sub>) constant at 40 mm Hg (torr). Therefore  $CO_2$  is the most reliable "normalizing" component in the sample, because it ordinarily has the most constant alveolar composition of any gas in the sample.

Alveolar  $PCO_2$  remains constant at 40 torr among normal individuals if ventilation is normal. The percent of  $CO_2$  in an alveolar sample is affected by the barometric pressure (altitude) at which the sample is collected. Alveolar air with a  $PCO_2$  of 40 torr in Miami (at sea level) will have a  $CO_2$  concentration of about 5.5% in dry air (40/(760-37)), while alveolar air in Denver (where barometric pressure is closer to 625 torr) will be near 6.8% (40/(625-37)). Significant differences in barometric pressure exist at different altitudes, as demonstrated by Miami and Denver. However, using a single correction factor, alveolar concentration will simplify the process without introducing significant error, because all the samples will be normalized to the same (constant)  $CO_2$  level.

Research studies, using an alveolar concentration of 5.5% will be adequate for calculating the correction factor for CO<sub>2</sub>. However when the absolute alveolar pressure for the trace gases is important, you may adjust the instrument to your specification.

#### CO2 (Correction Feature) for Methane (CH4) is only available on the BreathTracker SC.





# BreathTracker SC

BREATH HYDROGEN AND METHANE ANALYSIS WITH SAMPLE CORRECTION FEATURE

The ability to analyze H<sub>2</sub>, CH<sub>4</sub> and CO<sub>2</sub> provides physicians with necessary information to confidently diagnose carbohydrate malabsorptions and/or small intestinal bacterial overgrowth (SIBO).

The BreathTracker SC analyzes trace-gas concentrations of hydrogen ( $H_2$ ), methane ( $CH_4$ ) and carbon dioxide ( $CO_2$ ) in a patient's alveolar breath sample using solid-state sensors. The results are measured and displayed in parts per million (ppm) for  $H_2$  and  $CH_4$  and percent (%) for  $CO_2$ . The BreathTracker SC also utilizes an added feature for sample contamination detection and correction based on  $CO_2$  measured in patient samples.

As with all breath-tests, you may encounter sample contamination from various sources such as: unsupervised or improper collection, patients that are unable to follow directions, variations in ventilation (ie: patients taking a large inspiration in the early samples of a test and more normal breaths later in the test). The ability to detect and correct for these factors helps smooth out the sample inconsistencies resulting in more realistic patterns of gas production.

 $CO_2$  is the most reliable "normalizing" component in the sample because it ordinarily has the most consistent alveolar composition of any gas in the sample; the body physiologically regulates the alveolar  $CO_2$ -pressure (PACO<sub>2</sub>) around 40mmHg (torr).

Therefore, the  $CO_2$  correction factor is based on the concept that  $CO_2$  is present in the alveolar (lung) air at a virtually constant concentration while  $CO_2$  in room air is virtually zero (in fact it is present, but in extremely trace concentrations). If an alveolar air sample is accidentally contaminated (mixed) with room air, the  $CO_2$  concentration in the sample will be reduced, as will other gases in the sample.

Detecting this dilution, and by knowing the degree to which the  $CO_2$  is diluted, is indicative of improper sample collection or handling and makes it possible to apply a correction to the analysis of each trace gas, allowing the instrument to estimate the "true alveolar" concentration of these trace gases, unless the sample is completely invalid.

Studies have indicated the importance of measuring  $H_2$  and  $CH_4$ , as approximately 35% of healthy adult subjects are methane producers. These tests were for carbohydrate malabsorption and small intestinal bacterial overgrowth (SIBO). (*Reference: Clin Gastroenterolo Hepatol 2006 Feb;4(2):12390*)

Since the BreathTracker SC utilizes  $CO_2$  as an indicator for sample dilution and contamination detection, physicians have the ability to send patients home to collect their samples unsupervised which allows the physician and technicians to see more patients and analyze the breath samples at a later time.<sup>†</sup>

<u>Catalog Numbers:</u> QT05000-M - BreathTracker Digital SC, 120V/60Hz QT05001-M - BreathTracker Digital SC, 230-240V/50Hz	<b>Specifications:</b> Resolution: 1 ppm $H_2/CH_4$ ; 2% CO <sub>2</sub> Accuracy: $\pm 2-3$ ppm or 5% of full scale for $H_2/CH_4$ ; $\pm 1\%$ CO <sub>2</sub>
† Requires purchase of SamplXtractor System and EasySampler Kit	Linear Range: 2-150 ppm $H_2$ ; 2-75ppm $CH_4$ ; 0.1-7% $CO_2$
2712 West Diargo Street Milwoukee WI	





### BreathTracker DP BREATH HYDROGEN AND METHANE ANALYSIS

The capability to detect methane increases the ability to accurately diagnose and eliminate potential false negatives.



Studies have demonstrated the importance of hydrogen ( $H_2$ ) and ( $CH_4$ ) methane production, indicating approximately 35% of healthy adult subjects are methane producers when testing for carbohydrate malabsorption and small intestinal bacterial overgrowth (SIBO). (*Reference: Clin Gastroenterolo Hepatol 2006 Feb;4(2):12390*)

The BreathTracker DP measures both hydrogen and methane in a single sample of alveolar air. Several studies have found that significant volumes of methane and hydrogen are produced when bacteria metabolize sugar in the intestinal tract, and recent literature has focused on the interdependence and interaction of hydrogen and methane production in the colon. The reliability of the test is significantly improved when both  $H_2$  and  $CH_4$  are measured in the same sample and the temporal appearance of breath  $CH_4$  and  $H_2$  may indicate the location of the bacterial infection in the small intestine.

The BreathTracker DP separates the components using the basic principle of gas chromatography. Room air is used as the carrier gas, which is pumped through the system where the hydrogen and methane are separated from each other and from all other reducing gases. The hydrogen and methane are then carried sequentially past a solid-state sensor that is affected only by reducing gases.

The signals are then processed and the sample concentrations are shown on the instrument's display in parts per million (ppm).

Catalog Numbers:

QT05002-M - BreathTracker Digital DP, 120V/60Hz QT05003-M - BreathTracker Digital DP, 230-240V/50Hz <u>SPECIFICATIONS:</u> Resolution: 1ppm  $H_2$  and  $CH_4$ Accuracy:  $\pm 2-3$  ppm or 5% of full range for  $H_2$  and  $CH_4$ Linear Range: 2-150ppm  $H_2$ ; 2-75ppm  $CH_4$ 





## BreathTracker H2+

BREATH HYDROGEN ANALYSIS WITH SAMPLE CORRECTION FEATURE



Same great features as the BreathTracker H2 with the added sample correction feature to ensure that patients samples are "true alveolar" samples and corrected within reason if contamination occurs.

Also allows for physicians to send patients home with kits<sup>†</sup>

The BreathTracker H2+ is a basic hydrogen  $(H_2)$  trace-gas analyzer with the added feature of carbon dioxide  $(CO_2)$  detection which is used to help detect and correct for any patient sample contaminations which may result in improper H<sub>2</sub> values.

As with all breath-tests, you may encounter sample contamination from various sources such as: unsupervised or improper collection, patients that are unable to follow directions, variations in ventilation (ie: patients taking a large inspiration in the early samples of a test and more normal breaths later in the test). The ability to detect and correct for these factors helps smooth out the sample inconsistencies resulting in more realistic patterns of gas production.

Therefore, the  $CO_2$  correction factor is based on the concept that  $CO_2$  is present in the alveolar (lung) air at a virtually constant concentration; while  $CO_2$  in room air is virtually zero (in fact it is present, but in extremely trace concentrations). If an alveolar air sample is accidentally contaminated (mixed) with room air, the  $CO_2$  concentration in the sample will be reduced, as will other gases in the sample.

Detecting this dilution, and by knowing the degree to which the  $CO_2$  is diluted, is indicative of improper sample collection or sample handling and makes it possible to apply a correction to the analysis of each trace gas, allowing the instrument to estimate the "true alveolar" concentration of these trace gases, unless the sample is completely invalid.

Since the BreathTracker H2+ utilizes  $CO_2$  as a factor for sample dilution and contamination detection, physicians have the ability to send patients home to collect their samples unsupervised which allows the physician and technicians to see more patients and analyze the breath samples on another day.<sup>†</sup>

#### **Specifications:**

Resolution: 1 ppm H<sub>2</sub>/CH<sub>4</sub>; 2% CO<sub>2</sub> Accuracy:  $\pm$  2-3 ppm or 5% of full scale for H<sub>2</sub>/CH<sub>4</sub>;  $\pm$  1% CO<sub>2</sub> Linear Range: 2-150 ppm H<sub>2</sub>; 2-75ppm CH<sub>4</sub>; 0.1-7% CO<sub>2</sub>

Catalog Numbers: QT05004-M - BreathTracker Digital H2+, 120V/60Hz QT05005-M - BreathTracker Digital H2+, 230-240V/50Hz





## BreathTracker H2

BREATH HYDROGEN ANALYSIS

Hydrogen analysis only; economical solution best suited for facilities that do not require patient sample corrections to true alveolar air, and do not require methane analysis.



When cost is the underlying factor in determining which breath-testing instrumentation to purchase, the BreathTracker H2 is the most economical hydrogen  $(H_2)$  trace-gas analyzer. The BreathTracker H2 can allow you to begin testing for carbohydrate malabsorptions and small intestinal bacterial overgrowth with minimal investment in instrumentation.

Though limited to hydrogen analysis only, the BreathTracker H2 can be easily upgraded to the BreathTracker DP to include analysis of methane  $(CH_4)$  and/or the additional carbon dioxide  $(CO_2)$  sensor for sample contamination detection and correction which can be found on the BreathTracker H2+ and BreathTracker SC instruments, should the need arise for more comprehensive diagnosis results.

The short analytical time of 50 seconds or less and the capability of a quick, accurate calibration provides a specificity and accuracy unequalled by any other hydrogen-only analyzer in any price range.

The highest advantage of the BreathTracker instrumentation over competitor hand-held hydrogen monitors is the use of a solid-state hydrogen sensor which do not require periodic replacement unlike the electrochemical fuel-like sensors found in hand-held hydrogen monitors.

The BreathTracker system utilizes a sample loop and internal pump ensuring every sample is processed in the same fashion as each previous sample, unlike the electrochemical sensors which can be pressure sensitive, meaning the harder or softer the patient blows, the hydrogen values will differ.

The BreathTracker system flushes out any previous patient sample to eliminate any cross-interference and returns the instrument to the same internal baseline, unlike the electrochemical instruments which can leave residual hydrogen on the membrane and do not ensure that each sample is analyzed at the same baseline.

#### **Specifications:**

Resolution: 1 ppm  $H_2$ Accuracy:  $\pm$  2-3 ppm or 5% of full scale for  $H_2$ Linear Range: 2-150 ppm  $H_2$ 

<u>Catalog Numbers:</u> QT05006-M - BreathTracker Digital H2, 120V/60Hz QT05007-M - BreathTracker Digital H2, 230-240V/50Hz





### FRee Up COnGeSTiOn in YOUR OFFiCe, Send p ATienTS HOMe wiTH TeST kiTS!



The SamplXtractor<sup>TM</sup> Model SX-2 Plus is a stand-alone accessory designed for use with the BreathTracker<sup>TM</sup> and MicroLyzer<sup>TM</sup> breath-testing instrumentation.

Simplify the extraction of samples from vacuum tubes that are used with the patented EasySampler<sup>TM</sup> system for reliable injection into your breath-testing instrumentation.

By utilizing the SamplXtractor system, you now have the ability to use EasySampler<sup>TM</sup> kits to send patients off-site with test kits or transport samples between sites. This is especially useful if you cannot analyze samples immediately or cannot afford to congest your office with multiple patients testing over the length of time needed for sample collection with immediate analysis.

Use of this system is extremely simple and ensure the best extraction of patient samples from QuinTron evacuated tubes. Minimal maintenance requirements and no necessity for calibration make this accessory extremely beneficial and easy to use and maintain for nurses/staff or technicians of any type.

#### Products that are for use with the SamplXtractor Model SX-2 Plus are:

#### easySampler System

The patented\* EasySampler allows patients to collect samples off-site or in-house unsupervised for later analysis and only recommended for patients that can follow simple verbal and written instructions.

Kits are provided with easy instructions and all necessary supplies for the patient to perform the test, and are designed for easy and safe transport.

Each kit can be customized with your own literature, protocol, substrate and mailing labels.<sup>†</sup>

Samples can be stored for up to 14 days with minimal to no loss in sample integrity.

	TAKE HOME KITS AVAILABLE:	- 11 C	1
Catalog Number: QT01200-EX	• Lactose	1 12 13 X X Y	
Specifications:	• Bacterial Overgrowth with Lactulose	A State	
Width: 6.5"	• Bacterial Overgrowth with Glucose	11.00	
Height: 5.5"	• Fructose		
Depth: 8"	• Sucrose	* US Patent # 5,467,776	
Weight: 3.75 lbs (1.70 kg)	• d-Xylose	EasySampler Test (Substr	ate Not Shown)
Power: 24 Volts D/C	Custom Kit development available		

Custom Kit development available



† Customized test kits its are available upon request and have development fees not included in the cost of standard kits.



3712 West Pierce Street, Milwaukee, WI, USA www.QuinTron-USA.com Phone: (800)542-4448 / (414)645-4222

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## Choosing the Right Breath Collection Kits

### AlveoSampler<sup>™</sup>



The AlveoSampler system is a disposable collection system used to collect alveolar air in a standard syringe for immediate analysis, and is the most commonly used sampling system.

Single-patient use of this device eliminates the danger of inter-patient crossinfection, and will save time and money related to the cost of cleaning and sterilizing reusable collection components.

This system can only be used in-house on any BreathTracker or MicroLyzer instrumentation. Each kit contains all the necessary supplies and substrate desired for collection.

GASAMPLER™



### KIDSAMPLER™



The GaSampler system is used for the sampling and storing of alveolar air for immediate or later analysis. This system is designed only for in-house testing on any BreathTracker or MicroLyzer instrumentation.

This system can be used by non-technical personnel, or even by the patient without supervision after an explanation of the procedure.

This system uses multiple parts which may be purchased separately of in a complete kit; all parts are sold as disposable except the multi-patient foil laminate collection bags which can be used multiple times over multiple patient collections if handled properly.

The KidSampler system is similar to the GaSampler, except it can utilize a mouthpiece or a face mask for pediatric collection. This system is designed only for in-house testing on any BreathTracker.

This system uses multiple parts which may be purchased separately of in a complete kit; all parts are sold as disposable except the multi-patient foil laminate collection bags which can be used multiple times over multiple patient collections if handled properly.

Other pediatric collection systems are available for babies and neonatal patients.

### **EASYSAMPLER**<sup>®</sup>



The patented EasySampler kit allows patients to collect samples off-site unsupervised for later analysis or can be used in-house as well, but is not recommended for patients who cannot follow basic directions.

Kits are provided with easy instructions and all necessary supplies for the patient to perform the test. Each kit can be customized with your own literature and mailing labels\*.

This system can only be used with the purchase of a BreathTracker SC or H2+ analyzer and SamplXtractor<sup>™</sup> system.

Samples can be stored for up to 14 days with minimal to no loss in sample integrity and are designed for easy and safe transport.



## AlveoSampler Collection System: Storage Limits/Transferring Samples



### **ALVEOSAMPLER SYSTEM:**

The AlveoSampler System is an economical and disposable device used to collect alveolar air samples for subsequent analysis. It permits one-patient use of a modified Haldane-Priestley tube.

The alveolar sample is drawn into a syringe from the end-expiratory air blown through the device. During expiration through the mouthpiece, a vented polyethylene bag with a medium-resistance leak is filled to indicate that adequate dead space volume has been exhaled. As exhalation continues, air is then steadily drawn into the syringe by the operator. The bag serves as a check-valve to prevent contamination of the syringe sample with atmospheric air as long as the patient keeps the AlveoSampler mouthpiece in his/her mouth.

Use of the AlveoSampler removes the danger of inter-patient cross-infection, and saves time and money by eliminating the costs of cleaning and sterilizing reusable products.

#### **STORAGE LIMITS:**

After the alveolar air sample is collected and the syringe has been removed from the collection mouthpiece, the sample may be immediately analyzed. QuinTron syringes can only hold a sample for no longer than 2 hours. If you cannot analyze the sample within that time, please transfer the samples into a Sample Holding Bag (QT00842-P). <u>dO nOT USe A SYRinGe THAT iS nOT COMp</u> <u>ATiBLe, iT CAn JeOp</u> <u>ARdiZe YOUR SAMpLe.</u> <u>See product Compatibility Section for Syringes that are compatible with breath hydrogen testing.</u>

#### TRANSFERRING SAMPLES TO A SAMPLE HOLDING BAG:

- 1. Ensure the stopcock is closed after collecting your patient sample in the syringe.
- 2. Insert another stopcock into the small port on the Sample Holding Bag.
- 3. Insert your Patient Sample Drying Tube into the stopcock on the Sample Holding Bag.
- 4. Attach the syringe with stopcock to the other end of the Patient Sample Drying Tube.
- 5. Open the stopcocks on the syringe and Holding Bag and inject the sample into the Sample Holding Bag.
- 6. Close the stopcock on the Sample Holding Bag to ensure no sample expires from the port.
- 7. Remove the Patient Sample Drying Tube and syringe from the Sample Holding Bag.
- 8. Repeat the same procedure with a new Sample Holding Bag for each sample you wish to store.
- 9. You may reuse the Patient Sample Drying Tube until it has fully expired.



# GaSampler<sup>™</sup> SPK (Single-Patient Kits)



### GASAMPLER SPK (SINGLE-PATIENT KITS):

QuinTron's GaSampler Single-Patient Kits are another disposable, economical and convenient solution for breath collection kits for in-house breath testing collection and analysis.

These kits are designed to collect alveolar breath samples from patients for immediate analysis with any BreathTracker or MicroLyzer system.

This system can be used by non-technical personnel, or even by the patient with minimal to no supervision after assembly and explanation of the procedure, saving you and your technicians valuable time during the testing procedure.

Each kit is packaged to include all necessary components with or without the challenge dose (substrate/sugar) for successful collections of breath samples from a single patient during the entire test.

Samples are removed from the collection bag which is then flattened to remove any excess breath sample prior to collecting the next sample. Patient ID Tracking Labels are included in each kit ensure the technician uses the correct components for a specific patient when more than one patient is being tested.

Single-patient use of this kit eliminates the danger of inter-patient cross infection, and will ultimately save time and money related to the cost of cleaning and sterilizing reusable collection components.

#### **STORAGE LIMITS:**

See storage limits for the GaSampler Storage Limits section in this book for storage time limits for the Single-Patient GaSampler Collection Bags.

CATALOG NUMBERS FOR THESE KITS ARE LOCATED IN THE COMMON PRODUCTS AVAILABLE FOR ORDERING SECTION.



## Storage Limits/General Information: GaSampler System

### **GASAMPLER SYSTEM:**

The GaSampler can be handled by untrained technicians (or even by a patient without supervision, after having its operation explained) to collect a sample of up to 750mL of alveolar air for subsequent analysis.

The GaSampler system consists of two collapsible bags, a Teeconnector, mouthpiece and one-way flutter valve. The first portion of an expired breath, containing "dead-space" air, is directed into the Discard Bag then the alveolar air is diverted to the Collection Bag, where the sample can be removed for analysis (or transferred to the Sample Holding Bag) for later subsequent analysis.



After the alveolar air sample is collected and the Collection Bag cap is securely in place, the sample can be immediately analyzed by withdrawing the sample from the stopcock attached to the small port.

There are two types of GaSampler collection bags: Single-Patient and Multi-Patient.

### **STORAGE LIMITS:**

Single-Patient Bags hold a sample for a maximum of 3 hours. Multi-Patient Bags hold a sample for a maximum of 6 hours. If you cannot analyze within this time frame you must transfer the samples into Sample Holding Bags (QT00842-P). *(See Sample Holding Bag section for proper transfer of samples)* 

### SINGLE-PATIENT COLLECTION BAGS:

- Designed to collect multiple samples from one individual patient for immediate analysis.
- Once finished with the test the Collection Bag should be discarded.



(Your Port/Port Caps may differ in color and/or style.)

### **MULTI-PATIENT COLLECTION BAGS:**

• Designed to collect multiple samples from patient; once the test is completed you may wipe the outside of the bag with soap and water to allow the bag to be used with another patient. These bags have a limited life span so careful attention is required to ensure that the integrity of the bags is maintained.



#### never reuse any products that has been used on a patient with a communicable or infectious disease!

#### REVIEW THE "GENERAL CLEANING PRACTICES" SECTION FOR FURTHER INFORMATION.



## Ordering Supplies: GaSampler System

### **DISCARD BAG:**

This disposable polyethylene bag is used to separate the "dead-space" air from alveolar air which goes into the Collection Bag.

Catalog #: **OT00843-p** - 400mL Single-Patient Discard Bag (sold as each)

### **GAS COLLECTION BAG:**

These bags are metallized to make it impermeable to gases, and laminated so it is heat-sealable. They have a one-way port to fit the Tee, and a Luer-fitting and stopcock for attaching a syringe.

Catalog #: <u>**OT00841-p**</u> - 750mL Multi-Patient Collection Bag (sold as each)

Catalog #: <u>**OT00844-p**</u> - 250mL Multi-Patient Collection Bag (sold as each)

Catalog #: <u>**OT00830-p**</u> - 750mL Single-Patient Collection Bag (sold as each)

Catalog #: <u>**OT00834-p</u>** - 250mL Single-Patient Collection Bag (sold as each)</u>

### **TEE-MOUTHPIECE ASSEMBLY:**

This assembly completes the GaSampler when used with a Collection Bag and Discard Bag. It includes a plastic Tee, a removable one-way valve and mouthpiece. These are sold as disposables. Each component of the Tee-Mouthpiece Assembly can also be ordered individually.

Catalog #: <u>OT00854-p</u> - Tee-Mouthpiece Assembly (sold as each)

### **DISPOSABLE MOUTHPIECES:**

Mouthpieces are inexpensive enough to be disposable, but they can be cleaned, disinfected and reused if desired.

Catalog #: <u>OT00991-p</u> - Plastic Mouthpiece (sold as each)

### **SAMPLE HOLDING BAG:**

These small 250mL bags are fabricated from the same gas impermeable material as the Collection Bag. Samples are transferred from the Collection Bag through the stopcocks (or by syringe), thus freeing the Collection Bag for additional sampling.

Catalog #: <u>**QT00842-p</u>** - 250mL Multi-Patient Sample Holding Bag (sold as each)</u>

### **BENZ-ALL DISINFECTANT:**

Benz-All® is a concentrated disinfectant for the reusable components of the GaSampler. One 40cc bottle of Benz-All is sufficient to produce one full gallon of ready-to-use disinfecting solution. Rubber and metal instruments need only be soaked for 15 minutes, but may be left in the solution longer if necessary. And while not a cold sterilizer, Benz-All may be used for the storage of heat sterilized instruments.

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Catalog #: **OT00993-p** - Benz-All disinfectant (1 box = 15 bottles)

Benz-All® is a registered trademark of Xttruim Laboratores, Inc.













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## KidSampler<sup>™</sup> Collection System Information

The KidSampler collection system (GaSampler system for small children) is designed to collect up to 250mL of alveolar air from children who can follow simple verbal instructions. For children who cannot blow voluntarily through a mouthpiece, you may alternatively attach a face mask to the Tee-Piece in lieu of a mouthpiece.

### KIDSAMPLER COLLECTION SYSTEM COMPONENT Ordering Information:

Catalog #: QT00854-P - Tee-Mouthpiece Assembly Includes: one Mouthpiece (QT00991-P), one Tee-Connector (QT00850-P), one Flutter Valve (QT00851-5P)

Catalog #: QT00843-P - 400mL, Single-Patient Discard Bag -

Catalog #: QT00834-P - 250mL, Single-Patient Collection Bag

Catalog #: QT00844-P - 250mL, Multi-Patient Collection Bag

Catalog #: QT00883-L - 7.0cm, Disposable Toddler Face Mask

Catalog #: QT00884-L - 8.5cm, Disposable Child Face Mask

Catalog #: QT00885-L - 9.0cm, Disposable Adult Face Mask

Catalog #: QT00842-P - 250mL, Multi-Patient Sample Holding Bag

If you decide to use a face mask or need replacement component parts for the tee-mouthpiece assembly, it is recommended to purchase the tee-mouthpiece assembly components separately.

#### **INDIVIDUAL COMPONENTS:**









## KidSampler<sup>™</sup> Collection System Information

#### **Assembly:**

1. Assemble the Tee-Mouthpiece Assembly (QT00854-P). (If using a face mask, attach the face mask in place of the mouthpiece)

- 2. Attach the Discard Bag (QT00843-P) to the other end of the Tee-Connector in line with the Mouthpiece.
- 3. Insert the  $90^{\circ}$  side arm of the Tee-Piece into the large port on the Collection Bag.
- 4. Attach a stopcock (closed) into the small luer taper port on the Collection Bag.
- 5. If your patient weighs less than 100lbs/40kg, roll the Discard Bag down according to the scale printed on the bag to the approximate weight and staple or clip at that level. If your patient weighs 100lbs/40kg or more do not scale the Discard Bag down.

#### **COLLECTING A SAMPLE:**

After an approximately normal inspiration (avoid filling the lungs maximally), the patient places the Mouthpiece in his/her mouth, forming a tight seal around it with their lips. For children or patients who cannot understand the purpose of the procedure, it may be necessary to use a nose-clip, or just have them squeeze their nose, to assure that all the expired air goes through the mouth and into the Collection Bag. A normal expiration is then made through the mouth (do not blow hard) to empty the lungs of as much air as required to provide the alveolar sample. The first portion of the expired air will be used to fill the Discard Bag, after which the valves on the Tee-Piece and inside the Collection Bag will open (when the pressure goes up in the Discard Bag) and the remaining expired air will be diverted into the Collection Bag. When an adequate sample is collected, instruct the patient to stop expiring and remove the Mouthpiece.

### HANDLING YOUR SAMPLES:

After the alveolar air sample is collected in the Collection Bag and it is removed from the Tee-Piece, it can be analyzed immediately or stored in a Sample Holding Bag for later analysis. In either case, it is advisable to seal the large port with the collection bag port cap furnished with the collection bag. The use of the Port Cap assures the sample volume will not be lost due to a leak. Its use also prevents the contamination of the sample due to gas diffusion through the one-way valve leaflet in the large port if the sample is stored for a period of time prior to analysis.

The Collection Bag can be used to transport the sample to the analyzer or to transfer the sample into a Sample Holding Bag for storage before analysis. If the Collection Bag is needed for subsequent sample collections prior to analyzing the previous samples, it may be economical to store the sample a Sample Holding Bag (QT00842-P). *(See Sample Holding Bag section for proper transfer of samples)* 

The luer-taper syringe port on the Collection Bag is sealed with a plug and/or stopcock to prevent loss of sample during the collection and storage. By placing a finger on the back of the bag under the syringe port, you can close the small opening by pressing on the edge of the flange with your thumb. This will prevent the loss of sample from the bag while the plug is removed or stopcock is opened, and a syringe is put into the sampling port. The sample can then be drawn into the syringe for analysis.







## EasySampler<sup>TM</sup> Collection System



### EasySampler System:

The patented EasySampler System (US Patent # 5,467,776) was

designed to provide a method for filling vacuum tubes with a sample suitable for analysis with BreathTracker and MicroLyzer instrumentation which have the ability to detect Carbon Dioxide (CO<sub>2</sub>). It is necessary to use instrumentation which measure CO<sub>2</sub> because there are sources of sample dilution which require correction when the samples are analyzed. There is a residual volume of air in the tube, although it is evacuated as far as practical in its preparation. There may be a slight contamination with dead space room air during sample collection. Since the volume of the tube is limited to about 12mL and the sample loop (internal to the MicroLyzer SC or BreathTracker SC and H2+) may not completely flush, some residual carrier gas (room air) may dilute the sample in the sample loop.

The EasySampler is preferred by clinics and laboratories which analyze samples collected elsewhere and are mailed in for analysis. This is because of the convenience of the tube for handling, the stability of the sample in a glass tube which allows longer-term storage, and the simple, straight-forward technique of using the EasySampler System. Sample dilution is not a problem because the BreathTracker SC and H2+ and MicroLyzer SC are designed to correct for dilution of the trace gases by reference to the decreased concentration of  $CO_2$ .

Ordinarily, a correction factor of 1.2 to 1.5 is required to compensate for all the factors contributing to sample dilution. The correction factor applied to each sample permits a reliable picture of the pattern of trace-gas response to the challenge-dose of sugar ingested for whatever test is performed.

It is necessary to use unsterile vacuum tubes without anticoagulant for the sample collection because standard sterile tubes contain high concentrations of  $H_2^{-1}$  which will contaminate the sample. QuinTron recommends using only vacuum tubes provided by QuinTron for assurance of accurate samples.

### **STORAGE LIMITS:**

After the alveolar air sample is collected in the vacuum tube and the tube has been removed from the Tube/Needle holder, the sample may be immediately analyzed or stored for up to 14 days. After 14 days,  $CO_2$  may begin to decrease and the correction factors may become skewed. The tubes can be transported by truck or air without affecting the samples within the tubes when packaged correctly and analyzed within the required time frame.

1. Jensen, W.E.; O'Donnell R.T.; Rosenberg, I.H.; Karlin, d.A.; Jones, R.D. Gaseous contaminants in sterilized in evacuated blood collection tubes. Clim Chem. 1982;28:1406





## BabySampler<sup>TM</sup> Breath **Collection System Information**

A modified Hans Rudolph miniature non-rebreathing valve is combined with a disposable (single-patient) face mask and QuinTron's gas-impermeable Mini-Collection Bag, to permit the reliable collection of expired air samples from infants. A luer fitting on the collection bag permits the sample to be transferred to a syringe for storage and subsequent analysis. The 250mL bags fit the exhaust port of the non-rebreathing valve and have luer fittings which allow sample transfer with a syringe.

The collection bags (QT00844-P) are reusable, but inexpensive enough to be disposable if infection transmission might be a concern.



### **NEONATAL COLLECTION SYSTEM COMPONENT ORDERING INFORMATION:**

- Catalog #: QT00859-P Low-Deadspace, One-way, Non-Rebreathing Valve
- Catalog #: QT00855-P Disposable Adapter, Neonatal Mask to Tee-Piece
- Catalog #: QT00834-P 250mL, Single-Patient Collection Bag
- Catalog #: QT00844-P 250mL, Multi-Patient Collection Bag
- Catalog #: QT00881-L 5.25cm, Disposable Neonatal Face Mask
- Catalog #: QT00882-L 6.0cm, Disposable Infant Face Mask

Catalog #: QT00883-L - 7.0cm, Disposable Toddler Face Mask

#### LOW-DEADSPACE, ONE-WAY, NON-REBREATHING VALVE IN DETAIL

This non-rebreathing valve comes fully assembled and should not be modified or tamperred with.



## Sample Holding Bag Product Information

The Sample Holding Bag (QT00842-P) is a small bag of about 250mL capacity which is used to hold samples until the analyses can be completed. It is similar to the Mini-Collection Bag, except that it is equipped with only a sample small port and has no large port. (Custom sizes are also available)

When using a GaSampler system for sample collection, you can transfer samples directly from the Collection Bag into the Sample Holding Bag through a male-male connector which is supplied with the order for the Sample Holding Bags.

When using a AlveoSampler System to collect samples, the samples can be transferred into the Sample Holding Bags via the syringe used for sample collection and analysis at a later time.

The Sample Holding Bag volume is sufficient to allow several analyses with the BreathTracker/MicroLyzer, and they are inexpensive enough for the GaSampler system to be used for the



collection of additional samples so they can all be analyzed at the same setting.

**GaSampler Users:** It is recommended that a stopcock be put into the small luer port of both the collection bag and Sample Holding Bag prior to transferring the sample, to minimize losing or altering sample composition when it is transferred to the syringe.

### **STORAGE INFORMATION FOR THE SAMPLE HOLDING BAGS:**

- Prior to transferring samples into Sample Holding Bags from whichever collection device you used for • collection, it is recommended to dry the patient sample prior to storage by using the Patient Sample Drying Tube filled with Drierite<sup>®</sup>.
- Each Sample Holding Bag is designed to store a single breath sample for as long as 2 weeks with minimal • loss in sample integrity. These bags do not come in contact with patients directly and can be reused across multiple patients\*.
- When it is time to analyze the sample, withdraw from the small port with a syringe/stopcock.
- After the sample is analyzed, flatten the bag and withdraw any remaining sample out with a syringe until • you feel back pressure on the syringe plunger.

\*If you plan to reuse the bags for multiple patients, please review the section "General Cleaning/Sterilization Practices."

Drierite® is a registered trademark of W.A. Hammond Drierite Company, Ltd.



## Product Information: Indicating Drierite®

Indicating Drierite<sup>®</sup> is saturated with cobalt chloride. Indicating Drierite is blue when dry and changes to pink upon absorption of moisture. The color change is pronounced and clearly visible. This makes Indicating Drierite valuable when it is necessary to know with certainty that dryness is being maintained and to signal when the drying agent should be replaced.



Drierite is used to remove water vapor in patient breath samples prior to analysis or storage of samples. All QuinTron instrumentation utilize Drierite in some fashion. The use of Drierite is critical to keeping moisture out of your instrument. By using no Drierite (or allowing Drierite to expire), the following can occur: damage to the internal components, delays/damage in the instrument's sensor recovery, and adverse impact on patient sample results. If an instrument is damaged due to neglect in properly using this product, any service work may not be covered under warranty.

Drierite is typically poured into the Patient Sample Drying Tube (QT01135-K) which is inserted into the Sample Port on the instrumentation. When the Drierite is 3/4 expired (pink) the technician/end-user will empty the drying tube and replace the contents with fresh Drierite. Drierite absorbs small amounts of carbon dioxide (CO2) unless conditioned properly before use. Users which have instrumentation that utilize the CO<sub>2</sub> sensors are urged to condition the drying tube that has been filled with fresh Drierite with 60mL of calibration gas each time the expired Drierite is replaced to ensure that the Drierite does not absorb the CO<sub>2</sub> in the patient samples.

Users of the MicroLyzer Model 12i/12i+ and DP also utilize Drierite on the Front Panel Drying Tube. The Front Panel Drying Tube contents should also be changed when 3/4 of the Drierite inside has expired.

Users of the MicroLyzer CM series (including CM2 and CM2+) do not utilize Patient Sample Drying Tubes and therefore should not order Drierite. Users of the MicroLyzer CM series models should order the SivRite-10 cartridges which does contain Drierite, but also Molecular Sieve for separation of gases since these models do not have an internal column to assist with separation of patient gases.

10/20 Mesh Indicating Drierite Desiccant -<u>QT01156-C</u>



QT01135-K Sample Drying Tube All Models Except CM Series



Front Panel Drying Tube MicroLyzer 12i/12i+/DP Only



Drierite® is a registered trademark of W.A. Hammond Drierite Company, Ltd.



## QuinGas<sup>TM</sup> General Information

**QUINGAS:** QuinTron's special calibrating gases are used to calibrate breath-trace analyzers. They are checked against a primary standard prepared gravimetrically with NBS (National Bureau of Standards) traceable weights. Each cylinder is analyzed individually, with an error no greater than  $\pm 0.05\%$  absolute or  $\pm 2$  parts per million (ppm) of any component, which ever is less. Standard mixtures for MicroLyzers are 100 ppm H<sub>2</sub>, 50 ppm CH<sub>4</sub>, and 5% CO<sub>2</sub> nominal, with the actual analysis listed on the cylinder. Standard mixtures for BreathTrackers are 150 ppm H<sub>2</sub>, 75 ppm CH<sub>4</sub>, and 6% CO<sub>2</sub> nominal, with the actual analysis listed on the cylinder.

On request, QuinGas can be supplied as custom <u>dilutions</u> of the standard mixtures. *(Special dilution and set-up charges apply for custom gases)* 

QuinGas is provided in 1-liter totally disposable cylinders at ~250 pounds per square inch (psi) pressure. This is equal to ~17 liters of gas at atmospheric pressure. The cylinders have a regulating valve with a Luer-taper fitting, so they mate with a standard syringe for transferring the sample to the instrument. The valve is controlled with your hand for easy and safe operation.

**QUINGAS TANK STAND:** The QuinGas Tank Stand is an acrylic table-top stand designed to hold a cylinder(s) of QuinGas and some relevant supplies, like a syringe, the QuinTron screwdriver, valve removal tool, pencils, etc. Its use prevents the cylinder from rolling off the table, and keeps the area neat and orderly. These stands also have skid-proof, mar-proof rubber feet on the acrylic frame. The United States Occupational Safety and Health Administration (OSHA) requires the use of some type of securement for compressed air gas tanks, including QuinGas tanks.

**OUINGAUGE (PRESSURE GAUGE):** Used to measure the pressure in the QuinGas cylinder before it is empty, to indicate when a replacement cylinder should be ordered.

#### **SUPPLY ORDERING INFORMATION:**

Catalog #: QT07006-G - QuinGas Safety Tank Stand (holds three (3) tanks) Catalog #: QT07008-G - QuinGauge (Pressure Gauge) Catalog #: QT02592 - QuinGas Valve Removal Tool (For Safe Disposal of QuinGas Tanks)

#### BREATHTRACKER STANDARD CALIBRATING GASES ORDERING INFORMATIVAR Removal Tool

Catalog #: QT07210-G - QuinGas-1, 150ppm  $H_2$  (BreathTracker H2) Catalog #: QT07220-G - QuinGas-2, 150ppm  $H_2$ , 75ppm  $CH_4$  (BreathTracker DP) Catalog #: QT07225-G - QuinGas-2, 150ppm  $H_2$ , 6%  $CO_2$  (BreathTracker H2+) Catalog #: QT07230-G - QuinGas-3, 150ppm  $H_2$ , 75ppm  $CH_4$ , 6%  $CO_2$  (BreathTracker SC)

### MICROLYZER STANDARD CALIBRATING GASES ORDERING INFORMATION:

Catalog #: QT07011-G - QuinGas-1, 100ppm H<sub>2</sub> (MicroLyzer CM Series, 12i Series) Catalog #: QT07021-G - QuinGas-2, 100ppm H<sub>2</sub>, 50ppm CH<sub>4</sub> (MicroLyzer DP Series) Catalog #: QT07031-G - QuinGas-3, 100ppm H<sub>2</sub>, 50ppm CH<sub>4</sub>, 5% CO<sub>2</sub> (MicroLyzer SC)





## QuinGas<sup>TM</sup> Proper Use and Disposal

### **PROPER USE:**

The QuinGas transfer valve is used to remove calibration gas from the QuinGas cylinder for analysis in your BreathTracker breath-testing instrument.

- 1. Attach a 1-way stopcock to an approved QuinTron syringe.
- 2. Insert the blue transfer valve into the threaded opening on the top of the QuinGas cylinder. (Figure 1a) <u>dO nOT pUSH dOwn On THe TRAnsFer VALVe YeT!</u>
- 3. Insert the syringe with stopcock into the small opening on the transfer valve. (Figure 2a) <u>MAke SURe THAT THe STOpCOCk iS Open.</u>
- 4. <u>GenTLY</u> press down on the transfer valve to fill the syringe with <u>at least</u> 20 mL of calibration gas.
- 5. Close the stopcock and remove the syringe with stopcock. (Figure 3a)

The transfer valve should also be removed from the top of the QuinGas cylinder when not in use.

FAILURE TO REMOVE THE TRANSFER VALVE WHEN NOT IN USE MAY LEAD TO LOSS OF CALIBRATION GAS.

Press down gently and slowly, make sure that your stopcock is open when applying pressure to the blue transfer valve.



Figure 1a



Figure 2a



Be sure to stop applying pressure and close the stopcock before removing the syringe from the blue transfer valve.

Figure 3a

### **DISPOSAL:**

This tank disposal tool is used to release the remaining gas in the QuinGas cylinder for safe disposal.

- 1. Insert the valve removal tool into the threaded top of the tank.
- 2. Wiggle the tool until it catches the valve stem.
- 3. Twist the tool to the counter-clockwise 10 times to loosen the valve. *The cylinder valve does not need to be removed.*
- 4. Recycle cylinder. do not dispose of your valve tool.

#### Tank disposal Tool - Catalog number - QT02592

Varying local regulations exist across the country regarding recycling and what may or may not be acceptable for land-fill sites. The best thing is to recycle the cylinders so the metals can be reclaimed, but this may not be practical for your office. You will need to contact your local waste management company for more specific instructions if you require them. <u>Always disengage the valve for safe disposal.</u>



## Protocols for Breath Hydrogen/Methane Tests

Lactose: Mix 1 gram (gm) of lactose for each kg of patient's body weight (max of 25gm) into 6-8oz. of water.	Collect baseline sample, administer lactose. Collect additional samples every hour for three hours. (4 samples total)	Breath $H_2$ increases at least 20ppm <u>or</u> breath $CH_4$ increases 12ppm over the lowest preceding value within the test period <u>or</u> combined breath $H_2$ and $CH_4$ increases at least 15ppm may be indicative of a positive study.
Fructose: Mix 1 gram (gm) of fructose for each kg of patient's body weight (max of 25gm) into 6-8oz. of water.	Collect baseline sample, administer fructose. Collect additional samples every hour for three hours. (4 samples total)	Breath $H_2$ increases at least 20ppm <u>or</u> breath $CH_4$ increases 12ppm over the lowest preceding value within the test period <u>or</u> combined breath $H_2$ and $CH_4$ increases at least 15ppm may be indicative of a positive study
Sucrose: Mix 2 grams (gm) of sucrose for each kg of patient's body weight (max of 50gm) into 6-8oz. of water.	Collect baseline sample, administer sucrose. Collect additional samples every 30 minutes for three hours. (7 samples total)	Breath $H_2$ increases at least 20ppm <u>or</u> breath $CH_4$ increases 12ppm over the lowest preceding value within the test period <u>or</u> combined breath $H_2$ and $CH_4$ increases at least 15ppm may be indicative of a positive study
Small intestinal Bacterial Overgrowth (S.I.B.O.) #1: Mix 1 gram (gm) of lactulose for each kg of patient's body weight (max of 10gm) into 6-8oz. of water.	Collect baseline sample, administer lactulose. Collect additional samples every 20 minutes for three hours. (10 samples total)	An increase of at least 20ppm within the first 2 hours (small intestine) followed by a larger peak (colonic) may be indicative of a positive study. <b>note</b> : Some studies do not present statistical double peaks, but plateau instead.
Small intestinal Bacterial Overgrowth (S.I.B.O.) #2: Mix 1 gram (gm) of glucose for each kg of patient's body weight (max of 100gm) into 6-8oz. of water.	Collect baseline sample, administer glucose. Collect additional samples every 20 minutes for three hours. (10 samples total)	$H_2$ or $CH_4$ increases at least 12ppm over the lowest preceding value within the test period may be indicative of a positive study.
d-Xylose: Mix 1 gram (gm) of d-Xylose for each kg of patient's body weight (max of 25gm) into 6-8oz. of water.	Collect baseline sample, administer d-Xylose. Collect additional samples every 20 minutes for three hours. (10 samples total)	An increase of $H_2$ or $CH_4$ after 60 min. may be indicative of intestinal transport capacity. Note: If an increase in $H_2$ or $CH_4$ occurs prior to 60 min., SIBO is suspected and a test should be performed.
Sorbitol: Mix 0.25-0.50gm of sorbitol for each kg of patient's body weight (max of 10gm) into 6-8oz. of water.	Collect baseline sample, administer sorbitol. Beginning 40 minutes after ingestion of sorbitol, collect samples every 10 minutes until the H2 and/or CH4 rise 3ppm over the previous level for at least 3 successive intervals. Reduce samples to 20 minutes after 2 hours.	If breath $H_2$ increases over 30ppm and the patient is experiencing cramping, the test may be indicative for sensitivity to sorbitol.

<u>do not stop any testing early without the physicians approval.</u> Physicians may alter the protocols or their interpretations depending on their patient/office needs. However, if any portions of the above protocols have been modified, QuinTron may not be able to assist with testing questions you may encounter.



# LAC Breath Test Kit Program

The **LAC\_CHECK** breath-test kit program is designed to allow physicians and practices to determine if the business of breath-testing is practical for their practice without investing in any instrumentation. This program is free of charge to enroll in, there are no annual fees or costs for any breath-test kits or shipping<sup>\*</sup>. Patients can perform the test at home or in the office under supervision and the test is reimbursable under CPT code 91065.<sup>\*\*</sup> This program is only available in the United States.

#### **BASICS OF THE PROGRAM**

Kits acquired through the program must be ordered by a physician or physician's office. Kits must be shipped to the office/facility and then dispersed by the office to the patient. The test kits contain all necessary components and paperwork for the patient to successfully complete the test. Physicians should consult and prepare patients for the test by reviewing the procedure for collection of samples and help with any insurance paperwork. The test is then performed by the patient, either at home or in the physician's office. Once all the breath samples have been collected, the kit should be returned to the address printed on the outer packaging.

All kits returned to QuinTron's exclusive laboratory will be analyzed on top-of-the-line BreathTracker SC instrumentation, which provides the highest level of accuracy in measurement of trace gases.

#### **PHYSICIAN INSURANCE AND BILLING INFORMATION:**

The CPT code generally used by physicians ordering LacCheck kits is 91065, with a modifier of -26 attached to the code and can be written as 91065-26. This denotes the professional component as separate from the technical component of the test which is billed directly by the laboratory.

In order to prove medical necessity for the breath test, the proper diagnostic codes must be provided to the laboratory by the physician.

#### Some codes that may be applicable are:

- 271.3 Intestinal disaccharidase deficiencies and disaccharide malabsorption
- 271.9 Unspecified disorder of carbohydrate transport and metabolism
- 558.9 Other and unspecified noninfectious gastroenteritis and colitis
- 564.9 Unspecified functional disorder of the intestine
- 579.9 Unspecified intestinal malabsorption
- 789.06 Abdominal pain

These tests are typically covered under Medicare and other insurance companies; patients are urged to speak with the laboratory that will analyze these kits to ensure that their insurance will cover the test or choose to pay out of pocket.

#### **QUINTRON'S LACCHECK KITS ARE ANALYZED BY:**

Commonwealth Labs, Inc. 320 Washington Street Norwell, MA 02061 Phone: (800) 292-9019

\*Shipping methods other than standard ground will be billed at cost. \*\*Insurance is billed directly by the laboratory analyzing the samples.

Physicians/offices can only bill for the professional component of the test which is CPT 91065-26.



3712 West Pierce Street, Milwaukee, WI, USA www.QuinTron-USA.com Phone: (800)542-4448 / (414)645-4222

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## Patient Preparation Guidelines for Testing

All patients are different and patient medical history unknown to QuinTron must be taken into consideration prior to and during any breath-testing procedure. These guidelines can be modified by the physician to accommodate patients with special needs. The avoidance of foods listed herein are not limited to only the foods outlined below, they help serve as an umbrella of foods to avoid. Any questions related to preparation should first be consulted with the patient's physician or nutritionist prior to consulting QuinTron.

#### THE GUIDELINES BELOW ARE TO BE FOLLOWED FOR ALL HYDROGEN BREATH TESTS.

- Patients will be NPO (Nothing by mouth) for 12 hours prior to the test. Only water may be consumed.
- Patients should avoid foods listed below 12 hours prior to the NPO request.
- No smoking, including second-hand smoke, for at least 1 hour before or at any time during the test.
- No sleeping or vigorous exercise for at least 1 hour before or at any time during the test.
- Recent antibiotic therapy, runny diarrhea or colonoscopies may affect these breath tests, therefore medical staff and physicians should consult with patients about these conditions prior to performing any test.
- If any of the above conditions apply, rescheduling the patient will most likely be necessary.
- Drinking water only during your breath-test is allowed in moderation.

Even though patients are NPO for 12 hours prior to the test, it is also required to avoid certain foods at least another 12 hours prior to the NPO request beginning.

Listed below are generic *avoidance* groups and are not limited to what is listed. If you and/or the patient are uncertain if something may affect the test, <u>dO nOT COnSUMe</u> the product and/or consult the physician.

- **GRAIN PRODUCTS:** Pastas, whole grains products (including cereals and melba toast), brans or high-fiber cereals.
- **FRUITS:** Fruit juices, applesauce, apricots, bananas, cantaloupe, canned fruit cocktail, grapes, honeydew melon, peaches, watermelon. Raw and dried fruits like raisins and berries. Yogurt which contains fruit.
- <u>VEGETABLES:</u> Vegetable juices, potatoes, alfalfa sprouts, beets, green/yellow beans, carrots, celery, cucumber, eggplant, lettuce, mushrooms, green/red peppers, squash, zucchini.
- <u>VEGETABLES FROM THE CRUCIFEROUS FAMILY</u>: Broccoli, cauliflower, brussels sprouts, cabbage, kale, swiss chard, beans, lentils, corn, etc.
- <u>NUTS, SEEDS, BEANS:</u> All nuts, seeds and beans, as well as foods that may contain seeds.
- <u>ALL DAIRY PRODUCTS (EXCEPT EGGS)</u>: Milk, cheese, ice cream, yogurt, butter.
- MEATS, PASTAS, CORN OR PRODUCTS THAT CONTAIN CORN (EXPECT THOSE LISTED BELOW)

#### SUGGESTIONS FOR THE PATIENT'S LAST MEAL TO CONSUME PRIOR TO NPO CAN BE:

- Baked or broiled chicken or turkey. (Salt and pepper only)
- Baked or broiled fish. (Salt and Pepper only)
- Plain steamed white rice.
- Eggs.
- Clear chicken or beef broth.

#### These guidelines are adapted from various hospital organizations and studies.

QuinTron has *not* developed these preparations or protocols for breath hydrogen testing; physicians have ultimate authority as to how they choose to prepare their patient for the breath test, in accordance with the physician's own interpretation guidelines.

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3712 West Pierce Street, Milwaukee, WI, USA www.QuinTron-USA.com



## Frequently Asked Questions

**IMPROPER PREPARATION OF THE PATIENT:** The inappropriate choice or incomplete avoidance of food by the patient on the night before the test will provide a high, but gradually falling level of hydrogen  $(H_2)$  on which the test will be superimposed. This is because the amount of fiber in the colon will be elevated at the beginning of the test, and will fall during the hours of the measurement. Even if  $H_2$  is produced from the challenge-dose of carbohydrate, it may not exceed the initial baseline level by enough to be classified as a positive test.

**SLEEPING:** Allowing the patient to sleep during the test will cause an increase in breath- $H_2$ . This probably has two causes. Hypoventilation, which is an inadequate rate of air turn-over in the lung, slows down the rate of  $H_2$ -removal from the blood. Sleep also decreases motility, which slows down the movement of carbohydrates through the colon and allows a longer time for  $H_2$ -production. Thus, intermittent sleeping during the test will interfere with its reliability and should not be allowed.

**HIGH BASELINES:** High fasting levels of trace gases at the beginning of the test may suggest that the patient did not follow instructions for complete avoidance of carbohydrate and fiber the night before; it also may suggest that the patient has small intestinal bacterial overgrowth (SIBO).

**NORMALIZING BREATH-GAS MEASUREMENTS:** One of the sources of error in trace-gas analyses is contamination of the alveolar sample with dead space air during its collection. The problem is minimized by properly using the QuinTron GaSampler system or the QuinTron Single-Patient AlveoSampler System to collect the alveolar sample. However, if they are not used according to instructions, or if the syringe is contaminated with room air during transfer of the sample to the BreathTracker or MicroLyzer, the H<sub>2</sub> and/or CH<sub>4</sub> in the sample may be diluted so that falsely low concentrations will be indicated. The BreathTracker SC, H2+ and MicroLyzer SC instruments can be used to correct the analysis of trace breath-gases for such contamination. It is based on the concept that carbon dioxide (CO<sub>2</sub>) is present in alveolar air at a virtually constant concentration, while it is essentially absent in room air. Therefore, if alveolar air is erroneously mixed with room air, the concentration of CO<sub>2</sub> will be reduced, as will that of any trace gases present in the sample. By knowing the degree to which the CO<sub>2</sub> was diluted, it is possible to apply a correction to the analysis of the trace-gases as well, thus being able to calculate the true "alveolar" concentration of the sample which was contaminated.

**SMALL INTESTINAL BACTERIAL OVERGROWTH (SIBO):** Bacterial overgrowth exposes the complex sugars and other soluble carbohydrates in the small intestine to bacterial fermentation instead of allowing them to be hydrolyzed enzymatically and absorbed in the relatively sterile intestine. If bacteria are introduced into the small intestine, they can survive and thrive in the nutritionally rich environment. As indicated above the harsh, acid environment of the stomach kills most bacteria, so there is a low bacterial count in the proximal part of the intestine (the duodenum and the jejunum). However, in achlorhydria (lack of acid production in the stomach) bacteria may pass into the small intestine and colonize there. Alternately, conditions of intestinal hypomotility ("blind-loop" syndrome or other causes of "stasis") permit bacteria to invade the small intestine from the colon. These conditions permit an increase in bacterial count to over 10<sup>5</sup> (100,000) bacteria per milliliter (mL) of intestinal contents, which defines the condition called "bacterial overgrowth." The condition leads to symptoms similar to those for carbohydrate malabsorption. It also destroys some vitamins, interferes with the absorption of fatty acids and competes for sugars and other foodstuff ordinarily absorbed in the jejunum. Thus, it is a serious digestive disturbance which can be treated effectively, but only if it is diagnosed.



## General Cleaning/Sterilization Practices

Most hospital infection committees insist that any part which can cause cross-contamination between patients be either sterilized or discarded after use. Follow the regulations for *your* institution.

#### If you don't already know, find out!

Elevated heat, chemicals and sterilizing gases reduce the life of plastic products. Good cleaning practices involve the following steps:

**DISASSEMBLE AND PREWASH:** This step allows the removal of particulate matter, and allows the surface to be cleaned (and if necessary, sterilized).

The one-way values should be completely disassembled so the value flaps and diaphragms can be thoroughly cleaned and dried. They can be disassembled without tools, washed, dried and then reassembled. It is recommended that any opposing surfaces be *lightly* greased and the value reassembled for storage, to prevent misplacing the components.

<u>CLEANING AND DISINFECTION</u>: Strict attention should be paid to temperature and chemicals used for the sterilization of plastic ware. Do not use temperatures at or exceeding 45°C or 113°F on plastic products. Thus, autoclaving must be avoided. Chemicals such as denatured alcohol or alcohol based solutions, or solvents such as acetone and all hydrocarbons should not be used. They may permanently fog, crack or discolor plastics and may also adversely affect your patient samples and/or our instrumentation when analyzed.

Mild soap (detergent) and warm water are particularly useful for cleaning plastic. Cold-sterilization solutions, such as Benz-All<sup>®</sup>, Cidex<sup>®</sup>, Sporicidin<sup>®</sup>, Metricide<sup>®</sup> or Glutarex<sup>®</sup> are acceptable disinfectants which should not damage plastic ware under ordinary use, though they may cause wrinkling and/or discoloration of rubber valve flaps, and, thus require their replacement.

**<u>RINSE AND DRY:</u>** The rinse procedure is important. Sterile water is recommended for rinsing after sterilization. Following adequate cleaning without sterilization, a distilled water rinse is recommended, but this is impractical in many laboratories.

A thorough drying is necessary. The valves and components are dried best in a warm-air oven kept below the temperature limit ( $45^{\circ}C/113^{\circ}F$ ). Thorough drying of the pieces minimizes the multiplication of bacteria on the plastic ware.

**INSPECT AND PACKAGE FOR STORAGE:** After each cleaning, inspect and verify that the item is clean and dry, and that it has not been deformed or cracked in the cleaning process. They should be reassembled and checked for proper function, then packaged appropriately for storage or reuse, according to your institution's protocol.

**CLEANING LAMINATED BAGS:** QuinTron's gas-impermeable bags can be cleaned on the external surface with soap and water and/or by wiping with a damp cloth. Its outer surface is not ordinarily sterilized.

No method is known which will guarantee to clean and sterilize the inside of the bag. You should replace the bag if it is suspected of being contaminated.

**DISCLAIMER:** QuinTron has collected this information from the suppliers of material used to manufacture products, and from the manufacturers of products offered for sale by QuinTron. We believe that the information is the best and most reliable which is available on the subject. However, QuinTron and its representatives assume no obligation or liability for any recommendation furnished or for results obtained with respect to this information, whether or not it is used as recommended.



### Common Products Available for Ordering

CATALOG #	DESCRIPTION	Additional Information
AlveoSampi	<u>Ler™ System Kits</u>	
QT00822-P	AlveoSampler Kit - Lactulose (SIBO)	Includes 10gm of unflavored lactulose
QT00827-P	AlveoSampler Kit - No Substrate	Does not include any substrate
QT00828-P	AlveoSampler Kit - Lactose	Includes 25gm of orange flavored lactose
QT02604	AlveoSampler Kit - Fructose	Includes 25gm of unflavored fructose
GASAMPLER	™ <u>Single-Patient Kits (GaSampler SPK</u> )	
QT00869-P	GaSampler Single-Patient Kit - Lactose	Includes 25gm of orange flavored lactose
QT00870-P	GaSampler Single-Patient Kit - Fructose	Includes 25gm of unflavored fructose
QT00895-P	GaSampler Single-Patient Kit - Lactulose	Includes 10gm of unflavored lactulose
QT00892	GaSampler Single-Patient Kit - No Substrate	Does not include any substrate
BREATH COL	LECTION BAGS - USED WITH GASAMPLER, KIDSAM	pler, <u>BabySampler</u>
QT00830-P	750mL Single-Patient Collection Bag	
QT00841-P	750mL Multi-Patient Collection Bag	
QT00834-P	250mL Single-Patient Collection Bag	
QT00844-P	250mL Multi-Patient Collection Bag	
QT00843-P	400mL Single-Patient Dead-Space Air Discard Bag	
QT00842-P	250mL Multi-Patient Sample Holding Bag	
ADDITIONAL	Components for Breath-Testing	
QT01122	Patient Timer for testing intervals	Alarms/Beeps with set minute intervals
QT01727-V	One-Way Plastic Stopcock	Used with all breath-testing systems
QT01741	30mL Bulk Non-Sterile Syringe	Most economical and commonly ordered
FACE MASKS	Adapters/Neonatal Supplies	
QT00881-L	5.25cm, Neonatal Face Mask	
QT00882-L	6.0cm, Infant Face Mask	
QT00883-L	7.0cm, Toddler Face Mask	
QT00884-L	8.5cm, Child Face Mask	
QT00885-L	9.0cm, Adult Face Mask	
QT00885-XL	10cm, Large Adult Face Mask	
QT00855-P	Disposable Mask Adapter	For Neonatal or Infant Masks
QT00890-P	ScissorValve <sup>™</sup> Collection Device	
DESICCANTS	FOR PATIENT SAMPLES AND INSTRUMENTATIO	<u>DN</u>
QT01156-C	10/20 Mesh Indicating Drierite®	All instruments (except CM series)
QT02658	Funnel, for filling Drying Tubes with Drierite	Used with Drierite 10/20 mesh
QT01154-C	SivRite-4 Desiccant	Required on all instrumentation
QT00436-J	SivRite-10 Refill Starter Kit	MicroLyzer CM Series Only
QT00435-J	SivRite-10 Refill Kit	MicroLyzer CM Series Only



### Common Products Available for Ordering

CATALOG #	DESCRIPTION	Additional Information
INSTRUMENT M	aintenance Products	
QT00527-T	Foam Filter Plugs (pack of 10)	Used with QT01135-K
QT00573-T	Snoop Leak Detector (1 oz. bottle)	
QT01135-K	Patient Sample Drying Tube	All instruments (except CM series)
QT01138-K	MicroLyzer 12i Front Panel Drying Tube	
QT01139-K	MicroLyzer DP Front Panel Drying Tube	
QT01140-K	Water Barrier/Dust Trap (pack of 5)	All BreathTracker instruments
QT002599	SamplXtractor Maintenance Kit	Model SX-2
QT09525/12-J	O-Rings, 1/4" (Pack of 12)	
QT900566-J	O-Ring Tool Set	Includes 25-1/4" o-rings and o-ring tool
QT900568-M	O-Ring Lubricant (1/2 oz. jar)	
QUINGAS <sup>TM</sup> CA	LIBRATION GAS TANKS	
QT07011-G	QuinGas-1 (100ppm H2)	MicroLyzer CM Series and 12i Series
QT07021-G	QuinGas-2 (100ppm H2, 50ppm CH4)	MicroLyzer DP Series
QT07031-G	QuinGas-3 (100ppm H2, 50ppm CH4, 5% CO2)	MicroLyzer SC
QT07210-G	QuinGas-1 (150ppm H2)	BreathTracker H2
QT07220-G	QuinGas-2 (150ppm H2, 75ppm CH4)	BreathTracker DP
QT07225-G	QuinGas-2 (150ppm H2, 6% CO2)	BreathTracker H2+
QT07230-G	QuinGas-3 (150ppm H2, 75ppm CH4, 6% CO2)	BreathTracker SC
Additional Co	<u>omponents For QuinGas Tanks</u>	
QT02592	QuinGas Valve Removal Tool	Used to disengage valve for tank disposal
QT07006-G	QuinGas Tank Safety Stand (Holds 3-Tanks)	OSHA requires tanks to always be secure
QT07008-G	QuinGauge Pressure Gauge	Used to check psi levels in QuinGas Tanks
QT01760-V	QuinGas Calibration Syringe (60mL)	Replace at least once every 6 months
SUGARS AND SU	<u>BSTRATES</u>	
QT02100-100-S	Maltose, 100gm Bottle	Special Order Item, Unflavored
QT02300-500-S	Glucose, 500gm Bottle	Unflavored
QT02350-100-S	Glucose Intolerance Orange Flavored Beverage	100gm pre mixed in 10 oz. water
QT02400-500-S	Lactose, 500gm Bottle	Unflavored
QT02425-S	Lactose, 25gm packet (LacTest® Brand)	Orange Flavored
QT02500-10-S	Lactulose, 10gm packet	Unflavored
QT02600-500-S	Sucrose, 500gm Bottle	Unflavored
QT02700-25-S	d-Xylose, 25gm packet	Unflavored
QT02800-500-S	Sorbitol, 500gm Bottle	Special Order Item, Unflavored
QT02900-25-S	Fructose, 25gm packet	Unflavored
QT02900-500-S	Fructose, 500gm Bottle	Unflavored
ADDITIONAL CO	MPONENTS FOR SUGARS AND SUBSTRATES	
QT02248	Sugar Scoop with conversion chart	



## Collection System Component Matrix

#### THE COLLECTION SYSTEM COMPONENT MATRIX CAN BE USED TO HELP END-USERS DETERMINE THE PRODUCT COMPONENTS UTILIZED IN EACH COLLECTION SYSTEM.

CATALOG # & DESCRIPTION	GaSampler™	KidSampler <sup>TM</sup>	BabySampler <sup>TM</sup>	Additional Info.
QT00830-P - 750mL Single-Patient Collection Bag	Х	Х		Includes: Large port cap and one-way stopcock
QT00834-P - 250mL Single-Patient Collection Bag	Х	Х	Х	Includes: Large port cap and one-way stopcock
QT00841-P - 720mL Multi-Patient Collection Bag	Х	Х		Includes: Large port cap and one-way stopcock
QT00844-P - 250ml Multi-Patient Collection Bag	Х	Х	Х	Includes: Large port cap and one-way stopcock
QT00842-P - 250mL Multi-Patient Sample Holding Bag	Х	Х	Х	Includes: One-way stopcock and male-male luer adapter
QT00843-P - 400mL Discard Bag	Х	Х		
QT00850-P - Tee-Piece Only	Х	Х		
QT00851-P - Flutter Valve for Tee-Piece	Х	Х		
QT00854-P - Tee-Mouthpiece Assembly	Х	Х		Product Assembled With: 1-QT00850-P, 1-QT00851-P, 1-QT00991-P
QT00855-P - Disposable Mask Adapter for Pediatric Face Masks			Х	Only needed for Infant and Neonatal Face Masks, attaches face mask to Tee-Piece.
QT00859-P - Low Deadspace - One-Way Tee-Piece Assembly			Х	
QT00881-L - 5.25cm, Neonatal Face Mask			Х	
QT00882-L - 6.0cm, Infant Face Mask			Х	
QT00883-L - 7.0cm, Toddler Face Mask		Х	Х	
QT00884-L - 8.5cm, Child Face Mask	Х	Х	Х	
QT00885-L - 9.0cm, Adult Face Mask	Х	Х		
QT00991-P - Universal Plastic Mouthpiece	Х	Х		
QT01727-V - One-Way Plastic Stopcock	Х	Х	Х	

#### **COLLECTION SYSTEMS**

Only products sold as "Multi-Patient" can be safely used inter-patient pending proper use, storage, handling and cleaning practices. <u>You should follow your institution's practices regarding disposable/inter-patient products.</u>

All other products not listed as Multi-Patient are for Single-Patient Use and are not recommended for reuse with different patients.



## BreathTracker Maintenance Matrix

#### THE BREATHTRACKER MAINTENANCE MATRIX CAN BE USED TO HELP END-USERS DETERMINE THE MAINTENANCE PRODUCTS UTILIZED IN BREATHTRACKER SYSTEMS.

	1100000	Contract Million	LIZER		
CATALOG # & DESCRIPTION	<u>SC</u>	<u>dp</u>	<u>H2</u> +	<u>H2</u>	Additional info.
QT01154-C - SivRite-4 Desiccant	Х	Х	X	Х	Attaches to Air-Intake port on the BreathTrack- er, replace when beads change color indicated on label.
QT01156-C - 10/20 Mesh Indicating Drierite <sup>®</sup>	Х	Х	X	Х	Used to remove water vapor in patient samples via Patient Sample Drying Tube. Replace contents when 3/4 pink.
QT07210-G - QuinGas-1 (~150ppm H <sub>2</sub> )				Х	Reorder when psi reaches below 50psi.*
QT07220-G - QuinGas-2 (~150ppm H <sub>2</sub> , 75ppm CH <sub>4</sub> )		Х			Reorder when psi reaches below 50psi.*
QT07230-G - QuinGas-3 (~150ppm H <sub>2</sub> , 75ppm CH <sub>4</sub> , 6% CO <sub>2</sub> )	Х				Reorder when psi reaches below 50psi.*
QT07008-G - QuinGauge, Pressure Gauge	Х	Х	X	Х	Used to check psi levels in QuinGas cylinders, replace if lost or broken.
QT02592 - QuinGas Valve Removal Tool	Х	Х	X	Х	Used to disengage valve on QuinGas cylinders for disposal.
QT01140-K - Water Barrier/Dust Trap (Package of 5)	Х	Х	X	Х	Should be replaced at least once every 6 months or if dirty/discolored.
QT01135-K - Patient Sample Drying Tube	Х	X	X	Х	Filled with Drierite, and 2-Foam Filter Plugs. Used in-line with instrument and patient sample.
QT00527-T - Foam Filter Plugs	Х	X	X	X	Used with Patient Sample Drying Tube and should be replaced periodically.
QT01741 - 30mL Bulk Non-Sterile Syringe	Х	X	X	Х	Used for injection of QuinGas into instrument or transferring of samples.
QT01735-V - 35mL Monoject Plastic Syringe	Х	X	X	X	Used for injection of QuinGas into instrument or transferring of samples.
QT01760-V - 60mL Monoject Plastic Syringe	X	X	X	X	Used for injection of QuinGas into instrument or transferring of samples.

#### Breathracker Models

All products listed above do not need to be replaced when analyzing multiple patient samples.

Maintenance materials are used to ensure longevity of the BreathTracker system. Failure to replace components when needed can result in:

damage to the product(s), adversely affecting patient samples, and voiding of your instrumentation's warranty!

If there are any questions regarding these products or their use please consult with QuinTron's Customer Service Department.

\*psi = pound per square inch \*ppm = parts per million

Drierite® is a registered trademark of W.A. Hammond Drierite Company, Ltd.



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## Usage Limits/Transferring Samples: GaSampler

### **Recommended Product Usage Limits:**

#### Single-Patient products are not to be cleaned and should be discarded after patient testing is complete.

Catalog #	description	Recommended Usage Limits
QT00830-P	750mL - Single-Patient Collection Bag (Unprinted) (Two Ports)	Replace each bag after 12-18 sample collections
QT00834-P	250mL - Single-Patient Collection Bag (Unprinted) (Two Ports)	Replace each bag after 12-18 sample collections
QT00843-P	400mL - Dead-Space Air Discard Bag	Replace each bag after each patient (Single Patient)

We expect the multi-patient collection bags to last for a respectable period of time, say for 10-20 patients, but *NOT* indefinitely. The number of uses for the bags is dependent on how the bags are handled.

Continuously filling the bags to their maximum volume causes the development of creases and wrinkles and also stretches the seams along the edges, resulting in both damaging the product and adversely impacting the integrity of the sample. Careful handling of the bags increases the length of use of the product and ensures the validity of the breath study.

The recommended usage limits indicated below are based on QuinTron's in-house testing; usage limits may not be the same for all facilities depending on how the bags are handled. Inter-patient cleaning is still recommended for all products that are sold/used as Multi-Patient.

\* Multi-Patient Collection Bags require special attention, see "Cleaning/Sterilization Practices" on laminated bags for more information.

#### TRANSFERRING SAMPLES TO A SAMPLE HOLDING BAGS:

- 1. Prior to collecting samples with collection bags it is advisable to insert a closed stopcock to the small port for easy transfer and/or withdraw from the Collection Bag for analysis.
- 2. After the breath sample is collected, remove the Tee-mouthpiece Assembly from the large port on the Collection Bag.
- Insert the bag port cap onto the large port securely.
  (Your port and/or port cap color/style may vary from the ones pictured)
- 4. Insert a stopcock into the small port on the Sample Holding Bag.
- 5. Insert your Sample Drying Tube into the stopcock on the Sample Holding Bag.
- 6. Attach the stopcock on the Collection Bag to the other end of the Patient Sample Drying Tube.
- Patient Sample Drying Tube
- 7. Open both stopcocks and gently apply pressure to the Collection Bag until an adequate sample volume is transferred into the Sample Holding Bag.

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- 8. Close the stopcock on both the Sample Holding Bag and Collection Bag to ensure no sample expires.
- 9. Remove the Patient Sample Drying Tube and syringe from the Sample Holding Bag.
- 10. Repeat the same procedure with a new Sample Holding Bag for each sample you wish to store.
- 11. You may reuse the Sample Drying Tube inter-patient until it has fully expired.



#### LACTOSe MALABSORpTiOn AnALYTiCAL ReCORd

Patient Name of	or #:		Γ	Date of Test:	
Weight:	DOB:	_			
Substrate Give	n			<u>Notes:</u>	
Nurse					
Referring Phys	sician				
Symptoms (Che	eck All That Apply):				
Nausea	Weight Loss	Diarrhea			
Vomiting	Weight Gain	Constipation	Bloating	Other	

<sup>+</sup> The CH<sub>4</sub>values can only be measured on the BreathTracker or MicroLyzer models SC or DP. Technicians are urged to document all values indicated by the instrument for the physician. The Corr, is the correction factor determined for the  $H_2$  and  $CH_4$  samples that are contaminated and are only available with the BreathTracker SC, H2+ and MicroLyzer SC. If your samples have a correction factor above 4, the sample is invalid.

Clock Sample Time ppm H <sub>2</sub> pp	$m \operatorname{CH}_4^\dagger \operatorname{CO}_2^{\circ}$ %	Corr.*			SA	MPLIN	IG SCI	HEDUL	.E & G	RAPH	
Baseline (BI )	150					= Hydrogen $CH_4$ = Methane $CO_2$ = Measured $CO_2$ Corr Correction Factor					
Test solution administered			140							+	$\square$
#1 - 30min			140								
			130								<b> </b>
2 - 60min			В 120								
ŧ3 - 90min			r 110 e								
			a 100 t								
4 -120min			h 90								
t5_150min			v 80	$\vdash$				+ $+$		+-+-	+-+
			a 70					+		+	$\square$
6 -180min			u 60								
The standard protocol or	nlv requires s	ample	s 50								
to be taken every 60 m	inutes for 3 h	nours.	p 40								
			m 30								
			20								+
Additional samples are optic	onal, and should be		10							+	$\square$
performed only by the approv	val of the physician	<u>ı.</u>	X=H <sub>2</sub> 0								
Do not stop the test early unless	<u>the physician appr</u>	oves.	0=CH <sub>4</sub>	3L 15	5 30	45 6	0 75	90 10	5 120 1	35 150 1	165 180
						Black	Hydroge	mes (n en Red	= Methan	ie	
Final Reading			Phys	ician	Signa	ature _					
				, Qu	This anal <u>y</u> inTron ac	ytical recor	d was desig ability for di	ned by Quin agnosis or	nTron and is sample valu	s to be used as les written on	a tool. this form.
QUINTRON 3712 West www.Quin	t Pierce Street, Milwauk nTron-USA.com	kee, WI, USA	39					©2010 - 0	QuinTron Ir	1strument Con	apany, Inc.

Phone: (800)542-4448 / (414)645-4222

### FRUCTOSe MALABSORpTiOn AnALYTiCAL ReCORd

Patient Name or #:			Date o	f Test:
Weight:	DOB:	г		
Substrate Given				<u>Notes:</u>
Nurse				
Referring Physician	n			
Symptoms (Check A	ll That Apply):			
Nausea	Weight Loss	Diarrhea		
Vomiting	Weight Gain	Constipation	Bloating	Other

<sup>+</sup> The CH<sub>4</sub>values can only be measured on the BreathTracker or MicroLyzer models SC or DP. Technicians are urged to document all values indicated by the instrument for the physician. \*The Corr. is the correction factor determined for the H<sub>2</sub> and CH<sub>4</sub> samples that are contaminated and are only available with the BreathTracker SC, H2+ and MicroLyzer SC. If your samples have a correction factor above 4, the sample is invalid.

Clock Sample Time ppm $H_2$ ppm $CH_4^{\dagger}$ $CO_2^{\circ}\%$ Corr.*	SAMPLING SCHEDULE & GRAPH											
Baseline (BL)	_ 150	H <sub>2</sub> = Hydro	ogen CH <sub>4</sub>	= Methane	e CO <sub>2</sub> = M	easured C	O <sub>2</sub> Corr (	Correction	Factor			
Test solution administered	140											
#1 - 30min	- 130											
#2 60min	120											
#2 - 00mm	- B r 110											
#3 - 90min	e - a 100						+					
#4_120min	t 00						$\square$					
#4 -120mm	_ 11 90						+					
#5 -150min	_ V _ 70					—	$\square$					
#C 190	a 70 I				+	—	$\vdash$					
#6 -180mm	_ u 60 e											
The standard protocol only requires sample	s 50											
to be taken every 60 minutes for 3 hours.	<sup>-</sup> p 40								40			
	m 30								30			
	20								20			
Additional samples are optional, and should be	10								10			
performed only by the approval of the physician.	X=H <sub>2</sub> 0-	31 15	30 4	5 60	75 90	105 1	20 135	150 16	 35180			
Do not stop the test early unless the physician approves.	0=CH <sub>4</sub>		00 4	Compli	70 00			100 10	100			
				Black = H	ydrogen	Red = $N$	Ites) Iethane					
Final Reading	Phys	ician S	Signatı	ıre								
		]	This analyti	ical record w	vas designed	l by QuinTr	on and is to	be used as	a tool.			
3712 West Pierce Street, Milwaukee, WI, US	SA	Qui	minon acco	epts no nabl	ing for diag	IUSIS OF SAII	ipic values	withen on t	.1115 101111.			

www.QuinTron-USA.com

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### BACTeRiAL OVeRGROwTH (SiBO) AnALYTiCAL ReCORd

Patient Name or a	#:							Г	)ate	of T	-st.					
Weight:	_ DOB:															
Substrate Given										<u>N</u>	otes:					
Nurse																
Referring Physici	an															
Symptoms (Check	All That Apply):															
Nausea	Weight Loss	Diarrhea														
Vomiting	Weight Gain	Constipa	tion	l	_ B	loat	ing			О	ther					
<sup>†</sup> The CH <sub>4</sub> values can only be r *The Corr. is the correction fa If your samples have a correct	neasured on the BreathTracker or MicroLy actor determined for the $H_2$ and $CH_4$ sampling factor above 4, the sample is invalid.	yzer models SC or les that are contami	DP. T inated	echnicians and are or	are urg ily avai	ed to d lable w	ocumer ith the	nt all va BreathT	lues in racker	dicated SC, H2	by the ir + and M	nstrum IicroLy	ent for tl /zer SC.	ie physio	cian.	
Sample Time	ppm $H_2$ ppm $CH_4^{\dagger}$ $CO_2^{\circ}$	6 Corr.*				S	AM	PLIN	IG S	CHE	EDUI	LE 8	& GR	APH	<u> </u>	
Baseline (BL)				150	H <sub>2</sub> = Hy	droge	ר CH₄	= Meth	iane	CO <sub>2</sub> =	Measur	ed CC	D <sub>2</sub> Corr.	- Corre	ction Fa	actor
Test solution administered				140												
1 - 20min				130										$\pm$	$\pm$	
2 - 40min			_	120										$\pm$	$\pm$	12
			́В r	110										$\Rightarrow$	$\mp$	<b>⊣</b> 1¹
<sup>±</sup> 3 - 60min			e a	100										$\mp$	$\pm$	<b>⊣</b> 1(
4 - 80min			t h	90										$\mp$	$\mp$	ç
15 100 :			v	80										$\mp$	$\mp$	3 –
5 -100min			a	70										$\mp$	$\mp$	$\exists 7$
ŧ6 -120min			u	60										$\mp$	$\mp$	76
ŧ7 -140min			e s	50											+	<u> </u>
			р	40											$\pm$	
*8 -160min			m	30												_ 3
¢9 -180min				20												_ 2
The standard to be taken	protocol only requires sampl every 20 minutes for 3 hours	<u>es</u> •	X=	10 н о <sup>.</sup>												1
Additional san performed only	nples are optional, and should by the approval of the physic	<u>l be</u> cian.	0=	CH <sub>4</sub>	3L 1	53	04	5 6 Sam	0 7 pling	5 90 g Tim	) 10 es (m	5 12 ninut	20 135 tes)	5 150	165	180
Do not stop the test	<u>t early unless the physician a</u>	pproves.						Black	= Hyd	lrogen	Red	1 = Mo	ethane			
Final Reading	·			Phys	iciar	n Sig	nati	ıre _								
C				5	Q	This a uinTro	nalytic n accep	al recor	d was o ability	lesigned for diag	l by Qui nosis or	inTron sampl	and is to e values	) be used written	1 as a to on this	ol. form.
QUINTRO	3712 West Pierce Street, Milwww.QuinTron-USA.com Phone: (800)542-4448 / (414	waukee, WI, US	A	41						(	- 2010 - QT	Quin7 02444	Fron Inst Rev C -	rument ( - Catalo;	Compar g/Info B	ıy, Inc. sooklet

### GLUCOSe MALABSORpTiOn/SiBO AnALYTiCAL ReCORd

Patient Name or #:							Г	)ate	of T	est.					
Weight: DOB:							L			0.51.					
Substrate Given									<u>N</u>	otes	:				
Nurse															
Referring Physician															
Symptoms (Check All That Apply):															
Nausea Weight Loss	_ Diarrhea														
Vomiting Weight Gain	_ Constipat	tion		_ B	loat	ing			С	the	r				
<sup>†</sup> The CH <sub>4</sub> values can only be measured on the BreathTracker or Mic $*$ The Corr. is the correction factor determined for the H <sub>2</sub> and CH <sub>4</sub> sa If your samples have a correction factor above 4, the sample is inval	roLyzer models SC or I amples that are contami lid.	DP. Te	echnicians and are or	are urg Ily avail	ed to de able wi	th the	nt all va BreathT	ues in racker	licated SC, H2	by the + and M	instrun MicroL	ient for t yzer SC.	he phy	sician.	
Sample Time ppm $H_2$ ppm $CH_4^{\dagger}$ CO	°2% Corr.*				S	AM	PLIN	IG S	CHE	EDU	LE	<u>&amp; G</u>	AP	<u>+</u>	
aseline (BL)			150	H <sub>2</sub> = Hy	droger	n CH <sub>4</sub>	= Meth	ane	CO <sub>2</sub> =	Measu	red C	⊃₂ Corr.	- Corr	ection	Facto
fest solution administered			140										$ \rightarrow $	$ \rightarrow $	
1 - 20min			130										$ \downarrow$	$ \rightarrow $	
2 - 40min		_	120										$\dashv$		
		B r	110												
3 - 60min		e a	100										$\dashv$	$\Rightarrow$	
4 - 80min		t h	90										$\dashv$	$\dashv$	
5 100		v	80										$\dashv$	$\dashv$	
5 -100min		v a	70										_	$\dashv$	$\square$
6 -120min		u u	60										$\dashv$	$\dashv$	
7 -140min		e s	50										$\square$	$\square$	
		р	40												
8 -160min		m	30										$ \rightarrow $		
9 -180min			20										$ \rightarrow $	$ \rightarrow $	
The standard protocol only requires sam	nples		10										$\Rightarrow$	$\Rightarrow$	
Additional assertion and shared and shared		X=  0=0	H₂ 0+ CH₄ B	H 3L 1	53	0 4	5 60	) 7	59	0 10	)5 12	20 13	5 15	0 16	 5 18
Additional samples are optional, and sho performed only by the approval of the phy	<u>uld be</u> ysician.		4				Sam	pling	g Tim	es (I	ninu d – M	l <b>tes)</b>			
Do not stop the test early unless the physician	n approves.						DIACK	- riyu	rogen	AC	a — 1VI	culane			
Final Reading			Phys	iciar	ı Sig	nati	ıre _								
-			-	Q	This a uinTro	nalytic 1 accep	al record ats no lia	l was d bility i	lesigned for diag	l by Qu nosis o	inTror r samp	and is to le values	o be us s writte	ed as a n on thi	tool. s form
<b>QUINTRON</b> 3712 West Pierce Street, J www.QuinTron-USA.com Phone: (800)542-4448 / (	Milwaukee, WI, US n 414)645-4222	A	42							©2010 O	- Quin T0244	Tron Ins 4 Rev C	trumen	t Comp	any, Ir Book

#### QuinTron instrument Company, inc. (Limited w arranty on BreathTracker instrumentation)

QuinTron Instrument Company ("QuinTron") warrants that the products, instruments and all components thereof purchased from QuinTron ("Product(s)") shall be free from defects in material and workmanship for a period of three (3) years from the date of delivery of the Products to the original retail purchaser or end-user of the Product ("Warranty Period"), as specifically set forth hereunder ("Limited Warranty"). For purposes of this Limited Warranty, the term "Products" shall not include the internal chromatographic separating column ("ICS Column"), unless the ICS Column performs poorly or is non-functional immediately upon receipt by the original retail purchaser or end-user, which notice shall be provided to QuinTron in writing not more than five (5) business days after delivery of the ICS Column. The term "Products" shall not include any wear and tear parts or other consumable parts and items for the Products.

Upon receipt of the Product by the original purchaser or end-user, QuinTron shall be provided with the Warranty Set-up Information Form provided with the Product to be registered with QuinTron. The Warranty shall be non-transferable except with prior written notice from QuinTron. To exercise this Limited Warranty, the original purchaser or end-user must be registered and QuinTron must receive written notice of a valid warranty claim within the Warranty Period, which includes the submission of a completed warranty information form and repair packing list ("Warranty Claim"), all sent to QuinTron at: QuinTron Instrument Company, Attn: Product Warranty Department, 3712 West Pierce Street, Milwaukee, WI 53215 – U.S.A. Contact QuinTron's customer service department at 414-645-4222 or toll free (within the Continental U.S. and Canada) at 1-800-542-4448 to obtain a warranty information form and repair packing list.

The Product(s) subject to the Warranty Claim must be made available to QuinTron at any place and time as designated by QuinTron for inspection, repair and/or replacement. If QuinTron determines the Product(s) subject to the Warranty Claim was/were defective in material or workmanship in the manufacturing process, in QuinTron's sole discretion, then the Warranty Claim shall be valid and QuinTron shall repair or replace, in QuinTron's sole discretion, the defective Product(s) within a reasonable time thereafter at no charge. This Limited Warranty shall not be applicable to, and a Warranty Claim shall not be valid for, defective Product(s) whereby the defect was caused, in part or in whole, by the action, inaction or misuse of the Product(s) by the retail purchaser or end-user, a shipper/carrier for the Product(s), or any other individual or entity other than QuinTron, as determined by QuinTron in QuinTron's sole discretion. The retail purchaser or end-user shall bear all costs in providing the Product(s) to QuinTron and QuinTron shall be responsible for all costs in returning the repaired or replaced Product(s) to customer or end-user for a valid Warranty Claim.

This Limited Warranty shall remain in effect for the Warranty Period only if, as determined by QuinTron in QuinTron's sole discretion, all of the following have occurred:

1. The Product(s) was/were operated and used at all times in accordance with the Owner's Manual for the Product(s);

2. There is no evidence of modifying, altering, tampering, mishandling, accidental damage, neglect or unauthorized use or repair done to the Product(s) by any individual or entity other than QuinTron;

3. The Limited Warranty was registered with QuinTron upon QuinTron's receipt of the Warranty Start-up Information form from the original purchaser or end-user prior to the occurrence of valid Warranty Claim;

4. The Product(s) was/were continually owned and maintained by the original purchaser or end-user, or a transferee expressly approved by QuinTron in writing; and

5. All other terms of this Limited Warranty set forth hereunder are complied with and/or satisfied.

#### This Limited w arranty shall be the only warranty, express or implied, for the product(s).

QUINTRON HEREBY DISCLAIMS ANY EXPRESS WARRANTY NOT PROVIDED HEREIN, AND ANY STATUTORY OR IMPLIED WARRANTY, GUARANTEE OR REPRESENTATION AS TO THE DESCRIPTION, PERFORMANCE, QUALITY, MERCHANTABILITY, COMPLETENESS, NON-INFRINGEMENT, FITNESS OR SUITABILITY FOR ANY PARTICULAR PURPOSE, AND ABSENCE OF HIDDEN DEFECTS OF/WITH THE PRODUCTS, WHICH BUT FOR THIS PROVISION, MIGHT ARISE BY IMPLICATION, OPERATION OF LAW, STATUTE, CUSTOM OF TRADE OR COURSE OF DEALING, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ALL OF WHICH ARE HEREBY EXCLUDED AND DISCLAIMED. THE PRODUCTS ARE SOLD ON AN "AS IS" AND "AS AVAILABLE" BASIS.

#### Disclaimer:

The Products are specifically designed for the purpose as set forth in the Owner's Manual for the Products and for no other purpose. The Products should only be used and operated by those skilled individuals that have read and fully understand the Owner's Manual and are of legal age and sound mind, and only in a manner consistent with its specifically designed purpose as set forth in the Owner's Manual.

THE REMEDY OF REPAIR AND REPLACEMENT PROVIDED FOR HEREIN SHALL BE THE CUSTOMER OR END-USER'S SOLE AND EXCLUSIVE REMEDY IN THE EVENT OF A BREACH OF THIS LIMITED WARRANTY. ADDITIONALLY, UNDER NO CIRCUMSTANCES SHALL QUINTRON BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, INCLUDING BUT NOT LIMITED TO, LOST PROFITS AND PUNITIVE DAMAGES, AND TO THE EXTENT ALLOWED BY LAW, FOR PERSONAL INJURY OF ANY PERSON AND FOR DAMAGE OR LOSS OF ANY PROPERTY, ARISING FROM THE OWNERSHIP, SALE OR USE OF THE PRODUCTS OR A BREACH OF THIS LIMITED WARRANTY, WHETHER BASED IN CONTRACT, TORT OR ANY FORM OF STRICT LIABILITY.



## QuinTron Product Return Policy

#### **GENERAL RETURN POLICY:**

You may return unopened/never used items sold and fulfilled by QuinTron Instrument Company within the time allowed based on product return allowances (contact QuinTron for the Return Information Sheet).

QuinTron will pay the return shipping costs if the return is a result of QuinTron's error. We will even supply you with a return shipping label that you can print out! However if the error is not due to QuinTron, you will be responsible for sending the product(s) back to QuinTron.

#### FEES/ REFUNDS:

All items returned to QuinTron are subject to a 15% restocking fee.

If the return is due to an error on behalf of QuinTron the restock fee will be waived.

Any item that is not in its original condition, damaged, have missing parts for reasons not due to an error by QuinTron, or have a return policy of zero (0) days will not receive a credit of any amount, and will result in an invoice to you for any additional shipping costs incurred by QuinTron for the shipping/receipt of the returned product. Outbound/Inbound shipping charges will result in an invoice to you unless QuinTron is at fault and shipping charges are marked as prepaid by QuinTron on the replacement/exchange order acknowledgement.

#### **HOW REFUNDS ARE ISSUED:**

Any mode of payments received for products or services will result in a credit to your customer account which can then be applied to future purchases. Use of credit for future purchases must be used with 12 months of issuance of credit.

No cash or direct monies will be refunded or issued.

#### EXCHANGES (Must be received within 2 weeks from date of RMA):

If you received a faulty item and need to exchange it for the same or different item, QuinTron must approve the exchange prior to any replacement product being issued. QuinTron will issue you a Return Material Authorization (RMA) which must be included with your returned product. If the RMA is not included with the return it may result in a major delay in your return and could result in a refusal of the return.

QuinTron will generate a replacement/exchange order which will reference your original Purchase Order number (if used). If this procedure does not meet your facilities return procedure you must let QuinTron know prior to requesting a replacement so we may make special accommodations. Once your replacement/exchange order is generated you will receive also an order acknowledgement. You must review the acknowledgement carefully. Any changes that need to occur must occur prior to the replacement product shipping. If QuinTron is responsible for paying outbound shipping costs the Freight Terms on the acknowledgement will state "Prepaid". If the acknowledgement states "Billed" or "Collect" in the Freight Terms section you will be paying for shipping of products. If this is not correct you must contact QuinTron prior to your replacement/exchange product shipping.

Only when we receive the original item will any potential credits be submitted for final disposition. You do not have to wait for us to receive the original item prior to placing an order for the replacement.



## **Contact Information**



### U.S. Office



www.QuinTron-USA.com

QuinTron instrument Company 3712 w est pierce Street Milwaukee, wi 53215 USA

Customer Service: Phone: (800) 542-4448 (Toll-Free US & Canada Only) Phone: (414) 645-4222 Fax: (414) 645-3484 E-mail: Sales@QuinTron-USA.com

Technical Support: (800) 542-4448 (Toll-Free US & Canada Only) (414) 645-3778 E-mail: Support@QuinTron-USA.com

### **European Union Office**



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