INTRODUCTION

The BreathTracker SC analyzer provides a quantitative measurement for both hydrogen (H_2) and methane (CH_4) in parts per million (ppm) and carbon dioxide (CO_2) as a percentage of an alveolar air sample. The addition of a stand-alone accessory, AlveoVac, provides an automatic extraction of breath samples from the approved Quintron breath collection device into the BreathTracker SC analyzer for analysis.

Performance Specifications for the BreathTracker SC analyzer

1. Temperature: optimal storage and operation temperature of 20.5 to 22 degrees Celsius.
2. Relative humidity: optimal operation within 25% - 60%
3. High humidity conditions will cause the desiccant consumables to be replaced more frequently. Atmospheric pressure: optimal operation and storage within 500 – 1000 hPa
4. BreathTracker SC and AlveoVac optimal performance requires purchase of compatible products which include any modifications from QuinTron Instrument Company, Inc. Use of incompatible products, i.e. Syringes and stopcock, void the warranty.
5. Avoid near contact with direct sunlight, carbon monoxide, smoking materials, alcohol, and silicone vapor.
6. Significant temperature changes can cause changes in sensor baselines which may result in inaccurate analysis results and error messages.

SPECIMEN COLLECTION, TRANSPORT & STORAGE

Patient breath samples collected according the ‘Patient Instruction Brochure’.

Samples must be analyzed within 14 days of the patient collecting them.

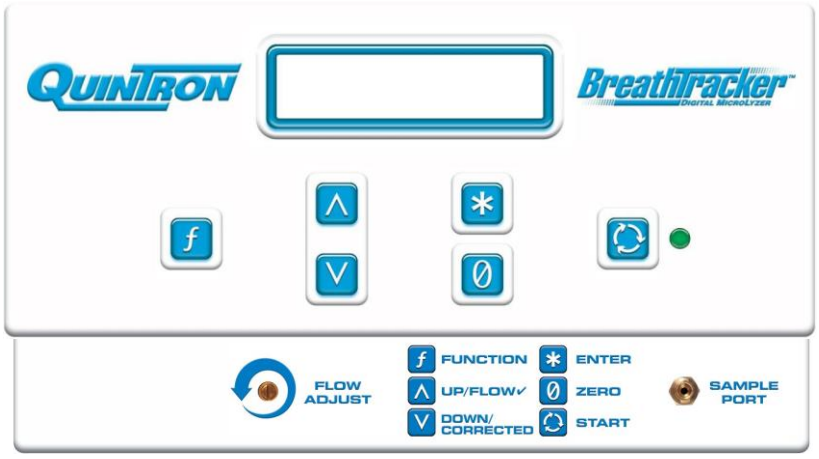
MATERIALS AND REAGENTS

1. Quintron BreathTracker SC
2. Quintron AlveoVac Extraction System

3. SivRite-4 room-air conditioning desiccant
4. Dust barrier
5. SamplXtractor (AlveoVac) vial adapter (blue)
6. QuinGas calibration gas.
7. QuinGas regulator
8. 30 ml plastic luer lock syringe, in 10ml increments.
9. 1-way plastic stopcock
10. Output extraction system tubing
11. Blue plastic vial adapter
12. Test tube rack

Important reminder about reagents:
When opening a new vial or container write the **DATE, TIME** opened and initial it.

Instrumentation Overview – FRONT



1. The **UP** key is a dual function switch. In the Data mode, the UP key increases the

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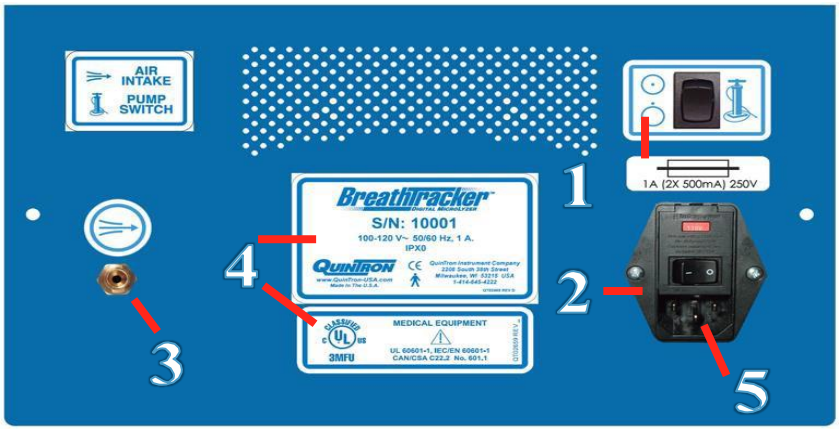
concentration for H_2, CH_4, or CO_2 to match the QuinGas calibration tank values. Pressing this key in the *Run Ready* or *Cal Ready* modes displays the flow rate.

2. The **DOWN** key is used to decrease the QuinGas calibration tank values within the Data mode. In the Run mode, this key allows the user to toggle between displaying "corrected" or "actual" analyzed concentrations.
3. The **ENTER** key is used to both access the menu and confirm settings.
4. The **ZERO** key clears the display in the *Run Ready* or *Cal Ready* modes.
5. The **START** key initiates sample analysis and also returns the system to the *Run Ready* mode after recovery is completed.
6. The Tri-color LED alerts the operator of the status of the analyzer.
   - Green (Solid): ready for sample analysis
   - Amber (Solid): analysis in process
   - Red (Blinking): analysis done, recovery in process
   - Green (Blinking): analysis and recovery complete (*Ready for next sample*)
7. The **FUNCTION** key is used by QuinTron Technical Support Staff.
8. **FLOW ADUST**: To adjust the flow rate of the analyzer to 60mL/min (± 3mL/min), insert the flat end of a screwdriver into the Flow Adjust screw. Turn the screw clockwise to decrease the flow rate or counterclockwise to increase flow rate.
9. **SAMPLE PORT**: Inject samples into the Sample Port for analysis.

PROCEDURE

Instrumentation Overview – BACK



1. **Pump Power** Switch On ⏻ / Off ○
2. **Main Power** Switch On | / Standby ◯
3. **Air Intake Port**: Connect the SivRite desiccant tubing to the Air Intake Port.
4. Identification and Safety Compliance Information for serial number and power rating.
5. Power Entry Module: Connect a compatible power cord here.

Warmup instructions

BreathTracker SC should remain powered at all times. To initialize warmup, both MAIN POWER and PUMP POWER must be turned ON.

In the event of a power failure, relocation of the instrument or change of SivRite-4, follow these guidelines:

1. Main power has been turned off more than 3 days.
   Warmup: minimum 48 hours required prior to analysis of samples.

2. Main power on for 48 hours or more with PUMP POWER turned off.
   Warmup: minimum 8 hours with pump powered on, required prior to analysis of samples

3. Relocation of analyzer
   Warmup: minimum of 2 hours required if analyzer has been turned on for at least 8 hours.

4. Installation of new SivRite-4 desiccant
   Warmup: minimum 2 hours required if analyzer has been turned on at least 8 hours.

Calibration

When to perform calibration:

- Immediately prior to analyzing samples.
- When the analyzer has been idle for at least 30 minutes prior to analyzing additional samples.
- After relocation of the analyzer.
- After replacing the SivRite-4 desiccant.

6. Confirm the analyzer has met the warmup requirements.

7. Press the ENTER key to access the main menu.

8. Press the UP key until "To Select Data" is shown. Press the ENTER key.

9. Press the UP or DOWN keys to match the H_2, CH_4, and CO_2 values printed on the QuinGas calibration tank label. If no change press OK and go to step 10. Press the ENTER key to accept each value and advance to the next screen. If no change is required, press ok and go to step 10.

10. Press the UP or DOWN keys to set the Alv. CO_2% concentration to 5.5%.

11. Press the ENTER key to advance to the "Cal Ready" display.

12. Inject a minimum of 20 mL of calibration gas into the sample port.

13. Press the START key to begin calibration. The calibration is complete is complete when the LED is blinking red; however, the end-user must wait for the LED to blink green before proceeding.

14. Confirm the values displayed match the calibration tank values within ± 3ppm for H_2/CH_4 and ±0.2% CO_2.

15. Wait for the recovery to complete which is indicated by a blinking green LED.

16. Press the START key to clear the sample.

Quality Control

Perform after a successful calibration when the analyzer recovery period is complete:

1. In the ***Run Ready***, or patient mode, inject a minimum of 20 mL of calibration gas into the sample port and press the START key.
2. Press the DOWN key when the analysis is complete.

   Values should be within ±3ppm for H_2/CH_4 and ±0.2% CO_2 compared to the displayed calibration values.

   If the values are not within the acceptable range, press START to clear the sample and repeat the calibration procedure.
3. Document the QC results on the QC chart.

Preparation of samples and documentation for testing

1. Accession the samples.
2. Attach the small bar-coded order number to the top of the requisition and large one on the SIBO log sheet.
3. Place a patient ICL label in the bottom right-hand side of the SIBO log sheet.
4. Unpack the sample, check tubes for cracks or breaks, line tubes in order as per requisition in the test tube rack ensuring they are marked #1 through #10.
5. Document any broken tubes on the SIBO log sheet.
6. Verify the sample tube labels match the requisition.
7. Verify the requisition and collection chart is complete.

8. If patient did not document the collection times on the requisition, transcribe the times from the tubes and document this on the requisition (i.e. Times transcribed from the tubes).

9. Complete the information on the SIBO RESULT LOG SHEET.

Sample Analysis

1. Complete the calibration and QC procedures.

2. Attach the blue end of the output tubing to the AlveoVac **out-port**.

3. Attach the clear end of the output tubing to the sample port on the BreathTracker.

4. Screw the dust barrier onto the **in-port** on the top of AlveoVac, then screw the blue vial adapter onto the top of the dust barrier.

5. Turn the main power switch on by flipping the switch up, the AlveoVac pump will initiate briefly and the startup screen will display.

6. Press the Enter key to enter the Main Menu of the AlveoVac.

7. Follow the onscreen prompts to enter the "Extract Sample" mode.

8. Gently push the glass vial straight onto the vial adapter piercing the septum of the vial. The vial adapter will hold the glass vial in place.

9. Press the **run** key to begin extracting the sample. The pump will run for three seconds. Do not remove the vial until extraction and analysis has completed.

10. After extraction is complete, press the **start key**  on your BreathTracker to begin analysis.

11. After analysis has finished, record the results, in duplicate, in the result chart. **Note: The analyzer does not store the data.**

12. Remove the vial from the vial adapter by pulling straight up on the vial.

13. Press ZERO to clear.

14. Repeat steps 8-12 until all sample tubes are completed.

15. Document on the back of the requisition when the specimen is processed. Proceed to step 16 if you are the person doing the report.

16. Forward results for reporting.

Preventative Maintenance

1. Replace the SivRite-4 desiccant when blue beads turn pink. (See SivRite-4 product label for instructions).

2. Replace the dust barrier(s) on the sample port and the air-Intake port every six months. Replace more often if dirty or discolored.

3. Replace output tubing if it is clogged, broken or has any visible particles inside.

4. After 400 samples are extracted, the AlveoVac will prompt the user on the display when it is time to change the vial adapter and dust barrier. Once the user changes the vial adapter and dust barrier, press the Enter key to reset the sample counter.

   If you must replace the vial adapter or dust barrier prior to the maintenance screen prompt (i.e. vial adapter breaks or is dull or dust barrier is dirty/clogged), press the Run key while in the scrolling main menu. Change the vial adapter and dust barrier, then press the Enter key to reset the counter.

Safety Precautions

The plastic vial adapters for AlveoVac contain plastic needles which are exposed when the adapter is connected to the in-port of the AlveoVac. Use caution when attaching to AlveoVac and when inserting vials, do not stick your finger into the adapter.

TROUBLESHOOTING

FLOW RATE MESSAGE

If the flow rate message appears, the analyzer must be adjusted to the optimal flow rate.

1. Using the QuinTron screwdriver, adjust the flow rate to 60 (±3) mL/min via the flow adjust. Press the ENTER  key to return to the previous screen.
2. Confirm that the operator is not pressing the UP  key in the in the *Run Ready* or *Cal Ready* screen.

"ERR"

1. Confirm the calibration tank has a pressure above 50 psi.
2. Confirm the consumables are not damaged (e.g. the syringes or stopcocks are not cracked)
3. Review Sections 8 and 9, attempt calibration again.
4. If "ERR" persists, contact QuinTron.

"OVR" / "MAX"

This message is displayed during calibration or patient sample correction when analyzed values are above the limit the BreathTracker can accurately measure. Confirm the SivRite-4 desiccant is NOT expired.

1. If "OVR" occurs during CAL, attempt calibration again and confirming SivRite-4 desiccant has not expired.
2. If "OVR" or "MAX" occurs during RUN (patient sample).
    a. Dilute the sample in syringe by 50% (e.g. 15mL sample + 15mL room air) and analyze again. If successful, press the DOWN  key and multiple the $H_2/CH_4/CO_2$ values by two.
3. If "OVR" or "MAX" persists, contact QuinTron.

Negative Values Displayed During Analysis

1. Re-calibrate the analyzer.
2. Perform the QC analysis.

3. If the problem persists, contact QuinTron.

UNABLE TO ADJUST FLOW RATE OR ZERO FLOW

1. Confirm Pump Power is ON.
2. Confirm the bottom seal on the SivRite-4 desiccant bottle has been removed.
3. Confirm the SivRite-4tubing and/or dust barrier from the desiccant bottle to the air-Intake port is not obstructed. This tubing can be removed while the pump is running to see if there are any changes in the flow rate.
4. If the problem persists, contact QuinTron.

ANALYZER READS CONSISTENT ZERO VALUES for all gases measured after extraction (including CO2).

1. Ensure that the output tubing from the AlveoVac to your gas analyzer is connected securely and in the correct direction. The blue luer end should be attached to the AlveoVac sample out-port and the clear check valve end of the tube should be attached to your gas analyzer.

2. Perform the **Sample Validity Test** below.
   - Detach the blue vial adapter from the sample in-port.
   - Withdraw 30mL of QuinGas (calibration gas) into a QuinTron syringe with stopcock attached.
   - Insert the syringe with calibration gas into the dust barrier on the Sample In-Port on the AlveoVac.
   - Open the stopcock on the syringe, activate extraction, and then watch for the syringe plunger to descend.
     - After extraction is complete, start analysis of the sample on your gas analyzer.

     If the extraction was successful and the **uncorrected** values displayed on the analyzer were within tolerance of the values listed on your QuinGas tank (tolerance: ± 3ppm H2/CH4, ± 0.2% CO2) then the BreathTracker and AlveoVac are operating properly.

     Confirm sample collection techniques are accurate.

     If the sample validity test was is unsuccessful, contact Quintron.

QUINTRON CONTACT INFORMATION

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REFERENCES

1. **Quintron BreathTracker SC product information sheet; www.breathtests.com**
2. **Biohealth Laboratory; www.biohealthlab.com/sibo**
3. **Quintron QTL0097 AlveoVac product information sheet**
4. **Quintron protocols and interpretation help sheet; 2013 Quintron**
5. **Quintron BreathTracker Preventative Maintenance Product List; SLPM14109 RevA**
6. **BreathTracker QTL0088 Rev D(corrected) Product Sheet; 2016**
7. **SIBO Breath Tests & Gastroenterology 1998; QT01605**

Record of Edited Revisions

Manual Section Name: Small Intestinal Bacterial Overgrowth Testing Procedure

Full document review included in all updates. Bi-annual review conducted when no revision had been made within 2 years.

Page Number / Item	Date of Revision	Edited by: