Package Insert
PyloPlus® UBT Kit for PyloPlus® UBT System
Breath Test for Detection of *H. pylori*
In vitro Diagnostic Medical Device
For Prescription Use Only

SECTION 1. PACKAGE INSERT
This package insert includes information for conducting the *H. pylori* breath test using PyloPlus® UBT (Urea Breath Test) System for analysis with the PyloPlus UBT Kit and PyloPlus® UBT Analyzer.
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All reference to ARJ in this document refers to the company ARJ Medical, Inc.

SECTION 2. INTENDED USE
The PyloPlus® UBT system is intended for use in the qualitative detection of urease associated with *H. pylori* in the human stomach and is indicated as an aid in the initial diagnosis of *H. pylori* infection in adults 18 years old and older. The PyloPlus® UBT system consists of the PyloPlus® UBT Kit and the PyloPlus® UBT analyzer. The analyzer is an infrared Spectrometer used for the measurement of the ratio of $^{13}CO_2$ to $^{12}CO_2$ in breath samples. The PyloPlus® UBT system is for use by trained health care professionals as prescribed by a physician.

Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician.

SECTION 3. SUMMARY AND EXPLANATION
Since the isolation of the spiral urease-producing *Helicobacter pylori* (*H. pylori*) bacteria in 1983 by Drs. Marshall and Warren, a significant amount of evidence is now present, indicating that the bacteria are an important pathogen in the upper GI tract of humans. *H. pylori* is associated with a number of GI conditions including chronic gastritis, peptic ulcer disease, and varying degrees of dyspepsia. Methods available for detecting current infection of the human stomach by *H. pylori* are generally divided into two (2) general types: Invasive and Non-invasive.
Invasive methods are so named because they include, as a first step, an esophagogastroduodenoscopy ("EGD") with collection of gastric biopsies. These biopsies are then examined by one or more detection methods: histological examination of stained tissue, microbiological culture of the organism, or direct detection of urease activity in the tissue. Biopsy based methods are expensive, entail some patient risk and discomfort and may give false negative results due to sampling errors or when colonization of the gastric mucosa is patchy.
Non-invasive methods include serological testing, fecal antigen test, and urea breath test. Several serological tests that detect serum antibodies to *H. pylori* are commercially available. A positive result with a serologic test cannot distinguish between current infection and past exposure to infection and, therefore, is not a conclusive indicator of current gastrointestinal colonization by *H. pylori*. Urea breath tests are a noninvasive method for detecting current *H. pylori* infection.

^{13}C-urea breath tests provide a non-invasive and non-hazardous analysis of the exhaled breath. The PyloPlus® UBT (described in the next section) measures the $^{12}CO_2$ and $^{13}CO_2$ components of the exhaled breath before and after the oral ingestion of ^{13}C-enriched urea. This establishes the baseline ratio of $^{13}CO_2/^{12}CO_2$ and the post ingestion ratio of $^{13}CO_2/^{12}CO_2$ determine the Delta Over Baseline (DOB) (change in the $^{13}CO_2/^{12}CO_2$ ratio).

SECTION 4. PRINCIPLES OF THE PYLOPLUS® UBT BREATH TEST

4.1. PRINCIPLE OF THE TEST

The PyloPlus® UBT non-invasive breath test is a diagnostic test that analyzes a breath sample before and after ingestion of ^{13}C-enriched urea; it is used to identify those patients with *H. pylori* infection.

The PyloPlus® UBT breath test is performed as follows: a 75 mg ^{13}C-urea powder and 3.0 g citric acid flavoring powder are dissolved in water, and the resulting solution is ingested by the patient. The presence of the citric acid creates an acidic environment in the stomach and delays the transfer of the ingested solution to the duodenum. These two characteristics facilitate the decomposition of the urea by *H. pylori*, if present. Thus, in the presence of urease associated with gastric *H. pylori*, ^{13}C-urea is decomposed to $^{13}CO_2$ and NH_3 according to the following equation:

H. pylori urease $2\ ^{13}C\text{-urea} + 2\ H_2O_2 \xrightarrow{\text{H. pylori urease}} 2\ ^{13}CO_2 + 2\ NH_3$. The $^{13}CO_2$ is absorbed into the blood and then exhaled in the breath. Absorption and distribution of 13CO2 is fast. Therefore, the cleavage of urea by the *H. pylori* urease that produces the $^{13}CO_2$ occurs immediately after the solution is ingested and enables immediate detection of increased $^{13}CO_2$ in the exhaled breath of *H. pylori*-positive patients. Analysis of the breath samples is performed by the PyloPlus UBT analyzer (Infrared Spectrophotometer) located at a medical facility. In the absence of gastric *H. pylori*, the ^{13}C-urea does not produce $^{13}CO_2$ in the stomach because there are no enzymes that can decompose the urea in the stomach.

4.2. DESCRIPTION OF THE PYLOPLUS® UBT DIAGNOSTIC DRUG COMPONENT

The diagnostic drug component of the kit is ^{13}C-urea, a synthetic urea contained in a granulated powder for reconstitution with potable water to provide a clear solution for oral administration. The carbon in the drug component is predominantly Carbon-13, a stable, naturally occurring, non-radioactive isotope of carbon; the relative abundance of Carbon-13 is greater than or equal to 99% in the synthetic drug component.

Each dose of ^{13}C-urea is supplied in a polyethylene-lined foil pouch and contains 75 mg of ^{13}C-urea. ^{13}C-urea is the diamide of $^{13}C^{-}$carbonic acid and is highly soluble in water (1 gram per mL at 25°C). It has the following chemical formula: $^{13}CH_4N_2O$. An average adult body normally contains about 9 grams of urea, which is a product of protein metabolism. Urea in the body is referred to as natural isotopic abundance urea since it is composed of 98.9% ^{12}C-urea and 1.1% ^{13}C-urea.

SECTION 5. WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only. The reconstituted ^{13}C-urea powder and the citric acid flavoring solution are taken orally as part of the diagnostic procedure.
2. In the case of accidental overdose – drink water and call the physician.
3. A negative result does not rule out the possibility of *H. pylor*i infection. False negative results can occur with this procedure. If clinical signs suggest *H. pylori* infection, retest with a new sample or an alternate method.
4. A false positive test may occur due to urease associated with other gastric spiral organisms observed in humans such as *Helicobacter heilmanni*.
5. A false positive test could occur in patients who have achlorhydria.
6. Antimicrobials, Proton Pump Inhibitors and bismuth preparations are known to suppress *H. pylori*. Ingesting these medications within two weeks prior to performing the breath test may produce false negative test results.
7. If particulate matter is visible in the reconstituted ^{13}C-urea powder and the citric acid flavoring solution after mixing for 30 seconds, the solution should not be used.

8. The following are potentially interfering substances typically found in a patient's breath that were not tested using the PyloPlus UBT System to determine their effect on the test results. The potential sources considered were:
    - Mouthwash
    - Chewing gum
    - Carbonated beverages
    - Cigarette smoke
    - Acetone (to simulate the effect of ketone production that may result from some diets)
    - Alcohol

SECTION 6. SHELF LIFE AND STORAGE

The PyloPlus UBT Kit should be stored at 15°-30°C (59°-86°F) with an expiration date of 24 months. Do not use beyond the expiration date stated on the label.

SECTION 7. INSTRUMENTS

The PyloPlus UBT analyzer (infrared spectrophotometer) is required for analysis of breath samples. For detailed information on the PyloPlus® UBT analyzer, reference the Operator's Manual.

SECTION 8. PATIENT PREPARATION

1. The patient should have fasted at least 1 hour before administering the PyloPlus UBT Kit.
2. The patient should not have taken antimicrobials or Proton Pump Inhibitors within 2 weeks prior to administering the PyloPlus UBT. If PPIs are used within 2 weeks of testing, false negative test results may occur, and the test should be repeated 2 weeks after discontinuation of PPI treatment. A positive result for a patient on PPI could be considered positive and be acted upon.

SECTION 9. BREATH COLLECTION AND PREPARATION

9.1 Materials provided in each PyloPlus UBT Kit:

- One (1) pouch of ^{13}C-urea powder
- One (1) packet of citric acid flavoring
- Test instructions
- One (1) Quick Reference Instructions (QRI)
- Two (2) breath collection bags, one (1) blue bag for the BASELINE sample and one (1) red bag for the POST sample.
- One (1) drinking straw
- One (1) sample transport bag

9.1.2 Materials needed but not provided

- A 15-minute timer
- Potable water

9.2 Step-By-Step Procedure

Time intervals listed in the following step-by-step procedure are critical.

9.2.1 Verify that the patient has been prepared for the test as specified in Section 8. above.

9.2.2 Open the PyloPlus UBT Kit, which should contain all the materials listed in Step 9.1. Label each breath collection bag to maintain patient identification using a felt tip permanent marker, or according to your laboratory or office procedure.

9.2.3 Collect the BASELINE breath sample according to the following steps:

a) Pick up the blue breath collection bag.
b) Remove the twist-off cap from the mouthpiece of the breath collection bag.
c) Instruct the patient to: (1) breathe normally; (2) take a deep breath then hold their breath for 10 seconds; (3) partially exhale in the room, before fully exhaling into the mouthpiece of the bag.
d) Replace the cap firmly on the mouthpiece of the bag.

> **Note**: *If the patient has not held their breath for 10-seconds or does not fill the bag completely, there is a possibility a test result will not be obtainable.*

> **Note**: *The bag is not fully closed if the cap does not click into place. Not fully closing the bag my cause the breath sample to slowly leak out.*

9.2.4 Prepare the ^{13}C-urea solution no more than 50 minutes before administering it to the patient. Urea slowly decomposes in water.
a) Pick up the citric acid flavoring packet and tear open. Place contents of citric acid flavoring packet into ^{13}C-urea pouch by tearing open the pouch and carefully pouring contents of the citric flavoring packet into the open ^{13}C-urea pouch.
b) Add approximately 100 ml drinking water (about 1/3 full) to the ^{13}C-urea pouch.
c) Close the Ziplock feature of the ^{13}C-urea pouch securely and shake the mixture for up to 30 seconds.
d) Instruct the patient to drink all of the drug solution with the straw provided directly from the ^{13}C-urea pouch, without stopping. Advise the patient NOT to 'rinse' the inside of his/her mouth with the drug solution before swallowing. Discard the straw after the patient has finished drinking the drug solution.
9.2.5 Set the timer for 15 minutes. The patient should sit quietly and should not eat, drink or smoke during the 15-minute interval.
9.2.7 After 15 minutes have elapsed, pick up the red (pink) breath collection bag. Collect the POST-SAMPLE breath sample according to the procedure described in Steps 9.2.3 b through 9.2.3 d.
9.2.8 Store the specimens at 15°-30°C (59°-86°F) until analysis is performed.
9.2.9 Perform breath sample analysis within 7 days of breath sample collection. If desired, use the plastic sample transport bag for transport of the breath samples.

SECTION 10. QUALITY CONTROL

Complete operating information, including self-diagnostic instrument routines and user maintenance procedures provided in the Instruction manuals for the PyloPlus UBT analyzer. Additionally, each office laboratory or test facility should follow its own internal procedures for quality control.

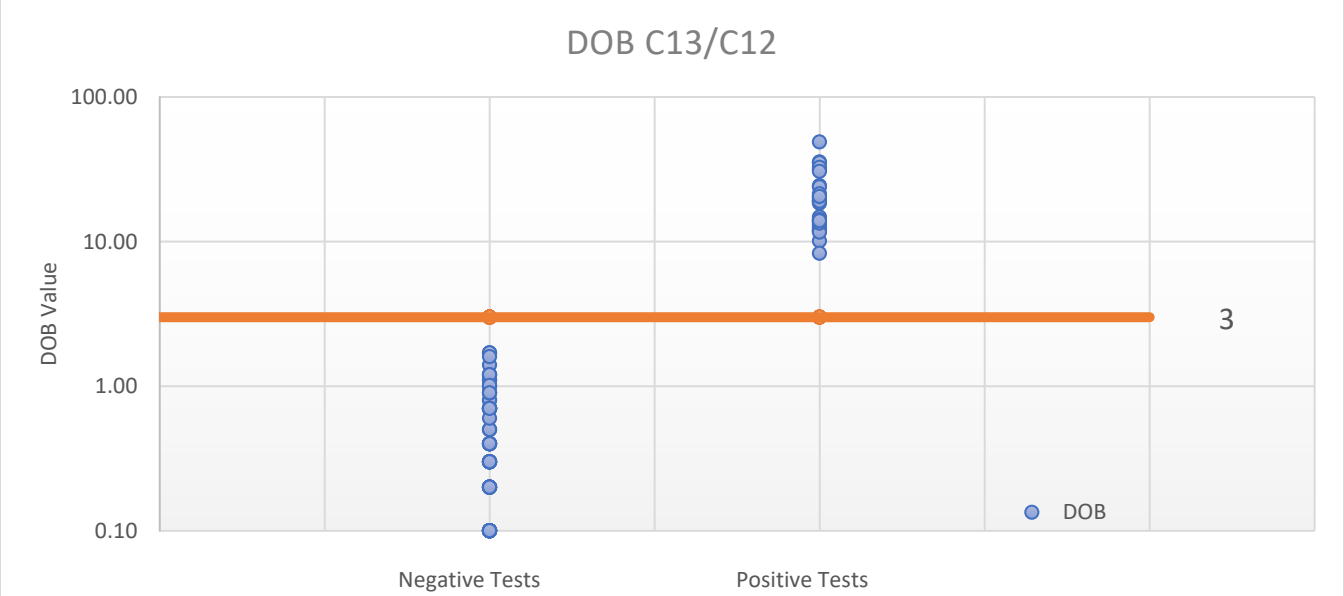
SECTION 11. TEST RESULTS

11.1 The Test Method
The ratio of $^{13}CO_2$ to $^{12}CO_2$ in breath samples is determined by the PyloPlus UBT analyzer (an Infrared Spectrophotometer).
11.2 Calculation of Results
The result is provided as the Delta over Baseline (DOB) which is the difference between the ratio of $^{13}CO_2/^{12}CO_2$ in the POST-DOSE sample and the corresponding ratio in the BASELINE sample. No calculations are required by the user.
11.3 Determination of the Cutoff Point
The cutoff point is the value used to discriminate between *H. pylori*-infected and uninfected individuals.

The Delta Over Baseline cutoff point was confirmed to be 3.0 in a controlled study of 115 adult patients (30 infected and 85 uninfected). The cutoff point was confirmed by comparing the PyloPlus® UBT test result (DOB) positive and negative patients, to the composite reference standard (pathology, rapid urease, and culture when available). The 115 adult patients used for the cutoff study are the first 115 of the total 316 prospectively enrolled patients from the pivotal study.

Figure 1 below shows the PyloPlus® UBT test cutoff point graphically, which distinguishes *H. pylori*-positive and negative patients.

Figure 1.



11.4 INTERPRETATION OF RESULTS

A PyloPlus® UBT test result of equal to or greater than 3.0 Delta Over Baseline is interpreted as diagnostically positive, indicating the presence of urease associated with *H. pylori*. A PyloPlus® UBT test result of less than 3.0 Delta Over Baseline is interpreted as diagnostically negative, indicating the absence of urease associated with *H. pylori*.

The 3.0 DOB cutoff point applies to both initial diagnosis and post-treatment (eradication) monitoring of *H. pylori* infection. For more details, refer to section 12.

SECTION 12. LIMITATIONS OF THE TEST

12.1 Safety and effectiveness in patients under the age of 18 years have not yet been established.

12.2 The specimen integrity of breath samples and reference gases stored in breath bags under ambient conditions has not been determined beyond 7 days.

12.3 A correlation between the number of *H. pylori* organisms in the stomach and the PyloPlus® UBT test results has not been established.
12.4 Data is insufficient to recommend the use of this test on pregnant and lactating women.

SECTION 13. EXPECTED VALUES

Delta Over Baseline values, as determined by the PyloPlus UBT System from the pivotal clinical study, reported 63 positive and 250 negative results from the prospectively enrolled population. The negative results had a DOB range from 0-2.9. The positive results ha d a DOB range of 3.4-90.5
A histogram of the distribution of Delta Over Baseline values from pre-therapy positive and negative patients is shown in figure 2A and 2B.

Figure 2A. Distribution of Data for Pre-Therapy Negative Patients as Determined in the Pivotal Clinical Study

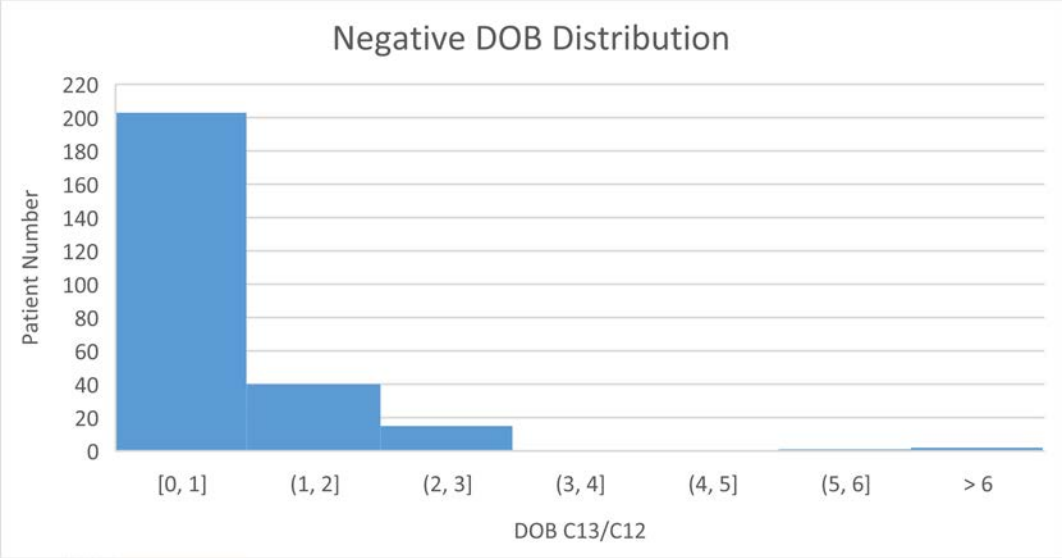
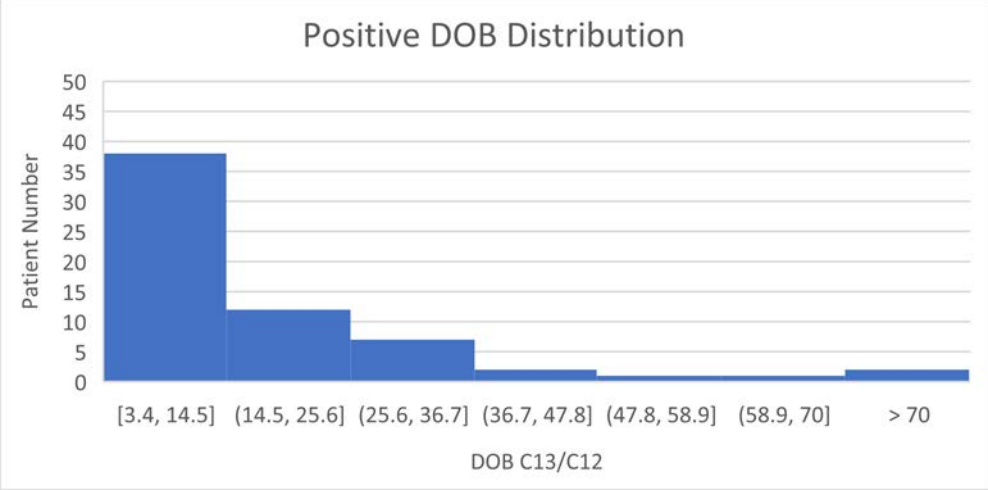


Figure 2B. Distribution of Data from Pre-Therapy Positive Patients as Determined in the Pivotal Clinical study



SECTION 14. PERFORMANCE CHARACTERISTICS

14.1. The primary outcome measure for clinical validation of the PyloPlus UBT is a composite reference method consisting of culture (when available), histology, and rapid urease test.

14.2 Analytical Performance Characteristics for the PyloPlus UBT analyzer. Refer to the Instruction Manual for the instrument.

14.3 Clinical Performance in Clinical Trials.

Experimental Design

The data presented here was collected from a prospective, non-randomized, open-label, pivotal clinical trial, designed to assess the sensitivity and specificity of the PyloPlus® UBT test compared to EGD biopsy in determining the status of gastrointestinal infection with *H. pylori* (pre-therapy phase). There were 316 adult pre-therapy patients at 6 USA based sites including 1 USA based reference laboratory.

Patients were evaluated by at least two of three diagnostic methods

1. Histopathology: Biopsy specimens, fixed with 10% buffered formalin, were cut into 4 mm sections stained with Giemsa stain, and examined by an experienced pathologist.
2. Rapid Urease Test: Biopsy specimens were tested for urease activity with an FDA-cleared test according to the package insert.
3. *H. pylori* culture (when available): Biopsy specimens were sent to a USA based laboratory for culture analysis.

Results

The results are presented in two-way contingency tables. The exact binomial distribution was used to calculate the lower and upper limits of the 95% confidence intervals of the performance statistic.

Pre-Therapy

The analysis of safety and effectiveness was based on the 316 evaluable patients that had been enrolled over the duration of 16-months. Of the 316 patients who completed the testing no adverse events were reported.

The analysis of safety and effectiveness of the PyloPlus UBT System was assessed by determining the ability of the test to measure active metabolism of urea pre- and post-ingestion of ^{13}C-urea for initial diagnosis of persons suspected of *H. pylori* infections in the stomach. There were 34 patients positive by the CRM and 110 patients determined to be negative by CRM. The analysis contained only congruent results obtained by CRM (histology, rapid urease test and culture when available). The calculated performance is provided in table 1. below. Patients on PPIs (172) are omitted from the primary analysis because of the potential for a false negative result from the CRM.

Table 1. PyloPlus Performance-Primary Analysis

		Composite Reference Method		
		Positive	Negative	Total
ARJ PyloPlus UBT System	Positive	34	0	34
	Negative	0	110	110
	Total	34	110	144
Sensitivity	100%	95% CI	89.9%-100%	
Specificity	100%	95% CI	97.4%-100%	

An additional analysis was performed for the pre-therapy group that included patients who were determined to have been taking PPIs and patients not taking PPI at the time of testing. The analysis contained only congruent results obtained by CRM (histology and rapid urease test). When patients on PPIs (172) were included in the pre-therapy group, there were 64 patients positive by the CRM and 252 patients determined to be negative by CRM. There were 63 true positive results and 250 true negative results, two (2) false positive results and one (1) false negative results when the PyloPlus UBT System was compared to the CRM. The calculated performance is provided in table 2 below.

Table 2. PyloPlus Performance- Additional Analysis

		Composite Reference Method		
		Positive	Negative	Total
ARJ PyloPlus UBT System	Positive	63	2	65
	Negative	1	250	251
	Total	64	252	316
Sensitivity	98.40%	95% CI	91.7%-99.7%	
Specificity	99.20%	95% CI	97.2%-99.8%	

14.4. REPRODUCIBILITY AND REPEATABILITY RESULTS

Analytical studies were conducted to evaluate the reproducibility and precision (repeatability) of results when measurements are made by different technicians and/or using different PyloPlus® UBT analyzers, or when testing is done on different days and at different sites.

14.4.1. REPRODUCIBILITY ANALYTICAL STUDY

Three gas isotope pairs were used with Delta Over Baseline (DOB) values of 2.2 (high negative), 3.1 (low positive), and 9.50 (moderate positive). The study was conducted over 5 days at three different sites, with two operators/site to measure the DOB values for samples from each of the three sample pairs. The reproducibility study results demonstrated minimal differences in the standard deviation over different samples for both the operator, the devices and between days. Table 3 summarizes the results of the reproducibility study.

Table 3. PyloPlus Reproducibility

Sample	**Average DOB**	**Metric**	**Within Run**	**Between Runs (operator)**	**Between Days**	**Between Sites**
High Neg 2.2	2.27	SD	0.123	0.000	0.027	0.084
		%CV	5.417	0.000	1.180	3.690
Low Pos 3.1	3.18	SD	0.145	0.046	0.000	0.047
		%CV	4.559	1.442	0.000	1.469
Mod Pos 9.5	9.53	SD	0.144	0.000	0.042	0.000
		%CV	1.513	0.000	0.442	0.000

14.4.2. REPEATABILITY ANALYTICAL STUDY

The study was conducted at one site over 12 days with 2 measurements/day of three gas isotope pairs with DOB values of 2.2 (high negative), 3.1 (low positive), and 9.5 (moderate positive). The reproducibility study results demonstrated minimal differences in the standard deviation over different samples and different days. Table 4 summarizes the results of the repeatability study.

Table 4. PyloPlus Repeatability

Sample	Average DOB	Metric	Within Run	Between Runs	Between Days
High Neg 2.2	2.20	SD	0.077	0.000	0.056
		%CV	3.486	0.000	2.300
Low Pos 3.1	3.15	SD	0.051	0.000	0.048
		%CV	1.633	0.000	1.403
Mod Pos 9.5	9.66	SD	0.100	0.053	0.000
		%CV	1.035	0.546	0.000

14.4.3. CARRYOVER ANALYTICAL STUDY

A carryover study was conducted to evaluate the potential for sample to sample carry-over or cross contamination in the PyloPlus UBT System. Five runs were conducted using contrived gas, each run consisting of 10 tests. Testing consisted of alternating between contrived gas alternating between high negative 2.2 and high positive 29.3. Data from tests 1-10 in each run were used in the analysis.

The standard deviation for either the high negative or the high positive ≤ 0.10. The results indicate carryover between 2.2 and 29.3 is not a clinically significant amount. Table 5 summarizes the results of the Carryover study.

Table 5. PyloPlus Carryover

	High Negative 2.2			High Positive 29.3		
Day	**Within-run SD**	**Within-Run Variance**	**Mean**	**Within-run SD**	**Within-Run Variance**	**Mean**
1	0.07	0.030	2.3	0.05	0.002	29.2
2	0.07	0.030	2.3	0.08	0.003	29.3
3	0.05	0.022	2.24	0.007	0.000	29.2
4	0.1	0.043	2.3	0.007	0.000	29.3
5	0.07	0.030	2.3	0.1	0.003	29.2

SECTION 13. BIBLIOGRAPHY

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SYMBOL GLOSSARY

See instructions for use For single use only Prescription use only

Do not use if package is damaged Store at room temperature IVD In vitro diagnostic device

Manufactured by REF Reference number CE Made in compliance with CE regulations

EC REP European Representative

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CE IVD

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Instructions for Use of the $^{13/12}CO_2$–Breath Test Analyzer

PyloPlus UBT Analyzer

REF Model #PPUBT-02

– For In Vitro Diagnostics Use Only –

Limitation of Liability

All data and notes in these instructions were prepared in due consideration of the statutory standards and regulations, the present state-of-the-art, as well as our knowledge and experience.
Gulf Coast Scientific, Inc. (GCS) does not assume any liability for damages due to:

- the non-observance of the details of these instructions
- use of the product not as intended
- use by untrained staff
- unauthorized modifications of or technical changes to the equipment
- the use of non-authorized spare parts

We reserve the right to make technical changes for purposes of improvement of the functional characteristics and the further development of the products.

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Content

Intended Use

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The ^{13}C–Breath Test

The change of this ratio compared to the natural value is very low. Therefore, a relative description has been agreed on, termed as delta value (δ ^{13}C in ‰):

$$\text{delta} = 1000 * \frac{(\text{R}sample - \text{R}reference)}{\text{R}reference}$$

with R = $^{13}C/^{12}C$.

The standard international reference value is the PDB standard (Pee Dee Belemnite carbonate rock formation in South Carolina) with an R-value of 0.01123686. The delta value of the PDB standard is δ ^{13}C = 0 ‰.

The delta value of a baseline-sample for a Central European is approximately -25 ‰, which corresponds to an R-value of 0,010956. For an American, the measured value of the baseline is approximately -20‰, the R-value amounts to 0,011011.

Measuring of the $^{13}C/^{12}C$–Ratio

The PyloPlus UBT Analyzer works with a single-jet non-dispersive infrared spectroscopy industrial photometer. The measuring effect is based on the resonance absorption of gas specific rotation-vibration bands of gas molecules in the middle infrared range (wavelengths between 2.5 and 8 µm). Gas molecules differing in isotope atoms are identified by isotope individual resonance absorption bands.
The broadband infrared radiation generated by the radiator is alternately sent as a beam through the measuring and reference chamber of the measuring cuvette, using a wheel with alternating apertures. Thereafter, the two modulated beams enter the infrared detectors. The infrared detectors are double layer transmission detectors with a front and a rear chamber, both filled with the gas component to be measured. Hence, the selectivity is determined by the infrared detector.
In the presence of the component to be measured, the IR-radiation gets weaker on passing through the measuring chamber of the measuring cuvette, and then enters the front chamber of the receptor. As a result, the radiation intensity balance between the measuring and reference beam is being disturbed.
The energy difference leads to a temperature change, which results in a pressure variation in the front chamber of the receiver. This pressure variation is remodeled into a capacity change by deflection of a metal membrane sitting opposite to a fixed electrode. As a high-impedance direct voltage is applied to that membrane condenser, a corresponding periodical alternating voltage signal is produced.

Restrictions of the Application

Limits of the Procedure

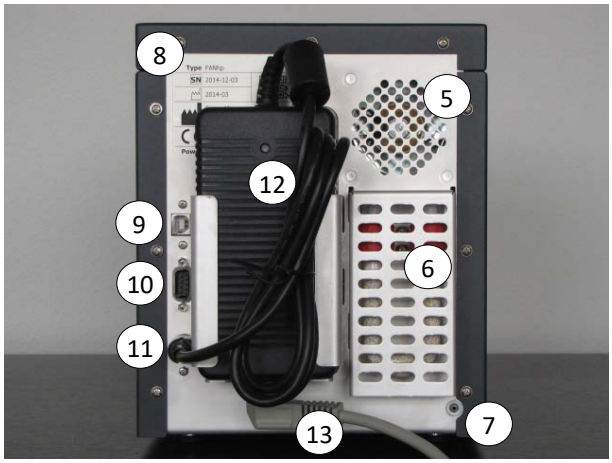
- Safety and effectiveness in patients under eighteen (18) years of age have not yet been established.
- The specimen integrity of breath samples and reference gases stored in breath bags under ambient conditions has not been determined beyond 7 days
- A correlation of the number of *H. pylori* organisms in the stomach and the PyloPlus UBT System results have not been established.
- Data is insufficient to recommend the use of this test on pregnant and lactating women.
- Analyzer is to be used with only the PyloPlus UBT kits.

Connectivity

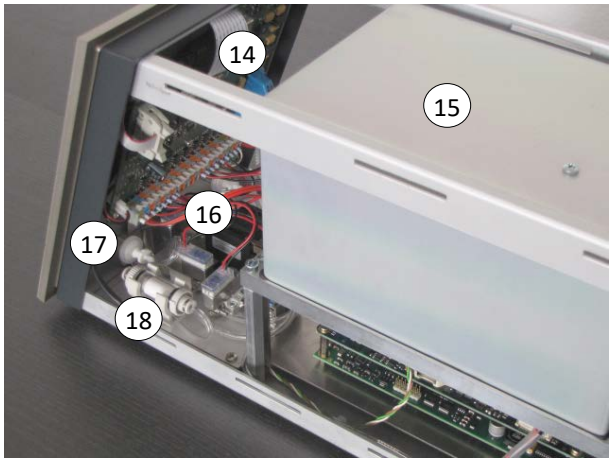
The PyloPlus UBT Analyzer is designed as a stand-alone device. Connection to a PC or a network during the measuring process is not provided.
For data export, an empty USB 2 flash drive formatted with FAT 32 can be used.

Components of PyloPlus UBT Analyzer

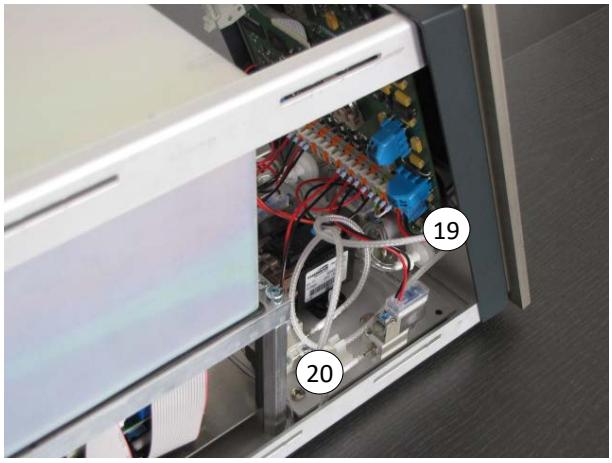
1. screen with touch sensor
2. USB 2 connection port for barcode scanner or flash drive
3. connection port for the first breath test bag of the HP test
4. connection port for the second breath test bag of the HP test



5. speaker
6. CO_2 absorber
7. gas outlet
8. nameplate
9. service interface
10. printer port
11. 24 V connector
12. 24 V DC adapter
13. mains power cord



14. micro controller
15. infrared spectrometer
16. pump
17. inlet filter 2
18. air filter



19. inlet filter 1
20. NAFION gas dryer

Symbols

CE	CE conform per Directive 98/79/EC
	Manufacturer
	Pay attention to instructions for use
	No household waste; for removal, send back to the manufacturer
SN	Serial number (including date of manufacture)
IVD	In vitro diagnostic device
	corrosive (content of CO_2 absorber)
	irritant (content of CO_2 absorber)
	breakable, handle with care (at carrier box)
	keep dry, store in a dry place (at carrier box)

top side, keep upright (at carrier box)

Electrical Power Supply

The PyloPlus UBT Analyzer is delivered with a 24 V table power supply licensed for medical devices. The direct voltage socket is at the back of the device. The power supply can be fastened with an included mount.
Being that the PyloPlus UBT Analyzer is designed for continuous operation, switching on/off occurs via the power plug. A separate switch does not exist.

Control Electronics

A microcontroller controls all measuring processes as well as the pneumatic system and the infrared analyzer. An AMOLED display with capacitive touch technology provides an operating interface and receives the input from the user.
The front USB port (type A) can be used for transferring data to a USB flash drive or connecting a barcode scanner to import patient IDs.
The rear of the unit contains ports for the receipt printer, a service interface (USB type B) and the speaker.

Pneumatic System

This unit comprises the bag connectors, a membrane pump, a NAFION® gas dryer as well as the CO_2 absorber mounted at the back.
The CO_2 absorber generates CO_2-free air from ambient air. This *zero gas* is needed for zero adjustment during linearization and measuring.
The absorber is filled with a specialized grain of soda lime and fits to the flow conditions in the PyloPlus UBT Analyzer. It is also furnished with protective filters.
The use of CO_2 absorber provided by Gulf Coast Scientific is strongly recommended (see p. 20 for order number).

An internal counter registers every use of the absorber. Upon exceeding 1000 uses*, an absorber symbol flashes on the main screen. Please exchange the absorber a soon as possible (see p. 21). The efficiency of the absorber is checked prior to every measurement, and an error message is displayed in case of an insufficient zero gas production (see p. 25).

*This threshold value is a guidance value. It is based on operating experience in a well-ventilated room with an average number of persons. Under differing conditions the capacity of the absorber can be reached sooner or later. Differing conditions may be a small room highly frequented by persons or a big, air-conditioned room.

Before every measurement, the system is flushed with ambient air via an air filter, after which all CO_2 from the air within the system is removed via the absorber pipe (*zero gas)*.
Following this process, the collected breath sample from the bag plugged to the respective port is dispatched over the inlet filter and valve into the infrared spectrometer. Zero gas from the system and the sample are mixed by two by-pass valves, and the humidity of the mixture is adapted via the gas dryer.

Infrared Spectrometer

The spectrometer determines, as described in page 4, the $^{13}C/^{12}C$–ratio of the CO_2 from the breath sample. The spectrometer requires a specific internal temperature to operate effectively which it automatically stabilizes before use. The process may take a short period time if the unit has been shut off.

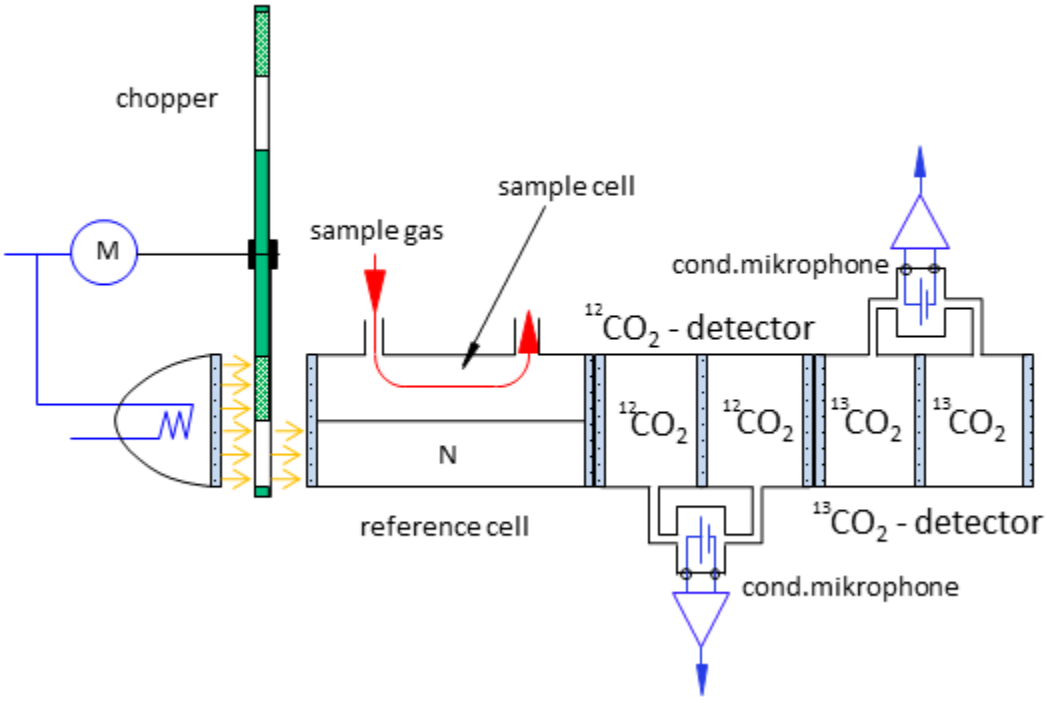


Figure 1: Structure of the infrared spectrometer in principle

Preparation for Use

Materials and Equipment

All materials required to operate the device and/or equipment are contained in the scope of supply.
Not enclosed are the necessary test kits for processing the HP breath test; these can be ordered separately from Gulf Coast Scientific, Inc.
A list of consumable supplies, optional accessories and spare parts are located on page 20.

Compatible Materials for Analysis

The PyloPlus UBT Analyzer has been designed for the analysis of human breath.

Breath Collection Bags

The PyloPlus UBT Analyzer has been designed to operate with the PyloPlus Breath Bags as supplied by Gulf Coast Scientific, Inc. Use of any other bags not approved by Gulf Coast scientific, Inc. voids all warranties and can result in false readings.

Filling Breath Test Bags Correctly

The PyloPlus UBT Analyzer determines the $^{13/12}$C-ratio of the human breath. Therefore, a minimum concentration of CO_2 in the exhaled air is required.
Only the metabolized air from the alveolar air sacs is usable, not the ambient air from the oral cavity and the bronchia.

To collect a proper sample, follow the step below:

1. Have patient sit in a comfortable position.
2. Ask the patient to breathe normally
3. Have the patient take a deep breath then hold their breath for 10 seconds.
4. After 10 seconds instruct the patient to partially exhale in the room, before fully exhaling into the mouthpiece of the bag. The bag should be fully expanded.
5. Replace the cap firmly on the mouthpiece of the bag or connect directly to the analyzer to prevent any loss of breath sample.

Unpacking

1. Carefully open the shipping box
2. Remove the accessory box and manual
3. Carefully lift the analyzer from the box vertically and place the analyzer in a safe location
4. Remove all protective covers
5. Remove accessories from the box
6. Place protective cover and accessory box back into the shipping box

Caution: Do not dispose of the shipping box or packing materials
Warranty claims will only be valid, if the device is shipped in in the original packing.
Take transportation safety measures according to the symbols located on the carrier box.

Check for Completeness

Items included:

- Transport box
- Breath test analyzer PyloPlus UBT Analyzer
- Absorber and cover (attached to the device)
- Table power supply with mount
- Power supply cord
- Starter set of breath test bags
- Spare sealing rings for bag connectors
- Manual

Preparation of the Installation Site before Installation

Surrounding Area

The PyloPlus UBT Analyzer is a sensitive analytical device, which can be influenced by vibrations and variations in temperature. Please chose the installation site carefully and avoid the following:

- shocks, vibrations as well as uneven installation surfaces
- direct heat by sun or heating equipment
- direct drafts by air conditioners or open Windows
- heat accumulation (the device is temperature-stabilized and must be in the position to emit some heat)
- influence of aggressive gases and extreme dust

Please find further requirements with respect to the surroundings in the technical specifications (see p. 26).

Power Supply

The PyloPlus UBT Analyzer requires a connection to a 110V power outlet. The device has a power supply with wide-range input, so no settings need to be made at the installation.
Please find the electrical supply data and the consumption values on the nameplate at the back.
Precautions should be taken to protect the device from power surges or uneven power supplies.

Placement

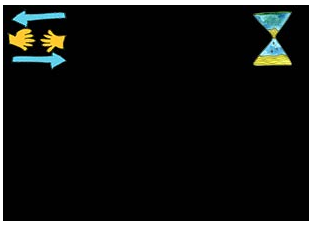
Place the device with the screen to the front. Consider the space requirements in front of the device for the breath test bags to be plugged in later.

Start-Up

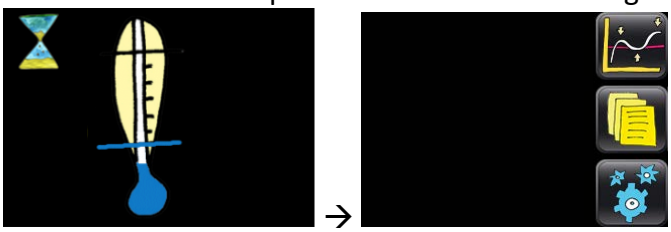
Switch On

1. Attach the plug to an approved 110V electrical supply.

The device shows the start screen while waiting for the spectrometer to be ready for communication. Then the internal data exchange is started.



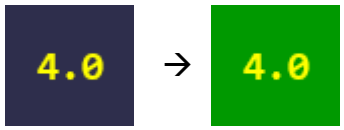
2. If you want to import patient-IDs by barcode scanner, plug the USB connector into the USB front port.
3. Then wait until the spectrometer reaches its target temperature (55 °C, duration about 2 h).



4. Once the device is ready it will produce a loud beeping sound and the main screen will appear.

Operation of the Touch Screen

All actions at the PyloPlus UBT Analyzer are triggered by pressing a button on the screen. If the device is idle (screen saver), you can activate it by touching the screen at any time.



To change numerical values, activate the corresponding field by tapping.

Adjust the value with the arrow keys.

Exit sub–screens with the OK (confirmation) or ESC (abortion) button

Device Settings

Push the button “settings “to change device settings according to your wishes:

→ 

This symbol corresponds to the settings for date and time.
Tap on the number you want to change and adjust the correct value with the arrow keys.
Exit the screen with the OK-button (green checkmark).

→ 

Push this button to adjust the brightness to the surroundings.
(sun = brighter, moon = shaded).

→ 

Push the button repeatedly to adjust the volume of the acoustic signals to the surroundings.
(loud, medium, off)

Self-test

At first use of a new device, please conduct first a linearization (see next item) and then a system test as described on p. 18 before you start measuring.

Daily Operation

Linearization

The linearization determines the dependency of the delta-value to the $^{12}CO_2$-concentration of a sample. The resulting curve is required for the internal correction of the measurement data.
Inhaled air from the operator can be used as reference gas with a $^{13/12}C$–ratio in the range of human breath.
To record the curve the gas is gradually diluted with CO_2–free air and its delta–value (see p. 4) is measured.

1. Push the button “linearization “in the main screen:

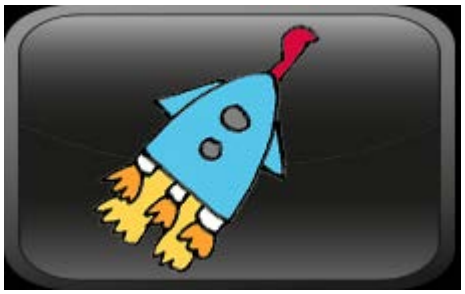
2. Fully exhale into a breath test bag (see p. 11).
3. Plug the bag on the PRE (left port).
4. Push the start button:

5. Wait for end signal and remove the bag.

From the screen “linearization” you can print a selection of previous results (max. 32) or save it to a USB flash drive (see p. 17) at any time.

Measuring

After having collected the second breath sample, an HP-test can be analyzed without further preparations. A special organization of the measuring process is not required because the PyloPlus UBT Analyzer has only two sample ports. Hence only one test can be measured at the same time.

1. If available, switch on the receipt printer.
2. Push the button “Measurement “:

3. In the screen “Measuring “you are invited to plug on the bags of the breath test to be measured onto the bag connectors and then start the measurements:


When installing a breath bag to a bag connector take extra caution to handle the bag only at the welded connection piece.
Do not press the bag at all after removing the sealing cup; this may cause loss of the sample gas!
Always put the first sample of the breath test onto the connector at the left PRE and the second onto the connector at the right POST.

4. If you want to use a barcode scanner, plug it into the front USB–port and import the patient ID.
   The read ID is shown on the screen.
5. Start the measuring with the button in the upper right:

6. The single steps of the measuring are symbolized by different graphics on the screen.
   During this time, shocks to the measuring system should be absolutely avoided.
7. As soon as the measuring is completed, the device gives an acoustic signal and shows the stored result on the screen.
   You can note the results, or – if the receipt printer is attached and switched on – record additional details on the printout (see also printing and exporting data see p. 17).
8. Remove the breath test bags and discard them.

Evaluation

For the evaluation of a measurement you do not need to do anything. After analyzing both breath test bags, the result screen is shown automatically.
There you can see the date and time of the measurement, the patient–ID (if imported), the result as DOB–value and a diagnosis proposal as a symbol:

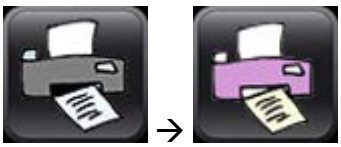
HP-negative

HP-positive

In addition, on print–outs and upon data export (see below), the cut-off settings values and the diagnosis proposal are displayed in text form.

You can show the result screen by pushing the button “results “and assort your memorized results using the arrow keys.
The PyloPlus UBT Analyzer has a memory for 300 measuring results. When the memory is full, the oldest results are replaced by the newer ones.

Printing and Exporting Data



You find a button “print “in the screens “results“, “linearization”, “system check“ (p. 18) and “dryer check”. In case the button is disabled, turn on the printer.

If you do not have a printer, you can save the data for backup or further evaluation. The button on the screen is enabled when you plug in a suitable USB flash drive.

Push the respective button to switch to the data selection screen.

Adjust the desired data area with the arrow keys after tapping on start or end time, respectively.
The current day is already pre-set, so you can have a list of the daily measurements immediately.
If you adjust the area to exactly one in result list, this is printed in a layout as in the case of automatic result printing.

For printing or saving the list push the respective button again now.

During the USB transfer, a waiting symbol is shown. It only takes seconds.
Do not remove the USB stick until the main screen is shown again.

Data Format

The data are saved as text format. You can open the file on your PC (double-click) and print it out, or you process the data with an Office Program.

You find the data saved as follows:

PYLOPLUS UBT ANALYZER (directory PyloPlus UBT Analyzer)
- 20140206 (directory – YY+MM+DD)
  - NT070811.TXT (text dryer test – NT+hour+minutes+seconds)
  - SC081022.TXT (text system test – SC+ hour+minutes+seconds)
  - LI083033.TXT (text linearization – LI+ hour+minutes+seconds)
  - BT084544.TXT (text breath test list – BT+ hour+minutes+seconds)
  - …

Special Functions

System Test

The system test executes a self–test of the device hardware. You can print or store the report of the status.

A system test is required at the first start-up. In addition, start a system test if you are prompted by a service technician or monthly, to proof and record the correct function of the device.
For a system check blow into two breath bags (see p. 11) and plug them onto PRE and POST.

Wait for the end signal; the shown result is printed automatically when the printer is switched on.
From the screen “system test” you can print a selection of previous results (max. 4) or save it to a USB flash drive (see p. 17) at any time.

Inspection of the NAFION® Gas Dryer

The humidity of the breath samples has an influence on the measured delta–value. To compensate, a gas dryer is built into the device. Its function should be checked periodically.
For this check several measurements are done from one bag; the difference of the delta–value from the first to the last measurement shall not exceed a certain value.

Start this check when prompted by a service technician or quarterly, to proof and record the correct function of the device.

The check can be performed only after a rest time > 2 hours. Therefore, do it in the morning before starting the daily measurements (otherwise, the device will show the hourglass instead of the start button).

Blow into a breath test bag (see p. 11) →
Plug bag on PRE →

Wait for the end signal, the shown result is printed automatically when printer is switched on.

From the screen “dryer test” you can print a selection of previous results (max. 4) or save it to a USB flash drive (see p. 17) at any time.

If you get an error message, please immediately request a service technician to change the sample gas dryer (order-No. see p. 20).
If you need to analyze breath tests urgently, until then always measure one set of breath bags with your own breath before measuring patient’s breath tests.

Check of the DOB Measuring Function (Calibration)

To prove the correct evaluation of the breath tests, the evaluation of a known difference in $^{13/12}$C-ratio of two test gases must be checked at least annually. You need one or more pairs of DOB test gases in bags (see p. 20).
Run a normal measuring process and document the results as usual.

On the test gas bags, there is a label with the DOB value that the analyzer should show as result with ± 10 % precision. If this is not the case, ask your service technician for performing a slope correction.
That correction is performed using a special software via the service interface of the device and is allowed for persons authorized by GCS only.
If the correction cannot be performed, send the device for factory calibration to GCS (see p. 24).

Firmware-Update

Latest versions of the PyloPlus UBT Analyzer program (“firmware”) can be transferred to the device using a PC and a standard USB 2 cable.
The necessary Windows software, the firmware update file, and appropriate instructions can be obtained by contacting Gulf Coast Scientific, Inc. technical service.

Execute an update only if asked by a service technician! Follow the instructions strictly; otherwise your PyloPlus UBT Analyzer may become unusable.

Procedure when turning off

Turning off the IVD device

You can switch off the device without special measures by pulling the mains power plug.

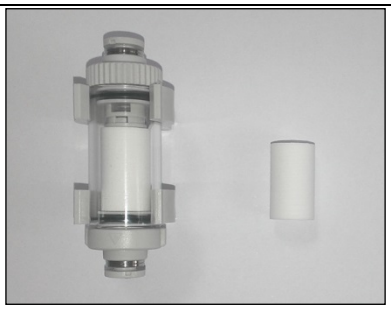
Temporary Shut-Down of the IVD device

If you utilize the device every day, leave it on over the weekend. Turn off the PyloPlus UBT Analyzer only for longer breaks; protect the analyzer from dust and humidity.

Annex

Accessories and Spare Parts

The following consumption items and spare parts can be obtained from GCS, Inc. or your service partner:

Name	Order–No.	Description
absorber UR CO_2 absorber U-shaped	F301–GA–00	
NAFION® spare part gas dryer with connecting hoses	F301–GW–07k	
Insert for air filter	F306–GW–03k	
filter for sample inlet	Z10-P-M-07	Syringe filter 2µm with Luer lock connection
breath test bag 0.3l	F201–VP–05a	One-way-bag for all breath tests
mouthpiece for breath test, straw	F201–VP–06a	PP-straw for breath test bags, one-way
DOB test gas in bag	DOB–B–01	test gas to control the $^{13/12}C$ measuring function
barcode scanner, approved by GCS	FAUT–BC–01	bar code scanner approved by GCS for the use with PyloPlus UBT Analyzer
receipt printer	Z10–A–P–01	receipt printer with serial interface for PyloPlus UBT Analyzer
printer paper rolls	Z10–A–P–02	spare roll thermal printer paper for PyloPlus UBT Analyzer receipt printer
O-ring	FKT–BE–72k	set of gaskets for bag connectors, suitable for breath test bags

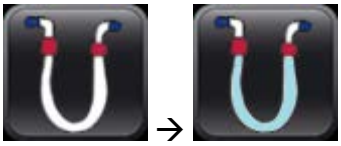
Warnings and Precautions

- Use only original spare parts and accessories from GCS. Use only consumables tested by GCS. Otherwise proper functioning of the device cannot be ensured. In case exchanging the power cord use adequate rated only.
- Interventions and repairs may only be carried out by GCS, Inc. or by persons authorized by GCS, Inc.
- The manufacturer considers itself only responsible for the basic safety, reliability and performance of the PyloPlus UBT Analyzer if the device is used in accordance with the instructions for use.
- The device shall only be operated by trained staff.
- If you move the device or take off parts of it take care not to injure yourself at sharp edges. Do not lift the device by the front plate or by any of the detachable parts.
- The touch screen is made from glass. Avoid any force that may break the glass. Do not touch a broken display.

Maintenance

Steps to Exchange the CO_2–Absorber

For handling the absorber please observe the safety measures applying.
A safety data sheet is available. See address page 24.

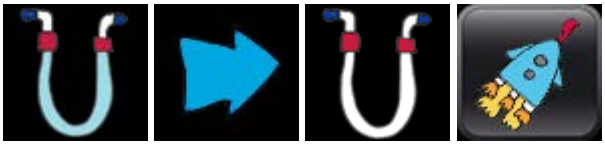
1. 

   If the absorber symbol flashes in the main screen, exchange the absorber as soon as possible. Push the button to get to the screen “absorber change”.

   Alternatively, you can go to “absorber change” via the screen “settings”.

2. In the screen “settings“ you are asked by an animation to exchange the absorber and then to start the check of the new one.

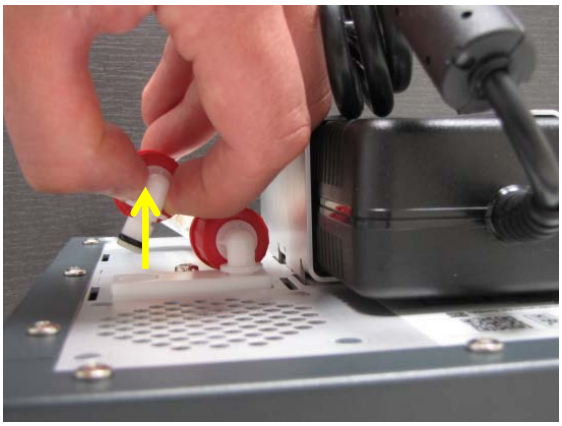
   

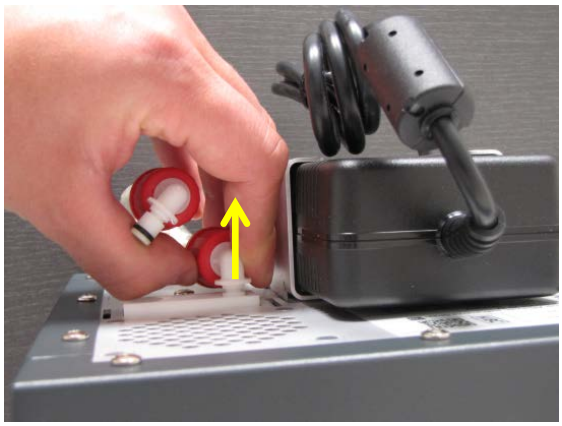
3. When changing the absorber, follow the steps below:

   Move the absorber cover up and backwards.

Pull the used absorber out of the socket backwards.

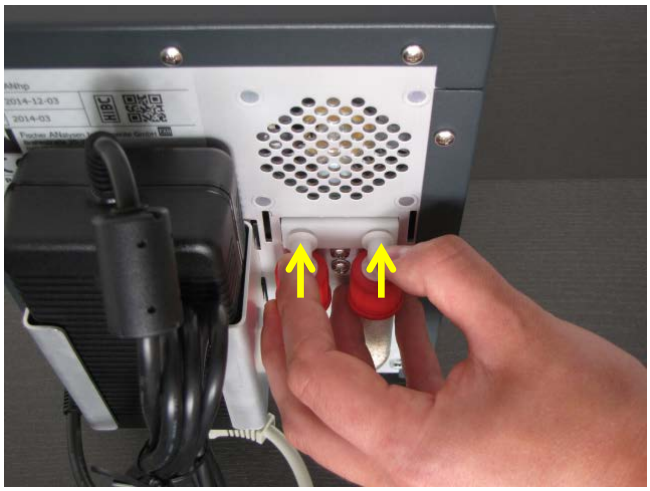
Do not dispose the absorber but send it for regeneration to GCS, Inc. or your service partner.



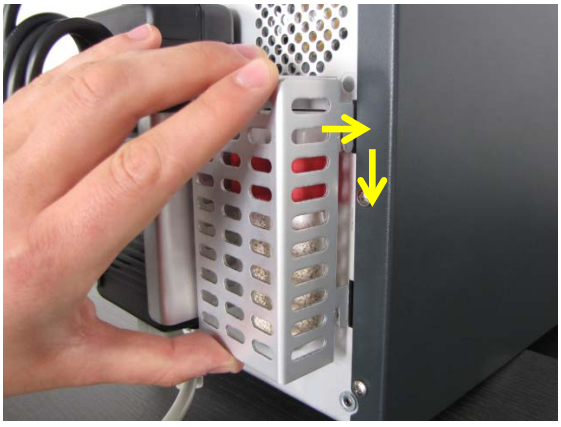


Adjust the connections of the absorber and push them into the socket.

Caution! Do not expose the glass tube to any force. Danger of injury. Take adequate protective measures.



Return the cover.



4. 

When finished, push the button “start“.
The function of the new absorber is tested and if successful, the internal counter is reset.

Air Filter , Inlet Filter and NAFION® Gas Dryer

The air filters, the inlet filters and the NAFION® gas dryers are to be changed by a service technician during the annual inspection or when required (see p. 18).
The necessary instructions to perform this are provided together with the spare parts to authorized persons.

Cleaning of the Device

The device can be wiped off with a mild cleaning solution (dishwashing liquid) on a cloth. Avoid wetness; liquids must not enter the device.

Warranty

The standard sales and delivery terms of the seller apply.
The claim to warranty expires, if repairs or changes of the device were carried out.

Service and Contact Information

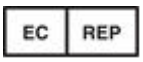
Gulf Coast Scientific, Inc.
209 State Street East
Oldsmar, FL 34677

Phone	813-855-1557
Fax	813-854-2340
E-mail	info@gulfcoastscientific.com
Website	www.gulfcoastscientific.com

Contact for device support:

Phone	813-855-1557
E-mail	service@gulfcoastscientific.com

EC Representative:



Obelis S.A.
Bd Général Wahis,
53- 1030 Brussels

Suggestions and proposals for improving this manual or for correction of mistakes are gladly welcome.

Errors

During every measurement, the firmware of PyloPlus UBT Analyzer monitors important parameters. In case of failure the user will be alarmed by an acoustic signal.
Corresponding information is shown on the main screen.

Error	Explanation	Remedial Action
0x0001	Failure during internal communication with the built-in infrared spectrometer.	Separate the device from the power supply for 30 s and connect it again then (see p. 12).
0x0002	Zero gas failure – the CO_2 absorber is exhausted.	Exchange the absorber (see p. 22).
0x0004	Zero-point failure – invalid zero point of at least one infrared detector.	Start a linearization (see p. 15). Do not expose the device to any concussions.
0x0008	The backup battery of the clock is exhausted.	Inform your service partner. At a restart of the device, the screen “date and time” will be shown. Adjust calendar and clock (see p. 14).
0x0010	Data transfer failed (printer / USB Memory Stick / barcode scanner)	Check the attached device and its cables. Repeat the process. Only use equipment approved by GCS.
0x0020	At least one of the breath samples contained a CO_2–concentration too low to be analyzed.	In future, follow the instructions for sampling at page 11 and handle the bags as described on page 16.
0x0040	The built-in infrared spectrometer reports an internal failure.	Probably the device must be sent for repair. Perform a system test and deliver the resulting report and a detailed problem description to your service partner.
0x0080	The check of the gas dryer has shown an insufficient performance.	The NAFION® gas dryer inside the device must be exchanged, see p. 18 also. Inform your service partner.
0x0100	During a self-test of the device, the inlet valve for PRE did not work.	Make sure you did not forget to install a freshly blown up breath bag onto the connector receptacle. . Repeat the test. If the error persists, send the system test report (see p. 18) and a detailed problem description to your service partner.
0x0200	During the self-test of the device, the inlet valve for POST did not work.	
0x0400	During the self-test of the device, a failure of the circulation valves has shown.	Send the system test report (see p. 18) and a detailed problem description to your service partner.
0x0800	The absorber counter has reached the limit.	Exchange the absorber (see p. 22).
0x1000	The process was stopped by the user.	
0x2000	Failure while performing the detector end-point calibration.	Make sure you did not forget to install a new calibration gas bag onto the connection advised. Repeat the calibration procedure. If the error persists, deliver a system test report (see p. 18) and a detailed problem description to your service partner.
0x4000	The temperature control was bypassed by the user.	Wait until the working temperature is stable and repeat the analysis of the breath test affected.

In case of co-occurring failures occur (e.g. during a system test) the error numbers will be shown added up.

If you cannot recover the error, please send a system test report and a detailed problem description to your service partner.

Specifications

measuring range:	$^{13}CO_2$: 80 … 800 ppm, $^{12}CO_2$: 0,8 … 8 vol.–%
precision of delta value: (> 1.5 vol.–% CO_2)	single measurement: ± 0.3 ‰ intra–individual: ± 0.4 ‰ extra–individual: ± 0.5 ‰
delta range:	delta (^{13}C δ): –50 … 250 ‰
warm-up time:	1 h until working temperature (55 °C) is reached 6 h until maximum stability
sample volume:	50 ml (> 1.5 vol.–% CO_2)
measuring time for one sample:	2 … 2.5 minutes
screen:	2.8“ AMOLED with capacitive touch sensor
dimensions (w * d * h):	195 * 450 * 240 mm
weight:	9 kg
storage temperature:	5 to 45 °C
operating temperature:	15 to 35 °C
operating voltage:	100 … 240 V AC, 47 … 63 Hz, 26 W (95 W max.)
operating atmospheric humidity:	< 75 % RH (not condensing)
height for work:	–400 … 2200 m o.S.L.
expected life time:	> 5 years

EMC– Radiation and –Immunity

The PyloPlus UBT Analyzer fulfils the corresponding requirements for IVD–Equipment in the norms

- DIN EN 61326–1: 2013–09 (IEC 61326–1: 2012)
- DIN EN 61326–2–6: 2013 (IEC 61326–2–6: 2012)
- EN 55011: 2009 + A1: 2010 (IEC/CISPR 11: 2009, mod. + A1: 2010)
- EN 61000–3–2: 2006 + A1: 2009 + A2: 2009 (IEC 61000–3–2: 2005 + A1: 2008 + A2: 2009
- EN 61000–3–3: 2008 (IEC 61000–3–3: 2008.

Environment

This device meets the safety regulations of the DIN EN 61010–1.

Details on Disposal

All electrical devices produced by GCS, Inc. are for commercial use („business to business“– B2B) exclusively. With this, the device is WEEE–relevant and must not be disposed at municipal places.
GCS, Inc. commits to recycle the devices produced by the company at no charge at the end of the use and to subject them to properly regulated disposal procedures. Costs for packaging and transport are at the customer’s account.

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