



H₂ Check Operating Manual

Federal (USA) law restricts this device to sale by or on the order of a physician or licensed practitioner.

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PLEASE NOTE: After inserting the battery, you MUST wait at least one (1) hour before use or calibration.

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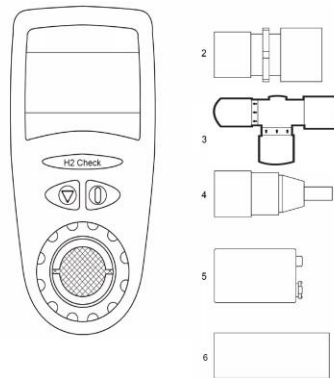
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Package Contents

The H₂ Check is supplied with:

1. H₂ Check (#BH02)
2. Plastic mouthpiece adapter for single breath tests (#PSA1800)
3. 3 special two way valves for multiple breath tests (#RB20)
4. Reducing connector for calibration (#MEC1007)
5. 9 Volt Battery
6. 5 Disposable cardboard mouthpieces (#3301)
7. Hard shell plastic carry case (#CS101)
8. Operating Manual (# OPM01)



Keypad Interface



= ON/OFF Power button



= Select Function button

* See cleaning guidance on page 10

Overview

The H₂ Check is a hand-held Hydrogen (H₂) monitor used in the screening and diagnosis of lactose malabsorption, a condition that produces increased hydrogen levels in the blood when unabsorbed lactose reacts with bacteria in the intestines. This increased level of hydrogen is expired and can be measured after ingestion of lactose following a period of fasting.

It may also be used for other Hydrogen related tests like:


- Lactose intolerance
- Carbohydrate malabsorption
- Carbohydrate breakdown deficiencies
- Bacterial overgrowth
- Intestinal transit time
- Sucrose malabsorption
- Fructose malabsorption
- Lactulose bacterial overgrowth
- Sorbitol malabsorption

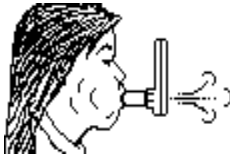
It is the responsibility of the user to use the instrument in the appropriate way.

Clinicians using this device request the patient to breath in and out through a special two-way valve disposable mouthpiece adapter for a period of one minute. This valve allows expired air to pass through the instrument while allowing fresh air to be inspired. The Hydrogen concentration is then displayed in parts per million (ppm). A single expel breath option is also available, but the best results are obtained using multiple breathing mode over a period.

Operation


Insert the 9V battery (supplied) by removing the battery cover and clipping the battery in place, and then replace the battery cover. **PLEASE NOTE: After replacing the battery, you must wait at least one (1) hour for the sensor to charge before calibration or use.** Insert the special two-way valve plastic mouthpiece adapter followed by a cardboard mouthpiece.


Turn the H₂ Check ON by pressing power button  . A countdown timer will start from 10 seconds during which time the subject should be encouraged to hold their breath. When the countdown timer reaches zero it will display the blow icon. The subject should place their lips around the Cardboard





mouthpiece and breath in and out deeply ensuring the lungs are fully emptied. They should continue breathing for one minute when the unit will beep and display the results in PPM.


In a single blow mode (ref: Operation mode), the subject should be encouraged to hold the breath during countdown period. When the timer reaches zero it will display the blow icon. The subject is requested to blow gently and continue blowing until their lungs are completely empty.

 The maximum reading the H₂ Check can measure is 500 PPM. Any reading above that will be displayed as --- (overflow).

After examining the readings, the unit can be switched off using the ON/OFF power key .

 The Hydrogen sensor is sensitive to temperature. The best results are obtained at ambient of 68° F. If the unit is moved from one environment (Example Car) to another (Laboratory), then it must be placed in the new environment for at least 30 minutes for internal temperature to stabilize before use.

 To save the battery, the unit will switch OFF automatically after three minutes if not used.

 Before repeating the measurement, the unit must be turned OFF and the mouthpiece and adapter removed for at least one minute to allow residual gas to disperse and any moisture to evaporate.

If the device is switched ON too early or the subject is allowed to blow into it before the end of the countdown, the following message will appear:

There is already some
H₂ on the
Sensor



Switch OFF the unit and wait for one minute. If the problem persists, remove any solvent (such as alcohol wipes) from the vicinity of the sensor and expose the device to ambient

air for at least 24 hours. If the problem still persists, contact your distributor.

Warning/Cautions


- ⚠ If higher than expected levels of H₂ are displayed, medical attention should be immediately sought
- ⚠ Cleaning with products that contain alcohol may result in permanent damage to the sensor
- ⚠ The battery should be changed when the low battery icon appears on the display
- ⚠ The disposable cardboard mouthpieces are single-use only. The two-way valve for multiple breath tests are single-use only
- ⚠ Please only use accessories supplied by Micro Direct to ensure the device performs as intended.


User Menu

The user menu allows the user to either calibrate the unit or set the mode of operation. To enter the User Menu, switch ON the unit with select key  pressed. Do not release the select key  until the User Menu appears.

User Menu

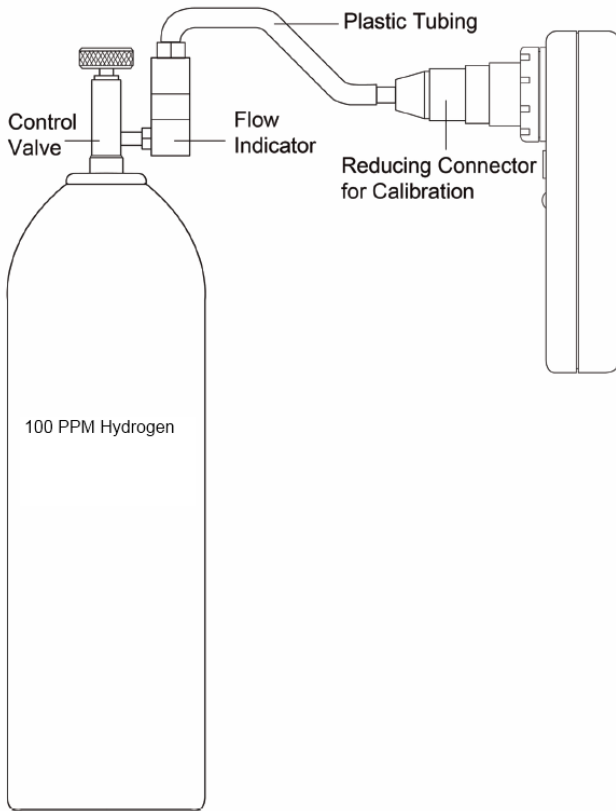
Calibrate
Set Unit
Exit

The first option is highlighted. To move between options, press the select key  momentarily (< 0.5 S). To select the



highlighted option, press the select key  for at least 3 seconds.

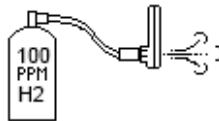
Calibration


The device should be recalibrated at least once a month.



To calibrate the device, perform the following steps:

1. Connect the control valve (#MC22) to the 100 ppm calibration gas cylinder (#MH10) shown in the diagram above.
2. Connect the short plastic tubing reducing connector (#MEC1007).
3. Switch ON the device with the select key  pressed until the device displays 'Calibration'. Release the select key .
4. The unit will countdown from 15 to 0 and will display the calibration icon.





5. Attach the connector and turn the control knob fully counter-clockwise until knob will not turn any further. The supply of gas is .25 L/second.
6. Apply this flow until the device beeps after 45 seconds. The device will display the gas concentration reading.
7. If the reading is not 100 ppm, press the select key  for at least 3 seconds to accept the new calibration value. The device will say 'done' and will show 100 ppm.





Ideally, the calibration should be performed at the ambient temperature of approximately 68° F.



It is advisable to accept the calibration even though it displays 100 ppm (i.e. the ideal reading). This will reset the 'calibration due' timer.

 Switch OFF the device if the calibration was incorrectly performed. Do not press the select key .

 To prevent incorrect calibration, only the readings within the range of 80-120 can be calibrated. An 'Error' message will be displayed if the calibration is accepted for readings outside this range. Switch OFF the device; wait for a minute and it is now ready for use.

 If the device is not calibrated for a month, the device will beep three times before the countdown starts and will display the following message: -


Calibration Expired
Please Calibrate
the unit
The reading is not
Guaranteed

The message will appear for three seconds and then the device will operate as normal. Calibration should be performed as soon as possible.

Operation mode

To change operation mode, select 'Set Unit' from the User Menu. The following option will be displayed.

Set Unit
Breathing Mode
Blow Mode
Exit


The current mode will be highlighted. To select a different mode, press the Select key  momentarily until the desired mode is highlighted, and then select it by pressing the key for at least 3 seconds.


Battery Life

The 9V battery should provide at least 30 hours of continuous use. The battery also powers the sensor continuously, so it will have a shelf life of approximately 60 days. When the battery is low, the battery low icon will be displayed for three seconds when the device is switched on.



The device can still be used, but it is advisable to replace the battery. Please wait for five minutes after replacing the battery for the sensor to charge before using the device

 It is recommended to use a lithium 9V battery.



 The device will need recalibration after the replacement of the battery.

If the battery is very low such that the reading is not reliable, the device will display the 'battery dead' icon and will not operate until the battery is replaced.



Power Saving



To save battery power, the device will automatically turn itself off three minutes after the last key press. Remove battery from the device if the unit will not be used for three months. Remember, calibration will be required when the battery is reconnected.

 To prevent the device from switching off, press the select key  within three minutes of the last press or when the reading is first displayed.

Cleaning

It is recommended that the plastic mouthpiece adapter (PSA1800) is replaced after approximately 250 tests or 1 month. Re-use could increase the risk of cross contamination, thus between tests, it can be cleaned using a mild detergent solution, then rinsed with water and left to dry thoroughly.

The device can be cleaned using non-alcohol wipes.

-  Do NOT wipe down the inside of the mouthpiece where the cell is located. Doing so will result in moisture getting on the cell causing permanent contamination to the cell.
-  Cleaning with products that contain alcohol may result in permanent contamination of the sensor.

Servicing

If your unit requires servicing, please contact your authorized distributor or Micro Direct, Inc. directly.



The H₂ Sensor should be replaced every two years.

service@mdspiro.com

Telephone: (800) 588-3381

Spares

Part Number	Description
MH15	H2 Calibration kit, 17 Liters H2 balance Nitrogen
MH10	H2 Replacement calibration gas 17 Liters H2 balance Nitrogen
MC22	Replacement control valve
MEC1007	Reducing connector for calibration
PSA1800	Mouthpiece adapter with valve
3301	Mouthpieces 100 per bag
3304	Nose Clips 20 per pack
RB20	Special two-way valve mouthpiece for multiple breath tests, 20 per box
48-70	Protex Disinfectant Wipe

Specifications

Gas Detected	Hydrogen
Concentration Range	20-500 PPM (value below 20 is not reliable).
Maximum Overload	2000 PPM
Detection Sensor Used	Electrochemical fuel cell
Sensitivity	1 PPM
Accuracy (repeatability)	±5% or ±5 ppm whichever is greater
Operating Temperature	41-86 degrees Fahrenheit
Ideal Operating Temperature	68 degrees Fahrenheit
Operating Pressure	Atmospheric 10%
Operating Humidity	30% to 90% RH
Operating Altitude	Sea level to 6000 ft
Storage Temperature	-4 to + 158 degrees Fahrenheit
Storage Humidity	15% to 90% RH
Sensor Life	2 years, 6 month warranty
Sensor Drift	<2% per month
Display	128 X 64 pixels Graphic LCD
Power Supply	Single 9V battery
Weight (approximate)	6.35 ounces including battery
Dimensions	5.3" x 2.6" x 2.4"

Symbols



In accordance with Directive 93/42/EEC

0120



Type B Device

Environment

This instrument complies with directive EEC89/336 electromagnetic compatibility but may be affected by cellular phones and by electromagnetic interference exceeding levels specified in EN 50082-1:1992



To avoid the potential effects on the environment and human health as a result of the presence of hazardous substances in electrical and electronic equipment, end users of electrical and electronic equipment should understand the meaning of the crossed-out wheeled bin symbol. Do not dispose of WEEE as unsorted municipal waste and have to collect such WEEE separately.

Important Information Regarding Electromagnetic Compatibility (EMC)


Medical devices may be susceptible to electromagnetic interference from other devices such as PC's and mobile telephones. Electromagnetic interference may impair the operation of the medical device and could create a potentially unsafe situation.

In order to regulate the requirements for EMC, to limit unsafe product situations, BS EN 60601-1-2 standard has been implemented. This standard defines the levels of Immunity to electromagnetic interference as well as the levels of electromagnetic Emissions for medical devices. As a medical device, the H₂ Check conforms to BS EN60601-1-2 standard for both Immunity and Emissions.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The H ₂ Check is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated Immunity IEC 61000-4-3	10 V/m	10 V/m	Avoid use in environments likely to exceed 10 V/m
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 k V air	+/- 6 kV contact +/- 8 k V air	No restrictions in the intended environment
Electrical fast transient/burst IEC 61000-4-4	N/A	N/A	None
Surge IEC 61000-4-5	N/A	N/A	None
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	N/A	N/A	None
Power Frequency (50/60 Hz) magnetic field IEC 61000-4-8	N/A	N/A	None
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The H ₂ Check is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emission Test	Compliance level	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The H ₂ Check uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Group B	The H ₂ Check can be used in domestic light and heavy industrial environments.
Harmonic emissions IEC 61000-3-2	[Not Applicable]	
Voltage fluctuations / flicker emissions IEC61000-3-3	[Not Applicable]	
	[See 5.2.2.1c) and Figure 1]	The H ₂ Check is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplied buildings used for domestic purposes.
	[See 5.2.2.1 c) and Figure 1]	The H ₂ Check is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplied buildings used for domestic purposes.
RF Emissions CISPR 14-1	Complies	The H ₂ Check is not suitable for interconnection with other equipment.
RF Emissions CISPR 15	Complies	The H ₂ Check is not suitable for interconnection with other equipment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The H ₂ Check is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the H ₂ Check including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

<p>Conducted RF IEC 61000-4-6</p>	<p>3 Vrms 150 KHz 80 MHz</p>	<p>[V₁] V</p>	<p>Recommended separation distance</p> $d = \frac{[3.5]}{V_1} \sqrt{P}$
<p>Radiated RF IEC 61000-4-3</p>	<p>3 V/m 80 MHz to 2.5 GHz</p>	<p>[E₁] V/m</p>	$d = \frac{[3.5]}{E_1} \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \frac{[7]}{E_1} \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Fields strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p>			
<p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the H₂ Check is used exceeds the applicable RF compliance level above, the H₂ Check should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the H₂ Check.</p>			
<p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V₁] V / m</p>			