CO Check + / CO Check + Baby
Operating Manual

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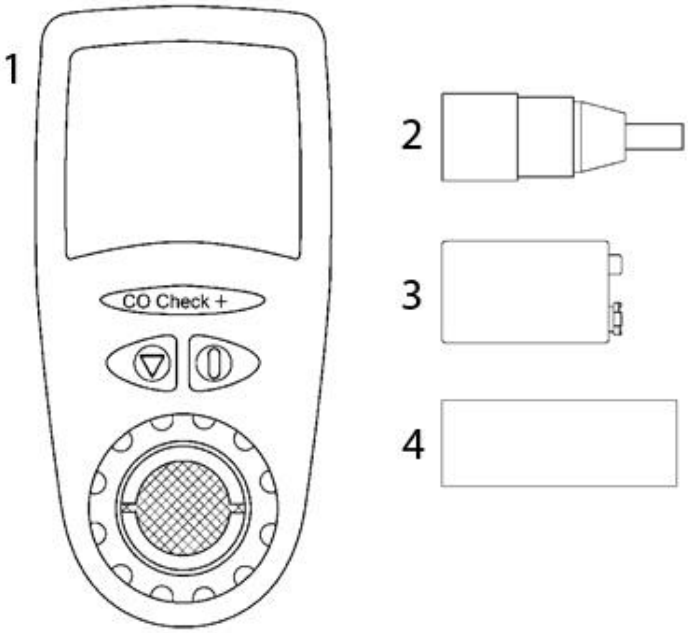
CONTENTS

Package Contents

The CO Check+ / CO Check+ Baby are supplied with:

1. CO Check + (Cat. No. CO10) / CO Check + Baby (Cat no. CO15)
2. 22 mm reducing connector for calibration
3. 9 Volt Battery
4. SafeBreath™ filtered cardboard mouthpieces (Box of 200 Cat No. FM200) or cardboard mouthpieces (Bag of 100 Cat No. 3301)
5. Soft shell carry pouch
6. Operating Manual



Keypad Interface


= ON/OFF Power button


= Select Function button

* See cleaning guidance on page 13.

Overview

All patients attending a smoking cessation program should have their smoking habits established and checked with the CO Check+/CO Check+ Baby at every visit. The results of an initial test may sound alarming to many smokers but within a few days of stopping, CO levels can drop to normal and it is very encouraging for a smoker to see this. CO monitoring is an extremely powerful tool for a smoking cessation counselor, physician or respiratory therapist.

Taking a test before a COPD patient stops smoking will help you gauge their level of nicotine dependence and taking it after they have stopped will give them real proof that what they are doing is working.

The best time to do a test is in the afternoon as CO levels fall over-night and morning readings can sometimes give misleadingly low results. High readings in the morning on the other hand, would be strong evidence of heavy inhalation and high nicotine dependence.

When the environmental reading is enabled, background CO levels are considered when carrying out a breath test. If the background levels are 10ppm for example, then when the person is taking a breath test this background reading of 10ppm will be considered.

For example, if the environmental monitor is ON and a reading of 10 ppm is detected and the patient records 3 ppm, then the measurement displayed will be the higher value i.e. 10 ppm.

Conversely, if the environmental monitor is OFF, then the measurement displayed, will be the actual value recorded by the patient i.e. 3ppm.

Intended Use

The CO Check+ / CO Check+ Baby is a hand held portable battery-operated device used for measuring the carbon monoxide (CO) concentration on the breath, calculating the percentage of carboxyhemoglobin (%COHb) in the blood and for the CO Check

+ Baby, also the percentage of fetal carboxyhemoglobin (%FCOHb).

They are specifically designed as a screening tool for smoking cessation.

They are easy to use, very accurate and require a single breath into the device to display CO results in parts per million (PPM) and the percentage of carboxyhemoglobin (%COHb) and the percentage of fetal carboxyhemoglobin (%FCOHb) - (CO Check+ Baby only).

Accessories

There are various accessories available for use with the CO Check+ / CO Check+ Baby device. The device may be used with either a standard 22 mm disposable cardboard mouthpiece and adapter or the SafeBreath™ filtered mouthpiece to eliminate the need for an adapter and to ensure maximum hygiene and avoid any risk of cross contamination. SafeBreath disposable cardboard filtered mouthpieces have a proven bacterial/viral efficacy >99%.*

Note: All cardboard mouthpieces are single patient use and should be disposed of after each patient – using the same mouthpiece for different patients, will increase the risk of cross contamination between patients.

Operation

Insert the 9V battery by removing the battery cover and clipping the battery in place, replace the battery cover. Insert the SafeBreath cardboard filtered mouthpiece or if not using a SafeBreath mouthpiece, insert the plastic mouthpiece adapter followed by a cardboard mouthpiece.

Turn the CO Check+ /CO Check+ Baby ON by pressing Power key .The device will display CO then the version number (ex. 4r) before starting the countdown timer of 15 seconds (CO Check+) and 10 seconds (CO Check+ Baby).

Encourage the subject to hold their breath until the unit beeps to start the test. The display will show the blow icon.

The subject should place their lips around the cardboard mouthpiece and blow gently and continue blowing until their lungs are completely empty. CO is collected in the last portion of the breath (alveolar breath).

Results Display

The CO Check+ / CO Check+ Baby will beep and show the final reading in PPM (parts per million).

By pressing the Select Function key the reading changes to %COHb (carboxyhemoglobin).

and then press Select Function key to display % FCOHb (fetal carboxyhemoglobin) - (CO Check Baby only)

Pressing again reverts back to PPM.

The maximum reading the CO Check can measure is 99 PPM. Any reading above that will be displayed as - - (over range).

After examining the readings, the unit can either be switched off using the ON/OFF Power key or another measurement can be carried out by pressing the Select Function key for at least three seconds.

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

Operation (Environmental Mode Enabled)

Insert the 9V battery by removing the battery cover and clipping the battery in place, replace the battery cover. Insert the SafeBreath cardboard filtered mouthpiece or if not using a SafeBreath mouthpiece, insert the plastic mouthpiece adapter followed by a cardboard mouthpiece.

Turn the CO Check+/CO Check+ Baby ON by pressing Power key. The device will display CO then the version number (ex. 4r) before starting the countdown timer.

The unit will countdown for 10 seconds to ensure the sensor is stabilized.

When the countdown timer reaches zero, it will display the current environmental reading

Press the Select Function key and the unit will start ‘breath hold’ countdown timer of 15 seconds (CO Check+) and 10 seconds (CO Check + Baby). Encourage the subject to hold the breath until the unit beeps to start the test. The display will show the blow icon.

The subject should place their lips around the cardboard mouthpiece and blow gently and continue blowing until their lungs are completely empty. CO is collected in the last portion of the breath (alveolar breath).

Results Display

The CO Check+/CO Check+ Baby will beep and show the final reading in PPM (parts per million).

By pressing the Select Function key the reading changes to %COHb (carboxyhemoglobin).

and then press Select Function key to display % FCOHb (fetal carboxyhemoglobin) - (CO Check Baby only)

Pressing  again reverts back to PPM.

The maximum reading the CO Check can measure is 99 PPM. Any reading above that will be displayed as - - (over range).

After examining the readings, the unit can either be switched off using the ON/OFF Power key  or another measurement can be carried out by pressing the Select  Function key for at least three seconds.

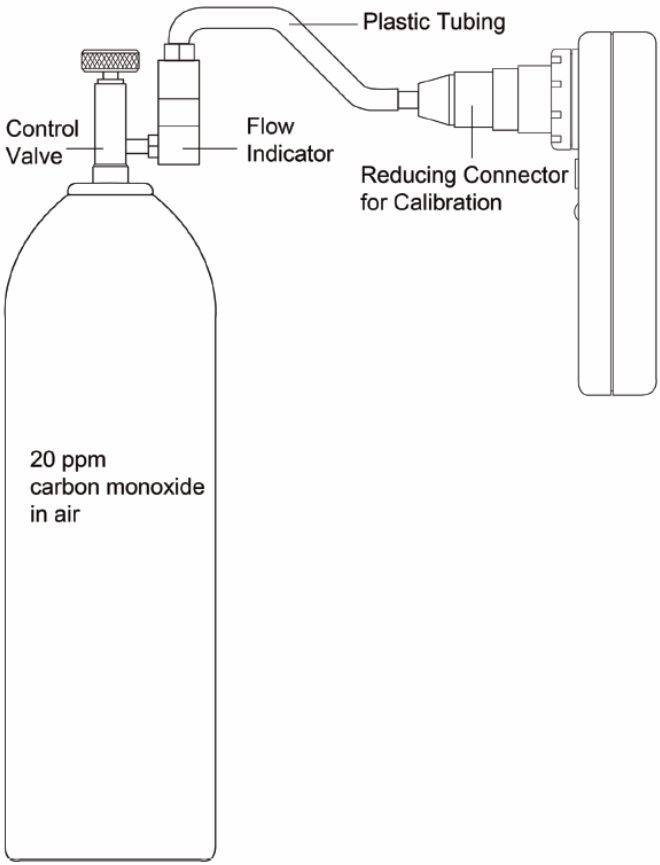
To save the battery, the unit will switch OFF automatically after three minutes if not used.

Warning/Cautions

- ⚠ If higher than expected levels of CO are displayed this could be due to CO poisoning and medical attention should be immediately sought.
- ⚠ The CO Check+ / CO Check+ Baby has a cross-sensitivity to hydrogen (from some gastro-intestinal disorders) which may affect the reading.
- ⚠ Cleaning with products that contain alcohol may result in permanent damage to the sensor. *See page 13 for non-alcohol wipes*.
- ⚠ The battery should be changed when the word ‘BAT’ appears on the display.
- ⚠ All mouthpieces including SafeBreath™ mouthpieces, are single patient use and should be disposed of after each patient – using the same mouthpiece for different patints will increase the risk of cross contamination between patients.
- ⚠ Please only use accessories supplied by Micro Direct, Inc. to ensure the device performs as intended.

Calibration

The device should be recalibrated once a month. Calibration gas can be purchased from Micro Direct, Inc. *see page14 for full ordering details*.



To calibrate the device, perform the following steps:

1. Connect the control valve (Cat. No. MC22) to the 20ppm gas cylinder. (Cat. No. MC10) calibration gas cylinder shown in the diagram above.
2. Connect the short plastic tubing reducing connector (Cat. No. MEC1007).

3. Put the device into calibration mode by pressing the Select Function key and turning the device on. Keep the select key pressed until the device displays ‘Cb’. Release the select key.

4. The device will countdown from 15 to 0 with CAL symbol ON. It will then display the blow icon.

5. Attach the connector and open the control valve (anti-clockwise) until knob will not turn any further. The supply of gas is .25L/minute.
6. Apply this flow until the device beeps after 20 seconds then turn the gas off. The device will display the gas concentration reading.
7. If the reading is not 20 ppm, press the Select Function key for at least 3 seconds to accept the new calibration value. The device will say ‘dn’ (done) and then will show 20 ppm.

It is advisable to accept the calibration even though it displays 20 ppm. This will reset the calibration due timer.

Switch off the device if the calibration was incorrectly performed. Do not press the Select Function key

⚠ To prevent incorrect calibration, only the readings within the range of 16-24 can be calibrated. An ‘Er’ (Error)

message will be displayed if the calibration is accepted for reading outside this range.

8. Switch off the device; wait for a minute and it is now ready for use.

If the device is not calibrated for six months, the device will beep three times before countdown starts and will display ‘Cd’ (Calibration due) for 3 seconds. Thereafter the device will operate as normal but the reading will not be guaranteed.

Setting Environment Mode

Environment reading on start-up can be disabled or enabled. Switch ON the unit and wait for the countdown to begin. When the number

approaches 5, press the Select Function key. When the unit beeps, release the Select Function key. At the end of the countdown, the unit will display ‘EN’ for 3 seconds following by either ‘OF’ (Off) – your current setting or ‘ON’ (On).

Press the Select key momentarily (< 0.5 sec), to change the mode. Press the Select key for more than 3 seconds to accept the mode either ‘ON’ or ‘OF”. Thereafter the unit will restart with your selected setting.

Battery Life

The 9V battery should give at least 30 hours of continuous use. When the battery is low, it will display ‘bL’ (battery low) for three seconds.

The device can still be used, but it is advisable to replace the battery.

It is recommended to use an Alkaline battery.

⚠ The device will need recalibration after the replacement of the battery. *Duracell notification - Alkaline batteries can be safely disposed of with normal household waste. Never dispose of batteries in fire because they could explode*.

If the battery is very low such that the reading is not reliable, it will display ‘bd’ (battery dead) and will not operate any more.

Power Saving

To save battery power, the device will automatically turn itself off after three minutes of the last key press. Do not remove the battery unless the device is not going to be used for a very long time. Remember, calibration will be required when the battery is reconnected.

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

Cleaning

The plastic adapters should be replaced on a monthly basis or after 250 tests (whichever is sooner). Between tests the adapter may be immersed in a cold disinfection solution or mild detergent sterilization solution then **MUST** be thoroughly rinsed in water and dried completely before reuse.

The device can be cleaned using non-alcohol wipes (s*ee page 14)*. Please be certain not to touch the surface of the sensor or allow moisture to do the same.

Cleaning with products that contain alcohol may result in permanent contamination of the sensor.

Servicing

If your unit requires servicing or repair, then please contact Micro Direct, Inc.

The CO Sensor should be replaced every two years.

If the device starts with ‘Er’ (Error) message, it should be returned for service.

Email: service@mdspiro.com
Tel: 800-588-3381 or 207-786-7808

Consumables

Catalog Number	Description
MC15	CO Calibration Kit (includes 20 ppm gas)
MC10	CO Replacement Tank (17 Liters)
MC22	Control Valve for Calibration
FM200	SafeBreath™ Mouthpieces (Box of 200)
3301	CO Mouthpieces (Bag of 100)
PSA1800	Intermediate Plastic Adapters
CS101	Soft Shell Carry Pouch
48-70	Protex Disinfectant Wipe
FC50	Fuel cell for CO Check+ / CO Check+ Baby

Specifications

Gas Detected	Carbon Monoxide
Concentration Range	0-99 PPM
Detection Sensor Used	Electrochemical fuel cell
Sensitivity	0.1 PPM (0-10 PPM range); 1 PPM (10-99PPM range)
Accuracy (repeatability)	2ppm
Operating Temperature	41 - 95 degrees F
Operation pressure	Atmospheric 10%
Operating Humidity	30% to 90% RH
Operating Altitude	Sea level to 6000 ft
Storage Temperature	68 - 158 degrees F
Storage Humidity	10% to 90% RH
Hydrogen cross-sensitivity	<12% at 68 degrees F
Sensor Life	2 - 5 years, 2 years warranty
Sensor Drift	<2% per month
Display	Custom LCD
Power Supply	Single 9V battery
Weight Approximately	Approximately 5 ounces
Dimensions	5” x 2.5” x 1.25”

Symbols

In accordance with Directive 93/42/EEC

0120

Type B Device

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 CO Check conforms to BS EN60601-1-2 standard for both Immunity and Emissions.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The CO 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	10V/m	10V/m	Avoid use in environments likely to exceed 10V/m
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV 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 CO 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.		
Emissions Test	**Compliance level**	**Electromagnetic environment guidance**
RF Emissions CISPR 11	Group 1	The CO 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	Class B	The CO Check can be used in domestic, light and heavy industrial

		environments.
Harmonic emissions IEC 61000-3-2	[Not Applicable]	
Voltage fluctuations / flicker emissions IEC 61000-3-3	[Not Applicable]	
	[See 5.2.2.1 c) and Figure 1]	The CO 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 CO 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 CO Check is not suitable for interconnection with other equipment.
RF Emissions CISPR 15	Complies	The CO Check is not suitable for interconnection with other equipment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The CO 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**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 KHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	[V1] V [E1] V/m	Portable and mobile RF communications equipment should be used no closer to any part of the CO Check, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3.5}{V1}] \sqrt{P}$ $d = [\frac{3.5}{E1}] \sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{}] \sqrt{P}$ 800 MHz to 2.5 GHz ……E1 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a, should be less than the compliance level is each frequency range. b Interference may occur in the vicinity of equipment marketed with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RD transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CO Check is used exceeds the applicable RD compliance level above, the CO Check should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CO Check.

b Over the frequency range 150 KHz to 80 MHz, field strength should be less that [V1] V/m