CO Check Pro
Operating Manual

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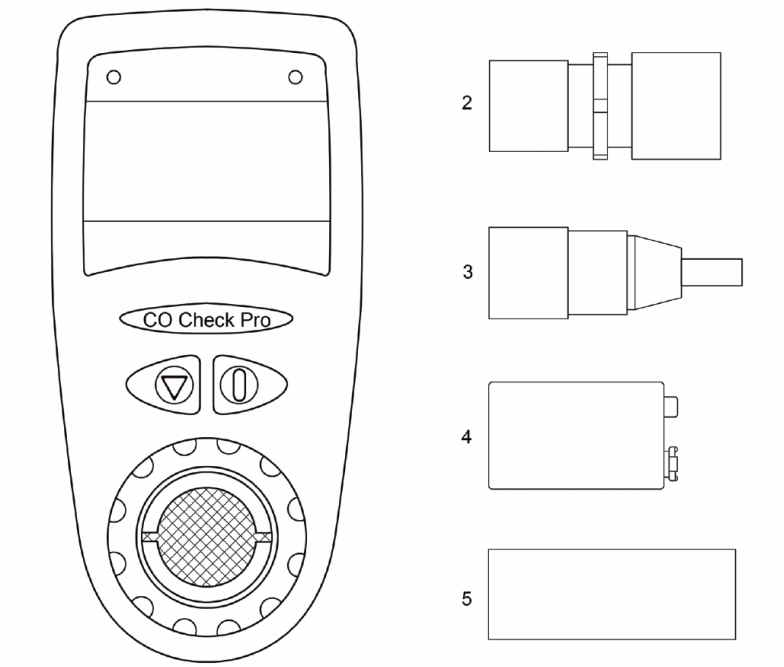
Caution: Federal Law restricts this device to sale by or on the order of a physician (or licenced practitioner)

Package Contents

The CO Check Pro device is supplied with:

1. CO Check Pro (#CO20)
2. 22 mm plastic mouthpiece adapter* (#PSA1800)
3. 22 mm reducing connector for calibration (#MEC1007)
4. 9 Volt Battery
5. 5 Disposable cardboard mouthpieces (#3301)
6. Hard shell plastic carry case (# CS101)
7. Operating Manual



Keypad Interface

= ON/OFF Power button

= Select Function button

* See cleaning guidance on page 14.

Overview

The CO Check Pro is handheld portable battery-operated device used for measuring the concentration of carbon monoxide (CO) in the breath and calculating the percentage of carboxyhemoglobin (%COHb) in the blood.

The CO Check Pro is designed to be used primarily as a screening tool for smoking cessation but it can also be used in physicians' offices, emergency departments and fire-fighting services. In smoking cessation clinics, it is used for checking the client's progress and compliance. General practitioners, emergency room personnel and fire-fighting services can use the device to quickly assess the level of suspected CO poisoning.

The CO Check Pro is easy to use, very accurate and requires a single breath into the device to display CO results in parts per million (PPM) and the percentage of carboxyhemoglobin (%COHb).

The CO Check Pro is based on an electrochemical fuel cell sensor, which works through the reaction of carbon monoxide (CO) with an electrolyte at one electrode, and oxygen (from ambient air) at the other. This reaction generates an electrical current proportional to CO concentration. Output from the sensor is monitored by a micro-processor, which detects peak expired concentrations of alveolar gas. This is then converted to percent carboxyhemoglobin (%COHb) using the mathematical relationships described by Jarvis et al[1], for concentrations below 90 ppm, and by Stewart et al[2] for higher levels. Raised levels of carboxyhemoglobin are most commonly caused by accidental smoke inhalation/CO poisoning or cigarette smoking. The CO Check Pro includes a countdown timer as an aid to time the breath hold period prior to exhalation.

References[1,2]

1. Jarvis MJ, Belcher M, Vesey C, Hutchison DCS
   Low cost carbon monoxide monitors in smoking assessment
   Thorax 1986; 41: 886-887
2. Stewart RD, Stewart RS, Stamm W, Seleen RP
   Rapid estimation of carboxyhemoglobin levels in fire fighters
   JAMA 1976; 235, 390-392

The CO Check Pro can also measure ambient CO when turned on to ensure that the environment is free from CO contamination (if enabled).

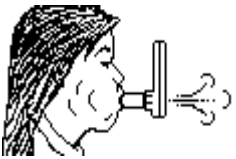
Intended Use

The CO Check Pro is used for the monitoring of carbon monoxide (CO) in an adult's exhaled breath. The CO Check Pro is for use in smoking cessation programs and can be used for the screening of CO poisoning and smoke inhalation. Also, the CO Check Pro can be used for ambient air monitoring. For use by healthcare professionals only.

Operation

Insert the 9V battery by removing the battery cover and clipping the battery in place then replacing the battery cover. Insert a SafeBreath mouthpiece (order #FM200); or if not using a SafeBreath mouthpiece, insert the plastic mouthpiece adapter (order #PSA1800) followed by a cardboard mouthpiece (order #3301).

Turn on the CO Check Pro by pressing the ON/OFF Power . The device will display the version number before starting the countdown timer. The "breath hold" timer will now count down from 15 seconds. Encourage the subject to hold their breath until the device beeps to start the test. The display will show the blow icon.



In the user menu, you can set the breath hold timer to a desired number of seconds i.e. you can set the breath hold to a minimum of 10 seconds if the subjects can't hold their breath for more than 10 seconds.

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).

The CO Check Pro will beep and display the final reading in PPM (parts per million). By pressing the Select Function key , the reading scrolls to %COHb (carboxyhemoglobin). Pressing the Selection Function key again reverts back to PPM.

⚠ The maximum reading the CO Check Pro can measure is 99 PPM. Any reading above that will be displayed as - - (which means it's over the range).

Colored lights are there to represent and provide a visual display of the resulting PPM reading. The colored lights represent the following:

0-6 ppm	=	Green Light
7-10 ppm	=	Yellow Light
11-20 ppm	=	Red Light
20+ ppm	=	Flashing Red Light

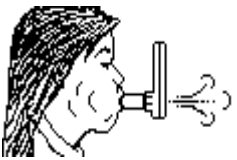
After examining the readings, the device can either be switched off using the ON/OFF Power key, or another measurement can be carried out by pressing the Select Function key for at least three seconds.

To save the battery, the device will switch OFF automatically after three minutes of non-use.

Operation – Environment Mode

Insert the 9V battery by removing the battery cover and clipping the battery in place then replacing the battery cover. Insert a SafeBreath mouthpiece (order #FM200); or if not using a SafeBreath mouthpiece, insert the plastic mouthpiece adapter (order #PSA1800) followed by a cardboard mouthpiece (order #3301).

Turn on the CO Check Pro by pressing the ON/OFF Power. The device will display the version number before starting the countdown timer. The device will countdown for 10 seconds to ensure that the sensor is stabilized. When the countdown timer reaches zero, it will display the current environment reading. Press the Select Function Key and encourage the subject to continue holding their breath until the device deeps and the blow icon appears.



In the user menu, you can set the breath

hold timer to a desired number of seconds (above the initial 10 seconds). i.e. An additional 5 seconds for a total of 15 or none if the subjects can't only hold their breath for 10 seconds.

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).

The CO Check Pro will beep and display the final reading in PPM (parts per million). By pressing the Select Function key  , the reading scrolls to %COHb (carboxyhemoglobin). Pressing the Selection Function key  again reverts back to PPM.

⚠ The maximum reading the CO Check Pro can measure is 99 PPM. Any reading above that will be displayed as - - (which means it's over the range).

Colored lights are there to represent and provide a visual display of the resulting PPM reading. The colored lights represent the following:

0-6 ppm	=	Green Light
7-10 ppm	=	Yellow Light
11-20 ppm	=	Red Light
20+ ppm	=	Flashing Red Light

After examining the readings, the device 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 device will switch OFF automatically after three minutes of non-use.

Warning/Cautions

⚠ If higher than expected levels of CO are displayed this could be due to CO poisoning and medical attention should be sought immediately.

⚠ The CO Check Pro 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 Supplies section on page 15 for non-alcohol wipes.*
- ⚠ The battery should be changed when the low battery icon appears on the display.
- ⚠ Please only use accessories supplied by Micro Direct, Inc. to ensure the device performs as intended.
- ⚠ The CO Check Pro is a screening device. Blood tests and examinations are required to validate possible CO poisoning.
- ⚠ The CO Check does not protect property or persons, and should not be used for industrial or domestic purposes (heating, faulty fireplace). It does not meet the standards of protection of persons against CO pollution.

The SafeBreath filtered mouthpieces and regular disposable cardboard mouthpieces are single-use only. Re-use of these single use mouthpieces can increase the risk of cross infection and the mouthpiece should be disposed of after use by the subject.

User Menu

This menu allows the user to either calibrate the device, set the environment mode option, select the breath hold count time or set the light colors.

To enter the 'User Menu', press the ON/OFF Power key  and the Select Function key  simultaneously. Do not release the keys until the User Menu appears.

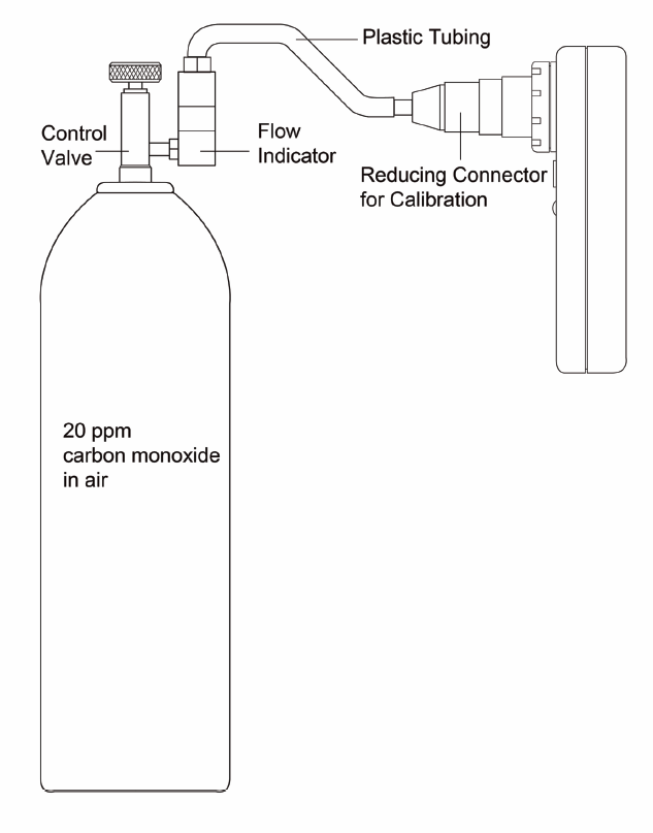
User Menu

Calibrate
Environment Mode
Breath Hold Time
Set Light colors
Exit

The first option is highlighted. To move between options, press the Select Function key . To select the highlighted option, press the Select Function key for at least 3 seconds to confirm.

Calibration

The device should be recalibrated at least once every six months. Calibration gas can be purchased from Micro Direct, Inc. (*See* Supplies for full ordering details on page 15).



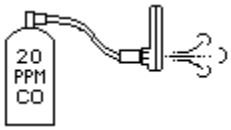
To calibrate the device, perform the following steps:

1. Connect the short plastic tubing connected to the regulator (#MC22) to the reducing connector found in the carry case (#MEC1007).
2. Connect the regulator to the 20-ppm calibration gas cylinder (#MC10) as shown in the diagram on the device page
3. To enter the User Menu, press the ON/OFF Power key and the Select Function Key simultaneously. Do not release the key until the user menu appears.

User Menu

Calibrate
Environment Mode
Breath Hold Time
Set Light colors
Exit

4. Calibrate is already highlighted. Press and hold the Select Function Key for at least 3 seconds to confirm the selection.
5. The device will countdown from 15 to 0 and then will display the calibration icon.



6. Attach the reducing connector to the CO Check Pro and turn the regulator knob fully counter-clockwise until knob will not turn any further. This will supply gas to the CO Check Pro at approximately 0.25 L/min.
7. Apply this flow for approximately 20 seconds until the device beeps then turn the regulator clockwise to shut off the flow of gas. The device will display the gas concentration reading.
8. 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 ‘done’ and then will show 20 ppm.

- It is advisable to accept the calibration even though it displays 20 ppm (i.e. the ideal reading). This will reset the ‘calibration due’ timer.
- Turn 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 ‘Error’ message will be displayed if the calibration is accepted for readings outside this range.

9. Turn 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 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.

Set Environment Mode

To enter the ‘User Menu’, press the ON/OFF Power key  and the Select Function Key  simultaneously. Do not release the key until the user menu appears.

User Menu

Calibrate
Environment Mode
Breath Hold Time
Set Light colors
Exit

The first option is highlighted. To select ‘Environment Mode’, press the Function key until ‘Environment Mode’ is highlighted. To select, press the Select Function key for at least 3 seconds to confirm.

The ‘Environment Mode’ screen will appear and the options are ‘On’, ‘Off’ and ‘Exit’. The current setting will be highlighted. Select the preferred option and press Select Function key for at least 3 seconds to confirm and the display will go back to the ‘User Menu’ screen.

Set Breath Hold Time

To enter the ‘User Menu’, press the ON/OFF Power key and the Select Function Key simultaneously. Do not release the key until the user menu appears.

User Menu

Calibrate
Environment Mode
Breath Hold Time
Set Light colors
Exit

The first option is highlighted. To select ‘Breath Hold Time’, press the Function key until ‘Breath Hold Time’ is highlighted. To select, press the Select Function key for at least 3 seconds to confirm.

If the environment mode is turned on, you can set it for an additional five seconds or none. This allows the subject to hold their breath while the device counts down for 10 seconds to sample the environment CO level then an additional 5 seconds for a total of 15 seconds prior to exhaling. If the subject can only hold their breath for 10 seconds, none would be selected.

If environment mode is turned off, the minimum breath hold time that can be set is 10 seconds.

Press the Select Function key momentarily (<0.5S) to scroll through the times, then press the Select Function key again for at least 3

seconds to confirm the required time and the display will go back to the ‘User Menu’ screen.

None
5 Seconds
10 Seconds
15 Seconds
20 Seconds
25 Seconds
30 Seconds

Set Light colors

To enter the ‘User Menu’, press the ON/OFF Power key  and the Select Function Key  simultaneously. Do not release the key until the user menu appears.

User Menu

Calibrate
Environment Mode
Breath Hold Time
Set Light colors
Exit

The first option is highlighted. To select ‘Set Light Colors’, press the Function key  until ‘Set Light Colors’ is highlighted. To select, press the Select Function key  for at least 3 seconds to confirm.

The following colored warning lights which are a visual display of the resulting PPM reading, can be pre-set to illuminate at any value within the following ranges:

Green	(0 to 20ppm)
Yellow	(0 to 20ppm)
Red	(0 to 30ppm)

Use the Select Function key  to scroll through the values, then press the Select Function key  again for at least 3 seconds to confirm the required value and the display will go back to the “User Menu’ screen.

Battery Life

The 9V battery should provide at least 30 hours of continuous use. 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.

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 so low 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. 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

If using the cardboard mouthpieces with the mouthpiece adapter instead of the SafeBreath filtered mouthpiece (#FM200), it is recommended that the plastic Mouthpiece Adapter (#PSA1800) is replaced after approximately 250 tests or one month. Re-use can increase the risk of cross contamination; therefore, it can be cleaned between test using a mild detergent solution then rinsed with water and left to dry thoroughly.

The device can be cleaned using non-alcohol wipes (see Supplies on page 15). Please be careful not to touch the surface of the sensor or allow any moisture to touch the sensor because it could cause permanent damage to the sensor.

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

Servicing

If your device requires servicing or repair, please contact Micro Direct, Inc. directly.

The CO Sensor should be replaced every two years.

Email: service@mdspiro.com

Telephone: 800-588-3381

Supplies

Order Number	Description
MC15*	Calibration Kit, 20 ppm CO balance Nitrogen
MC10	Replacement Gas, 20 ppm CO balance Nitrogen
MC22	Regulator for Calibration
FM200	SafeBreath Filtered Mouthpieces (Box of 200)
3301	Cardboard Mouthpieces (Bag of 100)
PSA1800	Mouthpiece Adapter w/valve
48-70	Protex Disinfectant Wipe
CS100	Replacement of Fuel Cell and Battery
GC01	CO Guide chart (CO Check Pro only)

* Calibration kit contains tank of CO calibration gas, regulator and tubing.

Specifications

Gas Detected	Carbon Monoxide
Concentration Range	0-99 PPM
Detection Sensor Used	Electrochemical Fuel Cell
Sensitivity	0.1 PPM (0-10 PPM Range) 1.0 PPM (10-99PPM Range)
Accuracy (repeatability)	2 ppm or ±5%, whichever is greater.
Operating Temperature	32 - 104^{O} Fahrenheit
Operating Pressure	Atmospheric 10%
Operating Humidity	30% to 90% RH
Operating Altitude	Sea Level to 6000 ft.
Storage Temperature	-4 - 158^{O} Fahrenheit
Storage Humidity	10% to 90% RH
Hydrogen Cross-Sensitivity	<12% at 68 ^{O} Fahrenheit
Sensor Life	2 - 5 Years, 2-Year Warranty
Sensor Drift	<2% per Month
Display	128 x 64 Pixel Graphic LCD
Power Supply	Single 9V Battery
Weight (approximate)	6 Ounces including Battery
Dimensions	5.5” x 2.5” x 1.25”
***Indicator levels**	Green 0 - 6 PPM Yellow 7 - 10 PPM Red 11 - 20 PPM Flashing red 20+ PPM

* Default Settings - User configurable

Symbols

CE 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.

Caution: Federal Law restricts this device to sale by or on the order of a physician (or licensed practitioner)

Important information regarding Electromagnetic Compatibility

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	3 Vrms 150 KHz to 80 MHz	[V1] V	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** $d = [\underline{3.5}] \sqrt{P}$

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E_1] V/m	$d = [\frac{3.5}{E_1}] \sqrt{P}$ $\frac{V_1}{}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}] \sqrt{P}$ 800 MHz to 2.5 GHz 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). 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 [V_1] V/m

Appendix A – CO Check Pro and Smoking Cessation

The CO Check Pro (#CO20) is an innovative Carbon Monoxide monitor that can be a useful tool for use in smoking cessation programs and clinics.

All people attending a smoking cessation program should have their smoking habits established and checked with the CO Check Pro 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 overnight 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.

One single breath of expiration into the CO Check Pro will give instant results in PPM and %COHB. Built-in color light indicators will also give an instant visual display.

Appendix B – CO Check Pro and Environmental Capture

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

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

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