

iCOquit[®] Smokerlyzer[®]

User Manual

CE
2797



*Your personal CO device, to help you quit smoking,
one breath at a time.*

Definitions

WARNING: Indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury.

CAUTION: Indicates a potentially hazardous situation, which, if not avoided, may result in damage to the device.

NOTE: Used to call attention to notable information that should be followed during use.

Important Information/Reminders

WARNING: The iCOquit® Smokerlyzer® device is for individual use. Do not share your device with anyone to lower the risk of cross-contamination.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the iCOquit® Smokerlyzer® including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. This equipment should be moved if necessary, to avoid interference.

CAUTION: Never use alcohol or cleaning agents containing alcohol or other organic solvents as these vapours will damage the carbon monoxide sensor inside the iCOquit®.

CAUTION: Do not use hand-sanitising products containing alcohol when using the device as this may damage the sensors.

CAUTION: Use of accessories not approved by the manufacturer will invalidate the warranty and may compromise the functionality of the device.

NOTE: Once the battery in the iCOquit® has become flat, the iCOquit® device will need to be disposed of, please see disposal guidance in the 'Disposal of Device' section of this manual.

NOTE: For advice and support on quitting smoking, please consult a Healthcare Professional.

Contents

Definitions.....	2
Important Information/Reminders	2
About this Manual.....	4
Compliance	4
Warnings.....	4
Cautions	4
Contraindications	4
Intended Use / Indications.....	5
Clinical Benefit	5
Instrument Layout	6
Installation and Set-up.....	6
User Interface.....	7
Using the iCOquit®	8
Connecting To An iCOquit® Device	12
Completing A Breath Test	13
Interpreting The Breath Test Result.....	14
Completing The Smoking Habits Questions.....	15
Navigation Drawer Menu Options	16
Troubleshooting	20
Cleaning	21
Technical Specification.....	22
Safety Information and Device Symbols.....	23
Buttons Explained	25
EMC Table/Environment.....	26
Performance Characteristics	30
Warranty.....	32
Disposal of Device	32
Vigilance	32
Responsible Manufacturer and Contacts.....	33

About this Manual

The User Manual provides instructions on how to operate iCOquit® Smokerlyzer® device and the iCOquit® app. It contains relevant information about the device, its uses and its care, including step-by-step instructions with screens and illustrations.

Compliance

The iCOquit® Smokerlyzer® has FDA clearance to market in the USA under 510(K) K211918.

iCOquit® Smokerlyzer® is CE marked according to the Medical Device Regulation (EU) 2017/745.

Please refer to the 'Safety Information' section of this manual for more information on the compliance of the iCOquit® Smokerlyzer®.

Warnings

1. The iCOquit® Smokerlyzer® device is for individual use. Do not share your device with anyone to lower the risk of cross-contamination.
2. Hands should be washed regularly in accordance with infection control practice.
3. Please do not attempt to modify the equipment in any way or use accessories not specified by the manufacturer. Any attempt to do so will invalidate the warranty and may compromise the safety of the device.
4. The iCOquit® Smokerlyzer® is not for use with other inhaled products.
5. The iCOquit® Smokerlyzer® is for indoor use only.

Cautions

1. Never use alcohol or cleaning agents containing alcohol or other organic solvents as these vapours will damage the carbon monoxide sensor inside the iCOquit®.
2. Do not use hand-sanitising products containing alcohol when using the device as this may damage the sensors.
3. Use of accessories not approved by the manufacturer will invalidate the warranty and may compromise the functionality of the device.

Contraindications

There are no contraindications.

Intended Use / Indications

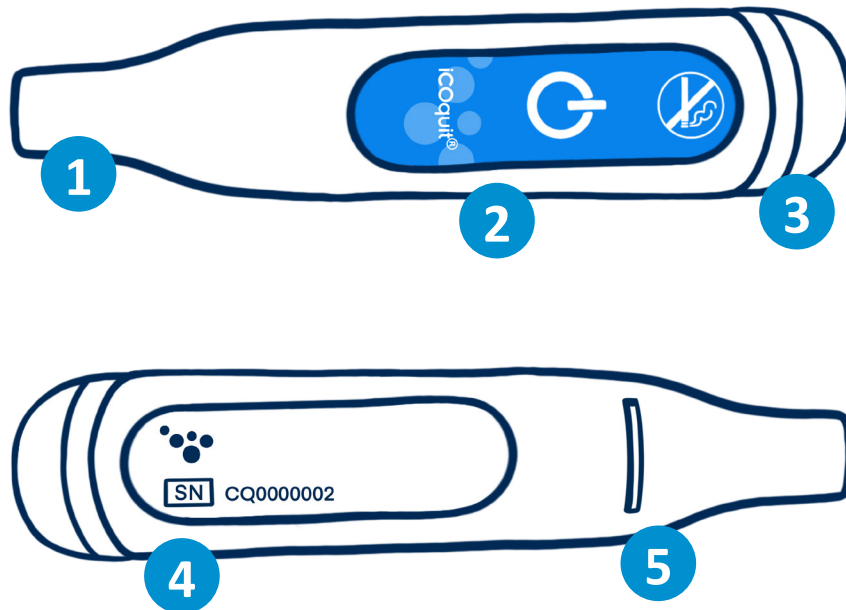
The iCOquit® Smokerlyzer® breath carbon monoxide (CO) device is intended for single patient use by cigarette smoking individuals, notifying the individual user of the amount of CO on their breath produced as a consequence of smoking activity. The Device can be used in smoking cessation programmes.

Clinical Benefit

The iCOquit® Smokerlyzer® is a breath test CO device intended for use by individuals trying to live a healthier lifestyle and improve their general wellness. Monitoring an individual's breath CO levels in ppm can act as a marker of recent smoking activity.

Tracking the CO levels from their phone can be used to encourage the individual to make lifestyle choices to reduce their smoking intake, which, as part of a healthy lifestyle, may help reduce the risk of smoking related chronic diseases.

Instrument Layout



1. Breath sample port
2. On/pairing button
3. LED light ring/pairing light
4. Information label including serial number
5. Breath exhaust.

Installation and Set-up

Downloading the iCOquit® app

App can be downloaded from the App Store or Google Play.

Connecting the iCOquit® device

To connect the device to the app, push the pairing button when instructed to. A blue light will flash once to show pairing is complete.

WARNING: The iCOquit® Smokerlyzer® device is for individual use. Do not share your device with anyone to lower the risk of cross-contamination.

NOTE: This can take up to 5 seconds and will only pair once initiated from within the iCOquit® app.

The device automatically disconnects after 10 seconds of inactivity or when a breath test is complete.

User Interface



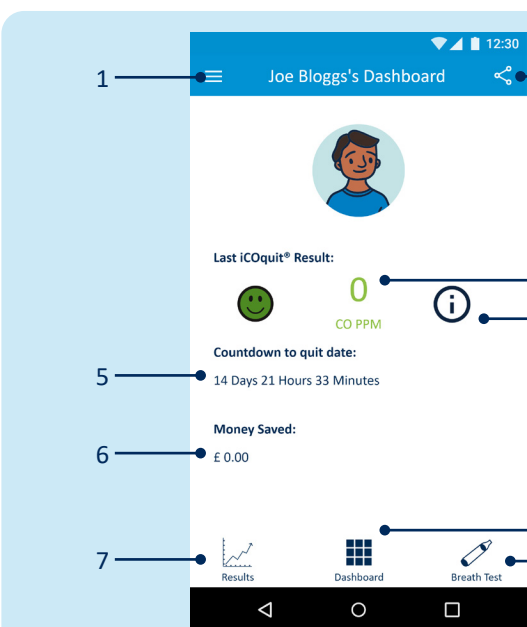
Splash Screen

The splash screen shall display upon starting the app. The splash screen shall disappear once the app has successfully loaded.



Sign In Screen

1. 'Email Address' field.
2. 'Password' field.
3. 'Remember Me' Remembers the users email address and password.
4. 'Forgotten Password?' button, starts a new forgotten password process.
5. 'Sign In' button, starts the authentication process.
6. 'Register' button, starts the user registration process.



Dashboard/Home Screen

1. Hamburger menu button, this will open the menu.
2. Share button, this will share the users last result.
3. The first dashboard shows the users latest CO PPM reading.
4. Information overlay appears on a tap gesture which provides result description.
5. The second dashboard shows days until quit date or if quit date has been reached, it will show number of days smoke-free.
6. The last dashboard shows amount of money user has saved.
7. 'Results' tab will navigate user to results graph.
8. 'Dashboard' tab will navigate user to dashboard.
9. 'Breath Test' tab will navigate the user to the first breath test page if it is not the active tab.

Using the iCOquit®

User Authentication and Registration

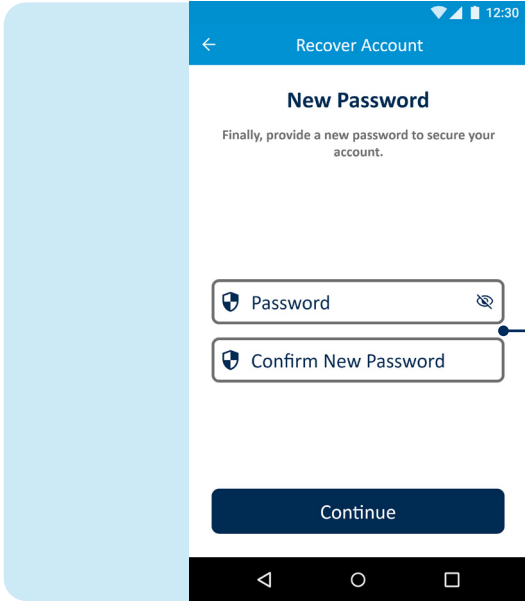
Authentication Screen Options

1. If the user already has an account they will need to complete the authentication fields and tap the 'Sign In' button
2. If the user is already a user, but has forgotten their authentication credentials, the user will need to tap the 'Forgotten Password?' button
3. If the user is not currently a registered user they will need to tap the 'Register' button.

Completing the Forgotten Password Process

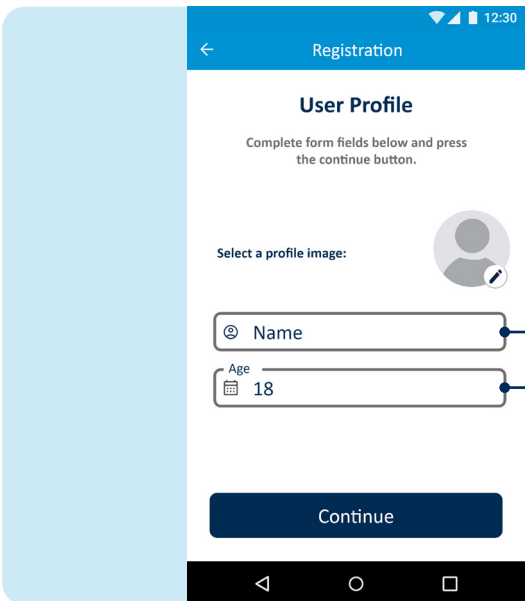
1. The user will to provide the email address they completed registration with and then tap the 'Continue' button.

2. The 9 digit password reset verification code will have been sent to the users' mailbox. The user will then need to tap the 'Continue' button.



- The last step is to provide a new password and rewrite that password and then tap the 'Continue' button.

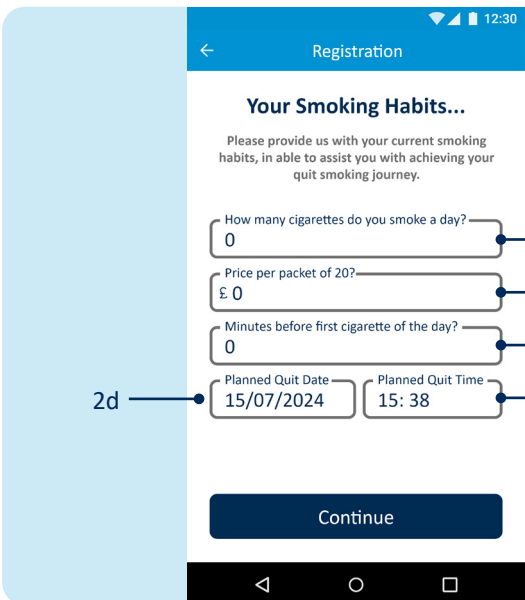
After the new password has been submitted, the app will return to the sign-in page.



Completing the Registration Process

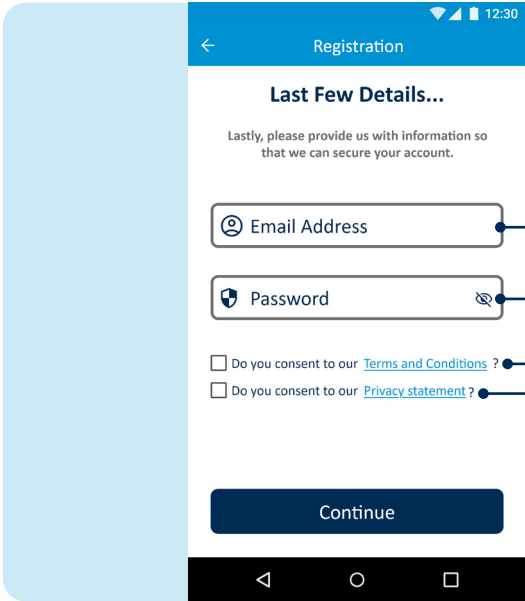
- The user will need to complete the user profile section of the registration process. This will involve:
 - Providing a name
 - Providing their age.

Once this has been completed the user will need to tap the 'Continue' button.



- The second part of the registration process is providing the users smoking habits. This will involve:
 - Providing the number of cigarettes smoked per day.
 - Providing the cost for a pack of 20 cigarettes.
 - Providing the number of hours before the users' first cigarette.
 - Planned quit date.
 - Planned quit time.

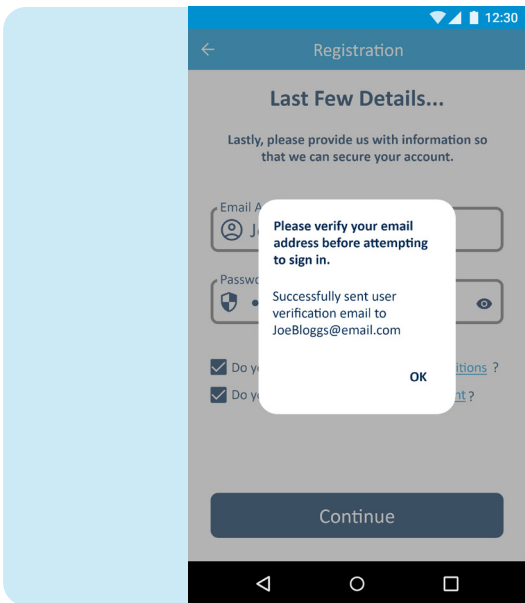
Once this has been completed the user will need to tap the 'Continue' button.



- 3. The final section of the registration process is providing details for authentication and consents. This will involve:
 - a. Providing a valid email address
 - b. Providing a password for authentication.
 - c. Agreeing to terms and conditions
 - d. Agreeing to the privacy statement.

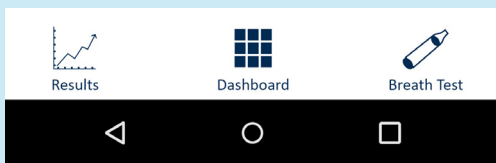
Once the user has provided the required information they will need to tap the 'Continue' button.

NOTE: The password requires an uppercase character, a lowercase character, a number and a special character to be accepted.

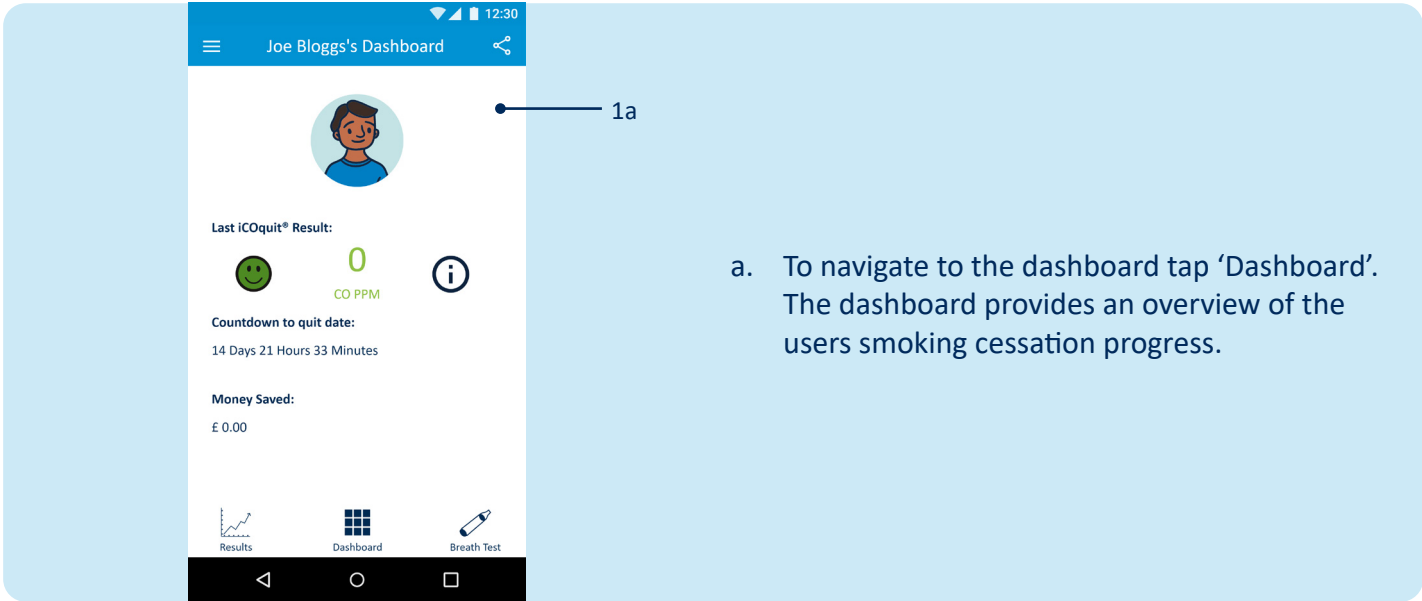


- 4. The user will then be navigated back to the sign in screen. The user must wait for their confirmation email before attempting authentication. The user must tap the link in the email to confirm their email address. After this the user will be authenticated and can return to the app and sign in using the details registered.

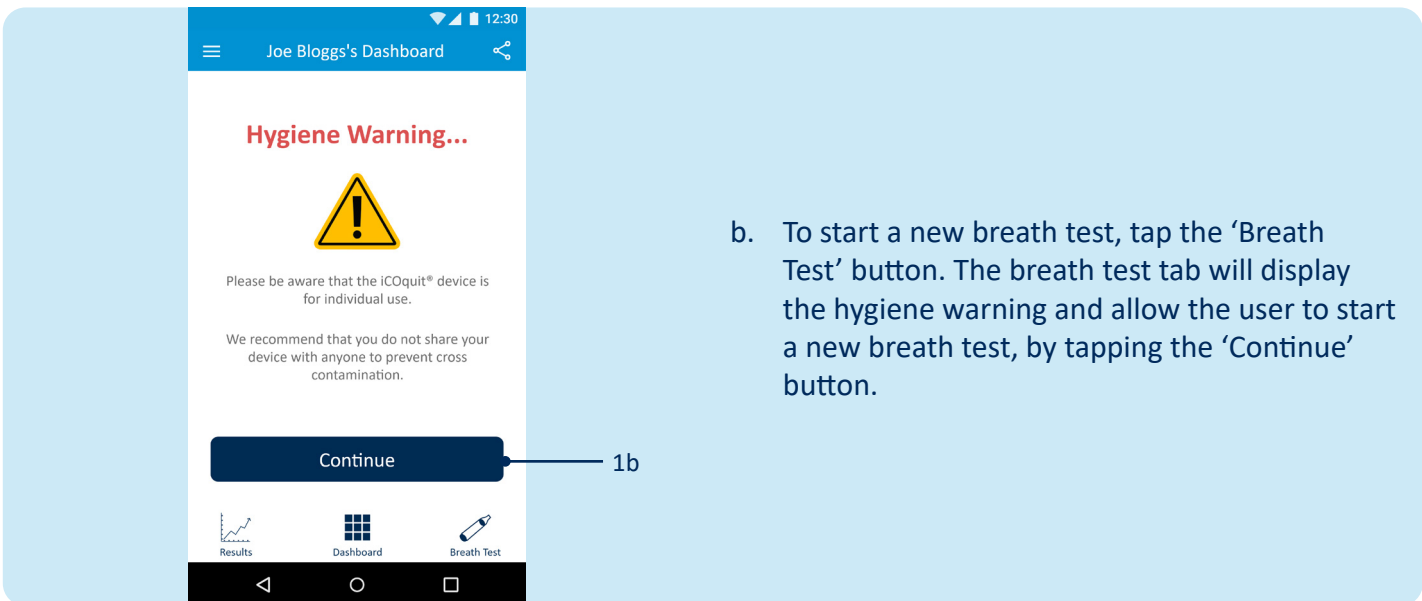
Tabbed Navigation Pages



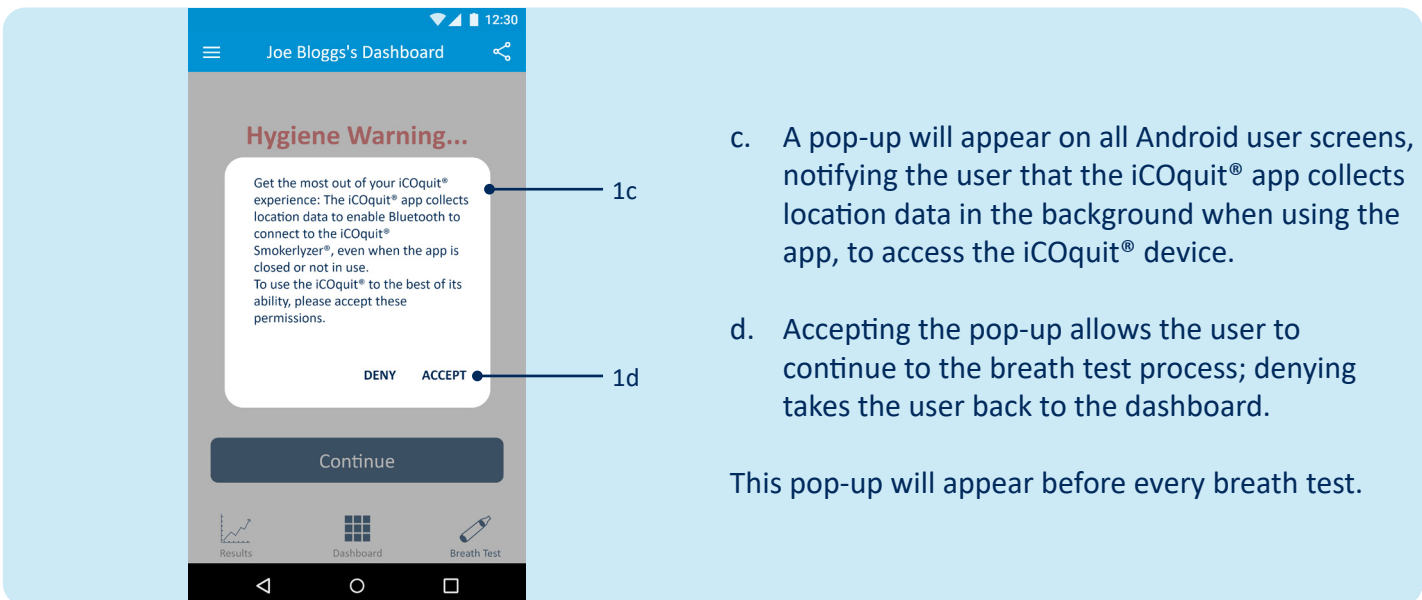
- 1. The tabbed navigation allows navigation between three pages; 'Dashboard', 'Breath Test' and 'Results' the selected item will be highlighted as dark blue while the unselected/non-active items will be grey.



- a. To navigate to the dashboard tap 'Dashboard'. The dashboard provides an overview of the users smoking cessation progress.

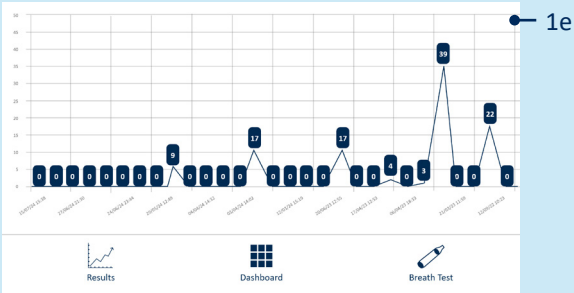


- b. To start a new breath test, tap the 'Breath Test' button. The breath test tab will display the hygiene warning and allow the user to start a new breath test, by tapping the 'Continue' button.



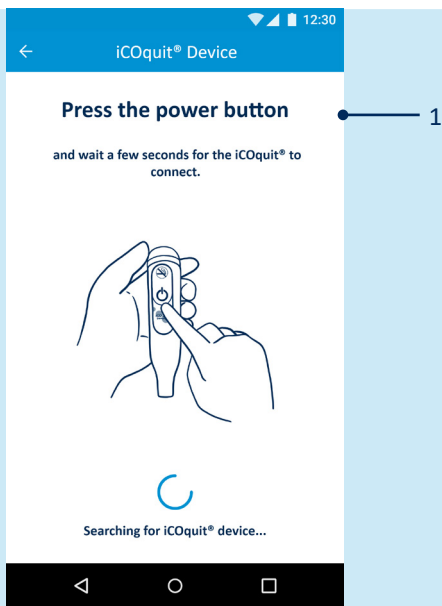
- c. A pop-up will appear on all Android user screens, notifying the user that the iCOquit® app collects location data in the background when using the app, to access the iCOquit® device.
- d. Accepting the pop-up allows the user to continue to the breath test process; denying takes the user back to the dashboard.

This pop-up will appear before every breath test.

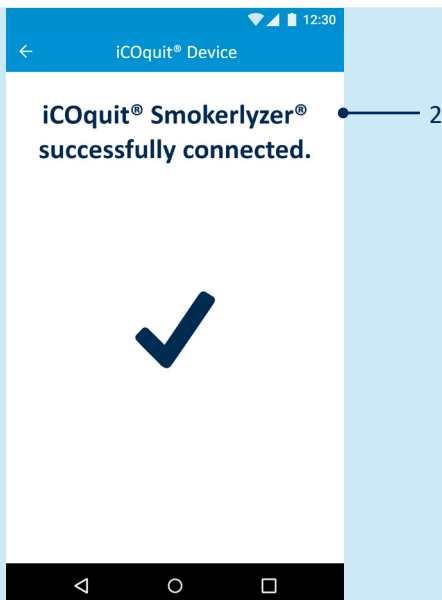


- e. To view historic breath test results, the user will need to tap the 'Results' button. The results are in date order with the latest reading displayed from the left and oldest reading displayed furthest to right.


Connecting To An iCOquit® Device



- 1. The Bluetooth® scanning phase will show a spinner while searching for a device.



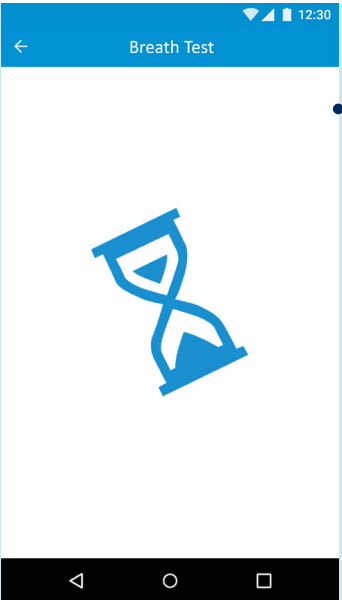
- 2. If an iCOquit® device has been found and successfully connected to, a tick shall be shown to indicate a successful connection between the smart device and iCOquit®.



The screenshot shows the 'iCOquit® Device' screen. At the top, there is a blue header with a back arrow and the text 'iCOquit® Device'. Below the header, the text reads 'Connecting unsuccessful, press to retry.' A large circular refresh icon is centered on the screen. At the bottom, there is a link: 'Still having trouble connecting? Please see the FAQ's page.'

3. If an iCOquit® device has not been found or was unable to successfully connect, a retry icon shall appear indicating connection has failed, but tap the icon to try again.

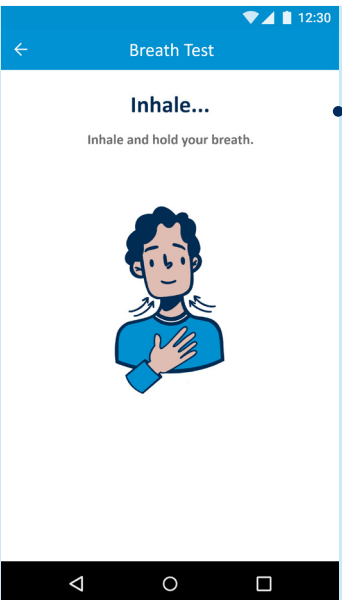
Completing A Breath Test



The screenshot shows the 'Breath Test' screen. At the top, there is a blue header with a back arrow and the text 'Breath Test'. The main content area features a large blue hourglass icon.

Breath Test Initialisation

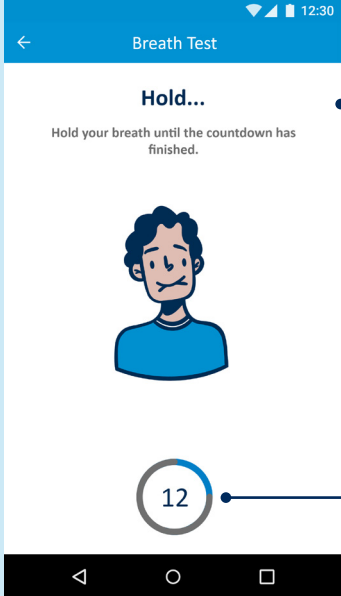
1. The first screen prompts the user to initiate the breath test. To do this the user will need to tap the 'New Breath Test' Button.



The screenshot shows the 'Breath Test' screen with instructions. At the top, there is a blue header with a back arrow and the text 'Breath Test'. Below the header, the text reads 'Inhale...' followed by 'Inhale and hold your breath.' Below the text is an illustration of a person in a blue shirt inhaling, with arrows indicating air entering their lungs.

Inhale Instructions

2. As prompted onscreen, take a deep breath.

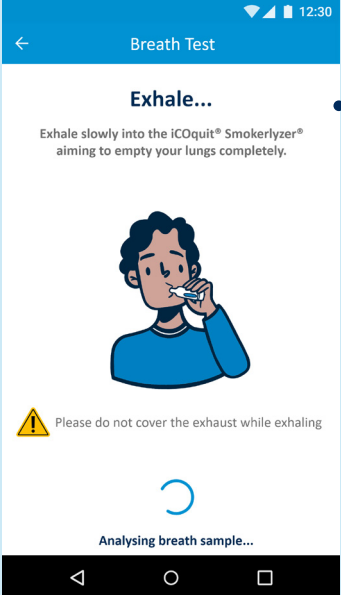


Hold...
Hold your breath until the countdown has finished.

12

Hold Instructions

3. As prompted onscreen, hold your breath until the countdown timer has finished.
4. If the 15 second inhalation countdown is unattainable, begin exhaling when ready and the device will begin measuring breath sample.



Exhale...
Exhale slowly into the iCOquit® Smokerlyzer® aiming to empty your lungs completely.

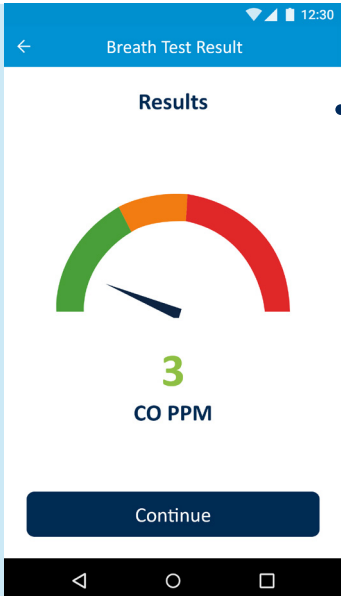
Please do not cover the exhaust while exhaling

Analyzing breath sample...

Exhale Instructions

5. Do not cover vent hole of device when performing a breath test.
6. As prompted on screen, exhale.

Interpreting The Breath Test Result



Results

3
CO PPM

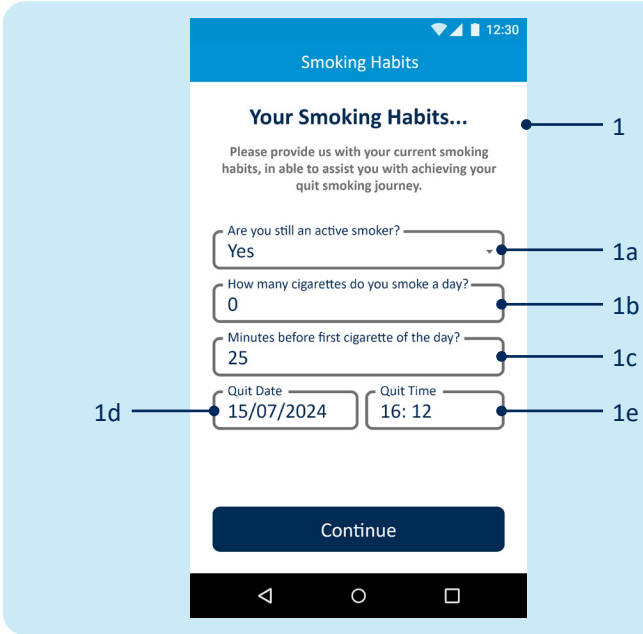
Continue

Interpreting Breath Test Result

1. Breath test result interpretation chart.
 - a. Green = Low CO PPM Reading.
 - b. Yellow = Moderate CO PPM Reading.
 - c. Red = High CO PPM Reading.

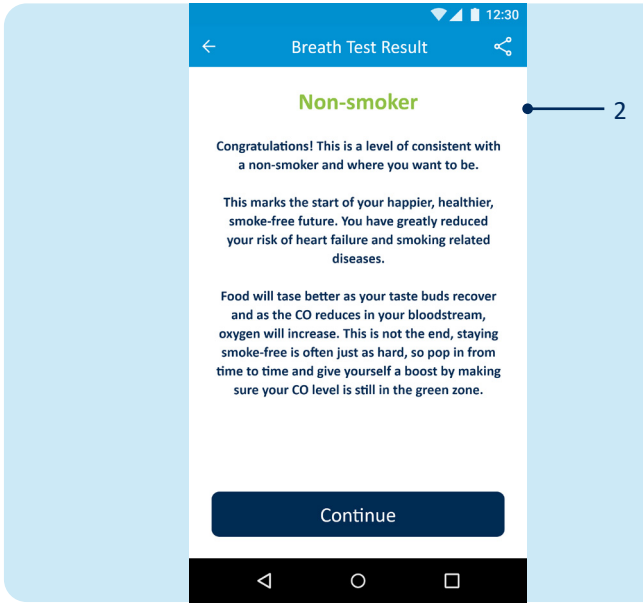
Once a breath test has been completed the user will be navigated to this screen where they will see their CO PPM result.

Completing The Smoking Habits Questions



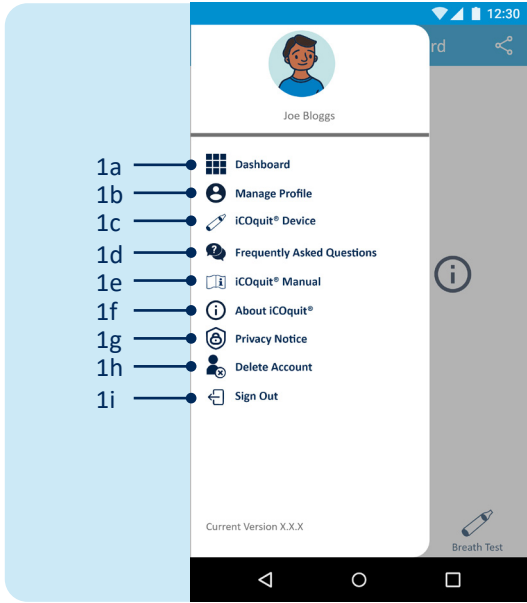
1. The user will need to complete the input fields relating to their smoking habits. This will involve:
 - a. Confirming whether they are still an active smoker.
 - b. Providing how many cigarettes they are actively smoking per day.
 - c. Providing the duration before the first cigarette of the day.
 - d. The day they quit or the day they anticipate quitting.
 - e. The time they quit or the time they anticipate quitting.

Once the user has completed the questions, they should tap the 'Update' button.

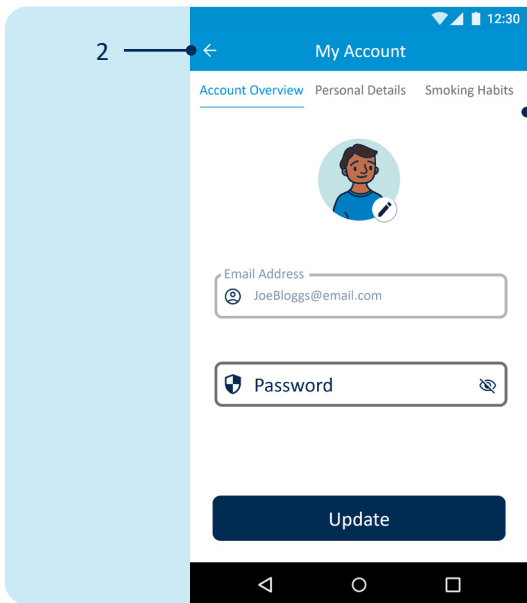


2. Once the answers have been provided and the user has tapped the 'Update' button, they will be provided with a result, which informs them of their smoking status. There are four results:
 - a. Non-Smoker
 - b. Light Smoker
 - c. Moderate Smoker
 - d. Heavy Smoker.

Navigation Drawer Menu Options



1. The navigation drawer contains nine menu items which can be navigated to upon tapping an item in the navigation drawer. The menu options are:
 - a. Dashboard.
 - b. App Settings.
 - c. iCOquit® Device.
 - d. Frequently Asked Questions.
 - e. iCOquit® Manual.
 - f. About iCOquit®.
 - g. Privacy Policy.
 - h. Delete Account.
 - i. Sign Out.

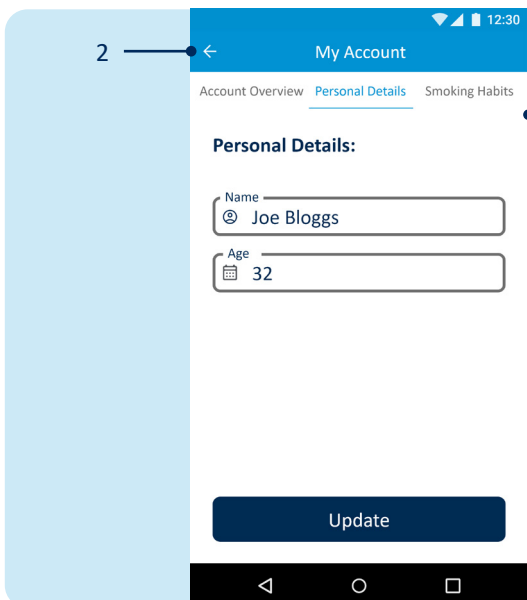


Manage Profile

Account Overview

1. A user can update their email address, password and profile picture.
2. A user can adjust their personal details by editing the form fields.

Once a user has finished making changes they will need to tap the 'Update' button.



Personal Details

1. A user can adjust their personal details by editing the form fields.
2. A user can adjust their personal details by editing the form fields.

Once a user has finished making changes they will need to tap the 'Update' button.

Smoking Habits

1. A user can update their smoking habit details by editing the form field.
2. A user can adjust their personal details by editing the form fields.


Once the user has made their changes they will need to tap the 'Update' button.

iCOquit® Device

NOTE: The user must complete the device connection process upon navigating to this screen.

1. A user can navigate away by tapping the back button symbol.
2. Upon successfully navigating to the device details screen, device details about the connected device will appear. These device details include:
 - a. Connection Status.
 - b. Device Serial Number.
 - c. Battery Life remaining.
 - d. Firmware Version.
 - e. Number of tests the device has conducted.
 - f. iCOquit® Activation Date.

NOTE: Once the battery in the iCOquit® has become flat, the iCOquit® will need to be disposed of, please see disposal guidance in Disposal of Device section.



1 — [Hamburger menu icon]

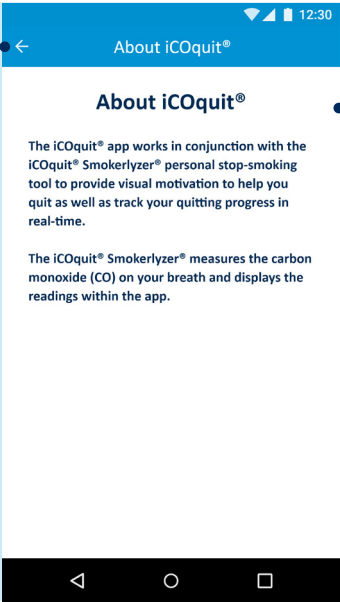
iCOquit® FAQs

2 — [WebView content]

User directed to the iCOquit® website

Frequently Asked Questions

1. The user can navigate away from the page by tapping the hamburger menu button.
2. Upon navigating to the page, a web view will appear which will display the iCOquit® support web page. The user will be able to navigate support articles on the web page within the app.



1 — [Back button icon]

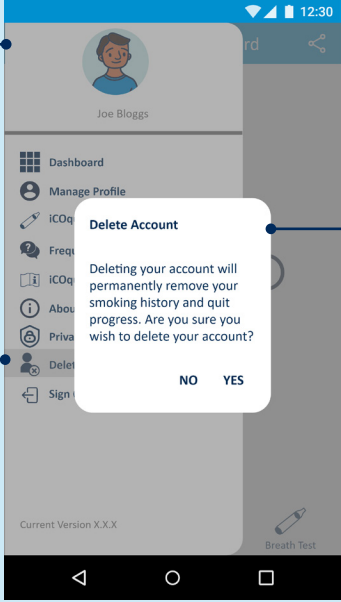
About iCOquit®

2 — [Text content]

About iCOquit®

1. The user can navigate away from the page by tapping the back button symbol.
2. Upon navigating to the page, the user will be provided with information on the iCOquit®.

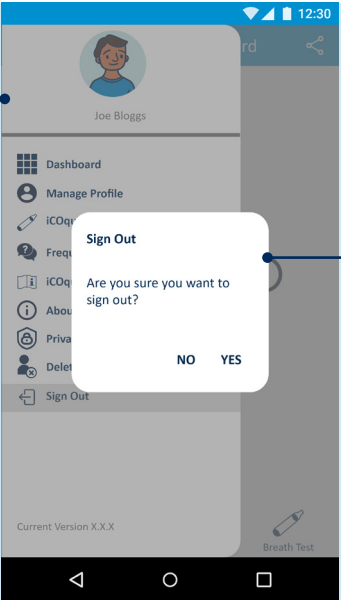
Delete Account



1. The user can navigate away from the page by tapping the back button symbol.
2. Upon navigating to the page, the user will need to the 'Delete Account' button to confirm they want to delete their account.
3. The user will then be presented with a dialog box to check that the input was not an error. To confirm that the user wants to delete their account, they will need to tap 'Yes' else they will need to tap 'No'.

Upon a user deleting their account, all stored data will be removed.

Sign Out



1. The user can navigate away from the page by tapping the back button symbol
2. Upon navigating to sign out a dialog will appear. If the user taps 'Yes' this sign the user out and navigate them to the authentication page, else if they tap 'No' the user will be navigated back to the user dashboard and will not be signed out.

Troubleshooting

Cannot connect the iCOquit® Smokerlyzer® to the app

- Make sure Bluetooth® is enabled on your smart device.
- Battery may be flat.

NOTE: *Once the battery in the iCOquit® has become flat, the iCOquit® will need to be disposed of, please see disposal guidance in Disposal of Device section.*

Network Error Occurred

- Please make sure you are connected to the internet.

Precautions to be taken in the event of changes in the performance of the iCOquit® Smokerlyzer®

- Leave in clean, dry area with fresh air (free from VOCs) for 24hrs.

Precautions to be taken regarding the exposure of the iCOquit® to reasonably foreseeable environmental conditions

- Leave in clean, dry area with fresh air (free from VOCs) for 24hrs.

What if I can't hold my breath for the recommended 15 second breath hold time?

- Bedfont® recommends that if you are unable to hold your breath for the recommended 15 seconds, to hold your breath for 10 seconds before exhaling into the device.

The iCOquit® failed to read my breath test

- If the iCOquit® fails to obtain a stable reading, an error screen will appear. Please retry the breath test.
- Leave in clean, dry area with fresh air (free from VOCs). If this does not resolve the issue, please contact Bedfont® or your local distributor.

If any of these issues persist, please contact Bedfont® or its distributors.

Cleaning

1. The iCOquit® Smokerlyzer® product is moulded with ABS and PC plastic, which is easy to keep clean.
2. After you have finished using the iCOquit® Smokerlyzer® to obtain your results, wipe the outside of the device with a lightly damp cloth, ensuring not to allow any water to enter the breath or exhaust ports in the device.
3. NEVER use alcohol or cleaning agents containing alcohol or other organic solvents as long-term exposure to these vapours will damage the CO sensor inside.
4. Under no circumstances should the instrument be immersed in liquid or splashed with liquid.
5. Please store in a dry location, keeping the device free from lint and dust to keep the device clean and clear from blockage.
6. Please keep the device out of direct sunlight to keep the device away from any unnecessary exposure to heat and light.









No additional maintenance or service required.





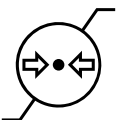



Technical Specification



Gas Measured	Carbon Monoxide (CO)
Detection principle	Electrochemical
Concentration range	0 - 100 ppm
Monitoring resolution	1 ppm
Monitoring accuracy	$\pm \leq 3 \text{ ppm} / \pm \leq 10\% \text{ of reading}^*$
Monitoring repeatability	$\pm \leq 3 \text{ ppm} / 5\% \text{ (within 120 sec)}^*$
Operating lifetime	12 months
Display	Via the iCOquit® mobile application
Battery Life	12 months and battery is non-replaceable
Power	3v Lithium-ion coin cell
T₉₀ response time	<30 Seconds
Operating temperature	15 - 35°C
Storage/Transport Temperature	0 - 50°C
Operating & Storage/Transport Humidity	10 – 90% RH non-condensing
Operating & Storage/Transport Pressure	912.0 – 1114.0 mbar
Dimensions	Less than 150 mm long x 30 mm diameter
Weight	Less than 100 g
Materials	Plastic casing: ABS and Polycarbonate
H₂ Cross Sensitivity	$\leq 6\%$
Time required to warm/cool from the minimum/maximum storage temperature before use	15 minutes

*whichever is greater



















Safety Information and Device Symbols

Glossary of Symbols			
Title of Symbol	Symbol	Explanatory Text	Symbol and Standard References
Consult instructions for use		Indicates the need for the user to consult the instructions for use	ISO 15223 – 1. Clause 5.4.3 ISO 7000 – 1641 IEC 60601-1, Table D.1, Symbol 11
Serial Number		Indicates the manufacturers serial number so that a specific medical device can be identified	ISO 15223 – 1. Clause 5.1.7 ISO 7000 – 2498
Non-ionizing electromagnetic radiation		To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment	IEC 60601-1-2 Clause 5.1.1 IEC 60417 - 5140
Keep dry		Indicates a medical device that needs to be protected from moisture	ISO 15223 – 1, Clause 5.3.4 ISO 7000 – 0626
Unique device identifier		Indicates a carrier that contains unique device identifier information	ISO 15223-1 Clause 5.7.10
Indicator of Medical Devices		Indicates the item is a medical device	ISO 15223-1 Clause 5.7.7
WEEE (Waste Electrical and Electronic Equipment)		DO NOT THROW IN GENERAL RUBBISH DISPOSAL/TRASH! – Waste Electronic Equipment	EN 50419 Directive 2012/19/EU, Annex IX
Date of Manufacture		Indicates the date when the medical device was manufactured	ISO 15223 – 1. Clause 5.1.3 ISO 7000 – 2497 FDA 21 CFR 801

Manufacture		Indicates the medical device manufacturer (*Note – Date of manufacture, name and address of manufacturer can be combined in one symbol	ISO 15223 – 1. Clause 5.1.1 ISO 7000 – 3082
Type BF Applied Part (Whole Device)		To identify a type BF applied part complying with IEC 60601-1	IEC 60417-5333 IEC 60601-1, Table D.1, Symbol 20
Temperature limit		Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223 – 1. Clause 5.3.7 ISO 7000 – 0632
Humidity limitation		Indicates the range of humidity to which the medical device can be safely exposed	ISO 15223 – 1. Clause 5.3.8 ISO 7000 – 2620
Atmospheric pressure limitation		Indicates the range of atmospheric pressure to which the medical device can be safely exposed	ISO 15223 – 1. Clause 5.3.9 ISO 7000 – 2621
Authorised representative in the European Community		Indicates the authorised representative in the European Community	ISO 15223 – 1. Clause 5.1.2
Single Patient Multiple Use		Indicates that the medical device may be used multiple times (multiple procedures) on a single patient.	ISO 15223 – 1. Clause 5.4.12 ISO 7000 – 3706
Degree of protection against ingress of liquid	IPX0 – not protected against water ingress	Degree of Ingress Protection Provided by Enclosure	IEC 60601-1, Table D.3, Symbol 2 IEC 60529
Recycling symbol		Indicates certain materials can be recycled	N/A

Non-standard Symbols			
Title of Symbol	Symbol	Explanatory Text	Symbol and Standard References
CE mark		Manufacturer's declaration of compliance to all relevant European Medical Device Regulations	Medical Device Regulation (EU) 2017/745
Bedfont® logo		Manufacturers logo	N/A
Type of protection against electric shock	Internally powered equipment	N/A	N/A
Degree of safety application in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide	Equipment not suitable for use in the presence of flammable mixtures	N/A	N/A

Buttons Explained

Inhale		Hold breath		Exhale	
App Settings		iCOquit® device		Frequently Asked Questions	
About iCOquit®		Privacy Policy		Initialising	
Delete Account		Loading		Sign out	
Retry		Battery life		Dashboard	
Light Smoker		Medium Smoker		Heavy Smoker	

EMC Table/Environment

Wireless

This device contains a Silicone Labs. Transmitter, SoC model: BGM11S Blue Gecko Bluetooth® SiP Module in compliance with FCC rules, Part 15 Spread Spectrum Transmitter.

Wireless Bluetooth® Low Energy (BLE) is used as a means of communication between the device and the iCOquit® App on iOS and Android smart devices. The iCOquit® App is a user interface to work in conjunction with the iCOquit® device. It is not time critical, there are no alarms.

Radio Technology: Bluetooth®: IEEE 802.3

Bluetooth® specification: BLE version 5.1

Bluetooth® Class / Power: Class 4.2 Bluetooth® module. TX power up to +8 dBm

RF frequencies: 2.4 GHz frequency range

The iCOquit® is not intended to be connected to any wireless adaptors.

The Bluetooth® device supports 128 & 256 bit encryption and a GPCRC Checksum. There is no need or provision to change this setting.

The iCOquit® is intended to connect to a smartphone or tablet & is not intended to be connected to any other wireless equipment.

Recommended controls for intended use environment: Ensure smart device has an up-to-date operating system from the smart device manufacturer.

The iCOquit® Smokerlyzer® complies with the Medical Device Regulation (EU) 2017/745 and the Medical Device Electromagnetic Compatibility standard IEC 60601-1-2 and EN 60601-1-2.

The iCOquit® device is suitable for the electromagnetic environment of typical domestic, commercial or hospital settings.

During the immunity testing described below the iCOquit® device continued to provide essential performance. We considered essential performance to be a CO reading within ± 3 ppb of inputted level. A deviation of ± 3 ppb has no physiological significance.

Emissions

Bedfont® Scientific Limited warrants the iCOquit® Smokerlyzer® product to be free of defects in materials and workmanship for a period of 6 months, whichever is first, from the date of shipment. Bedfont’s sole obligation under this warranty is limited to repairing or replacing, at its choice, any item covered under this warranty when such an item is returned, intact and prepaid, to Bedfont® Scientific Limited or the local representative. The warranty is automatically invalidated if the product is repaired, altered, labels removed or otherwise tampered with by unauthorised personnel, or have been subject to misuse, neglect or accident.

The iCOquit® device is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment – Guidance
IEC 60601-1-2 FCC part 15 Subpart B	30 MHz to 1GHz 1 GHz to 18 GHz 18 GHz to 30 MHz	The iCOquit® device 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.

Guidance and manufacturer’s declaration: Electromagnetic immunity			
The iCOquit® is intended for use in the electromagnetic environment specified below. The customer or the user of the iCOquit® should ensure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8kV contact ± 2, 4, 8 and 15kV air	± 8kV contact ± 2, 4, 8 and 15kV air	Floor should be wood, concrete or ceramic floor tile. If floors are covered with synthetic material the relative humidity should be at least 30%.
Power Frequency (50/60Hz) Magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical domestic, commercial or hospital environment.


Immunity

Electromagnetic Immunity		
The iCOquit® is intended for use in the electromagnetic environment specified below. The customer or the user of the iCOquit® should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment – Guidance
Radiated RF IEC 61000-4-3	10V/m (1kHz 80%) 80MHz-2.7GHz	The iCOquit® is suitable for the electromagnetic environment of typical domestic, commercial or hospital settings.

The iCOquit® has also been tested for immunity to RF wireless communications equipment as below

Immunity test	IEC 60601 Test level		Compliance level		Electromagnetic environment guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	385 MHz	27 V/m	385 MHz	27 V/m	The iCOquit® device is suitable for the electromagnetic environment of typical domestic, commercial or hospital settings.
	450 MHz	28 V/m	450 MHz	28 V/m	
	710 MHz	9 V/m	710 MHz	9 V/m	
	745 MHz	9 V/m	745 MHz	9 V/m	
	780 MHz	9 V/m	780 MHz	9 V/m	
	810 MHz	28 V/m	810 MHz	28 V/m	
	870 MHz	28 V/m	870 MHz	28 V/m	
	930 MHz	28 V/m	930 MHz	28 V/m	
	1720 MHz	28 V/m	1720 MHz	28 V/m	
	1845 MHz	28 V/m	1845 MHz	28 V/m	
	1970 MHz	28 V/m	1970 MHz	28 V/m	
	2450 MHz	28 V/m	2450 MHz	28 V/m	
	5240 MHz	9 V/m	5240 MHz	9 V/m	
	5500 MHz	9 V/m	5500 MHz	9 V/m	
	5785 MHz	9 V/m	5785 MHz	9 V/m	

Environmental Warnings

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the iCOquit® device. Otherwise, degradation of the performance of this equipment could result.
- The iCOquit® device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the iCOquit® device should be observed to verify normal operation. If operation is not normal, the iCOquit® or the other equipment should be moved.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Avoid exposure to known sources of EMI (electromagnetic interference) such as Magnetic Resonance Imaging (MRI) systems, diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as metal detectors.
-  Keep the iCOquit® outside the MRI scanner room.

Note that the presence of RFID devices may not be obvious. If such interference is suspected reorient equipment if possible, to maximize distances.

Performance Characteristics

54 paired CO measurements from the iCOquit® Smokerlyzer® and the Bedfont® Scientific Micro+™ Smokerlyzer® device were obtained, and concentrations for the Micro+™ device ranged from 0 to 99 ppm. A regression model was fit using the 54 paired CO measurements from the candidate and the Micro+™ devices that produced a line equation with a slope of 0.9732, a y-intercept of 0.9847 and a correlation coefficient of 0.9978.

Accuracy of the iCOquit® Smokerlyzer® device was also assessed by comparing the concordance between the color categories obtained from the iCOquit® Smokerlyzer® device and the Micro+™ Smokerlyzer® device, and the results are summarized in the following tables.

Micro+™: 18 Green results			
	Green	Amber	Red
iCOquit® Smokerlyzer®	18	0	0

Micro+™: 1 Amber results			
	Green	Amber	Red
iCOquit® Smokerlyzer®	0	1	0

Micro+™: 35 Red results			
	Green	Amber	Red
iCOquit® Smokerlyzer®	0	1	34

The discordant iCOquit® Smokerlyzer® result was 9 ppm.

Bedfont® Scientific evaluated between-run precision using simulated breath samples collected from three devices, with ten measurements per device for a total of 30 measurements per CO concentration tested. The results are summarized below:

CO concentration	0 ppm	21 ppm	51 ppm	102 ppm
Mean	0.4	20.8	50.3	103.7
SD	0.6	1.4	2.7	3.2
CV %	155.4	6.7	5.3	3.1
Low	0	18	47	97
High	2	23	55	111
n	30	30	30	30

The same data was used to calculate repeatability (within-run precision) and the results are summarized below:

CO Concentration	0 ppm										Mean	SD	CV
CQ25	0	0	0	0	0	1	2	0	0	1	0.4	0.7	174.8
CQ62	0	0	0	0	0	1	0	1	1	1	0.4	0.5	129.1
CQ65	0	0	0	0	0	0	1	2	1	0	0.4	0.7	174.8

CO Concentration	21 ppm										Mean	SD	CV
CQ25	22	22	22	22	22	20	20	20	21	20	21.1	1.0	4.7
CQ62	21	23	23	23	22	21	21	20	21	20	21.5	1.2	5.5
CQ65	21	21	22	20	21	18	18	19	18	20	19.8	1.5	7.5

CO Concentration	51 ppm										Mean	SD	CV
CQ25	51	52	52	52	52	47	49	47	48	47	49.7	2.3	4.7
CQ62	53	54	55	55	54	48	48	50	48	49	51.4	3.1	6.0
CQ65	51	52	52	52	53	47	47	47	49	48	49.8	2.4	4.9

CO Concentration	102 ppm										Mean	SD	CV
CQ25	103	103	103	103	101	99	104	105	102	104	102.7	1.7	1.7
CQ62	106	104	106	105	106	111	107	106	107	107	106.5	1.8	1.7
CQ65	102	97	99	97	101	104	107	107	101	105	102	3.7	3.6

Warranty

Bedfont® Scientific Limited warrants the iCOquit® Smokerlyzer® product to be free of defects in materials and workmanship for a period of 500 tests or 6 months, whichever is first, from the date of shipment. Bedfont's sole obligation under this warranty is limited to repairing or replacing, at its choice, any item covered under this warranty when such an item is returned, intact and prepaid, to Bedfont® Scientific Limited or the local representative. The warranty is automatically invalidated if the product is repaired, altered, labels removed or otherwise tampered with by unauthorised personnel, or have been subject to misuse, neglect or accident.

Disposal of Device



The iCOquit® Smokerlyzer® must be disposed of responsibly, please contact your local Bedfont® distributor where you purchased the iCOquit® Smokerlyzer® or your local authority for details of where and how you can return this item for environmentally safe recycling.

Vigilance

As a medical device manufacturer, Bedfont® Scientific Ltd. must have a vigilance system in place to report any adverse incidents which have been caused by its medical products.

An adverse event is identified meeting all three of the following criteria:

- An event has occurred; typical events include, but are not limited to:
 - A malfunction or deterioration in the characteristics or performance.
- The Manufacturer's device is suspected to be a contributory cause of the incident.
- The event led, or might have led to one of the following outcomes:
 - **Death of patient, USER or other person.**
 - **Serious deterioration in the state of health of a patient, USER or other person.**
- Manufacturers of medical devices must report an adverse event in the following timescales:
 - **Serious public health threat:** Immediately.
 - **Death or unanticipated serious deterioration in state of health:** Immediately, (without any delay that could not be justified) but not later than 10 elapsed calendar days following the date of awareness of the event.
 - **Others:** Immediately (without any delay that could not be justified) but not later than 15 elapsed calendar days following awareness of the event (UK reporting time frame is 15 days).

Any of Bedfont® Scientific Ltd. users who experience an adverse event relating to a product which meets the above criteria must immediately report this to Bedfont® and the National Competent Authority of which the country where the incident occurred.

Please contact Bedfont® Scientific Ltd. with all relevant information on:

Email: ask@bedfont.com

Telephone: 0044 1622 851122

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Issue 18 - August 2025, Part No: LAB806_USA_OTC

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MD 502905