iCOquit® Smokerlyzer®

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

User Manual

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2797

For use with the iCOquit® Mums to Be app

Definitions

WARNING: indicates a potentially hazardous situation, which, if not avoided, may result 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.

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® will need to be disposed of, please see disposal guidance in Disposal of Device section of this manual.

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

NOTE: The iCOquit® manual is only provided in electronic format and can be located on the iCOquit® Smokerlyzer® website: https://www.icoquit.com/manual/.

Contents

About this Manual

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

Compliance

iCOquit® Smokerlyzer® is CE marked according to the Medical Device Directive 93/42/EEC.

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

Warnings

1. Hands should be washed regularly in accordance with infection control practice.

2. 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.

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

Tracking the CO levels 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 or conditions.

Using the power of smartphone or tablet applications, the iCOquit® Smokerlyzer® device will have an intelligent live display via the iCOquit App or the iCOquit Mums to be App, guiding the user through the process of providing a breath sample for measurement. After the breath test, access is given to the results recording and reporting platform that can be accessed by the individual.

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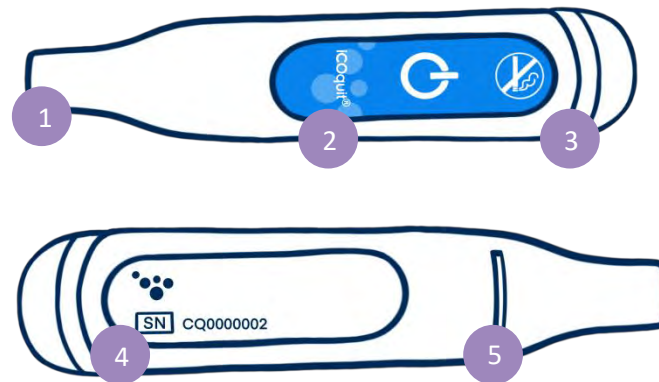
1. Breath sample port
2. On/pairing button
3. LED light ring/pairing light
4. Information label including serial number
5. Breath exhaust

Installation and Set-up

Downloading the iCOquit® app

The iCOquit® Mums to Be 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® maternity app.*

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

User Interface
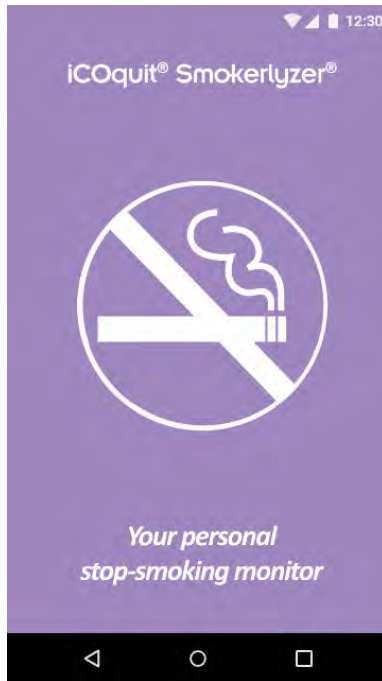
Splash Screen

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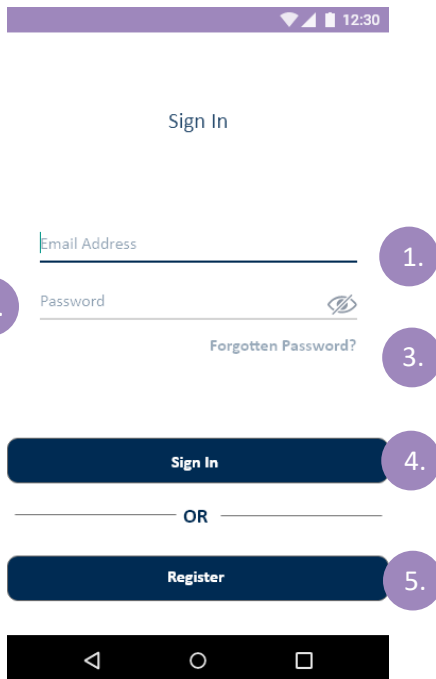
Sign in Screen

1. Email Address field.

2. Password field.

3. Forgotten Password button, starts a new forgotten password process.

4. Sign In Button, starts the authentication process.

5. Register button, starts the user registration process.
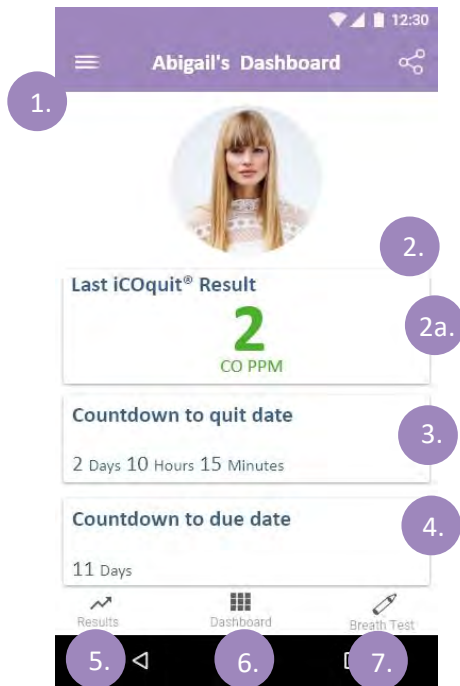
Dashboard/Home Screen

1. Hamburger menu button, this will open the menu.

2. The first dashboard shows the users latest CO PPM reading.
   a. Information overlay appears on a tap gesture which provides result description.

3. The second dashboard shows days until quit date or if quit date has been reached, it will show number of days smoke-free.

4. The last dashboard shows days until due date.

5. Results tab will navigate user to results graph.

6. Dashboard tab will navigate user to dashboard.

7. Breath Test Tab will navigate the user to the first breath test page if it is not the active tab.

Breath test

1. Press the breath test icon

2. Follow the steps on the iCOquit® Mums to Be app.

Using the iCOquit®

User Authentication and Registration

Authentication Screen Options

    a. If the user already has an account they will need to complete the authentication fields and tap the 'Sign In' Button.

    b. If the user is already a user, but has forgotten their authentication credentials, the user will need to tap the 'Forgotten Password' Button.

    c. If the user is not currently a registered user they will need to tap the 'Register' Button.

Forgotten Password

Account Details

Please enter your email address to recover your account

Email address

1.

Continue

Completing the Forgotten Password Process

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

Forgotten Password

Account Details

Please enter your email address to recover your account

Email address

2.

Continue

2. A verification code will be sent to the user's mailbox in order to reset password. The user will then need to tap the 'Continue' button.

3. A verification code will be sent to the user's mailbox in order to reset password. The user will then need to tap the 'Continue' button.
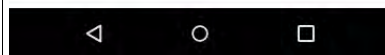
4. The last step is to provide a new password and rewrite that password and then tap the 'submit' button.
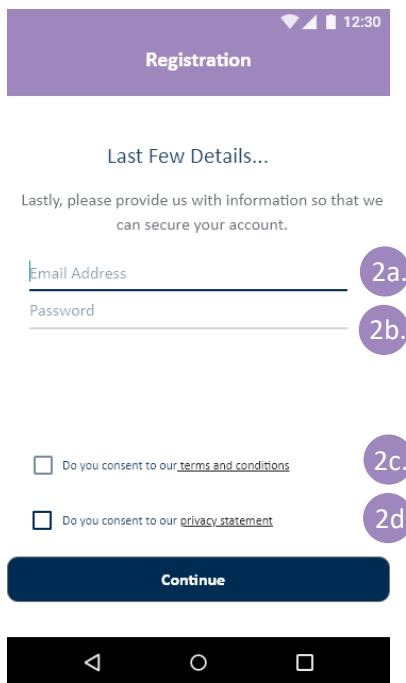
After the new password has been submitted, the app will return to the sign-in page.

Completing the Registration Process

1. The user will need to complete the user profile section of the registration process. This will involve:

   a. Providing a name.
   b. Providing their age.
   c. Providing their due date.
   d. Providing their planned quit date
   e. Providing their planned quit time

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

2. 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.*
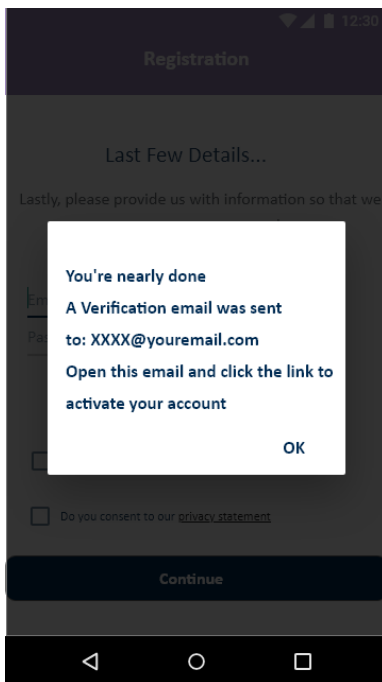
3. The user will then be navigated back to the sign in screen. The user must wait for their confirmation email before attempting authentication. The user must tap the link in the email to confirm their email address. After this the user will be authenticated and can return to the app and sign in using the details registered.
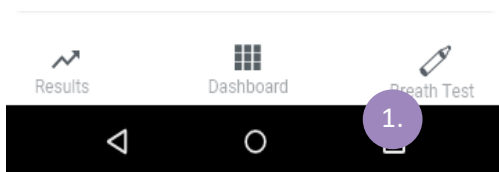
Tabbed Navigation Pages

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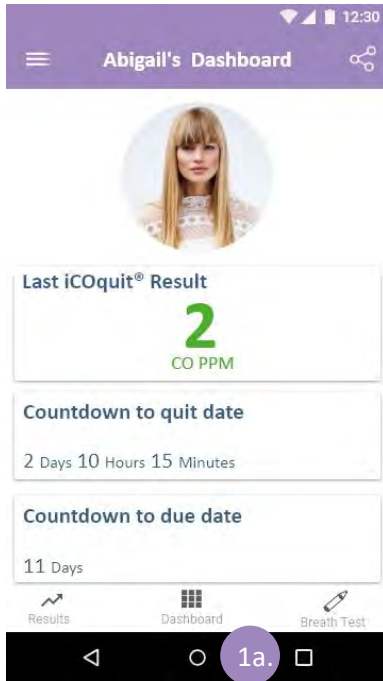
a. To navigate to the Dashboard tap 'Dashboard'. The dashboard provides an overview of the users smoking cessation progress.


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.
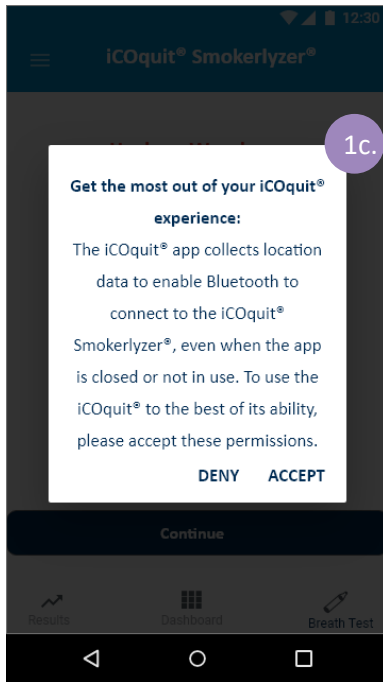
c. A pop-up will appear on all Android user screens, notifying the user that the iCOquit® app collects location data in the background when using the app, to access the iCOquit® device

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.
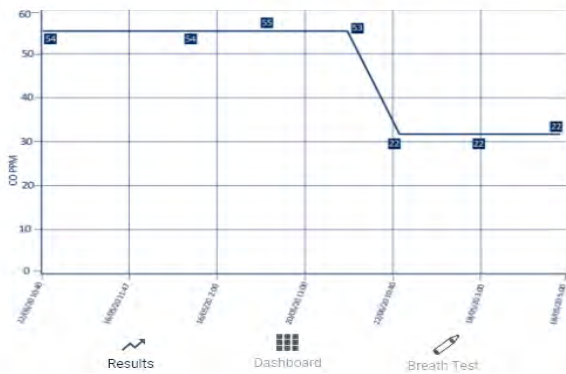
e. To view historic breath test results, the user will need to tap the 'Results' button. The results are ordered with the oldest reading displayed to the left and the latest reading displayed from furthest from the right.
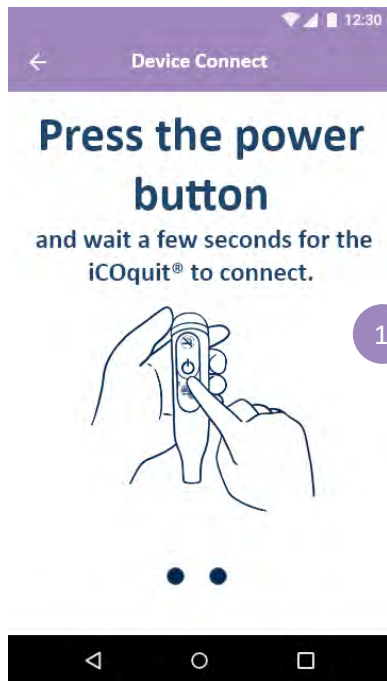
1. The Bluetooth® scanning phase will show a spinner while searching for a device.

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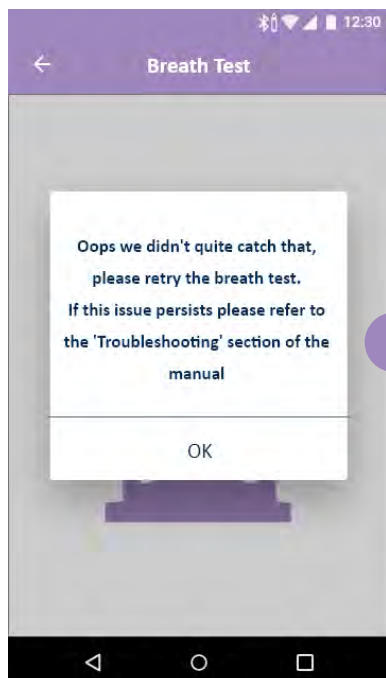
3. If an iCOquit® device has not been found or was unable to successfully connect, a retry icon shall appear indicating connection has failed, but tap the icon to try again.
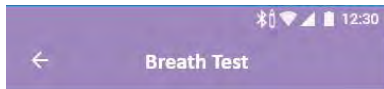
Completing a breath test
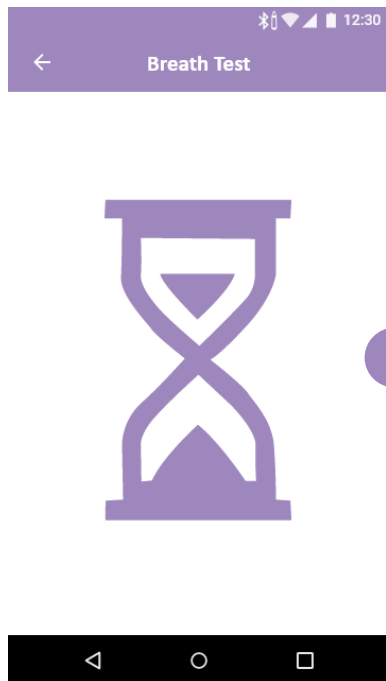
Breath Test Initialisation

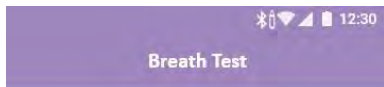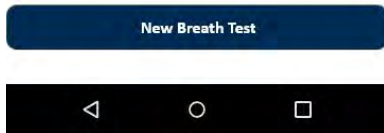1. An hourglass may appear while the sensor is preparing for the breath test.

2. If the iCOquit® fails to obtain a stable reading, an error screen will appear. Please retry the breath test.

3. 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.
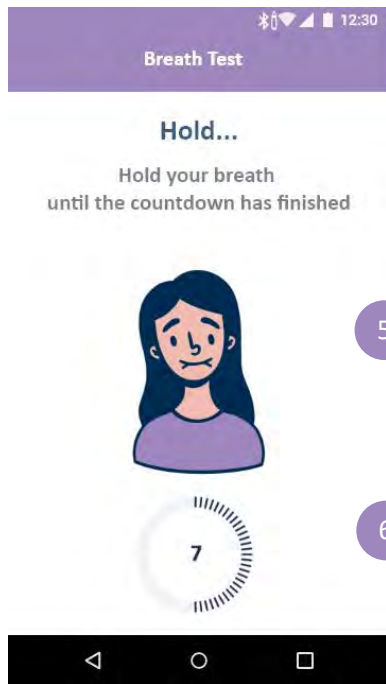

Inhale Instructions

4. As prompted onscreen, take a deep breath.

Hold Instructions

5. As prompted onscreen, hold your breath until the countdown timer has finished

6. If the 15 second inhalation countdown is unattainable, begin exhaling when ready and the device will begin measuring breath sample.

Exhale Instructions

7. Do not cover vent hole of device when performing a breath test

8. As prompted on screen, exhale.
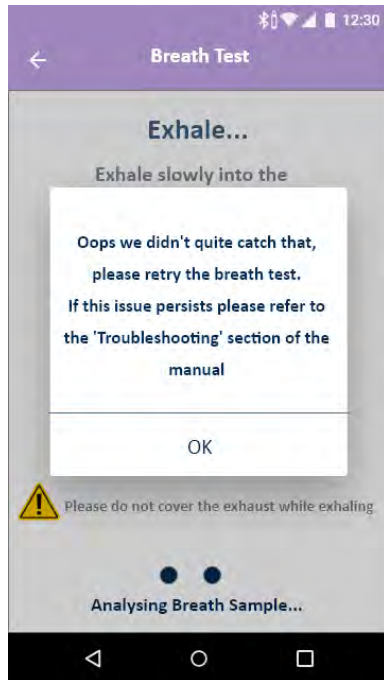
If the iCOquit® fails to obtain a stable reading, an error screen will appear. Please retry the breath test.

If this issue persists, please refer to the 'Troubleshooting' section of this manual.

Interpreting the breath test result

1. Breath test result interpretation chart
    a. Green = Low CO ppm reading
    b. Yellow = Moderate CO ppm reading
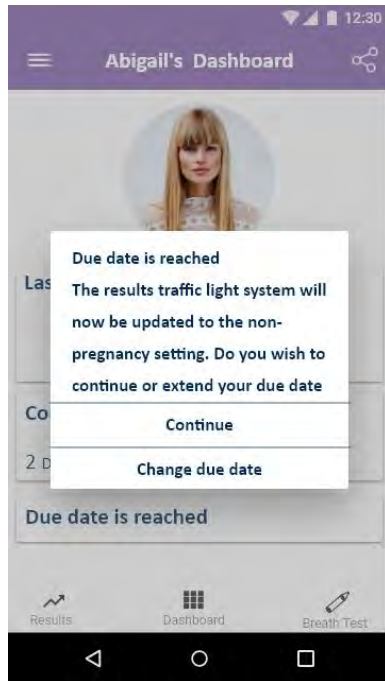   c. Red = High CO ppm reading

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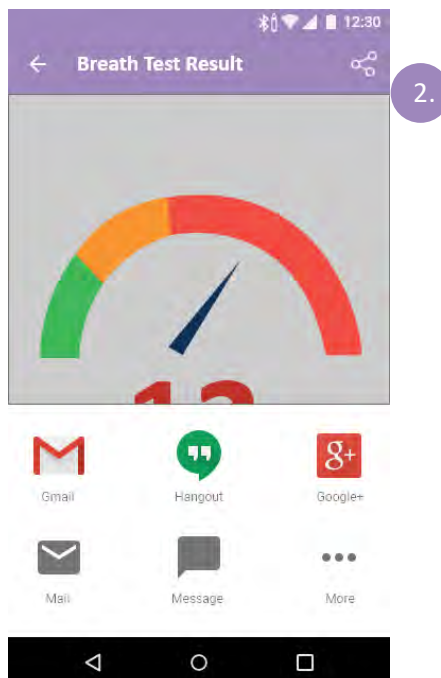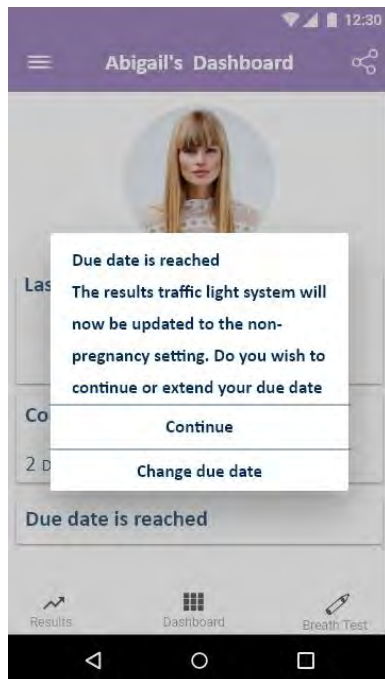

1. The user can share their results by pressing the share icon in the top right of the screen.

Pressing the share icon will allow the user to share their results through another application.
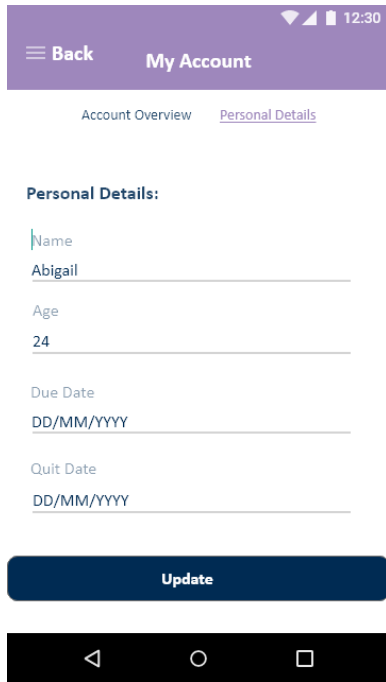
Due date options

Once the entered due date has been reached, a pop-up will appear to ask if the user would like to continue or to extend their due date.

If the user wishes to continue, their profile will be updated to show due date has been reached. The CO thresholds will be updated to of that of a non-maternity user. The due date field will read 'Due date is reached'.
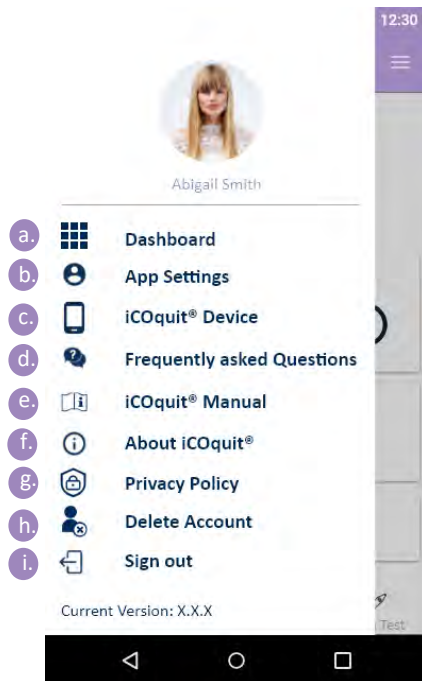
If the user chooses to change their due date, the pop-up will close and the due date is able to be updated.

The breath test results screen will now look like this.

Navigation drawer menu options

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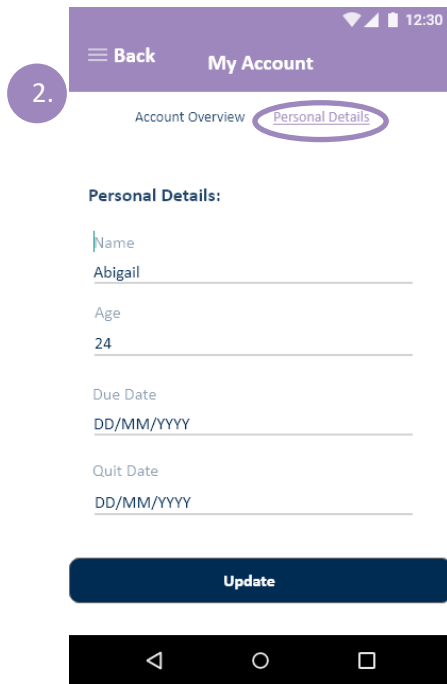
   a. Dashboard
   b. App Settings
   c. iCOquit® Device
   d. Frequently Asked Questions
   e. iCOquit® Manual
   f. About iCOquit®
   g. Privacy Policy
   h. Delete Account
   i. Sign Out
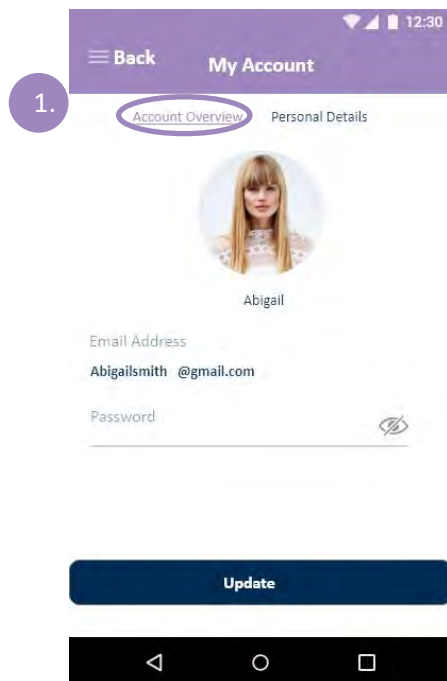
Account Overview

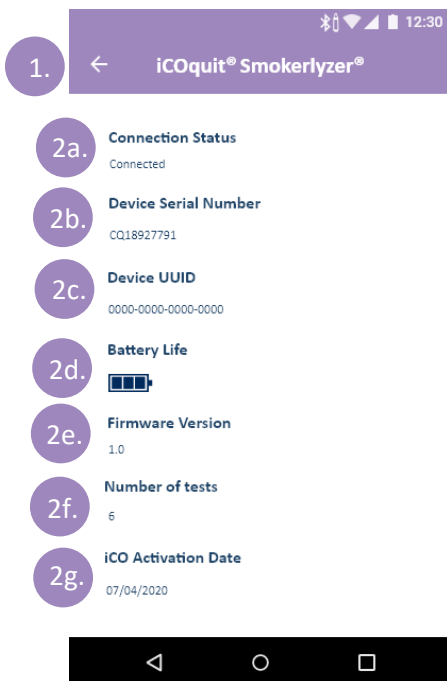1. A user can update their email address, password and profile picture.

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

Personal Details

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.

Device Details Page

Perquisite: 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. Device UUID
   d. Battery Life Remaining
   e. Firmware Version
   f. Number of tests the device has conducted
   g. 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 of this manual.*
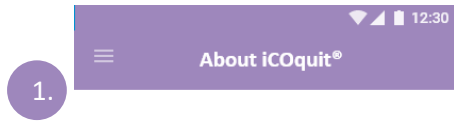
User taken to iCOquit® website 1.

Frequently Asked Questions

1. 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.
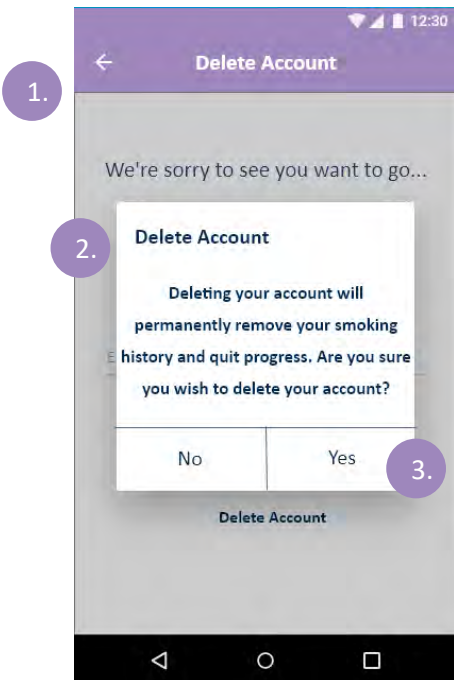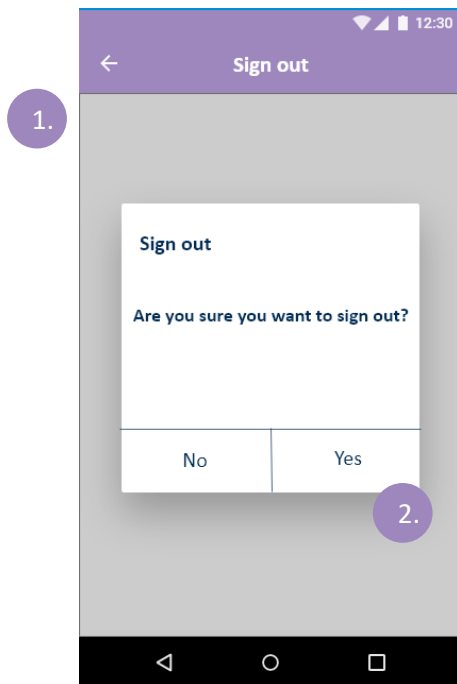
About iCOquit® page

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 press 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 of this manual.*

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.

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

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	±≤3 ppm/±≤10% of reading*
Monitoring repeatability	±≤3 ppm/5% (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
T_{90} 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 150mm long x 30mm diameter
Weight	Less than 100g
Materials	Plastic casing: ABS and Polycarbonate
H_2 Cross Sensitivity	≤6%
Time required to warm/cool from the minimum/maximum storage temperature before use	15 minutes

*whichever is greater

Safety Information and Device Symbols

Type of protection against electric shock	Internally powered equipment
Degree of protection against ingress of liquid	IPX0 – not protected against water ingress
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.
Refer to manual	
Serial Number	SN
Non-ionizing electromagnetic radiation	
CE mark	CE 2797
EC-REP	EC REP
Single Patient - Multiple Use	
Keep dry	
Dispose of according to WEEE	
Serial number	SN
Unique device identifier	UDI
Indicator of Medical Devices	MD
Manufacture by and date	

BF Applied Part – whole device	
Recycling symbol	
Bedfont® logo	

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**	

The iCOquit® Smokerlyzer® complies with the Medical Device Directive 93/42/EEC as amended by 2007/47/EC and the Medical Device Electromagnetic Compatibility standard IEC 60601-1-2 and EN 60601-1-2.

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.			
Guidance and manufacturer's declaration: Electromagnetic Immunity (IEC 60601-1-2)			
The iCOquit® Smokerlyzer® is intended for the use in the electromagnetic environment specified below. The customer or the user of the iCOquit® Smokerlyzer® should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Radiated Immunity EN61000-4-3:2006 + A1:2008 + A2:2010 IEC61000-4-3:2006 +A1:2007 + A2:2010	10V/m (1kHz 80%) 80MHz – 2.7GHz 3V/m (80% 1kHz) 2.7Hz – 6.0GHz 385 MHz 27 V/m PM 18 Hz 450 MHz 28 V/m FM 1 kHz sine 710 MHz 9 V/m PM 217 Hz 745 MHz 9 V/m PM 217 Hz 780 MHz 9 V/m PM 217 Hz 810 MHz 28 V/m PM 18 Hz 870 MHz 28 V/m PM 18 Hz 930 MHz 28 V/m PM 18 Hz 1720MHz 28 V/m PM 217 Hz 1845 MHz 28 V/m PM 217 Hz 1970 MHz 28 V/m PM 217 Hz 2450 MHz 28 V/m PM 217 Hz 5240 MHz 9 V/m PM 217 Hz 5500 MHz 9 V/m PM 217 Hz 5785 MHz 9 V/m PM 217 Hz	Criterion A	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (*A), should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: ((·))
Power Frequency Magnetic Immunity EN61000-4-	30 A/m magnetically sensitive equipment	Criterion A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home, commercial or hospital environment.

8:2010 IEC61000-4-8:2012	30 A/m 50 Hz and 60Hz		
ESD EN61000-4-2:2009 IEC61000-4-2:2012	2, 4, 8kV contact 2, 4, 8, 15kV air	Criterion B	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should at least 30%.
Notes:			
*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 RF transmitter, an electromagnetic site survey should be considered. If the measured field strength in the location in which the iCOquit® is used exceeds the applicable RF compliance level above, the iCOquit® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the iCOquit®.		

Emissions test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Radiated Emissions EN55011:2016+ A1:2017 FCC part 15 Subpart B	30MHz to 1GHz 30MHz to 25GHz	Class B	The iCOquit® is suitable for use in all establishments, including domestic establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Transmitter Radiated Spurious Emissions ETSI EN 300 328 V2.2.1:2019	30MHz to 12.75GHz	Class B	
Output Power (EIRP) ETSI EN 300 328 V2.2.1:2019	-10dBW (100mW) (<20 dBm)	Class B	
Occupied Channel Bandwidth (Antenna Port) ETSI EN 300 328 V2.2.1:2019	2.4 – 2.4835 GHz For non-adaptive with eirp < 10dBm BW < 5MHz	Class B	

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 thr local Bedfont® distributor where the iCOquit® Smokerlyzer® was purchased or the local authority for details of where and how the item can be returned for environmentally safe recycling.

References

1. Groman E, Riemerth A, Bernhard G, Appeltauer G, Schuster B, Veitsmeier I. Can carbon monoxide analysers be fuelled by alcohol intake? Tob Control. 2006 Apr;15(2):143. doi: 10.1136/tc.2006.015925. PMID: 16565465; PMCID: PMC2563566.

2. How long after drinking alcohol can we detect it with a breath alcohol tester? - AlcoPro [Internet]. AlcoPro. 2021 [cited 13 January 2021]. Available from: https://www.alcopro.com/knowledge-base/how-long-after-drinking-alcohol-can-we-detect-it-with-a-breat... breath test during this 13 hour period,alcohol test would give a negative result of.000.

Responsible Manufacturer and Contacts

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