

# iCOquit<sup>®</sup> Smokerlyzer<sup>®</sup>

## User Manual



CE  
2797

***Single-Patient-Use CO device, to help Mums to Be quit smoking remotely, 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® will need to be disposed of, please see disposal guidance in the 'Disposal of Device' section.

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

**NOTE:** If concerned about any results, 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>

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## About this Manual

The User Manual provides instructions on how to operate iCOquit® Smokerlyzer® device and the iCOquit® Mums-to-Be app. It contains relevant information about the device, 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 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. 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

The iCOquit® Smokerlyzer® breath carbon monoxide (CO) device is intended for single person use by individuals wanting to measure the amount of CO on their breath in the home environment, as a motivational aid to help them in their attempt to stop smoking. The iCOquit® can also be used by healthcare professionals with individuals in smoking cessation programmes and research.

The iCOquit® Mums-to-Be smartphone/tablet application will guide the user through the process of providing a breath sample for measurement. After the breath test, results can be shared via email and social media and stored in a results graph to show progress.

## Indications

Smoking as an aid to smoking cessation therapy.

## Clinical Benefit

General intended clinical benefits following use of the iCOquit® are:

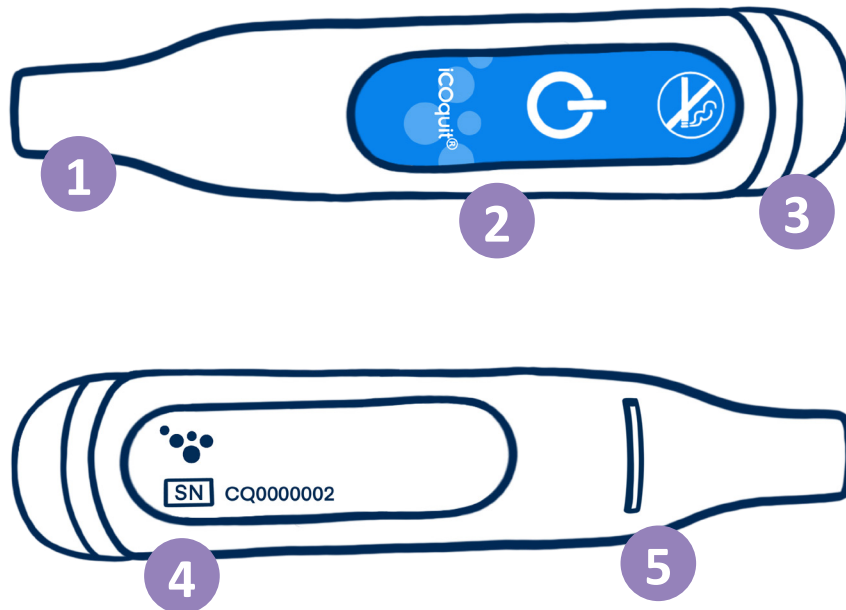
- To enable measurement of exhaled CO as a component of smoking cessation within a home or clinic environment with an average sensitivity of 81.8%.
- To enable measurement of exhaled CO as a component of smoking cessation within a home or clinic environment with an average specificity of 89.3%.
- To increase the 12-week quit rate by at least 3.47% when used as a component of smoking cessation, compared with standard smoking cessation without use of iCOquit®.
- To support smoking cessation quit rates for 4-weeks, 12-weeks and 36-weeks of 96.55%, 94.83%, and 94.83% respectively.
- To increase service user attendance of first smoking cessation appointments by 26.78%, compared with rates following non-use of iCOquit®.

## Patient Population

The target population for the iCOquit® comprises adults, which is defined as people of legal smoking age in the country of residence both laypersons (smokers), typically in the home environment, and medical professionals with an involvement in smoking cessation.

The iCOquit® is intended to be used by both laypersons and medical professionals in the home.

## Instrument Layout



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

## Installation and Set-up

### *Downloading the iCOquit® Mums to Be 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® Mums to Be app.

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

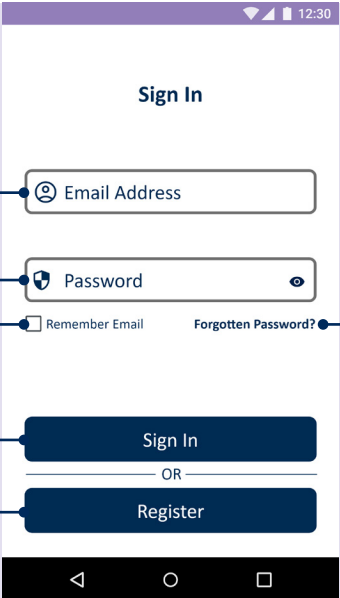
# User Interface



The splash screen features a purple background. At the top, the text 'iCOquit Smokerlyzer' is displayed. Below this is a white circular icon containing a crossed-out cigarette. At the bottom, the text reads: 'Your personal CO device, to help you quit smoking, one breath at a time.'

## Splash Screen

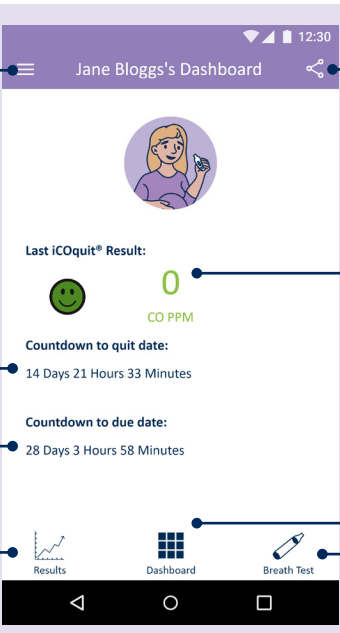
The splash screen shall display upon starting the app. The splash screen shall disappear once the app has successfully loaded.



The Sign In screen has a white background. It includes an 'Email Address' field (1), a 'Password' field (2) with an eye icon, a 'Remember Email' checkbox (3), and a 'Forgotten Password?' link (4). Below these are 'Sign In' (5) and 'Register' (6) buttons, separated by an 'OR' separator.

## 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.



The Dashboard/Home screen is titled 'Jane Bloggs's Dashboard'. It features a hamburger menu (1) and a share button (2). A user profile picture is shown. The 'Last iCOquit Result' is 0 CO PPM (3) with a green smiley icon. Two countdowns are displayed: 'Countdown to quit date: 14 Days 21 Hours 33 Minutes' (4) and 'Countdown to due date: 28 Days 3 Hours 58 Minutes' (5). A bottom navigation bar includes 'Results' (6), 'Dashboard' (7), and 'Breath Test' (8) tabs.

## 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. The second dashboard shows days until quit date or if quit date has been reached, it will show number of days smoke-free.
5. The last dashboard shows amount of money user has saved.
6. 'Results' tab will navigate user to results graph.
7. 'Dashboard' tab will navigate user to dashboard.
8. '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®

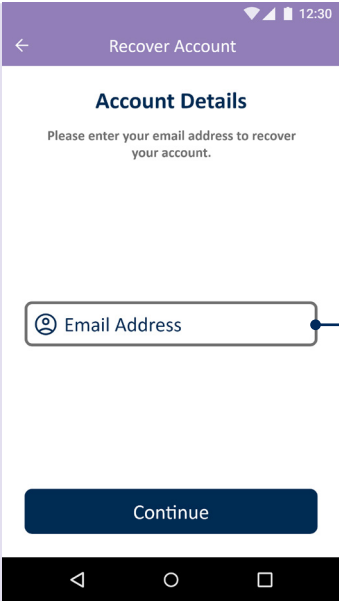
A screenshot of the iCOquit® mobile app's 'Sign In' screen. The screen displays a white background with a purple header. At the top, it says 'Sign In'. Below this are two input fields: 'Email Address' and 'Password'. Under the 'Password' field, there is a checkbox for 'Remember Email' and a link for 'Forgotten Password?'. At the bottom, there are two dark blue buttons: 'Sign In' and 'Register', separated by the text 'OR'. Three numbered callouts point to specific elements: '1' points to the 'Sign In' button, '2' points to the 'Forgotten Password?' link, and '3' points to the 'Register' button. The Android navigation bar is visible at the bottom.

### *User Authentication and Registration*

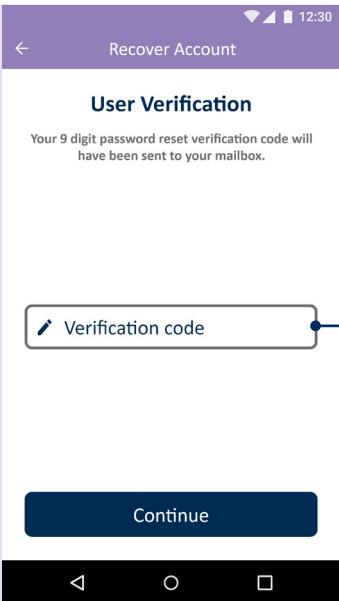
#### **Authentication Screen Options**

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.

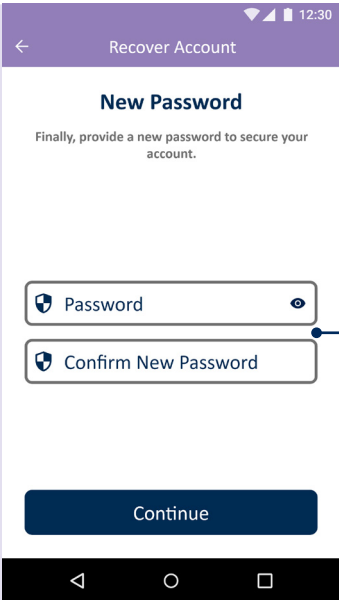
*Completing the Forgotten Password Process*



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

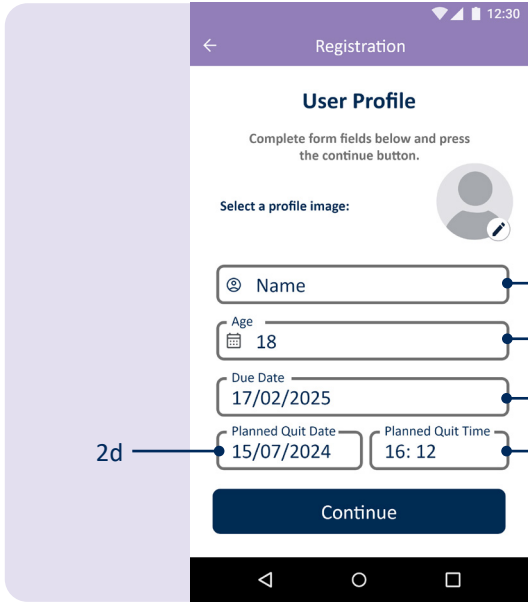


- 2. The 9 digit password reset verification code will have been sent to the users' mailbox. The user will then need to tap the 'Continue' button.



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

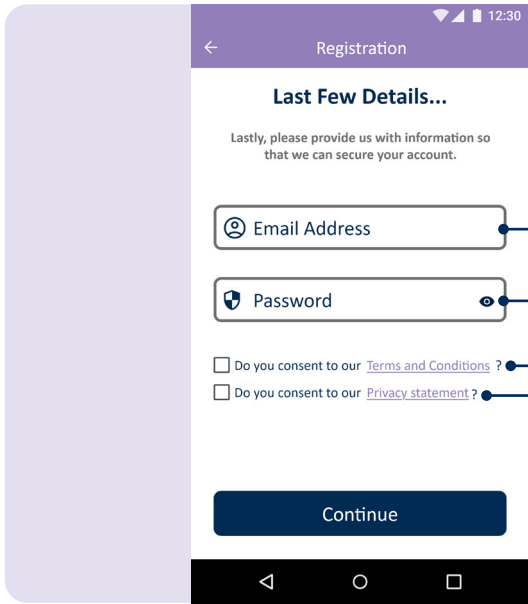
After the new password has been submitted, the app will return to the sign-in page.



*Completing the Registration Process*

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.

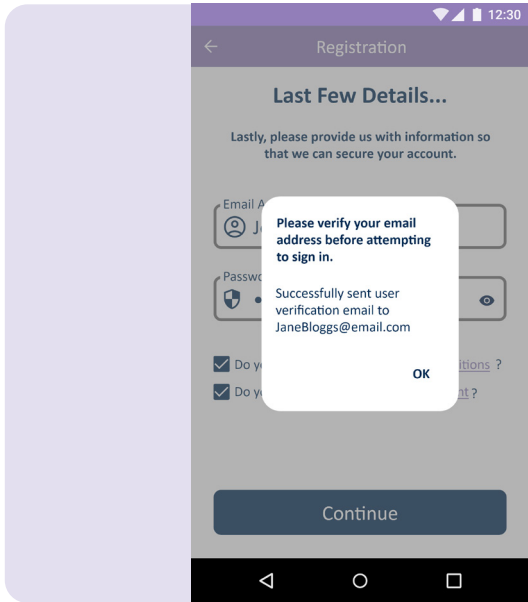
Once this has been completed the user will need to tap the 'Continue' button.



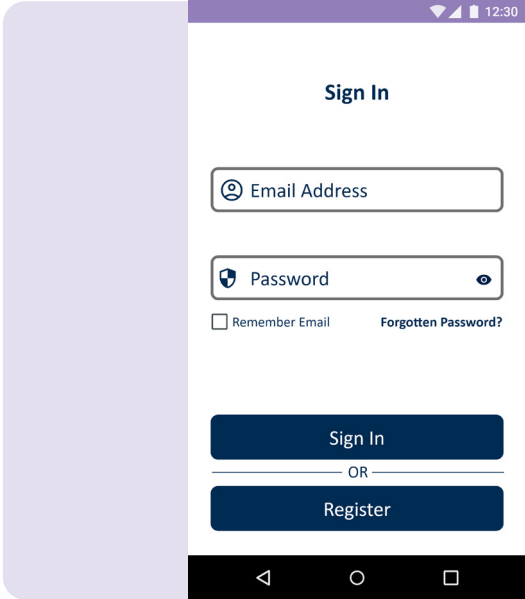
2. The final section of the registration process is providing details for authentication and consents. This will involve:
  - a. Providing a valid email address.
  - b. Providing a password for authentication.
  - c. Agreeing to terms and conditions.
  - d. Agreeing to the privacy statement.

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.

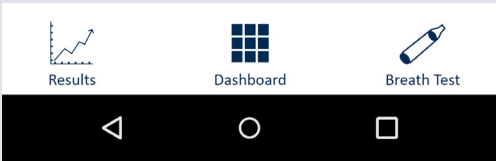


3. The user will then be navigated back to the sign in screen. The user must wait for their confirmation email before attempting authentication. The user must tap the link in the email to confirm their email address. After this the user will be authenticated and can return to the app and sign in using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

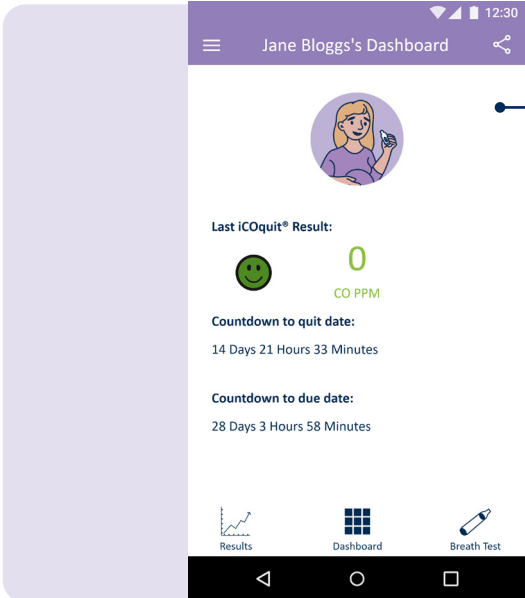


- 4. The user will then be navigated back to the sign in screen. The user must wait for their confirmation email before attempting authentication. The user must tap the link in the email to confirm their email address. After this the user will be authenticated and can return to the app and sign in using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

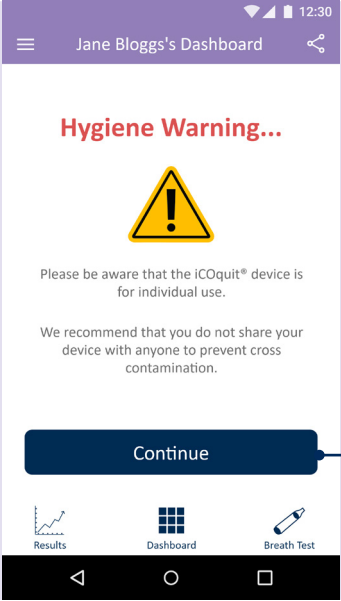
*Tabbed Navigation Pages*



- 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.

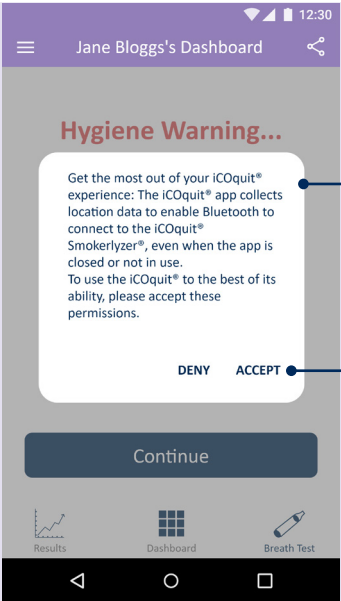


- a. To navigate to the dashboard tap 'Dashboard'. The dashboard provides an overview of the users smoking cessation progress.



The screenshot shows the 'Jane Bloggs's Dashboard' with a 'Hygiene Warning...' message. The message includes a warning icon and text: 'Please be aware that the iCOquit® device is for individual use. We recommend that you do not share your device with anyone to prevent cross contamination.' Below the message is a large blue 'Continue' button. At the bottom, there are three navigation icons: 'Results', 'Dashboard', and 'Breath Test'. A line points from the 'Continue' button to the label '1b'.

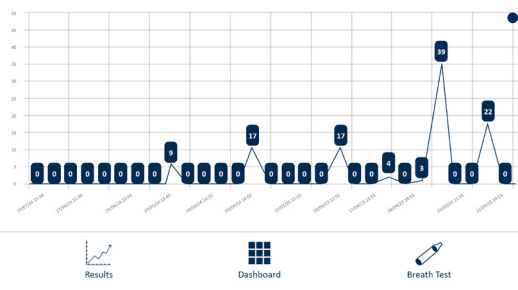
- b. To start a new breath test, tap the 'Breath Test' button. The breath test tab will display the hygiene warning and allow the user to start a new breath test, by tapping the 'Continue' button.



The screenshot shows the 'Jane Bloggs's Dashboard' with a location permission pop-up dialog. The dialog text reads: 'Get the most out of your iCOquit® experience: The iCOquit® app collects location data to enable Bluetooth to connect to the iCOquit® Smokerlyzer®, even when the app is closed or not in use. To use the iCOquit® to the best of its ability, please accept these permissions.' The dialog has 'DENY' and 'ACCEPT' buttons. Below the dialog is a 'Continue' button. At the bottom, there are three navigation icons: 'Results', 'Dashboard', and 'Breath Test'. A line points from the 'ACCEPT' button to the label '1d', and another line points from the dialog text to the label '1c'.

- c. A pop-up will appear on all Android user screens, notifying the user that the iCOquit® Mums to Be 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.

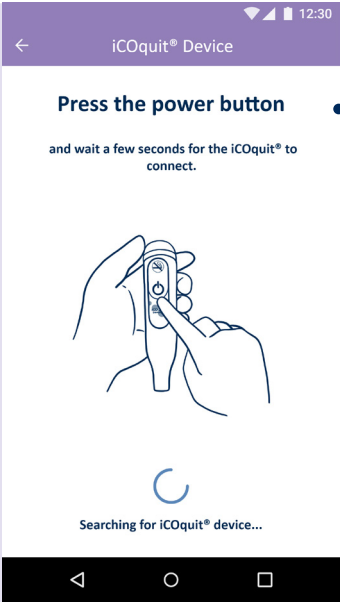
This pop-up will appear before every breath test.




The screenshot shows the 'Results' screen with a line graph of breath test data. The y-axis represents CO2 levels from 0 to 40. The x-axis shows dates from 10/01/2020 to 12/01/2020. The graph shows a series of data points, with the latest reading on the right being 39. Below the graph are three navigation icons: 'Results', 'Dashboard', and 'Breath Test'. A line points from the graph to the label '1e'.

- 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®.



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

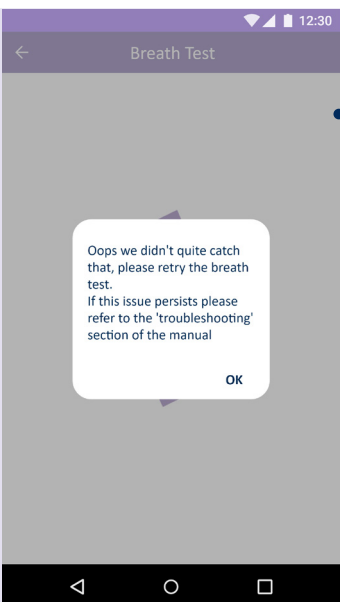
## Completing A Breath Test



1


*Breath Test Initialisation*

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



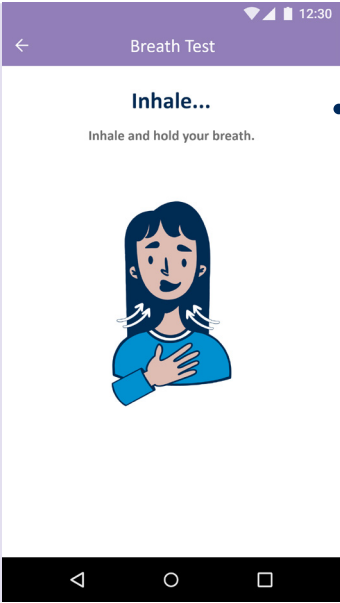
2

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



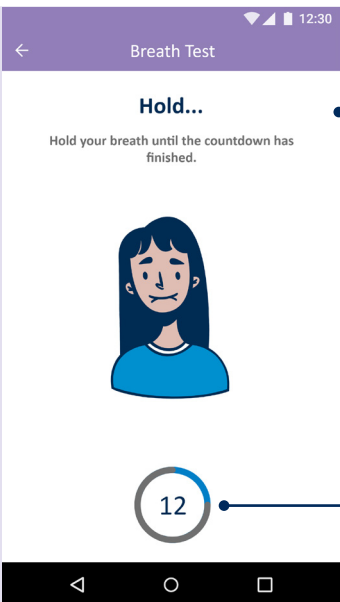
3

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.



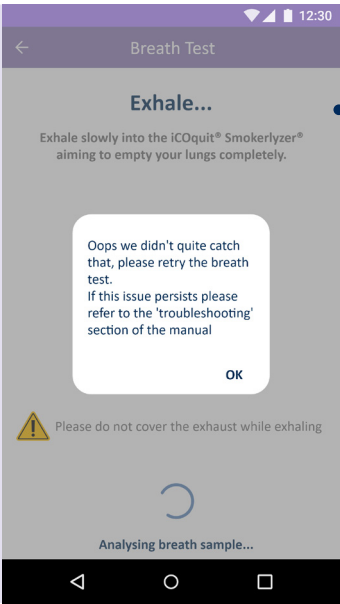
*Hold Instructions*

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 the breath sample.



*Exhale Instructions*

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




9

9. 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



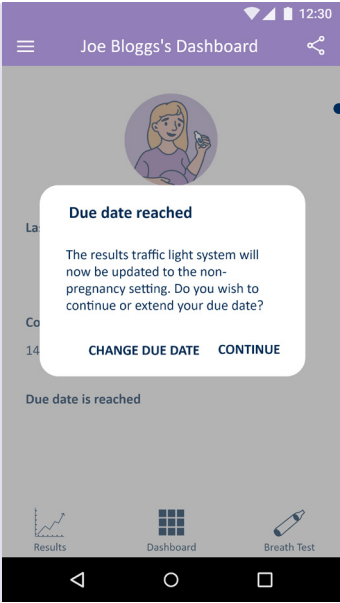
1

1. Breath test result interpretation chart.

- a. Green = Low CO PPM Reading.
- b. Yellow = Moderate CO PPM Reading.
- c. Red = High CO PPM Reading.

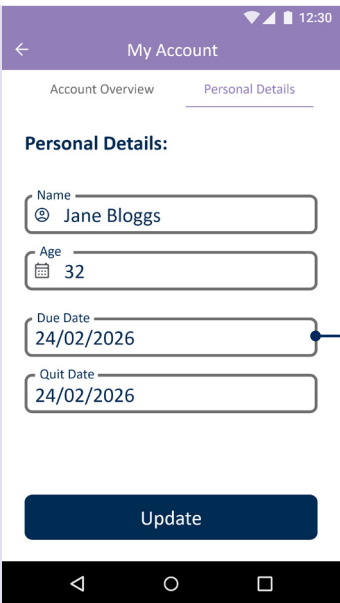
Once a breath test has been completed the user will be navigated to this screen where they will see their CO PPM result.

# Due Date Options




1. 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'.

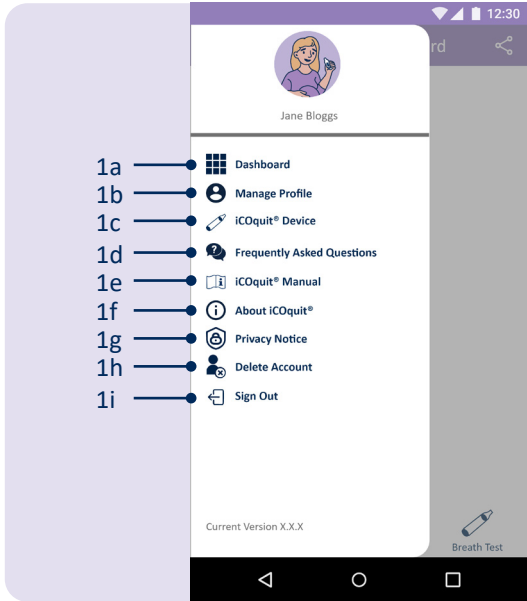


2. If the user chooses to change their due date, the pop-up will close and the due date is able to be updated.



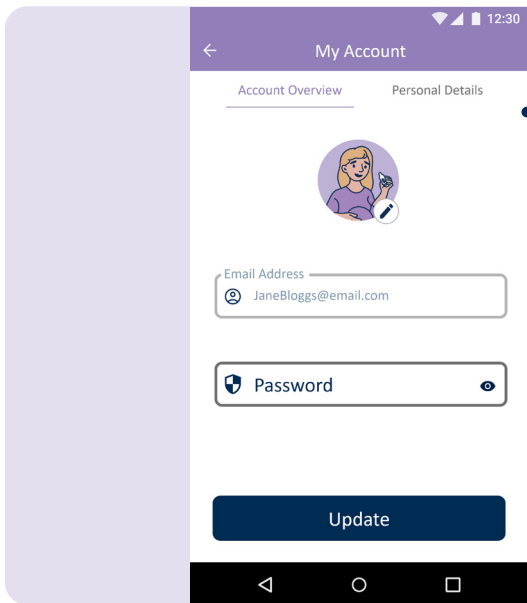
3. The breath test results screen will now look like this.

# Navigation Drawer Menu Options



1. The navigation drawer contains nine menu items which can be navigated to upon tapping an item in the navigation drawer. The menu options are:

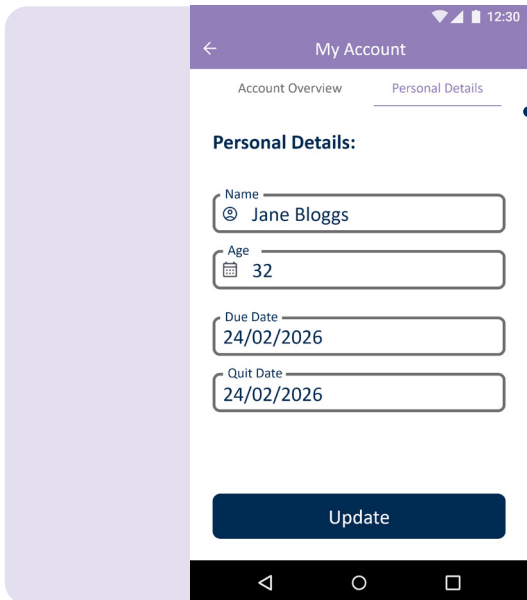
- a. Dashboard.
- b. Manage Profile.
- c. iCOquit® Device.
- d. Frequently Asked Questions.
- e. iCOquit® Manual.
- f. About iCOquit®.
- g. Privacy Policy.
- h. Delete Account.
- i. Sign Out.



## Manage Profile Account Overview

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

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



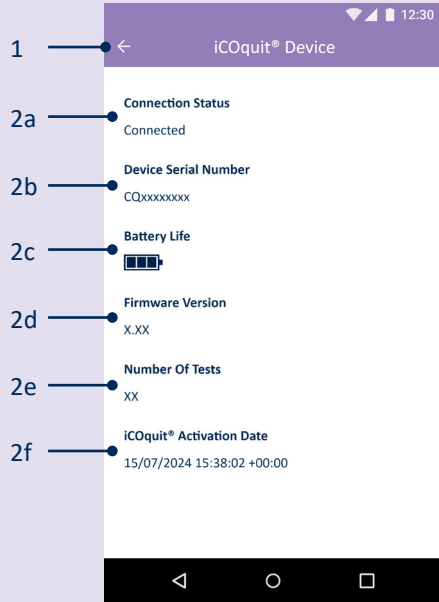
## Personal Details

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

Once a user has finished making 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.



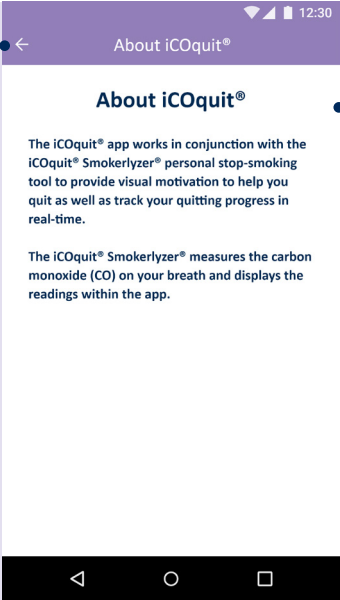
1. A user can navigate away by tapping the back button symbol.
2. Upon successfully navigating to the device details screen, device details about the connected device will appear. These device details include:
  - a. Connection Status.
  - b. Device Serial Number.
  - c. Battery Life remaining.
  - d. 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.



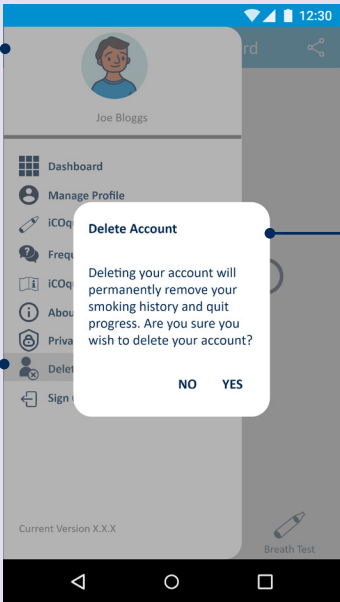
### Frequently Asked Questions

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.



*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' or 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, 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 24 hours.

### *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 24 hours.

### *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® Mums to Be mobile application
Battery Life	12 months and battery is non-replaceable
Power	3v Lithium-ion coin cell
T <sub>90</sub> 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	< 150 mm long x 30 mm diameter
Weight	< than 100 g
Materials	Plastic casing: ABS and Polycarbonate
H <sub>2</sub> 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


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	
Unique device identification	
Indicator of Medical Device	
Non-ionizing electromagnetic radiation	
CE mark	
EC-REP	
Single Patient - Multiple Use	
Keep dry	
Dispose of according to WEEE	
Serial number	
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	

## EMC Table/Environment

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.

<b>WARNING:</b> 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.			
<b>Guidance and manufacturer’s declaration: Electromagnetic Immunity (IEC 60601-1-2)</b>			
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	10 V/m (1 kHz 80%) 80 MHz – 2.7 GHz 3 V/m (80% 1 kHz) 2.7 Hz – 6.0 GHz 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 EN61000-4-8:2010  IEC61000-4-8:2012	30 A/m magnetically sensitive equipment  30 A/m 50 Hz and 60 Hz	Criterion A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home, commercial or hospital environment.
ESD EN61000-4-2:2009  IEC61000-4-2:2012	2, 4, 8 kV contact 2, 4, 8, 15 kV 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
<p>Radiated Emissions EN55011:2016+ A1:2017</p> <p>FCC part 15 Subpart B</p>	<p>30 MHz to 1 GHz</p> <p>30 MHz to 25 GHz</p>	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.
<p>Transmitter Radiated Spurious Emissions ETSI EN 300 328 V2.2.1:2019</p>	30 MHz to 12.75 GHz	Class B	
<p>Output Power (EIRP) ETSI EN 300 328 V2.2.1:2019</p>	-10 dBW (100 mW) (< 20 dBm)	Class B	
<p>Occupied Channel Bandwidth (Antenna Port) ETSI EN 300 328 V2.2.1:2019</p>	<p>2.4 – 2.4835 GHz</p> <p>For non-adaptive with eirp &lt; 10 dBm BW &lt; 5 MHz</p>	Class B	

## Warranty

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.

## 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](mailto:ask@bedfont.com)

Telephone: 0044 1622 851122

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