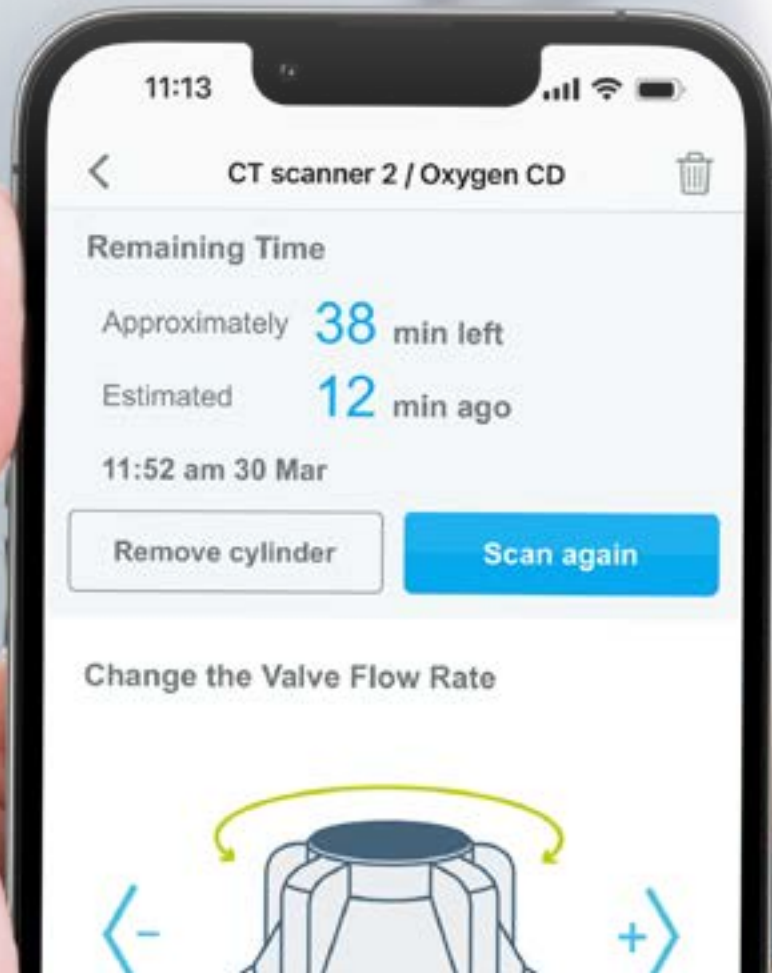


Remaining Time Estimator

Frequently Asked Questions



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(Click for answer)

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1. Is the Remaining Time Estimator app a Medical Device?

No, the app performs no medical function, nor does it give any diagnostic or clinical guidance, diagnosis or advice. Nor is the app an “accessory” to a medical device, as it is not needed for the cylinder package (of which the valve is a CE marked medical device) to meet it’s essential performance.

A medical device is defined and regulated by the EU Medical Device Regulation (MDR) and/or the UK’s Medical Devices Regulations 2002 and must carry a corresponding CE, UKCA and/or CE UKNI mark. The MHRA has specific guidance to help determine if an app is a medical device, which can be found here: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1105233/Medical_device_stand-alone_software_including_apps.pdf.

BOC’s evaluation of this process (page 6, flow chart) is as follows:

1. Is the app is a Computer Program or functional document > Yes
2. Does it have a medical purpose > No
3. Works in combination with one or more devices? > Yes
4. Enables the function of the device (an accessory)? > No
5. Not a Medical Device.

BOC have drawn this conclusion because:

- The app is not required to operate the cylinder package. The user can operate the cylinder package as defined by the legal manufacturer, known as “Essential Performance”, of the valve without the need to use the app (as has been done in the market for the past 20+ years)
- The app provides no diagnosis, suggestion, recommendation or advice about the therapy being administered. There is no method of inputting any information about the patient’s clinical status, so there is no function for the app to advise the user what to do.

The app merely advises when a cylinder may run out, based on the information about that cylinder inputted by the user. The app reminds the user that they remain responsible for the safe use of the cylinder package, and must check the content gauge regularly, as per BOC’s instructions and training material.



2. Has the Remaining Time Estimator app been developed to DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems

No. The app's development pre-dates the introduction of this standard and is based on a development for BOC's parent company Linde as a global solution. The app is also not a "medical" app, in that it performs no medical function.

As per the guidance for the standard <https://digital.nhs.uk/services/clinical-safety/applicability-of-dcb-0129-and-dcb-0160/step-by-step-guidance>, the app's development and deployment is not publicly funded (Step 1), nor does the app "influence, support or manage" direct care of patients (Step 3). The app performs no medical function. The app is not a replacement for the correct use of oxygen or heliox cylinders which includes (but is not limited to) appropriate patient monitoring and periodic checks of the cylinder's content gauge. Because of this, while recommended, the application of this standard is not mandatory.



3. What gas cylinders does the Remaining Time Estimator app work with

The app uses elements of BOC's healthcare cylinder packages to identify the cylinder characteristics and current content. The app will work with the following cylinder packages featuring integral valves:

Oxygen

- ZA
- CD
- DD
- HX
- ZD
- ZH
- ZX

Heliox

- HX



4. Can I use the Remaining Time Estimator app with cylinders from other suppliers, or non-medical BOC cylinders?

No. The app uses unique elements of BOC's healthcare integral valve products to identify the cylinder characteristics and determine the current gas content. To reduce input errors, the cylinder characteristics cannot be inputted manually but instead retrieved by the information in the product barcode and the gauge reader is specifically designed to read the gauges of our cylinder packages, so cannot be used on regulators attached to pin index or other valve types where the gauge design varies.



5. How does the Remaining Time Estimator app calculate the remaining time?

The app determines the cylinder characteristics from the product barcode printed on the collar of the cylinder.

This tells the app:

- The cylinder's capacity when newly filled (cylinder water volume x fill pressure)
- The valve's flow settings available

The app then determines the cylinder's current content by asking the user to point the device camera at the cylinder's content gauge.

The app detects the needle position and determines its position along the arc of the scale as a percentage, e.g. a "half full" cylinder is given a content of 50% by the app.

Finally, the app asks the user to select the flow rate they intend to use. The user can select from one of the flow rates on the control wheel (the app shows the flows available for the specific cylinder type scanned) or they can enter a custom flow rate by typing in a number.

The app now has all of the information it needs to determine the rate at which the remaining gas will leave the cylinder, i.e. how long it will take to empty it, and therefore provide an estimated remaining time.

The app applies safety tolerances to account for variances in the cylinder package, the flow rate, the accuracy of the gauge reading and the filling process to ensure the remaining time estimate is always on the safe side.

The app assumes the flow of gas starts as soon as the time remaining is calculated. If this is not the case, you can update the content scan once the cylinder has been saved by tapping back into the saved cylinder and conducting a new updated scan. This will give the app a revised starting pressure to calculate from.



6. How does the Remaining Time Estimator app ensure I get a safe remaining time estimate?

The app applies some tolerances to conservatively generate a remaining time estimate that is safe. There are a number of factors that can affect the amount of gas in the cylinder at the point of use, the rate at which it is predicted to leave the cylinder and the app's ability to accurately determine the cylinder's current content.

The nominal content (litres of gas) of BOC healthcare cylinders are stated on the collars and datasheets for each cylinder type and calculated by multiplying the cylinder water capacity by the filling pressure.

For example, a CD cylinder is a 2 litre cylinder filled to 230 bar, so the oxygen content is 460 litres (2 x 230). However, it is not practically possible to access the total amount of gas, as, by law, all healthcare gas cylinders are fitted with a residual pressure valve (RPV), which ensures a small amount of positive pressure is retained in the cylinder to prevent contamination and back flow into the cylinder.

To account for this, the app subtracts 10 bar from the theoretical cylinder capacity.

Integral valves which have built in flowmeters follow an ISO standard (EN ISO 10524-4:2008) which specifies the tolerance of each flow setting. While BOC and their suppliers are confident that our products exceed these requirements,

nonetheless, the app assumes that the valve is venting gas at the worst-case permitted by the standard. This is as follows:

Nominal (stated) flow rate	Permitted tolerance
0.01 – 1.5 L/min	+30%
1.5 L/min +	+20%

Following this principle, the app assumes, for example, if a flow rate of 2 l/min is selected, that the gas is leaving the cylinder at 2.4 l/min.

By assuming there is less gas in the cylinder than there actually is, and assuming it is leaving at a faster rate than actual, the app can provide a safe time remaining estimate.

The app also prevents the user from setting a reminder that is less than 5 minutes from the estimated empty time.



7. What data does the Remaining Time Estimator app collect?

None. The app does not collect any user data. There is no telemetry or other functionality in the app that connects to a BOC or Linde-controlled server. There is no place to enter data into the app that can be accessed or retrieved by BOC.

The user's device operating system (iOS or Android) collects general information about what apps are used and the app stores from Apple and Google provide this information to BOC. This includes, for example, number of app installs, uninstalls, crashes and number of instances the app was started across the install base. This information is anonymised and only displayed in aggregate, never identifiable to any specific user or their details. It also does not contain any information about what the user does within the app.

The user accepts these terms and conditions from Google or Apple when they started using their device for the first time. These terms and conditions are between the user and Google/Apple and are unrelated to BOC or its parent company.



8. What permissions does the Remaining Time Estimator app need on my device & why?

The app requires the following permissions to work:

Android:

Permission	Reason
Photos/Media/Files	To store images from the camera of the barcode scan and gauge scan when setting a time remaining. The app stores the images, analyses them for the details needed and then deletes the images.
Storage	To save details of cylinder scans and retain the time remaining estimate, even if the device or app is restarted.
Calendar	If enabled in settings, the user can add estimated cylinder empty times and dates as calendar entries.
Camera	Camera is needed to scan the cylinder barcode and gauge.
Other:	
- Disable screen lock	- Disable screen lock is needed to prevent the device from locking while scanning a cylinder (since no user touch input is required for 30+ seconds, some devices may lock).
- Prevent device from sleeping	- Prevent device from sleeping is needed for the same reason as Disable Screen lock.
- Run at startup	- Run at startup is required to ensure the app can continue to count down and send a low content reminder notification, even if the user restarts their device.
- Control vibration	- Control vibration is required to vibrate the device when a low content alert notification is sent.
- Set an alarm	- Set an alarm is required to set the low content reminder notification

iOS:

Permission	Reason
Calendar	If enabled in settings, the user can add estimated cylinder empty times and dates as calendar entries
Camera	Camera is needed to scan the cylinder barcode and gauge.
Notifications	The app can send immediate notifications by default. The app will also ask the user to enable "Critical Alerts" on first start. This is to allow the app to send low content reminder notifications with an audible warning even when the device is in Silent, Do Not Disturb or other profiles.
Mobile Data	Mobile data is requested by most apps by default to allow the user to access Siri & search functionality. This can be disabled with no impact on app performance.



9. How does the Remaining Time Estimator app give me an audible alert, even when my device is on silent/do not disturb? How can I disable/revoke this?

The app uses the built-in features of Android and iOS to give high priority alerts, irrespective of the device's current notification profile.

Android

Android 8+ supports notification "Categories" and the "urgent" category allows notifications to be displayed and make a sound, even if the device is in "Do Not Disturb" or "Silent" mode.

Note that some device manufacturers may use different terminology, and not all may implement this in the same way. BOC advises users to test how their specific device performs.

Within the Remaining Time Estimator app, this feature is referred to as "louder notifications". The app will, where supported by the device OS, make an audible alert sound and display an associated visual notification.

To disable "louder notifications", follow these steps:

1. Tap the menu button, top left
2. Tap Settings
3. Tap "Louder notification" switch to disable it.

iOS

iOS 12 and up supports a feature called "Critical Alerts". This allows apps with certain permissions to notify the user of an event or alert, even when the device is in Do Not Disturb or silent mode.

The app will play an alert sound and present a message on the device when the cylinder empty notification is due.

The app will ask permission to enable this feature the first time you run it. If you decline, then, depending on your device notification profile at the time, you may not get an audible alert and/or a visual notification on the lock screen.

To disable "Critical Alert" permissions for the Remaining Time Estimator follow these steps:

4. Launch Settings app from the device home screen
5. Tap Notifications
6. Scroll until you find Remaining Time Estimator app and tap
7. Toggle "Allow Critical Alerts" off.



10. How can I provide BOC with feedback about the Remaining Time Estimator app?

BOC welcomes your feedback on your experience with the Remaining Time Estimator app. You can provide feedback on the app specifically via the following channels:

e-mail: remainingtimeestimatorapp@linde.com or bohealthcare-uk@boc.com

Phone: 01609 306 010

Twitter: [@BOCOnline](https://twitter.com/BOCOnline)



11. How does the minimum/maximum restock limit feature within the Gas Calculator feature work?

The gas calculator allows you to add up the total amount of gas currently contained within multiple cylinders.

Some situations, such as paramedic or remote clinical sites may have a requirement that they hold a minimum or maximum amount of oxygen. This can be a minimum or maximum number of full cylinders of a certain size (or combination of multiple sizes), or a minimum or maximum amount defined simply in litres of oxygen.

The Remaining Time Estimator app allows you set a minimum and/or maximum amount of litres and will display how far over (for maximum) or under (for minimum) you currently are with the cylinders you've added to the list.

As an example, a vehicle or location may have a maximum permissible oxygen amount of 2,000 litres. Within the app, the user can set this as the maximum stock level. When the user starts scanning cylinders, the app estimates the content in litres and adds them together. When the threshold (2000) is met, the app will display the number of litres above the maximum the user has added. In the example below, the total scanned is 2669 litres above 2000 litres.



12. If I add multiple cylinders to the Gas Calculator to add up the amount of gas I have and get a remaining time estimate, will this remaining time estimate update? Can I set an alert to be notified when the cylinders will run out?

No, the app does not start counting down the amount of gas remaining based on what is scanned. This is not the intention of the calculator. The reason for this is because, it's unlikely that a user would use all cylinders at the same time at the same flow rate; they are more likely to use one at a time. The app doesn't know which one the user would use first, so it doesn't start counting.

If you want to have a countdown of the gas in a specific cylinder and/or set a reminder notification, use the Remaining Time calculator from the home screen by tapping the + button and following the prompts.



13. What devices and operating systems can the Remaining Time Estimator app work on?

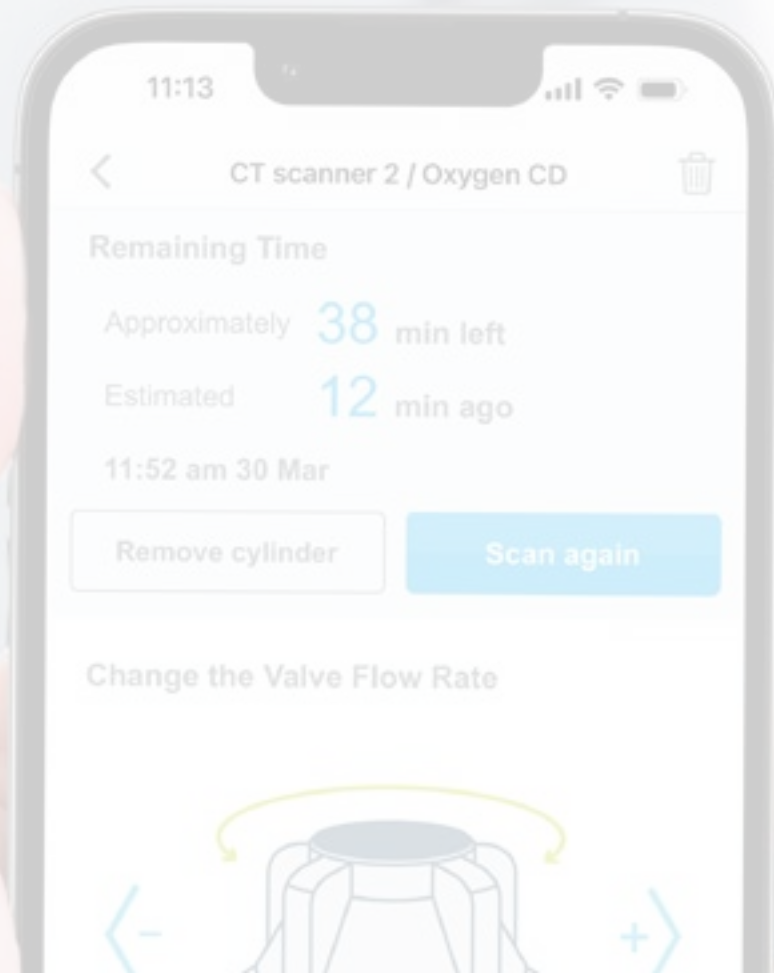
Android

Android 8+ is supported, though not all features may be supported in all versions of Android.

iOS

Version 12.1





Are you interested in
finding out more?

boconline.co.uk/en/services/healthcare-services/time-remaining-estimator-app