

# QCovid® Online Risk Calculator R1 V1 - Instructions for Use

COMPANY CONFIDENTIAL UNCONTROLLED IF PRINTED PRODUCT  
DEVELOPMENT

- [Introduction](#)
- [Product Details](#)
- [Intended Use](#)
- [Safety Information](#)
  - [Safety Instructions](#)
  - [Cautions](#)
  - [General Precautions](#)
- [Pre-Use Requirements and Dependencies](#)
- [Software Installation, Upgrade and Configuration](#)
- [Step by Step Instructions](#)
- [Troubleshooting](#)
- [Technical Specifications](#)
- [Regulatory Information](#)

## Introduction


The QCovid® Online Risk Calculator R1 provides a web user interface around the QCovid® Calculation Engine R1 software library. This library is a risk prediction algorithm to estimate hospitalisation and mortality outcomes from COVID-19 in adults. The website enables a user to enter a simple medical history for a patient and then uses the library to determine their risk of the aforementioned outcomes. The results are presented as absolute risks, risks relative to an individual with no risk factors, and also as a centile ranking within the general population.

It is a CE marked, Class I medical device (software as a medical device) under the Medical Devices Directive 93/42/EEC.

## Product Details


<b>REF</b>	QCovid® Online Risk Calculator
<b>LOT</b>	R1 (v1.0.0)

# Intended Use


	<p>QCovid Online Risk Calculator R1 is a clinical decision support tool intended to facilitate individualised discussions between medically trained professionals and patients about COVID-19 risk. Clinical conversations could include advice to shield to limit the risks of catching the virus, health promotion opportunities (such as losing weight) to reduce the risk of serious illness if infected, and COVID-19 risk mitigation in the workplace.</p> <p>The QCovid Online Risk Calculator has been developed for public health purposes rather than for individual therapeutic or health care decisions, except for interventions aimed at prevention of infection.</p> <p>Please read this instruction manual thoroughly before using the QCovid® Online Risk Calculator. Please keep these instructions for future reference.</p> <p>The website is not intended to support automated processes, but only manual use via a web browser application.</p>
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# Safety Information

## Safety Instructions

	<p>Please follow the mandatory safety information supplied with the QCovid® Online Risk Calculator.</p> <p>The QCovid® Online Risk Calculator cannot take the place of clinical assessment. No medical decision should be based solely on results provided by the risk calculator. This is a labelled misuse of the QCovid® Online Risk Calculator.</p> <p>Users should take careful note of any disclaimers or warnings that appear on the calculation results page. In certain situations approximate results are shown with a warning, whilst all results carry a disclaimer relating to their inherent limitations. Before using the QCovid® Online Risk Calculator, users should review the published QCovid® research article (<a href="https://doi.org/10.1136/bmj.m3731">https://doi.org/10.1136/bmj.m3731</a>) to ensure that its limitations are understood.</p>
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## Cautions

	<p>Please follow the cautionary information when implementing the QCovid® Calculation Engine.</p> <p>Clinicians are expected to apply their own clinical judgement to further risk stratify patients and are not expected to rely solely on the output from the QCovid® Online Risk Calculator in order to appropriately manage and advise their patients regarding COVID-19.</p>
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## General Precautions

The use of the QCovid® Online Risk Calculator is contraindicated as follows.

- People under the age of 19.
- People who have already had a diagnosis of COVID-19.
- It is not intended that this tool is used to make treatment decisions following admission to hospital.
- It is not intended to predict the expected outcomes of patients under different treatments.
- It is not intended to automatically remove people from a high risk group, or to deny anyone care, as QCovid is likely to underestimate risk in previously shielded groups.

## Pre-Use Requirements and Dependencies

Use of the QCovid® Online Risk Calculator requires use of a web browser. The website has been verified on the following web browsers:

- Google Chrome 87.0

## Software Installation, Upgrade and Configuration

There is no installation necessary to use the QCovid® Online Risk Calculator.

## Step by Step Instructions

In the instructions below, please interpret the word “click” to denote either the act of using a mouse to click on an item, tapping on the item using a touch screen, or similar activation using a keyboard.

1. Upon visiting <https://qcovid.org/>, the user is presented with the home page.

1. If they have not previously visited the site in the chosen web browser, a cookie information side panel, will be displayed. The user should then click on either the “I Accept” or “I Do Not Accept” buttons to register their acceptance, or otherwise, of non-essential cookies. The side information panel will then close.
2. The cookie panel can be reactivated using the “C” button in the bottom right on the browser window.
3. Further information regarding cookies can be obtained using the Cookies link in the page footer.
2. The home page presents background information about the QCovid® Online Risk Calculator with a navigation bar at the top of the page. These include Frequently Asked Questions (FAQ), related Publications, the Licence and details of the Algorithm.
3. In the page footer, the user can find:
  1. The version of the QCovid® Calculation Engine, which is provided for reference.
  2. A link to the privacy notice.
4. Clicking on the Calculation link in the top navigation bar begins the process of a risk calculation.
5. If the user has not previously accepted the Licence, then they will be taken to the Licence page where they must first read and accept to the licence terms. Clicking on Accept Licence will then take them to the calculation. The licence acceptance is remembered for one day by their web browser, after which time the user must accept the licence again.
6. The user is then presented with a single-page web form via which they enter the personal and clinical information of the subject.
  1. Age, height and weight are entered using text boxes, must be entered. Age is entered as a whole number of years. Only centimetres and kilograms are supported for height and weight respectively. The ranges are as follows, and are included in the validation messages which will display if an out-of-range value is entered.
    1. Age: 19-100
    2. Height: 140-210cm
    3. Weight: 40-180kg
  2. UK postcode is also entered using a text box but can be left blank. The postcode is only used to determine the appropriate Townsend deprivation score to use. Use of a blank postcode yields the UK-wide average score. If the entered postcode is unknown, then the UK-wide average score will be used and a warning will be displayed.
  3. Biological sex is entered via radio buttons, restricted to male or female. There are insufficient data to model alternatives or related hormone treatments.
  4. Ethnicity is selected from a list of options, which includes “Ethnicity not stated”.
  5. Housing category is entered via a radio button list.
  6. The clinical information is entered, mostly via check boxes, though some items are presented as radio button or drop-down lists.
    1. Note that chemotherapy is specified via group options of Group A, Group B, or Group C. As noted on the FAQs page, these are detailed in the supplementary materials of the published QCovid® research article (<https://doi.org/10.1136/bmj.m3731>).

7. The user should select if the subject was on the shield patient list in 2020. This has no bearing on the calculation results, but controls a warning message that will be shown on the results page.
7. The user clicks a Calculate. If there are no validation issues with the form, then the user will be taken to the results page. Otherwise, they should review the validation messages and click Calculate again.
8. The risk assessment results are presented on the results page, with risks shown for both COVID-associated dead and COVID-associated hospital admission. The text on the results page explains the meaning of them as pertaining to a 90-day period similar to the first wave of COVID-19 in the UK.
  1. Absolute risk (*a*), which is the percentage chance of a person either dying or being admitted to hospital. It is also indicated as a “1 in ...” format, e.g. 0.1% corresponds to “1 in 1000”.
  2. Absolute risk (*b*), which is the equivalent percentage for a person of the same age and sex, but without any risk factors. It is also indicated in the “1 in ...” format.
  3. Relative risk (*a/b*), which is the ratio of the two and denotes how much more likely the subject is suffer death or hospitalisation than a person with no factors.
9. The value absolute risk of death is presented also in terms of the centile ranking, e.g. 68 of of 100, where 100 is most at risk.
10. The BMI (body mass index) calculated from the supplied height and weight is shown. Note that if this value is too high or too low, then the closest in-range value will have been used and a warning will be displayed regarding this. The valid range is 15-47 kg/m<sup>2</sup>.
11. Other warnings relating to the inputs are shown on the results page and should be noted.
12. To start another calculation, the user should click on the Calculation again in the top navigation bar.

## Troubleshooting



The FAQ link, available on the navigation bar at the top of each web page, provides answers to frequently asked questions.

## Technical Specifications

[QCovid® Online Risk Calculator R1 V1 - Software Requirements Specification](#)

## Regulatory Information

(List in here the appropriate regulations and standards the (product name) is compliant with). List also the registered manufacturer details.

	<p>Oxford University Innovation</p> <p>Buxton Court 3 West Way Oxford OX2 0JB</p>
	<p>This device fulfils the provisions of the European Commission (EC) Directive 93/42/EEC (Medical Devices Directive).</p> <p>This software product has been designed according to:</p> <p>ISO 13485:2016 - Medical devices - Quality management systems for medical devices</p> <p>ISO 14971:2019 - Medical devices — Application of risk management to medical devices</p> <p>IEC 62304:2006 Amd 1:2015 - Medical device software – Software lifecycle processes</p> <p>DCB0129:2018 - Clinical risk management: its Application in the manufacture of health IT systems.</p> <p>This device has been developed under the strict quality management system of Oxford University Innovation</p>