	Type of document: Record	Reference: REC-R1-027
	Title : Instructions for Use COBOX	Version: 3.0


# COBOX

## Instructions for use




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## 1. Introduction

QUANTIQ.IO. "COBOX" is a software as a medical device that allows the measurement of the pulse rate and respiratory rate using a regular optical camera.

### 1.1. Terms used in this document

**Customer:** one that purchases and integrates COBOX to their system/device.









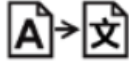
**User:** the person who will use COBOX (the patient or the healthcare professional).


### 1.2. How to use this manual

The document intended to guide healthcare professionals and patients (customer and/or users) in the use of the COBOX under normal conditions. All customers and/or users must read this complete manual before using COBOX.

Customers and/or users can request a paper version of the user manual by sending a request to support service via the user interface, or via email at [support@quantiq.io](mailto:support@quantiq.io).

### 1.3. Symbols

Symbols	Descriptions	Symbols	Descriptions
	Device manufacturer: QUANTIQ.IO		Consultation of the indications for use (paper or digital format available)
	Release date.		Indicates to the user that it is necessary to consult the operating instructions for important safety information, such as warnings and precautions.
	Medical device.		CAUTION: Informs of any special care that the physician and/or user must exercise for safe and effective use of the medical device.
	Reference of the medical device. COBOX V1.0.1	UDI	UDI number
	Medical device that complies with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning medical devices.		Versions in French, English and Spanish are available.

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## 2. Identification and indications

### 2.1. Product name

**Medical device name:** Cobox

**Reference:** COBOX V1.0.1

**Version:** V1.0.1

**Basic UDI:** 3770027064COBOX1.0.0G2

**UDI-DI:** 3770027064015

### 2.2. Label



### 2.3. Intended Use


Quantiq.io software COBOX is an API (Application Programming Interface) targeted to be integrated into third-party softwares or workstations.

Once integrated, COBOX measures the heart rate and respiratory rates of a patient using a video selfie.

### 2.4. Intended purpose

#### - Characterization of Patient Population

COBOX is intended to be used on any patient above 18 years old.

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#### - **Medical Indication**

Cobox is intended to be used for general practice of medicine (routine check-ups and monitoring at home) where the heart rate and/or respiratory rate of a patient needs to be assessed.

#### - **Contraindications**

COBOX should not be used in situations of vital emergency (where the prognosis is life threatening).

COBOX should not be used by patients under 18 years old.

COBOX should not be used by patients unable to remain static for 30 seconds. This would include patients suffering from pathological tremors (e.g. patients suffering from Parkinson's disease) or muscle spasms, which would prevent them from remaining static during the measurement.

COBOX should not be used by patients presenting a face skin stigma on a significant portion of the face (e.g. burn, graft etc.). Patients having significant facial hair or facial tattoos covering most of the face are also contraindicated.

COBOX is contraindicated for patients suffering from scleroderma.

COBOX does not provide a reliable heart rate result for patients with arrhythmia.


#### - **Characterization of User Profile**

COBOX is intended to be used either by healthcare professionals or by patients for self monitoring in routine check-ups including monitoring at home.

COBOX is easy to use and doesn't require any training or pre-existing knowledge.

#### - **Characterization of Use Environment Including Software / Hardware**

COBOX needs a video selfie to compute vital signs. The patient should have his face approximately centred and facing the camera, with his upper chest visible as indicated on the image below.

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COBOX should be used in a room with sufficient light (at least 100 lux). The illumination should be sufficiently stable in intensity (e.g. should not be used in a room with strobe light).

When using COBOX, patients should have their face visible (not wear a facial mask or any clothes covering the face). Patients should not wear excessive make-up.

COBOX analyses chest motions in order to compute the respiratory rate. Patients should have their chest visible and not wear clothes too wide as to completely mask the respiratory motion of the chest.

### Hardware environment


COBOX is intended to be integrated into third-party softwares or workstations. The third-party software is intended to be used on a smartphone, tablet, laptop or telehealth booth having a camera. The camera should have at least 15 fps and a resolution of 640x480 pixels. The camera should allow access to the exposure and white balance settings. The device needs to have at least 4 cores at 1.5GHz and 1Go Ram at 1500MHz available (not used by any other application).

## 2.5. Expected clinical benefits

COBOX is a software solution. As such, it does not require the user to own a dedicated medical device. This allows to measure vital signs in situations where it would not have been possible previously (for example, during a teleconsultation, or in remote patient monitoring when the patient does not have a medical device at home). Moreover, COBOX is easy and quick to use, and does not require any training or specific procedure to follow. COBOX therefore facilitates medical decision-making, promotes the use of telehealth and remote patient monitoring and allows a more regular follow-up.

Finally, measurements taken by COBOX are :

- Non-invasive
- They do not require any particular medical procedure
- They are contactless and do not require disinfection following the use of the solution by the user
- They make it possible to measure the Respiratory Rate in an automated and reliable way

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## In healthcare institutions

Measurements taken by COBOX are quick. Compared to the standard procedure used in emergency cares, we observe a decrease of 16% in the time to take vital measurements.

## 2.6. Safety, warnings and precautions for use

### Warnings

- There is no claim that COBOX can diagnose respiratory or cardiac pathologies.
- COBOX must under no circumstances be used in situations where the prognosis is life threatening. COBOX must be used only for non-serious situation of patient condition
- COBOX is not intended to be used for continuous monitoring, where the heart and respiratory rates are acquired without interruption for more than 1 hour.
- COBOX is able to measure all types of skin, however, skin with phototypes 5 and 6 is not contraindicated but the reliability is reduced.

### Safety in use

These precautions must be followed to ensure the effective use of the COBOX medical device. This manual contains warnings, cautions and other information to ensure the performance of COBOX. You must also follow locally applicable laws and regulations at all times.


COBOX meets the obligations of REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

To avoid any cybersecurity hazard, the use of an anti-virus/firewall updated is recommended. Use COBOX only from a device connected to trusted WiFi or LAN networks.

### Reporting a serious incident or risk of incident

Contact Quantiq.io team using the email [support@quantiq.io](mailto:support@quantiq.io) and the national competent authority if any serious incident (any malfunction) or risk of a serious incident resulting or likely to result in the death or serious deterioration of the state of health of a patient, user or third party involving a medical device occurs. This information must be reported without delay.

Contact a healthcare professional in case of heart rhythm disorder or any other possible syndrome.

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## 2.7. Performance characteristics of Cobox

Cobox can provide measures of heart rate and respiratory rate as accurate as conventional methods (the standard deviation error of the heart rate measure is less than 5 bpm (beats per minute) and the standard deviation error of the respiratory rate measure is less than 3 cpm (cycles per minute)).

Concerning the measures, in adults:

- a measure between 12 and 20 rpm (respirations per minute) is normal.
- a measure between 60 bpm and 100 bpm (beats per minute) is normal.


If the measures obtained with Cobox are out of these values, contact a healthcare professional immediately.

## 2.8. Potential undesirable side effects


No adverse effect related to the use of COBOX has been observed.

## 2.9. User requirements to use Cobox appropriately

To reach the expected performance, the user must comply with the prerequisites:


	The illumination of the subject needs to be sufficient (at least 100 lux)
	The patient should have significant face skin visible (no make-up or facial stigma on a significant portion of the face)
	The patient should remain static and not talk during the measurement process
	The patient should have significant chest visible (i.e. the chest should be placed in the field of view of the camera and the respiratory motion should not be hindered by significant layers of clothes)
	The patient should be above 18 years old

System requirements :

	The camera of the device needs to possess and give access to the auto-exposure and auto-white balance algorithms and the ability to lock them to the desired values.
	The device needs to have at least 4 cores at 1.5GHz and 1Go Ram at 1500MHz available (not used by any other application).
	COBOX needs the device to have an optical camera with a minimum resolution of 640 x 480 and minimum FPS of 15.

If those requirements aren't met, the only residual risk is the increase of the consultation time. Since Cobox does not aim to be used in emergency situations in which the measure could result in immediate danger to the patient, the residual risk about the use is thus defined as acceptable.



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## 2.10. Precautions for computer equipment

Cobox requires minimum hardware configuration to function properly:

- Android 9 to 12
- iOS 14 to 16
- Windows 10, 11
- MAC OS 12
- Linux 20.04, 22.04

## 3. Use of COBOX

### Customer

Customers integrate COBOX in their system/device with other telemedicine solutions such as health booths, online platforms or applications (smartphone, tablet, computer, health station, health cabin, medical device, teleconsultation, patient's remote workflow).


### User/patient

1. The user should be seated, if the device/system is intended to be used with a smartphone, tablet or computer, it is preferable to use it on a table. The health cabin, health station, needs to be equipped with a chair.
2. The user has to be sure that:
  - a. The illumination is sufficient.
  - b. The face skin is visible (don't wear a mask or significant make-up or facial stigma on a significant portion of the face).
  - c. Have a significant chest visible with no significant layers of clothes.
3. The user/patient faces the camera of the customer's system/device on which COBOX is integrated, **for 30 seconds**.



COBOX measures the pulse and the respiratory rate of the patient in real time by analysing the user's face. It is a one shot measurement. The measure is anonymous.

4. Results are displayed directly on the user/patient's system/device.

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If any problem is detected, it is shown in the customer system. This last one must display the message in the correct language to the user.

- When the measure is done, the user can stop safely the device/system using the customer recommendations to switch-off the device/system.

Do not use other applications when you use COBOX to assure the best performance of the API.

### 3.1. Personal data

COBOX does not store any data, neither on the device, nor on any remote server.

In the case where results provided by COBOX are stored by our customers, it remains their responsibility to be compliant with Health Data Hosting requirements.

## 4. Software customer integration

COBOX needs to be integrated into the customer's system/device. The instructions to integrate the API is explained in a specific document: "Instructions for COBOXs integration" (REC-R1-020). This last is distributed to the customer after commercial contracting by mail.

At the end of the integration, an audit to ensure the performance of COBOX is done following our internal procedures.

### Software licence key

QUANTIQ.IO provides its customers a licence key which must be set as a parameter when integrating COBOX. It contains an expiration date.

One month before the arrival of this date, QUANTIQ.IO will contact the customer to renew the contract if necessary and generate a new key. If the contract is not renewed, the service will be automatically terminated.


This key is sensitive and must never be communicated to third parties.

## 5. Update and maintenance

QUANTIQ.IO will update COBOX each time that an improvement/problem is detected and developed/solved. It is however necessary to use recent and updated versions of COBOX in order to guarantee a good performance.

If any update occurs, the customer will be notified and to integrate the new version he must contact Quantiq.io who will help him with the integration using the "Instructions for COBOXs integration" (REC-R1-020).

After each update, the customer has 3 months to install the new version. After this time, Quantiq.io will archive the old version and it won't be available any more. Also, all substantial modifications are informed to the competent authorities regarding regulation requirements.

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## 6. Contact and support

Customers can contact QUANTIQ.IO support by email using the following address : [support@quantiq.io](mailto:support@quantiq.io). The response time will depend on the SLA (Service Level Agreement) signed with the customer.

<https://QUANTIQ.IO/>



Date of publication of the notice: 12/12/2022

## 7. Validation of the document

### History of changes

Date	Version	Nature of the change
15/02/2022	1.0	Creation of the document
17/02/2022	2.0	completion of the document and missing sections
11/03/2022	2.1	last review of the draft version
12/12/2022	2.2	Cobox version updated
13/04/2023	2.3	Medical indication and characterization of user profile updated with the mention: routine check-ups and monitoring at home. Also the point regarding the safety (2.6) and software customer integration (4) were improved
06/06/2023	3.0	New point 2.10 was added to explain the precautions concerning the hardware configuration

### Approval of the document

Role	Function	Name	Date	Signature
Editor	QA Manager	Ericka White	06/06/2023	
Reviewer	CTO	Fabien NIEL	06/06/2023	
Approver	CEO	Alain HABRA	06/06/2023	