



Instruction for use



I. Introduction

Caducy is a medical device type software intended, in particular, as an aid to diagnosis by measurement of the heart rate and the respiratory rate of a patient by analyzing images from a webcam (computer, smartphone or tablet) after filming the face and upper chest for a few seconds.

Caducy can also measure two additional parameters, heart variability and stress level. These data are not for medical purposes but they enable assessment of levels of well-being.

Please read this user guide carefully to fully understand how the software works. If you have any further questions, encounter a problem, or would like to suggest improvements, please contact i-Virtual Customer Service at feedback-caducy@i-virtual.fr or visit our website at <https://www.caducy.com/>

II. Intended use of the software

Caducy provides healthcare professionals with remote diagnostic aid and well-being data, as part of a teleconsultation or home follow-up.

III. Indications

Caducy is a medical device for measuring heart rate and respiratory rate.

IV. Contraindications

- Caducy cannot provide a reliable heart rate result for people with arrhythmia.
- Caducy may not provide reliable results if the user has scleroderma.
- Caducy cannot provide measurements for patients suffering from pathological tremors or muscle spasms which prevent them from remaining static for the duration of the measurement.
- Caducy may not provide reliable results for people under the age of 18 and over the age of 80.



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V. Warnings/ Precautions

1. Warnings

- Caducy is a diagnostic aid but cannot under any circumstances serve as the sole reference for the formal establishment of a diagnostic.
- There is no claim that Caducy can detect respiratory or cardiac pathologies.
- Caducy cannot under any circumstances replace the advice of a doctor and / or healthcare professional. Never take any medicine or change any treatment based on a measurement result without consulting your doctor.
- Caducy must under no circumstances be used in situations where the prognosis is life threatening.
- Do not take measurements immediately after physical activity. In the case of teleconsultation, the healthcare professional must ensure that their patient is at rest before taking the measurement.
- The measurement for those with phototypes 5 and 6 is not contraindicated but the reliability is reduced.

2. Precaution of use

If one of the conditions set out below is not met, Caducy does not deliver the result of the measurement and refers to the condition of use for the user to take the measurement again:

- To achieve an accurate and reliable measurement, the patient must remain still during the acquisition time (30 seconds).
- Avoid sources of heat and humid places which can create condensation on the camera.
- The brightness must be sufficient and stable:
 - o Do not use in moving transport which could generate a fluctuation of luminosity.
 - o Do not use against the light or in the absence of light (natural or artificial).

3. General hardware and software minimum requirements

- The software requires minimal hardware configuration to function properly:
 - Android 7 to 12 with 2Gb of available RAM
 - iOS 12 to 15 with 2Gb of available RAM
 - Windows 7 to 10 with 2Gb of available RAM
 - Mac OS 10 to 12 with 2Gb of available RAM

The functionality of Caducy is guaranteed between the minimum and maximum versions specified. For later versions, the functionality of Caducy is not guaranteed.

- The web browsers and software platforms compatible with the minimum versions on which the widget has been successfully tested and validated are below:

	Safari	Chrome	Brave	Firefox	Edge	Opera
Windows (7/10)		96.0.4664.45	1.32.113	94.0.2	96.0.1054.41	81.4196.60
Mac OS X (Catalina 10.15)	14.6	96.0.4664.45	1.32.113	94.0.2		82.0.4227.23
Linux (Ubuntu 18.04/Debian 10)		96.0.4664.45	1.35.4	78.14.0 ESR		82.0.4227.23
iOS 12	14.3	96.0.4464.53	1.32.3	39.0		3.2.4
Android 7.1		96.0.4464.53	1.32.112	94.1.2		65.2.3381.61420



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- The chosen web browser must enable JavaScript functionalities.
- The minimum specifications for the camera are:
 - Minimum resolution of 640 x 480 pixels
 - Minimum 15 FPS (frames per second)
- Screen size: a minimum size of device screen is required for the proper use of the device and to allow readability of the text on the screen.
A screen with a diagonal size of 4 inches minimum is required for the proper use of Caducy. This applies to computer screens, laptop screens, tablets and smartphones.
- Contrast and brightness of the screen:
To ensure better readability of the text on the screen, it is essential that the screen (computer, laptop, smartphone, or tablet) is set to the maximum brightness setting to ensure better display contrast.
- Internet Connection: a minimum of **500KB/s** data rate (upload bandwidth) is required for the proper functioning of the Caducy.
- To ensure proper navigation on Caducy, please respect the environmental requirements recommended by the equipment manufacturer.

4. Precautions to ensure security

- To ensure a secure navigation on Caducy, adopt a cybersmart behavior using a regularly updated:
 - antivirus or malware software,
 - web browser and
 - operating system.
- Do not use the software in a non-secure environment: only use Caducy from a device connected to trusted WiFi or LAN networks.
- When using Caducy, from an application or from a web browser, avoid launching or running applications or services likely to degrade the performance of the device (processor and memory), reduce the bandwidth of the internet connection.
- It is strongly recommended to use recent and updated versions of the software application integrating Caducy, in order to guarantee compliance with the state of the art, to use the necessary security and to ensure the compatibility of the application with Caducy.

VI. Potential undesirable side effects

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

VII. Target patient groups

The device allows the measurement of heart and respiratory rates on anyone between the ages of 18 and 80 years.

The measurement for people of phototypes 5 and 6 is not contraindicated but the reliability of results is uncertain.



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In addition, reliable results cannot be obtained in some pathologies, in particular:

- In some cases of scleroderma.
- Pathologies causing tremors or significant spasms which do not allow the patient to remain static during the measurement.

VIII. Intended users

The intended users are:

- Healthcare professionals during a teleconsultation.
- Patients during home monitoring (see 'VII. Target patient groups').

The software is integrated into the teleconsultation platforms. It operates through a distant server and do not require any installation on the user computer, smartphone or tablet.

Users must be familiar with a computer, tablet or smartphone that has an internet connection and a webcam. The webcam allows the patient's face to be filmed in order to provide data to the software. The internet connection allows the transmission of these data to a remote server to perform the calculations necessary to provide the results. No prior training is necessary to use the software. However, reading this manual and observing the conditions of use are essential to perform the measurement correctly.

Users should ensure that computer equipment is fully powered or that it has sufficient charge level to perform the measurement. It is also necessary to have an adequate internet connection speed. A data rate of at least 4Mb/s is required for the proper functioning of Caducy.

In case of difficulty in using the software (disability, elderly, illiterate, those unfamiliar with IT tools), it is possible to obtain third person assistance.

IX. Clinical Benefits

There is no direct benefit to the patient from using Caducy. However, Caducy allows healthcare professionals to benefit from the measurement of physiological variables during teleconsultations, which has previously not been an option. This solution meets the challenge of increasing use of teleconsultations and can obtain a more comprehensive examination.

Caducy facilitates medical decision-making and promotes remote patient monitoring.

X. Device Performance

Caducy can provide heart rate and respiratory rate results as accurately as conventional methods (accuracy +/- 5 beats per minute for heart rate and +/- 4 cycle per minute for respiratory rate).

The lifetime of Caducy is determined by IT developments, it is limited to 3 years after the initial marketing of the medical device.

However, the life cycle of the medical device could be reduced if the support environment (hardware and/or software platforms) reach the end of their life or become unavailable or insecure or unstable.

i-Virtual does not guarantee correct operation and availability of services when using Caducy beyond the life cycle.

XI. Instruction for use

First, it should be noted that the subject of the measurement may be different from the user of the device. There could be three types of users: the “healthcare professional” who asks to launch Caducy, the "user" who initiates the measurement and the "patient" whose heart rate and respiratory rate are to be measured.

1. Instructions for the healthcare professional

During a teleconsultation, the role of the healthcare professional is to indicate the operating conditions to their patient so that the measurement is optimal. He should be aware of the instruction for the user and the patient below.

After acquisition of the measurement, the healthcare professional receives the values of heart rate, respiratory rate and heart variability, as well as the stress level. The results display is the same as in the patient’s user interface, refer to the images in Step 4 of “instruction for the user and patient” below.

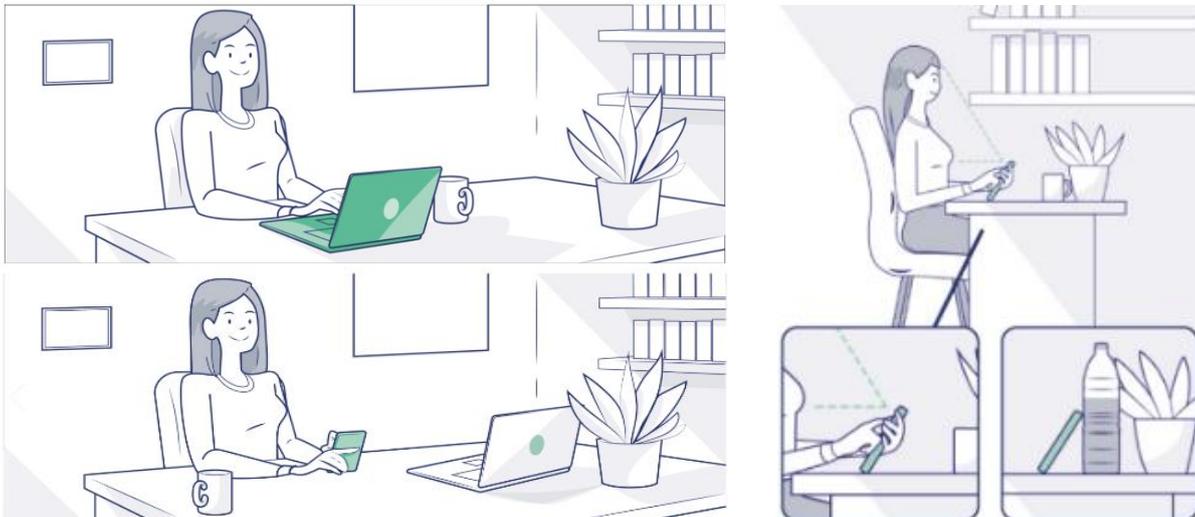
The healthcare professional can also ask the patient to take a second measurement if he found it necessary.

2. Instruction for the user and the patient

To use this software correctly, please follow the instructions below:

Step 1: Preparation

Before starting the measurement, the user must make sure that the computer hardware (computer, smartphone or tablet) is either hand-held on a stable surface or positioned on a stable support:



If the computer equipment used is a telephone, it is preferable to place the telephone against an object.

When using Caducy on a mobile device, tablet, or mobile phone, it must always be positioned in portrait mode with the camera facing upwards

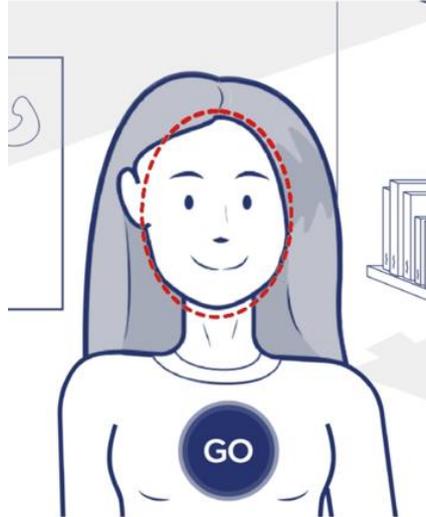
For normal use of Caducy, the user should be place themselves at a distance of between 40 cm and 60 cm from the camera of the device, which will ensure an optimal framing of their face.

In addition, the patient must comply with the following conditions:

- Take the measurement in a quiet, isolated place without source of disturbance or distraction (animals, children, movement of people, etc.).
- Not to be in motion (car, train, bicycle, bus, walk, run, etc.).

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- Make sure the camera is properly cleaned with a clean cloth before use.
- Prefer natural light to artificial light. The subject should not be placed against the light. In all cases, make sure that there is sufficient and consistent brightness.
- Have a sufficiently clear face (do not wear a hat, scarf, cap, mask, etc.).
- Be correctly positioned in front of the camera lens and do not move while shooting the video. The whole face must be centered and facing the area indicated on the screen:



Step 2: Triggering the measurement

The start of the measurement is achieved by the patient manually pressing the "GO" button.

Step 3: Acquisition of the measurement

Once the measurement is triggered, filming lasts about 30 seconds. To achieve an accurate measurement, the patient is asked to remain still during the acquisition time.

Throughout the acquisition, Caducy alerts the user if:

- the subject of the measurement does not remain sufficiently static,
- the surface of the skin is not sufficiently illuminated,
- there are significant variations in light,
- the equipment used (smartphone, tablet or computer) does not deliver a sufficient number of images per second.

If one of these conditions is not met, Caducy does not deliver the measurement result, returns to the conditions of use and therefore invites the user to start the measurement again.

Step 4: Calculation and display of the result

The values of heart rate, respiratory rate and heart variability, as well as the stress level, are displayed after a few seconds:



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Units of measurement of physiological parameters:
- heart rate in beats per minute (bpm)
- respiratory rate in cycles per minute (cpm)



Units of measurement for well-being parameters:
- heart variability in milliseconds (ms)
- stress level: from 1 to 5

Any serious incident which has occurred in connection with the medical device must be reported to i-Virtual and to the competent authority of the member state in which the user and / or the patient is established.

XII. Protection and security of personal data

As part of the Caducy conditions of use, i-Virtual is required to process personal data in order to analyze the patient's images and to provide diagnostic aid data as part of a teleconsultation (or home follow-up).

When i-Virtual processes personal health data, the patient is informed and must expressly consent to the processing of said data, in accordance with Article 9.2.a of Regulation 2016/679, otherwise, i-Virtual cannot perform the analysis of vital parameters.

Note that i-Virtual accommodates any processed health data with OVH, a certified health data host (HDS) and service provider (certificate n° 37387-1).

For more information about the management of their data, the methods of treatment and their rights, users and / or patients can consult the confidentiality policy provided and send their request to privacy@i-virtual.fr

XIII. Meaning of symbols

	Unique device identifier
	Product reference
	Medical device
	Manufacturer
	Date of manufacture
	Consult the instructions for use
	It is necessary to consult the operating instructions for any important safety-related information, such as warnings and precautions to be taken

XIV. Label


by


Software for measuring vital parameters



Caducy



Caducy - V1.0.0



03770024080001
V1.0.0



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AAAA-MM



Available online





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This medical device is a diagnostic aid but can in no way serve as the sole reference for the formal establishment of a diagnosis of respiratory or cardiac pathology. Cardiac variability and stress level are not for medical purposes and they make it possible to assess a level of well-being

This document is **version 7** of the Caducy 1.0.0 Instruction for use. It was published on **04/2022**.

i-Virtual is committed to continually improving the performance and security of Caducy. Please refer to the latest versions of this document, available on the Caducy homepage www.caducy.com. Further inquiries (including requests for an IFU in paper form) can be addressed to: feedback-caducy@i-virtual.fr