Caducy

Manufactured by
i-Virtual
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1. 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 these instructions 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 issue@i-virtual.ai or visit our website at www.i-virtual.ai

2. 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 under the supervision of healthcare professional.

2.1. Indications

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

2.2. 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.

• The measurement for those with phototypes 5 and 6 is contraindicated because the reliability is reduced.

2.3. Intended users

The intended users are:
-    Healthcare professionals during a teleconsultation.
-    Patients during home monitoring.

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. Users should not disconnect the webcam during the measurement and be sure to keep the webcam permission active. 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.
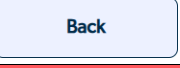
Users should ensure that computer equipment is fully powered or that it has sufficient charge level to perform the measurement. It is also necessary to have an adequate internet connection speed. A data rate of at least 500 kb/s is required for the proper functioning of Caducy.

Users must ensure that they comply with the environmental conditions of use of their computer, tablet or smartphone to ensure Caducy performance.

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

3. How Caducy works

3.1. User Interface

Symbol	Functionality
	The "**Menu**" button displays the "**Settings**" and the "**Instructions**" buttons
	The **"Settings"** button displays a page to select language. Once the user selects a language, all the information is presented in the chosen language. Each language is identified with a flag.
	The **"Instructions"** button allows the user to access the Instructions for Use, which also includes the Caducy label.
✕ or Leave	The **"Leave"** buttons allow the user to exit the widget at any time throughout the use of Caducy.
Next	The **"Next"** button allows the user to proceed to the next screen and reach the screen for initiating the measurement until the results are obtained.
← or Back	The **"Back"** buttons allow the user to return to the previous screen.
Start analysis	The **"Start analysis"** button allows the user to start a measurement.
Cancel	The **"Cancel"** button allows the user to cancel the measurement and return to the measurement main view.
● ● ● ●	The **"Pagination Indicator"** shows which page of the Caducy conditions of use is currently being displayed. There are clickable arrows on the left and/or right to navigate between pages.
Restart	The **"Restart"** button allows the user to launch a measurement whereas the "**Leave**" button is intended to leave the software.
📷	The **"Camera"** button allows the user to choose a camera.
?	The "**Feedback**" button allows the user to send a mail to issue@i-virtual.ai

3.2. 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.

3.2.1. 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 at 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.

3.2.2. 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:
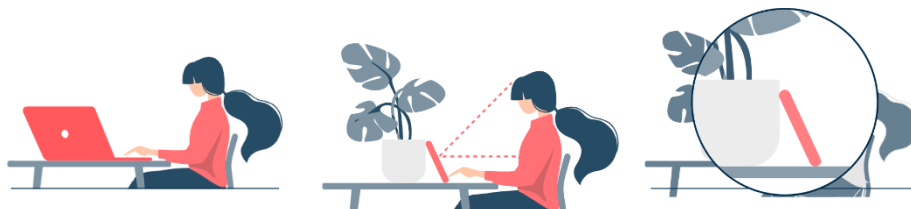
If the computer equipment used is a telephone, it is preferable to place the telephone against an object.

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 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.).
- 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.

Step 2: Triggering the measurement

The start of the measurement is achieved by the patient manually pressing the "start analysis" 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 enough 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:

📋 **Medical data**

♡ Heart Rate	🫁 Respiratory Rate
70bpm ⓘ	**12**cpm ⓘ
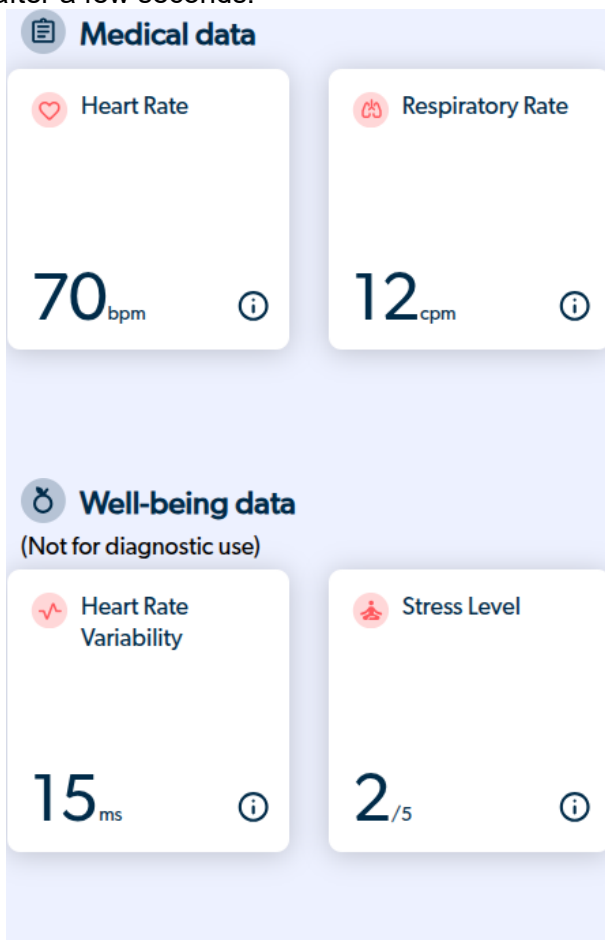
Units of measurement of physiological parameters:
- heart rate in beats per minute (bpm)
- respiratory rate in cycles per minute (cpm)

☿ **Well-being data**
(Not for diagnostic use)

∿ Heart Rate Variability	🧘 Stress Level
15ms ⓘ	**2**/5 ⓘ

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

These additional parameters for non-medical use are not supported by clinical evidence. The clinical evidence covers the medical use only.

The interpretation of the results is strictly the responsibility of the healthcare professional. In no case it should be done by the patient alone.

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.

Some average values and details are specified for information purposes in the interface. The sources are the following:
- For heart rate average values: Target Heart Rates Chart | American Heart Association
- For respiratory rate average values: Moore T. Respiratory assessment in adults. Nurs Stand. 2007 Aug 15-21;21(49):48-56; quiz 58. doi: 10.7748/ns2007.08.21.49.48.c4605. PMID: 17844906.
- For heart rate variability average values: Balewgizie S Tegegne, Tengfei Man, Arie M van Roon, Harold Snieder, Harriëtte Riese, Reference values of heart rate variability from 10-second resting electrocardiograms: the Lifelines Cohort Study, European Journal of Preventive Cardiology, Volume 27, Issue 19, 1 December 2020, Pages 2191–2194

3.3. Error handling

If the conditions of use are not respected or the widget is not used as intended, this may lead to problems which are indicated with error messages. Errors may be caused by inappropriate actions, incorrect settings, lack of hardware resources or other factors.
Error messages are indicated to help users understand what is wrong and correct their actions or settings so that the widget can correctly function.

Error Symbols	Displayed error message in the user interface	How to solve the problem?
	Please, do not interact with your device during the measurement.	The user must stay still throughout the 30-second measurement and check if the lightning conditions are optimal.
	Please, stay still during the measurement. Please, check the lighting conditions.	
	Please, respect the following conditions for use: • Make sure the battery of your device is charged, and the energy-saving mode is disabled. • Check that there is no other application active on your device.	
	Insufficient lighting. Please, increase the lighting conditions.	To ensure device's proper functionality, the user must make sure that the lighting conditions are optimal by increasing the brightness of the environment, adding an artificial light source or avoiding shaded areas.
	Your face is not correctly positioned within the frame. For optimal use, please: • Center your face within the frame, ensuring that it is fully visible. • Increase the lighting conditions.	
	Additional measurement required.	The user must repeat the measurement in compliance with all conditions of use to ensure the quality of the measurement.
	No video source. Please, connect a camera.	Check that the camera on your device is not being used by another application or process. To solve this problem, follow these steps: • Restart the browser • Restart the device • Check memory and resources • Check security settings

Error Symbols	Displayed error message in the user interface	How to solve the problem?
	Your camera is already being used.	To solve this problem, follow these steps: • Close other applications • Restart the device • Check security settings
	Permission denied. If you wish to continue, you must allow access to your camera and start again.	To solve this problem, follow these steps: • Check camera permission • Restart your browser
	Your camera is not supported by the browser.	To solve this problem, change your camera.
	Unavailable Internet connection. Please, verify your Internet connection.	
	The display size is not sufficient to use the medical device. For optimal use, please: • Switch in full-screen mode. • Orient your device in portrait mode. • Try again on a larger screen.	
	Server communication error: please try again later.	This message indicates that there has been a communication problem between your device and the server. To resolve this problem, follow these steps: • Check your Internet connection • Check security settings • Try again later If all these actions fail to resolve the problem, please contact the i-Virtual technical support at the e-mail address issue@i-virtual.ai

Measurement cancelled.

If the problem persists despite all these measures, it may be necessary to contact the technical support of i-Virtual for further assistance.

4. Warnings and precautions

4.1. 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 healthcare professional. Never take any medicine or change any treatment based on a measurement result without consulting your healthcare professional.

• 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.

4.2. 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).

5. Technical specifications

- The software requires minimal hardware configuration to function properly:
  - Android 13 to 15 with 2Gb of available RAM
  - iOS 16 to 18 with 2Gb of available RAM
  - Windows 10 to 11 with 2Gb of available RAM
  - Mac OS 13.6 to 15.0 with 2Gb of available RAM
  - Linux Ubuntu 22.04 LTS and 24.04 LTS 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 compatible web browsers (with the minimum and latest versions) on which Caducy has been successfully tested and validated are as follow:

Tested web browsers		Safari	Chromium-based	Firefox
Versions	**Minimum**	16	136	138
	Latest	18	138	140

- The chosen web browser must enable JavaScript functionalities.

- When using Caducy, users should not interact with the browser.

- The minimum specifications for the camera are:
  - Minimum resolution of 640 x 480 pixels
  - Minimum 15 FPS (frames per second)

- Specific recommendations about the camera:
  - Do not disconnect the webcam during the measurement and make sure to keep the webcam permission active.
  - If a webcam is added, the user will see it appear in the list of webcam choices in the user interface. This addition does not impact the measure in progress.
  - Check that the webcam is not used by another tab in the same web browser or other application or software.

- 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 and do not use the browser and/or the device in dark mode.

- Internet Connection: a minimum of **500 kb/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.

- If you have access to the i-Virtual platform, you can access the electronic version of the technical description. If not, you can reach out to the technical support at issue@i-virtual.ai.

- 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 orb services likely to degrade the performance of the device (processor and memory), reduce the bandwidth of the internet connection.

6. Potential undesirable side effects

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

7. 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.

8. 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 lifespan of Caducy is dependent by IT developments, it is limited to 3 years after the initial marketing of the medical device.

However, the lifespan of the medical device could be reduced if the support environment (hardware and/or software platform) reaches its end of life, becomes unavailable, insecure or unstable.
If Caducy is used beyond its expected lifespan, i-Virtual does not guarantee the proper functioning and availability of its services.

9. Data privacy and security

As part of the Caducy conditions of use, i-Virtual is required to process personal data in order to analyse 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° 37387-4).

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.ai

10.   Meaning of symbols

Symbol	Meaning
UDI	Unique device identifier
REF	Product reference
MD	Medical device
(manufacturer symbol)	Manufacturer
(release date symbol)	Release date
(instructions for use symbol)	Consult the instructions for use
(warning triangle symbol)	It is necessary to consult the operating instructions for any important safety-related information, such as warnings and precautions to be taken
CH | REP	Indicates the authorized representative in Switzerland

11. Label

Caducy by i-Virtual

Software for measuring heart and respiratory rates

MD Caducy

REF Caducy V1

UDI 03770024080001
V1.3.8

CE 2460

Available online

i-Virtual
19 avenue Foch
57000 Metz, France
www.i-virtual.ai

FR 2025-07

CH **REP** EUMEDIQ AG Grafenauweg
8 6300 Zug, Switzerland

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 purpose, and they make it possible to assess a level of well-being

This document is **version 22** of Caducy V1 Instruction for use. It was published in **2025/07**.

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.i-virtual.ai
Further inquiries (including requests for an IFU in paper form) can be addressed to: issue@i-virtual.ai