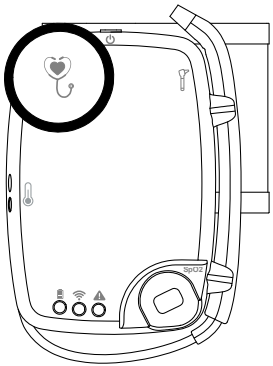
User Manual

One by Doc2U®

EN Version



One by Doc2U®

Content:

- One by Doc2U® device
- user's manual
- Otoscope throat examination sleeve
- Auricular speculums
- USB/micro USB cable

Dear customer,

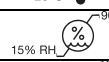
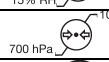
Thank you for choosing our medical device One by Doc2u®. Doc2u is committed to facilitating access to care for everyone, by recreating the quality and proximity of an in-office consultation. By trusting us, you free yourself from the constraints of a traditional consultation, while maintaining the essential contact with your doctor.

Read this manual carefully, keep it for future use and follow the instructions it contains

1. Glossary of symbols

Symboles	Description
CE	CE marking
	Warning (Triangle with yellow background and black borders)
	BF Type
	The device, its accessories and packaging must be recycled properly after use. Please observe local regulations and rules
RoHS	RoHS compliant product
UDI	Unique identifier device
SN	Serial number

Symboles	Description
LOT	Lot number
	Manufacturer
MD	Medical device
REF	Catalog reference
	No alarm for low SpO2 measurement
	Please read the user manual before use ISO 7010 – M002 (symbol with blue background and white pictogram)
IP22	IP degree of protection provided by the IEC 60529 standard
www.doc2u.fr 	Electronic user manual available at www.doc2u.fr

Symboles	Description
	Materials identification code
	French sorting instructions regading electronic device
	French sorting instructions regarding packaging.
	Temperature storage limits
	Humidity storage limits
	Pressure storage limits
	Do not use if packaging is damages
CH REP	Swiss representative

This product meets the following standards: EN ISO 10993-1:2020, EN ISO 13485:2016+AC:2018+A11:2021, EN ISO 14155:2020, EN ISO 14971:2019+A11:2021, EN ISO 15223-1:2021, EN ISO 20417:2021, EN 60601-1:2006+A1:2013+A2:2020+AC2016, EN 60601-1-2:2015, EN IEC 60601-1-6:2010+A1:2015+A2 :2021, EN 60601-1-11:2015+A1:2021, EN 60601-2-18:2015, EN 62304:2006+A1:2015, EN 62366-1:2015+A1:2020+AC:2015+AC:2018, EN IEC 80601-2-30:2019, EN ISO 80601-2-56:2017+A1:2020, EN ISO 80601-2-61:2019, EN ISO 81060-2:2019+A1:2020, ETSI EN 300 328V2.2.2:2019, EN IEC 62209-3:2019, EN 50566:2017, ETSI EN 301 489-1V2.2.3:2019, ETSI EN 301 489-3 V2.1.1:2019, EN ETSI EN 301 489-17 V3.2.4:2020

2. Warnings

- Device modifications are not permitted.
- Never use the device while it is charging
- One by Doc2U® is not a device for emergency situations: do not use the device on a person whose physical condition is critical, which could lead to severe consequences or death.
- If the device packaging, the device itself or any of its accessories are damaged or not intact – do not use the device.

- To charge the device, use only a charger as specified in §10.
- Stop using the device if it becomes abnormal or malfunctioning and remove it from your wrist immediately.
- Read all the information in the instruction manual and any other documentation in the package before using the device.
- Read the specific warnings for each medical tool in chapter §8.2.2, §8.3.2, §8.4.3, §8.5.2, and §8.6.2
- This device is intended for use only by persons who are not contraindicated as described in the §4
- This device is intended for personal use in a home, business premises or other locations with similar characteristics.
- This device contains small parts that may cause a choking hazard if swallowed by infants, toddlers, or children
- Use this equipment only for its intended purpose as described in this manual.
- If discomfort or skin irritation occurs, stop using this device and consult your doctor.
- Only use this device within the ambient temperature range specified in §15.1
- Do not expose this device to extreme storage temperatures outside the range defined in §15.1
- Storage above 35°C does not affect the safety of the battery but may affect its capacity.
- Use this device in relative humidity range specified in §15.1
- Use this device at atmospheric pressures range specified in §15.1.
- If the device is outside temperature range specified §15.1, leave it at room temperature (approximately 20°C) for at least twenty minutes before use to avoid compromising the accuracy of the measurements.
- This device should always be placed in a clean and dry place.
- Do not expose this device to sunlight, water or dust.
- Do not expose this device to electric shock.
- Do not use device during defibrillator use.
- Do not use the device together with other electrical medical equipment (EM) or any other device not

described in this user's manual. Doing so may cause this device to function improperly and/or compromise the accuracy of measurements.

- Do NOT use this device in the vicinity of high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment or computer tomography (CT) equipment. This may cause this device to malfunction and/or compromise the accuracy of measurements.
- Do NOT use this appliance in an oxygen-rich environment or near flammable gases.
- The results of the measurements are given as an indication and require the analysis of your practitioner.
- You should NEVER diagnose or treat yourself according to the readings. ALWAYS consult your doctor.
- NEVER attempt to open, disassemble, or repair the unit. This could compromise the accuracy of the measurements. If you have any problems, contact Doc2u or authorized representatives.
- This device is not intended to be used by persons with reduced physical, sensory, or mental capabilities. Persons with limited skills in the use of simple technologies (such as tablet use) may, however, use the device with the assistance of a more skilled caregiver.
- It may be dangerous to use accessories, spare parts and materials not described in the operating instructions.
- Do not maintain or service the appliance while it is in use. Only perform maintenance procedures specifically described in this user manual.
- This product emits radio frequencies (RF) in the 2.4 GHz band. DO NOT use this product in locations where RF is restricted, such as on an aircraft or in hospitals.

3. Intended use

One by Doc2u is a device able to be controlled by a remote practitioner in the context of a teleconsultation for general medicine. The device embeds 5 medical tools: thermometer, blood pressure monitor, oximeter,

otoscope, and stethoscope, to provide 6 physiological data: body temperature, blood pressure, oxygen saturation, heart rate, accurate video stream and sounds from heart and lungs.

These data are transmitted in real time to the practitioner, to make the teleconsultation as similar as a physical consultation.

The device is intended to be used by the patient itself or assisted by a third person.

4. Intended patient population, contraindications, and limitations of use

The use of the device is exclusively reserved to persons:

- In full possession of their cognitive abilities, which must be sufficient to use a product of this type (technological product of low complexity, like a tablet).
- If the patient cannot use the device himself, he can be assisted by a person fulfilling the above statement
- Over 18 years old for autonomous use.
- Over 12 years old for blood pressure measurement.
- Over 1 year old for children accompanied by an adult, and for all other available measurements. Except for the temperature which can be taken at any age.
- Whose wrist circumference is between 13cm and 19cm for blood pressure measurement.
- Whose acuity is sufficient to use a computer.
- Do not use the device on an open wound or on infected skin.

Blood pressure measurements should not be taken by people:

- Carrying an infusion.
- Having an arteriovenous fistula.
- Having a fracture or significant pain in the left arm.
- Having a wound or an inflammatory area on the wrist where the cuff will be applied.

5. Operating principle

5.1 Introduction

One by Doc2u® is a type IIa connected medical device, allowing the measurement of vital constants such as blood pressure, temperature, oxygen saturation and heart rate. The product can also capture video streams from precision cameras and audio streams from stethoscope-like subsystems. All of these data are transmitted over Wi-Fi connectivity, allowing for real-time remote access.

This product is used in the setting of a medical teleconsultation (general or specialist) aiming at obtaining a diagnosis based on the data of the device. The consultation is conducted by the health professional, who controls the measurements remotely, guiding the patient in the use of the various instruments. The health professional then retrieves the measured values on his interface.

The device is handled by the patient independently or assisted by a third party, not necessarily a health professional.

5.2 Clinical benefits

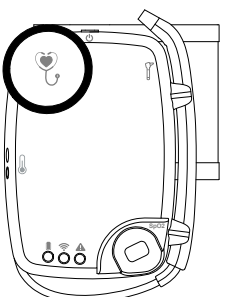
The clinical benefits claimed by Doc2U for its medical device One by Doc2U are:

Favorable phenomenon	Positive impact	Benefits level
Ease of use	Access to care and diagnosis	Very high
Enabling complete teleconsultation	Get a quick medical diagnosis	Very high
Provision of the device in remote areas	A response to mobility difficulties	Very high
Infrared temperature measurements	Increases the scope of remotely addressable consultation	Very high

Ear and Throat examination	Increases the scope of remotely addressable consultation	Very high
Blood pressure measurements	Increases the scope of remotely addressable consultation	Very high
Oxygen saturation measurements	Increases the scope of remotely addressable consultation	Very high
Heart and Lungs auscultation	Increases the scope of remotely addressable consultation	Very high
Enabling complete teleconsultation	Easier access to care	High
Enabling complete teleconsultation	Reducing the time spent in the waiting room	High
Enabling complete teleconsultation	Reduce the spread of infections and viruses	High
Enabling complete teleconsultation	Less travel and more consultation for practitionner	High

6. Description of the device

6.1 One by Doc2U device



MD REF ONEBD

6.2 Device Accessories

The One by Doc2U® device is supplied with the following accessories:

Name	Use/cautions
User manual	A manual containing all the information and warnings about the device and its use.
Otoscope ear protection	Single-use accessory to be used with the otoscope and allowing ear auscultation. **Cautions:** - Always ask the doctor what size to use according to the age of the patient. - Always use CE marked ear speculum. - Be sure to read §8.6 before use
Otoscope throat protection	Single-use accessory to be used with the otoscope and allowing mouth auscultation. **Cautions:** - Always use biocompatible and/or CE-marked otoscope throat protections. - Be sure to read §8.6 before use.
Micro USB cable	USB cable for charging the device. **Caution:** - Never use a USB cable presenting damages. - Always combine the USB cable with a charger that meets the requirements specified in §10

7. Switching on and connecting the device

7.1 Requirements

7.1.1 Teleconsultation room

A teleconsultation room is required to use One by Doc2U®. To know how to create a teleconsultation room please contact your One by Doc2U® provider. For more information, please refer to §18.

7.1.2 Internet connection

A broadband internet connection is required to use One by Doc2U®.

7.1.3 Wi-Fi network

A trusted Wi-Fi network using WPA2 encryption is required to use the One by Doc2U®.

7.1.4 Computer or other devices

A computer or tablet connected to the internet is required to use the One by Doc2U®. For security reasons,

it is recommended to use the latest version of the operating system and software.

Component	Requirement
Processor	Minimum Core I3 or equivalent
Memory	Minimum 4.0 GB RAM
Display	1366x768 resolution or higher
Operating system	Windows 10 or later MacOS 10.15 Catalina or later IOS 15 or later Android 9.0 or later
Peripherals	Standard camera, microphone, and speakers. *For practitioners using the stethoscope it is highly recommended to use headphones*

7.1.5 Web browser

A modern and up-to-date web browser is required to use One by Doc2U®. We recommend using Google Chrome.

7.1.6 Environment

For the best experience during the teleconsultation and for privacy concerns, it is recommended to be in a quiet and private place.

7.1.7 Risks

Using the One by Doc2U® without the recommended configuration may interfere with the teleconsultation. Performance limitations (bandwidth, computer configuration) may impede the optimal use of some features. Obsolete software (web browser in particular), obsolete operating system or an unsecured network may not guarantee compatibility and data confidentiality.

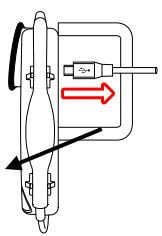
7.2 MD software update

The MD is automatically updated when connected to a Wi-Fi network. If any manipulation is needed, they will be displayed on your web browser when connecting the MD to a teleconsultation room.

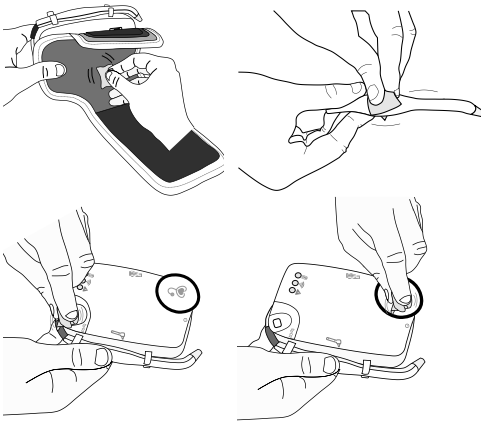
7.3 Switching on and connection

Please follow the step-by-step instructions on the interface provided by your teleconsultation provider (see §18 for more information) to connect your device to the teleconsultation room where you will join your practitioner.

1) Make sure that the device is unplugged before using it

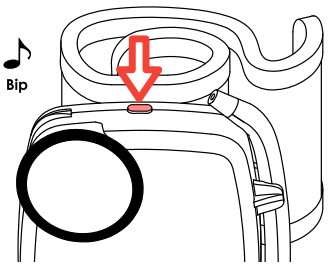


2) Disinfect your hands, and clean thoroughly the parts of the device that you will touch. Use a cloth slightly moistened with a neutral soap solution.

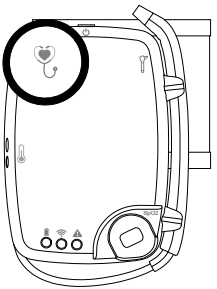


3) Enter your Wi-Fi router settings on the interface when prompted: **Use only a secured Wi-Fi network such as WPA2 wireless encryption.**

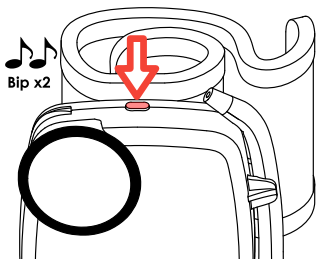
4) Press the power button once to turn on the device



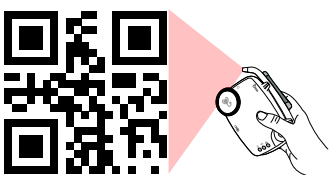
5) The power light glows green for a few seconds. The unit is on when this light tuns solid green.



6) When the device is turned on, start the otoscope camera by briefly pressing the ON/OFF button again the device beeps twice, the connection LED glows white and the camera LEDs flash: the camera is ready to scan.



7) Scan the QR-Code that appears on your screen with the camera of the otoscope → the device emits 3 beeps when the QR-Code has been detected.



Example of QR-code for illustration purposes

8) The connection light glows green for a few seconds, the turns solid bleu when the device is properly connected to the teleconsultation room.

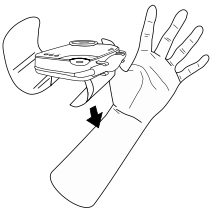
Is my device properly connected?

I heard the 3 beeps, the QR-Code was correctly scanned:

- Connecting to the Wi-Fi and the teleconsultation room may take a few seconds → The connection light breathes green for a few seconds and then turns solid blue when the device is connected to the teleconsultation room
- If 30s pass after the 3 beeps, and the connection light does not turn solid blue, there may be an error in entering the Wi-Fi credentials. Go back to the Wi-Fi step.

I did not hear the 3 beeps:

- Check that the camera is turned on and ready to scan: the device emits 2 beeps, the connection light is white and the camera LEDs flash twice every 5s: scan the QR-Code again until you hear the 3 beeps
- I increase the brightness of my screen if it is too low
- I check that the power light is green before scanning the QR-Code
- I enter my Wi-Fi credentials again if these steps did not work
- The camera lens may be dirty: clean it gently with a cloth slightly moistened with soapy water
- Your One by Doc2U® is now properly connected to the virtual teleconsultation room.
- Place the device on the inside of your wrist, tightening it properly so that it does not move.



- The practitioner will direct the session and guide you in the use of the various medical devices on your product.
- The practitioner has full control over the operation of the instruments and the measurements taken. Just follow the

instructions on the screen and the advice of your practitioner.

- The results you see on your screen are for reference only. Only a healthcare professional can make a diagnosis based on these results.
- Once your teleconsultation is over, the practitioner ends the session, and you automatically leave the virtual room. You can turn off your One by Doc2U® by pressing and holding the power button for more than 2 seconds.
- Disinfect the device again thoroughly, by cleaning the parts you touched with application.

8. Use of the different measuring devices

We remind you that the main objective of One by Doc2u® is to follow a live teleconsultation with your practitioner. Thus, the use of the various measuring devices present on the product will be explained to you step by step by the latter. You only have to follow precisely the instructions given on the screen of the interface, as well as the advice given by your practitioner so that your teleconsultation takes place in the best conditions.

In order to prepare for a teleconsultation, save time and make it easier to get started, it is necessary to carefully read the following instructions on the use of the different measuring devices present on your device.

8.1 Health and safety

Reminder: ⚠ Always UNPLUG THE DEVICE before using it. The device not be used while it is charging.

If you have not already done so, and before using the product, please disinfect your hands with a hydroalcoholic solution, and DISINFECT THE DEVICE with a cloth slightly moistened with a neutral soap solution.

8.2 Using of the blood pressure monitor

8.2.1 Presentation

1 in 3 adults has high blood pressure and most people with high blood pressure don't know it. Hypertension is the leading preventable cause of premature death in the world. The integrated blood pressure monitor in your device uses the principle of oscillometry to measure your blood pressure. It detects the flow of your blood and converts it into a digital measurement. To do this, the cuff inflates around your wrist, just as your practitioner does in his office.

8.2.2 Considerations and Warnings

8.2.2.1 Patient

- Have a rest for at least 5 minutes before taking a measurement.
- Do NOT use this monitor on babies, children or people who are unable to express themselves.
- Do NOT use the monitor on pregnant or pre-eclamptic people.
- Do NOT use this monitor on an injured wrist or a wrist under medical treatment.
- Do NOT place the wrist cuff on your wrist during an intravenous infusion or blood transfusion.
- NEVER diagnose or treat yourself based on the readings. ALWAYS consult your physician
- Do NOT make changes in the dose of medication taken based on the readings of this monitor. Follow the treatment prescribed by your physician.
- Consult your physician before using this monitor if you have common arrhythmias such as atrial or ventricular extrasystoles, atrial fibrillation, arterial sclerosis, poor blood flow, diabetes, pre-eclampsia and kidney disease, or if you are pregnant. CAUTION, these conditions, as well as any movement, shaking or shivering of the patient, may affect the measurement.
- Too frequent measurements can cause injury to the patient due to interference with blood flow.
- If you experience discomfort or skin irritation, stop using this monitor and consult your physician.

- Consult your physician before using this monitor on a wrist where there is an intravascular access or treatment or arteriovenous (A-V) shunt as temporary interference with blood flow may result in injury.
- Consult your physician before using this monitor if you have had a mastectomy.
- Consult your doctor before using this monitor if you have had a lymph node removal.
- Consult your doctor before using this monitor if you have severe circulation problems or blood disorders as the swelling of the wrist cuff may cause bruising.
- Check, by observing the wrist, that the operation of the blood pressure monitor does not lead to a prolonged deterioration of the blood circulation.
- Do NOT use this device in the vicinity of high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment or computerized tomography (CT) equipment. This may cause this device to malfunction and/or compromise the accuracy of the reading.
- REMINDER: Do not use the device in conjunction with other electrical medical equipment. This may cause this monitor to malfunction and/or compromise the accuracy of the reading.
- Avoid eating, drinking alcohol, physical activity and bathing for 30 minutes before taking a measurement.
- The cuff should be worn only on your left wrist.
- Measurements should be taken in a quiet environment.
- Remain still during measurement.
- Do NOT use this monitor in a damp place or a place where it may be splashed. This may cause damage to the monitor.
- DO NOT use this monitor in a moving vehicle such as a car.
- DO NOT drop or expose this device to strong shocks or vibrations.
- DO NOT use this monitor in places with high or low humidity or temperature.

- Use this device ONLY on people whose wrist circumference falls within the specified range of the wrist strap.
- Make sure this device is at room temperature before taking a measurement. Taking a measurement after an extreme change in temperature may result in an inaccurate reading. Doc2U recommends that the monitor be allowed to warm up or cool down for approximately 20 minutes when used in an environment at the temperature specified as the operating conditions, after being stored at the maximum or minimum storage temperature.
- The waiting time may vary from individual to individual depending on your physiological characteristics.
- The temperature of the wrist cuff may reach 41.1°C during prolonged use. Stop using the monitor if you feel discomfort due to heat.
- DO NOT crease the wrist cuff excessively.
- During measurement, make sure that no mobile device or any other electrical device that emits electromagnetic fields is within 30 cm of this device. This may result in incorrect operation of the device and/or cause an inaccurate reading.

8.2.3 Maintenance

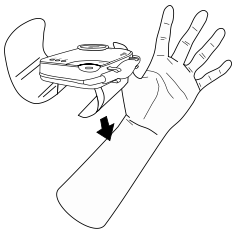
- Keep the cuff clean. If the cuff is dirty, clean it with a damp cloth. Do not rinse the cuff under a faucet.
- If the cuff is damaged, it can be changed by qualified personnel. See §16.1
- The calibration of the device can be checked by visiting maintenance.doc2u.com and following the method described on the web page. Consult your authorized Doc2U representative or Doc2U Customer Service at the address on the packaging for further information.

8.2.4 Notes on measuring

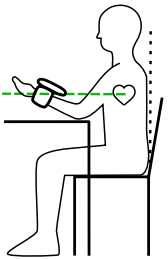
8.2.4.1 Autonomous patient

- Remove any clothing from your wrist to allow the cuff to fit directly on the skin.

- Wrap the cuff tightly around your wrist by closing the velvet band on the hooks.



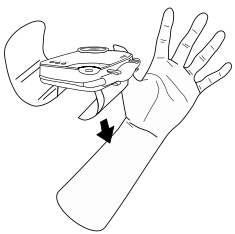
- Sit in a chair with your feet flat on the floor and the palm of your left hand facing upwards. Make sure you are in the position shown below to start the measurement: legs uncrossed, back and arm supported, middle of the cuff at the level of the right atrium of the heart and remain still in this position until the measurement is completed.



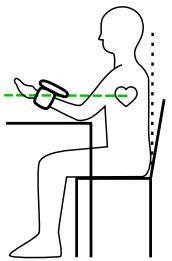
- Then follow the instructions on your screen.
- The cuff will inflate gradually while the measurement is being taken. The inflation stops as soon as the blood pressure and heart rate have been calculated. The cuff then deflates.
- If there is a problem with the system or if there is excess pressure, the measurement automatically stops, and the cuff deflates.
- If the error light flashes red and the unit beeps during the measurement, **REMOVE THE CUFF IMMEDIATELY**.

8.2.4.2 Assisted patient

- Remove any clothing from the patient's wrist to allow the cuff to fit directly on the skin.
- Wrap the cuff tightly around the patient's wrist by closing the velvet band on the hooks.



- Sit the patient in a chair with your feet flat on the floor and the palm of your left hand facing upwards. Make sure the patient is in the position shown below to start the measurement: legs uncrossed, back and arm supported, middle of the cuff at the level of the right atrium of the heart and remain still in this position until the measurement is completed.



- Then follow the instructions on your screen.
- If necessary, hold the patient's arm throughout the measurement.

- The cuff will inflate gradually while the measurement is being taken. The inflation stops as soon as the blood pressure and heart rate have been calculated. The cuff then deflates.
- If there is a problem with the system or if there is excess pressure, the measurement automatically stops, and the cuff deflates.
- If the error light flashes red and the unit beeps during the measurement, **REMOVE THE CUFF IMMEDIATELY OFT THE PATIEN'S WRIST**.

8.3 Using the infrared thermometer

8.3.1 Presentation

Our infrared thermometer measures your body temperature, using the forehead as the MEASUREMENT SITE, and operates in ADJUSTED mode. This means that the value measured by the optical sensor on the patient's forehead is then processed by an algorithm that returns the core body temperature (the skin temperature is different from the reference core body temperature). The temperature will be indicated either in degrees Celsius (°C) or in Fahrenheit (F).

8.3.2 Considerations and Warnings

8.3.2.1 Patient

- The measurement is done WITHOUT CONTACT with the skin, at a distance between 2 and 5 cm.
- The measurement should never be done in an environment below 15°C or above 40°C.
- Make sure that the skin is dry, and that the forehead is clear.

- Do not touch and/or scratch the infrared sensor lens.
- Always use a clinical thermometer for any temperature measurement.
- For calibration purposes and to allow physicians to estimate the accuracy of the measurement, the thermometer is equipped with a direct mode. This mode measures the surface temperature of the human skin.

8.3.2.2 Maintenance

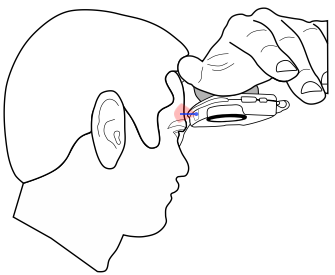
To clean the lens surface, gently spray it with compressed air, then use a damp pad to wipe it clean. Do not use any solvents.

8.3.3 Notes on measuring

- If the unit has been stored in a cool or warm place, wait at least 20 minutes for it to acclimatize to the ambient temperature before taking measurements.
- After strenuous exercise, always wait at least 10 minutes before taking a forehead temperature.

8.3.3.1 Autonomous patient

Point the infrared thermometer at your forehead. The measurement time must be at least 2 seconds Always follow the instructions on the screen and those of your practitioner.



8.3.3.2 Assisted patient

Point the infrared thermometer at the patient's forehead. The measurement time must be at least 2 seconds. Always following the instructions on the screen and those of the practitioner.

8.4 Using the pulse oximeter

8.4.1 Presentation

Hemoglobin oxygen saturation is the percentage between the capacity of oxyhemoglobin (HbO2) that has bound oxygen and that of all hemoglobins (Hb) combined (HbO2) in the blood.

Hemoglobin oxygen saturation is called SaO2 when measured by an invasive method. In our case, we refer to it as pulsed saturation, SpO2, because we use a non-invasive method.

It is a very important physiological parameter for the respiratory and blood systems. The oxygen saturation of hemoglobin in human blood can be decreased by several respiratory diseases.

Factors such as regulation of automatic organ malfunction caused by anesthesia, trauma following major surgery and certain medical examinations can also cause problems with oxygen supply, which can reduce the oxygen saturation of hemoglobin in humans. As a result, symptoms such as migraine, vomiting and asthenia can occur in patients. Therefore, it is very important to know a patient's hemoglobin oxygen saturation at the right time.

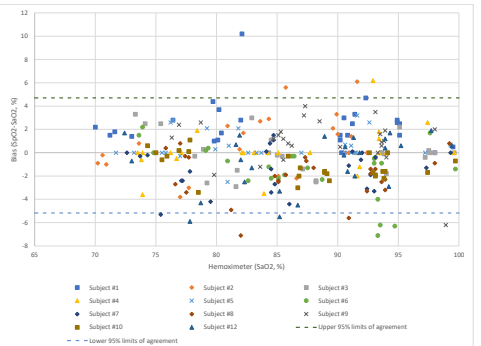
8.4.2 Measurement principle

The oximeter in your One by Doc2U® uses a non-invasive method to measure pulse oxygen saturation (SpO2) and heart rate, based on an optical sensor. This sensor allows

to determine the heart rate and SpO2, simply by placing one's finger on it. The measurement of oxygen saturation can be done without restriction of age, gender or particular physical condition.

The SPO2 measurement of the One by Doc2U® oximeter has been calibrated and clinically validated according to EN ISO 80601-2-61:2019, by comparison with blood samples from subjects under controlled hypoxia. The summary of the clinical study report states: "*The study included 12 subjects : 6 women and 6 man, all healthy, from 22-33 years old, male and female, having black or white skin*".

The associated modified Bland and Altman plot is:



The accuracy of heart rate measurement was tested with a functional tester.

The wavelengths used and the powers of the light sources used for this measurement are:

- Infrared: 940nm @250mA max.
- Red: 700nm @125mA max.

Do not hesitate to share this information with the health professional. It may be useful for his interpretation of the measurement.

8.4.3 Considerations and Warnings

8.4.3.1 Patient

- The sensor should not be immersed in water.
- Venous pulsations may cause an inaccurate measurement.
- Hypotension, severe vasoconstriction, severe anemia or hypothermia may cause an inaccurate measurement.
- Cold fingertips (in case of very low ambient temperature) may cause an inaccurate measurement.
- The device will not give a visual or audible alarm to indicate a low SpO2 reading, neither an abnormal heart rate. Always ask a healthcare professional to interpret the SpO2 and heart rate values displayed by the product to judge their normality.
- Measurements are sent and displayed every second, after a digital filtering process that can take up to 10s. Therefore, wait until the measurement is stable before considering it.
- The PI (Perfusion Index) measurement indicates the strength of pulse detection. This indicator quantifies the reliability of the value given by the pulse oximeter. For a reliable reading, wait until the PI is stable and at a correct value.
  - PI < 0.4: The data may not be reliable. The symbol ? indicates that the PI is <0.4.
  - PI > 0.4: the data is considered reliable
- The saturation measurement usually takes less than 20 seconds. We recommend that you do not place your finger in the oximeter's footprint for more than one minute.
- The temperature of the pulse oximeter's plastic footprint may reach 39.1°C during prolonged use (<10min). Stop using the pulse oximeter if you feel discomfort due to heat.
- The pulse oximeter should not be used for more than 10 minutes.
- Do not stare at the lighting LED, as it may irritate your eyes.

- If the latest measured value of SPO2 exceed 30 seconds, the user interface indicates that the displayed value is not the current value.
- The update period of the SPO2 value is 1s

8.4.3.2 Maintenance

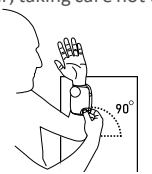
- A functional test device cannot be used to evaluate the accuracy of the pulse oximeter sensor.
- Verification of the oximeter's function can be verified with specific test equipment. Consult your authorized Doc2U representative or Doc2U Customer Service at the address on the package for more information.
- Any single functional tester cannot be used to assess the accuracy of a pulse oximeter.

8.4.4 Notes on measuring

- The finger must remain completely still during the measurement. Any movement can cause a loss of measurement.
- Ambient light does not affect the measurement

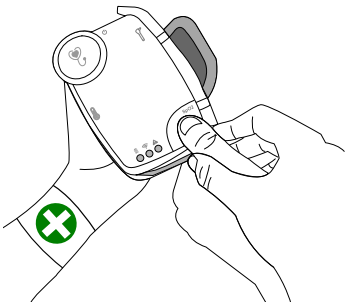
8.4.4.1 Autonomous patient

The finger should be placed on the pulse oximeter, no additional pressure is required. The sensor detects the presence of a finger. If the measurement is not taken when the sensor detects the presence of a finger, reposition your finger, taking care not to press it too hard.



8.4.4.2 Assisted patient

The finger should be placed on the pulse oximeter, no additional pressure is required. The sensor detects the presence of a finger. If the measurement is not taken when the sensor detects the presence of a finger, reposition the patient's finger, taking care not to press it too hard.



8.5 Using the stethoscope

8.5.1 Presentation

This stethoscope captures heart and lung sounds from a patient's body. By applying the stethoscope's membrane to the patient's back or torso, the device records and transmits live sounds from the heart, lungs, bronchi, etc. to your practitioner. He will then be able to establish a diagnosis by listening to these recordings.

8.5.2 Considerations and Warnings

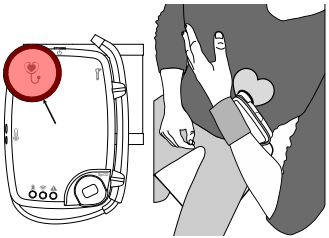
- To reduce the risks associated with very strong electromagnetic fields, avoid using the stethoscope next to radio or portable frequency signals and/or mobile R.F. devices.

8.5.3 Notes on measuring

- The measurement is possible on a light and thin garment.

8.5.3.1 Autonomous patient

Apply the membrane following the indications on your screen and given by your practitioner.



8.5.3.2 Assisted patient

Apply the membrane on the patient following the indications on your screen and given by the practitioner.

8.6 Use of the otoscope

8.6.1 Presentation

The otoscope integrated in your device consists of a plastic main body for easy handling and a camera with integrated variable intensity lighting. For hygienic purposes, the otoscope is compatible with disposable protections. By inserting the otoscope into your ears or mouth, your doctor has lived visual access to make an accurate and reliable diagnosis.

8.6.2 Consideration and Warnings

- After use, immediately dispose of used disposable protections ONLY in the trash.
- To reduce the risk of contamination and disease transmission, please clean your otoscope before and after each teleconsultation with a cloth lightly moistened with a neutral soap solution.
- The temperature of the tip of the otoscope can reach 44.2°C during prolonged use (<10min). Stop

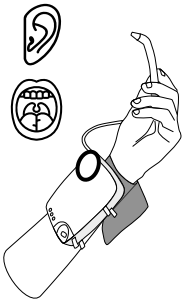
using the otoscope if you feel discomfort due to heat

- The use of the otoscope should not exceed 10min.
- Make sure the otoscope has no visible damage before use.
- Do not use in the presence of flammable anesthetics.
- Never use the otoscope without a disposable protection.
- Disposable protections must comply with CE requirements and intended for this use

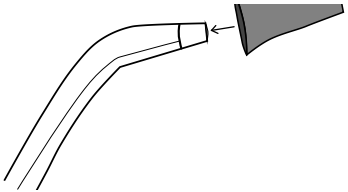
8.6.3 Notes on measuring

8.6.3.1 Autonomous patient

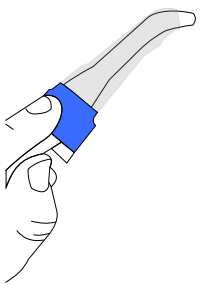
- Position the One by Doc2U® on your left wrist and fasten it securely
- Hold the otoscope in your left hand like a pen.



- Always use the otoscope with its disposable protection:
  - Ear speculums for ear observation, which must be changed for each ear:



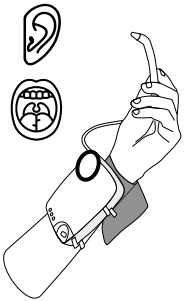
- Plastic sheath type disposable protections for the observation of the mouth.



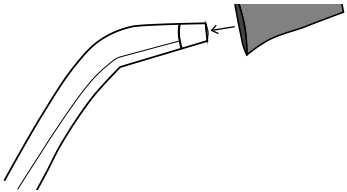
- Be careful not to push the otoscope down too hard when taking measurements, as this may cause injury.
- Then follow the instructions on your screen and the advice of your doctor, who can remotely adjust the light intensity at the end of the otoscope.

8.6.3.2 Assisted patient

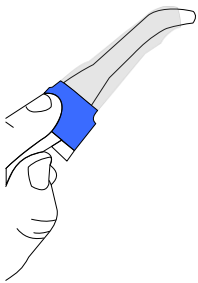
- Place the One by Doc2U® on the wrist of your dominant hand and fasten it securely
- Hold the otoscope in your like a pen.



- Always use the otoscope with its disposable protection:
  - Ear speculums for ear observation, which must be changed for each ear:



  - Plastic sheath type disposable protections for the observation of the mouth.



- Be careful not to push the otoscope down too hard when taking measurements, at the risk of injuring the patient.
- Then follow the instructions on your screen and the advice of the practitioner, who can remotely adjust the light intensity at the end of the otoscope.

9. Button operation

Device Status	Action son the button	Event
Off	Short press (<2s)	Switching on the device
On	Short press (<2s)	Switching on the QR-Code camera
On	Press for 2s	Shutdown of the device
On	Long press >10s	Forced shutdown of the device

10. Charging the device

(Triangle with yellow background and black borders) Reminder: Never use or attempt to turn on the unit while it is charging.

(Triangle with yellow background and black borders) Do not position the battery charger in such a way that it is difficult to disconnect from the mains.

(Triangle with yellow background and black borders) To recharge the device, it is necessary to use the USB adapter charger certified IEC 62368-1 or IEC 60601-1

Charger specifications

DC OUTPUT	5Vdc ; 1.2A
CERTIFICATIONS	IEC 62368-1 or IEC 60601-1

The power light tells you how much battery power is left in the unit.

Behavior of the power indicator	Device on load	Battery status indication
Static green	No	The device is switched on and its charge is above 50%.
Static orange	No	The device is switched on and its charge is between 50% and 25%.
Static red	No	The device is switched on and its charge is less than 25%.
Flashing red	No	The battery charge is critical, the device will automatically shut down
Breathing blue	Yes	The device is charging
Static blue	Yes	The device is fully charged

If the battery is empty, a full recharge takes about 3 hours.

The battery lithium ref LP103450JH 3.7V meets the safety requirements of IEC 62133-2:2017

11. Visual and audible signals

Action	Battery LED	Connection LED	Error LED	Camera LEDs	Buzzer
Switching on the device after a short press of the ON/OFF button	Green, breathing				1 short beep
Device switches to standby after pressing the ON/OFF button for 2s	Color of the current battery level, breathing				1 short beep
Device forced to sleep after a long press >10s					Long beep
Charging issue	Orange, flashing				
Attempt to turn on the device while it is charging	Red, triple flashing	Red, triple flashing	Red, triple flashing		3 shorts beeps
QR-Code camera is scanning		White, breathing		2 short flashes every 4s	2 shorts beeps
QR-Code has been decoded					3 shorts beeps

Action	Battery LED	Connection LED	Error LED	Camera LEDs	Buzzer
The device is connecting to the Wi-Fi		Green, breathing			
The device is connected to the Doc2U server		Green, static			
The device is connected to the Wi-Fi but does not have access to the Doc2U servers		Orange, steady			
The connection to the Wi-Fi has failed		Red, blinking for 10s			
The device is connected to a teleconsultation room		Blue, static			
The blood pressure measurement is outside the nominal blood pressure range			Yellow, static, 10s		

12. Troubleshooting

Problem	Probable cause	Recommended action
My device does not turn on	The battery of the device is completely discharged	Charge the device USB charger certified IEC 62368-1 or IEC 60601-1 (the battery light is glowing blue when the device is charging)
	The ON/OFF button has not been used properly	Press the ON/OFF button again for one second
	Device is plugged in and charging	Unplug the device before trying to turn it on again
My device does not scan the QR-Code correctly	Otoscope camera is not turned on	Wait until the battery light is solid green. Briefly press the ON/OFF button. The 2 beeps, the white breathing connection light and the flashes of the camera LEDs indicate that it is scanning
	The QR-Code has not been scanned correctly	Scan the QR-Code again, by slowly passing the camera of the otoscope in front of it, at less than 20cm from the screen.

Problem	Probable cause	Recommended action
	The device did not finish turning on at the time of the scan attempt.	Wait until the battery light is steady green before turning on the camera and scanning the QR-Code again
	The Wi-Fi credentials are wrong	Enter again your Wi-Fi identifiers before repeating the scanning phase
	The screen brightness is too low	Increase the brightness of your screen before scanning again
	The camera lens is dirty	Gently clean the camera lens with a disinfectant wipe
The temperature measurement does not work	The presence of hair or sweat on the forehead hinders the measurement	Clear your forehead and wipe it in case of heavy sweat
The blood pressure measurement displays an error message	There was too much movement during the measurement	Remain still and silent during the measurement
	There is a problem of overpressure in the cuff	Immediately remove the cuff from your wrist

Problem	Probable cause	Recommended action
	The position of the arm was not good during the measurement	Position your arm at an angle of about 30°, so that the device is at heart level
SpO2 measurement is not working properly	The pressure on the fingerprint of the pulse oximeter is too strong	Release the pressure and simply place your finger in the oximeter's footprint
	The fingertip is too cold	Wait a few seconds while warming my hands
	The position of your finger is wrong in the oximeter print	Make sure that the pad of your thumb is well positioned in the sensor's footprint

13. Electromagnetic compatibility and compliance with standards

Guidelines and manufacturer’s declaration – Electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The user must ensure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - Directives

Guidelines and manufacturer's declaration – Electromagnetic emissions		
CISPR 11 RF emissions	Group 1	The One by Doc2U® device uses RF energy only for its internal functions. Therefore, its RF emissions are very low and it is very unlikely to interfere with surrounding electronic equipment.
RF emissions CISPR 11	Class B	The One by Doc2u® device can be used in all establishments, including domestic establishments and those directly connected to the public low-voltage distribution network that supplies electricity to beats used for domestic purposes.

14. Essential performances

Within the framework of the intended use presented in §3, the essential performances of our device are:

Essential performances	According to (if provided)
Accuracy of the CLINICAL THERMOMETER or at least one of the following: — generation of a TECHNICAL ALARM CONDITION; — not providing an OUTPUT TEMPERATURE.	EN ISO 80601-2-56:2017+A1:2020 201.4.3.101
Limits of the error of the manometer	EN IEC 80601-2-30:2019 201.4.3.101

Essential performances	According to (if provided)
Reproducibility of the blood pressure determination and generation of technical alarm condition	EN IEC 80601-2-30:2019 201.4.3.101
For PULSE OXIMETER EQUIPMENT not provided with an ALARM SYSTEM that includes the capability to detect a PHYSIOLOGICAL ALARM CONDITION: SpO2 ACCURACY and pulse rate ACCURACY a or indication of abnormal operation	EN ISO 80601-2-61:2019 201.4.3.101
The video of the otoscope provides a consistent image regarding shape and color	
The sound of the stethoscope provides a consistent sound regarding speed and sensitivity	

15. Technical specifications

15.1 General specifications

Parameters	Specifications
Product description	Connected medical device gathering 5 medical measuring devices: - An infrared forehead thermometer designed in accordance with the requirements of standard EN ISO 80601-2-56:2017+A1:2020 - A wrist blood pressure meter with oscillometric measurement designed in accordance with the requirements of standard EN IEC 80601-2-30:2019 - A pulse oximeter with PPG measurement designed in accordance with the requirements of standard EN ISO 80601-2-61:2019 - An HD video-quality otoscope camera ensuring a faithful image in terms of the shapes and colours observed - An electronic stethoscope ensuring a faithful sound in terms of speed and sensitivity
Size (LxWxH)	13x10x9 (cm)

Parameters	Specifications
Weight	260g
Operating temperature range	From 5°C to 40°C (15°C to 40°C for the thermometer)
Operating humidity percentage range	15% to 90% RH
Operating atmospheric pressure range	700hPa to 1060hPa
Storage temperature range	-25°C to 70°C
Storage humidity percentage range	15% to 90% RH
Storage air pressure range	700hPa to 1060hPa
Protection class	IP22 (against solid objects larger than 12.5 mm and falling water up to 15° from the vertical)

15.2 Electrical specifications

Parameters	Specifications
Operating voltage	3.5V to 4.2V
Maximum operating current	1.0A

Parameters	Specifications
Load voltage	5V
Maximum load current	1.0A
Operating time from full charge in normal use	8h
Battery life	5 years

15.3 Blood pressure monitor

Parameters	Specifications
Cuff pressure	
Measuring range	0-300 mmHg
Pressure sensor accuracy	+/-3mmHg
Resolution	1mmHg
Blood pressure (adult)	

Parameters	Specifications
Measuring range	DIA: 40-130 mmHg SYS: 60-260 mmHg Heart rate: 40-180 bpm
Clinical accuracy	Blood pressure clinical accuracy were validated in a clinical trial. The results are within the margin of acceptance defined by the internationally recognized evaluation standard of blood pressure monitors EN ISO 81060-2:2019+A1:2020, developed by the European Society of Hypertension, British Hypertension Society and Association for the Advancement of Medical Instrumentation/American Heart Association
Pulse rate accuracy	1.20bpm
Resolution	DIA/SYS: 1mmHg Heart rate: 1bpm

Parameters	Specifications
Other	
Software overpressure protection	Yes, overpressure monitoring system independent of measurement software
Hardware overpressure protection	Yes, redundant deflate system
Maximum measurement time	< 85s

15.4 Thermometer

Parameters	Specifications
Measuring distance	2 to 5 cm
Resolution	0.1°C
Assigned output range	[34°C;42°C]
Laboratory accuracy in the assigned output range	+/-0.3°C max. According to ASTM E1965-98
Clinical Bias	0.08°C
Limits of agreement	0.41°C
Clinical repeatability	0.08°C

15.5 Pulse oximeter

Parameters	Specifications
SpO2	
Measuring range	70-100%
Accuracy (RMS)	2.49%
Resolution	1%
Wavelength	700nm (red LED) and 940nm (infrared LED)
Heart rate	
Measuring range	40-180 bpm
Accuracy	[40-180] bpm : < 2 bpm
Resolution	1 bpm

Note: Because pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to be within ±Arms of the value measured by a co-oximeter.

15.6 Stethoscope

Parameters	Specifications
Frequency band	[20 ;10000] Hz

15.7 Otoscope

Parameters	Specifications
Resolution	720p
Field Of View	100°

15.8 Wireless

Parameters	Specifications
Wireless connectivity	Wi-Fi a/b/g/n 2.4GHz

15.9 Service life

Parameters	Specifications
Maximum number of measurements	16 000 blood pressure measure
Estimated time equivalent (based on X uses/day)	5 years

16. Maintenance

16.1 Cuff change by qualified personnel

The device is not intended to be disassembled or opened except by Doc2U for product maintenance.

The cuff can be replaced if signs of wear and tear occur. Please contact Doc2U support §20 Contact & support to arrange for replacement.

16.2 Changing the stethoscope membrane by qualified personnel

The device is not intended to be disassembled or opened except by Doc2U for product maintenance.

The membrane can be replaced if signs of wear and tear occur. Please contact Doc2U support: §20 Contact & support to arrange for replacement.

16.3 Verification of the proper functioning of the SpO2 measurement by qualified personnel

Perform the measurement detailed in section 17 on a test person to verify proper operation of the pulse oximeter.

16.4 Calibration verification and maintenance

The accuracy of this multifunctional device has been properly tested and its durability has been designed for long-term use. In the context of medical use of the device, technical measurement checks must be carried out with the appropriate means. Doc2U generally recommends that the device be inspected every 2 years to ensure its proper functioning. Consult your authorized Doc2U representative or Doc2U Customer Service at the address on the packaging or in the documentation supplied.

17. Elimination

In the interest of environmental protection, the device should not be disposed of with household waste at the end of its service life. When your device no longer functions, it is important to return it to Doc2U. Doc2U will ensure that the device is disposed of in accordance with the relevant European standard - WEEE (Waste Electrical and Electronic Equipment).

(Triangle with yellow background and black borders) Disposal of the lithium battery: The lithium battery should not be disposed of with household waste. It may contain toxic heavy metals and must be treated in a special way.

18. Integration

Your One by Doc2U® send data to Doc2U® servers, these data are then transmitted to your teleconsultation provider that will display them to your practitioner.

For details on One by Doc2U® integration please contact us: see §20

19. Serious incident

In case of any serious incident that has occurred in relation to the medical device, please report it immediately to Doc2U (contact §20) and the authority having jurisdiction in your locale. Doc2U can give you the contact of the authority having jurisdiction in your locale.

20. Contact & support

You need help to use your product? You are facing a problem with the device? You have idea to share to

improve the product? Do not hesitate to contact us on our dedicated website:

support.doc2u.fr

Or by email:

support@doc2u.fr

Société Doc2U®

42 avenue du Général de Croutte,

31100 Toulouse, France

21. Warranty

Refer to the general and specific conditions of sales

22. Disclaimer

Information provided by Doc2u product is believed to be accurate and reliable. However, Doc2u assumes no responsibility for the use of such information, nor for any infringements of patents or other rights of third parties, that may result from its use.

The screenshots in this manual are used for explanatory purposes. Your actual screens may differ from the screenshots in this manual.

23. Returning the product

In the event of a product return, please contact your retailer or Doc2u if necessary. You will be informed of the details of the contents of the return. By default, we ask that the product be returned in the packaging in which you received it, with all its contents except for any disposable consumables. All carefully packaged to prevent damage during transport.

24. Document version history

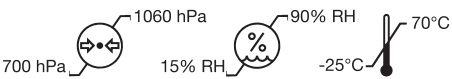
Date	Version	Modifications
June 2022	V15	First release
June 2022	V16	Add A2:2021 to EN IEC 60601-1-6
June 2022	V17	Add section 23 of returning the product
July 2022	V18	Adding information regarding SPO2 clinical validation
August 2022	V19	Updating the heart rate measurement accuracy of the pulse oximeter; Setting the refresh period for the SPO2 value.
March 2023	V20	Extension of the addressable population by temperature measurement
November 2023	V21	Adding CE logo and NB number
February 2024	V22	Addition of tri-packaging pictograms and environmental limit pictograms. Symbols table updated.
April 2024	V23	Deletion of the contraindication concerning "vasectomy-type surgery", which is irrelevant to this product and its use.
November 2024	V24	Removing quick user guide references Adding CHREP logo definition and CHREP representative

21-DOC-0111

CH REP

BIOSYNEX SWISS SA
Route de Roussemaison 100
2800 Delémont - Suisse

CE
1912



DOC2U

One by Doc2U®