Doctor Vida

Your pocket PCR

STAB vida

Your easy genetics laboratory

Equipment Doctor Vida® and *software*

Instructions for use

CE IVD

Reference: 133001002,133001003

HW version: 2.4.1; FW version: 6.1.1; Software Version: 3.2.0

Document version (v6): 28, August 2024

Medical device for diagnosis *In Vitro*

The manufacturer continues to improve its products and reserves the right to change the information at any time.

If the product is used in a manner other than that specified by the manufacturer, the device may be compromised. Refer to the warnings, precautions, measures to be taken, and limitations of use for the product.

The images, screenshots present in the document are for illustrative purposes only.

Content

Intended purpose

The Doctor Vida equipment (reference 133001002) is a semi-automatic instrument for isothermal amplification and qualitative molecular detection of nucleic acids by fluorescence. If there is no fluorescence emission or if it is residual, the target nucleic acids (e.g. RNA or DNA) are not detected or are below the detection limit of the technique. The equipment is fully controlled by a mobile phone application (Dr Vida Pocket PCR, reference 133001003) intended for diagnostic or research that should be used by health professionals. You are responsible for complying with safety procedures, including the use of necessary personal protective equipment, maintenance of equipment and facilities, and waste management.

Principles of operation

The Doctor Vida equipment should be used in combination with compatible reagents (Dr Vida Tests) and the Dr Vida Pocket PCR mobile phone application (133001003 reference), available on the App Store (Apple) and Play Store (Google), following the information described in the document.

Biological samples are collected by healthcare professionals following the good practice procedures referred to in the Dr Vida test instructions. The biological sample is added to the test tube and introduced into the Doctor Vida equipment for analysis. The Dr Vida Pocket PCR mobile app allows you to control the instrument and view the real-time analysis progress and result.

Quality Control

The Quality Report of the final product is available whenever requested by the customer. See the Manufacturer Information section.

Reagents for quality checks vary depending on the Dr Vida test used in combination with this product. Please refer to the sections quality control, materials supplied, and materials required but not supplied. In the instructions for use of the Dr Vida tests compatible with the product.

Applicable symbols

	See instructions for use		CE Marking
	Product Reference		In vitro diagnostic medical device
	Serial number		Temperature limits
	RoHS Compliance		Direct current (DC)
	Manufacturer		For internal use
	Expire date		The device is not intended for self-diagnosis

Atenção:

Follow the instructions presented in this document; Improper use may cause damage to the device or your health

Waste electrical and electronic equipment (WEEE) (Directive 2012/19/EU)

This symbol on the product or its packaging indicates that it should not be disposed of like other household waste. It is your responsibility to dispose of the device properly for the recycling of waste electrical and electronic equipment. The collection and selected recycling of this equipment helps to conserve natural resources and protect human health and the environment. For more information on where you can dispose of the device, contact the manufacturer or distribution company where you purchased the product.

Abbreviations

Abbreviation	Meaning
CC	Direct current
CE	European Compliance
CQ	Quality Control
EN	European standard
UE	European Union
FW	*Firmware*
HW	*Hardware*
IEC	International Electrotechnical Commission
IVD	Diagnostic *in vitro*
IVDR	In vitro diagnostic regulation
LED	Diode emissor of light
N/A	Not applicable
PDF	Portable document format
REEE	Waste electrical and electronic equipment

Abbreviation	Meaning
CC	Direct current
THAT	European Compliance
CQ	Quality Control
IN	European standard
EU	European Union
FW	*Firmware*
HW	*Hardware*
IEC	International Electrotechnical Commission
IVD	Diagnóstico *in vitro*
IVDR	In vitro diagnostic regulation

LED	Diode emissor of light
N/A	Not applicable
PDF	Portable document format
REEE	Waste electrical and electronic equipment
RoHS	Restriction of hazardous substances

Technical Specifications

Parameter	Specification
Power supply	LEDs: Verde (570nm +/- 20nm). Azul (470nm +/- 35nm)
Detection System	Silicon CMOS sensor with integrated Gaussian filters, 6 channels of multispectral detection at the visible wavelength between approximately: 430nm - 670nm with a half-height width (FWHM) of 40nm
Spectrum Channels	450, 500, 550, 570, 600 and 650 nm (+/-20nm)
Thermal System	Between +5ºC (above ambient temperature) and +95ºC. Max. heating: 0.22°C/sec.
Dimensions (h x w x d)	33,11 mm x 75,80 mm x 44,45 mm
Weight	58 Grams
Humidity Conditions	20% to 80%, non-condensing
Safety ambient temperature conditions	+5°C to +40°C The equipment is safe within normal safety conditions (IEC/EN 61010-1)
Ambient temperature conditions during equipment use (Operating Temperature)	+15°C to +30°C
Transport temperature	Room temperature
Power Supply Electrical Characteristics (Input/Output)	Entrance: 100- 240 VAC, 50/60 Hz Output: 5VDC, 2A
Electrical characteristics of the Doctor Vida equipment (Input)	5VDC, 1A
Maximum Usage Altitude	2 000 m
Bluetooth®	Bluetooth V4.2 BR/EDR, Bluetooth LE GPS / Camera Activated
Internet connection	IEEE 802.11b/g/n or mobile data
Warranty	Two years
Consumables	Compatible only with supplied plastic consumables

Warnings, precautions, safety measures and limitations of use

All users must read and comply with the instructions for use provided.

Failure to follow the instructions may cause damage to the equipment and/or cause damage to health. For your safety and to prevent damage to the equipment, it is important that the following safety precautions are read and understood before using the equipment. Please refer to the product datasheet for details.

Electricity

Standard electrical safety precautions shall be applied, including the following:

►Always place the machine in a location where, if necessary, the power supply can be immediately switched off.

►Use only the supplied power supply (Input: 100 – 240VAC, 50/60Hz| Output: 5VDC, 2A), or a similar certified power supply with the same specifications to operate the equipment.

►The maximum fluctuation for the main supply voltage is +- 10%.

► Do not touch switches or outlets with wet hands, or operate the equipment in wet environments.

► Do not operate the equipment if you detect any anomaly in the equipment and/or the power supply supplied, such as deformations, fractures, exposed wires, liquid spills, etc.

►Unplug the appliance from the wall outlet before cleaning it or to clean up any major liquid spills.

►Do not service electrical components unless you are qualified and authorized to do so.

► In the event of an electrical power failure, the analysis is interrupted and the test is invalid. The test tube should be discarded and the test will have to be repeated with a new test tube.

Fluids and reagents

►Always handle liquid samples and transfer them to the test tube away from the equipment to prevent any fluids from penetrating the inside of the equipment.

►Never incubate explosive, flammable and/or reactive substances in the equipment.

► Never immerse the equipment in any liquid at any time.

Physical medium

►Do not use the equipment on materials (plates, fences, sheets, mats, etc.) that are not sufficiently resistant to high temperatures. Note that during operation, it is normal for the equipment to heat up slightly, especially underneath it.

►Never touch the inside of the equipment, to avoid the risk of burning.

►Do not use other materials (plates, slides, etc.) instead of test tubes designed to be operated with the equipment.

Electrostatic discharge (ESD)

► The equipment is sensitive to static. Electrostatic discharges greater than 2000 volts can interfere with the normal operation of the USB ports on the equipment. Handling precautions are necessary when working in environments with high static. In environments of high static electricity, wear an anti-static wrist strap and take other anti-static precautions before handling the equipment - ESD STM5.1-1 1998 Class 1C.

Operating environment

►Operate the equipment indoors only, with an ambient temperature between 15°C and 30°C and humidity levels between 20% and 80% (non-condensing).

►Não operar o equipamento em um ambiente perigoso ou potencialmente explosivo.

►Do not attempt to remove the cap and/or test tube, or move the equipment, while it is performing a test.

►Operate the equipment only on a level surface, with the lid facing upwards.

Equipment Ratings

Power supply: 100-240 VAC, 50/60 Hz

Equipment Input Supply: 5VDC, 1A (min.)

Pollution degree 2

Installation Category II

Operating humidity: 20% to 80%, non-condensing

Operating temperature: 15°C to 30°C

Bluetooth®: Bluetooth V4.2 BR/EDR and Bluetooth LE specification with GPS and camera support

Wi-Fi: IEEE 802.11b/g/n and mobile data

For indoor use only

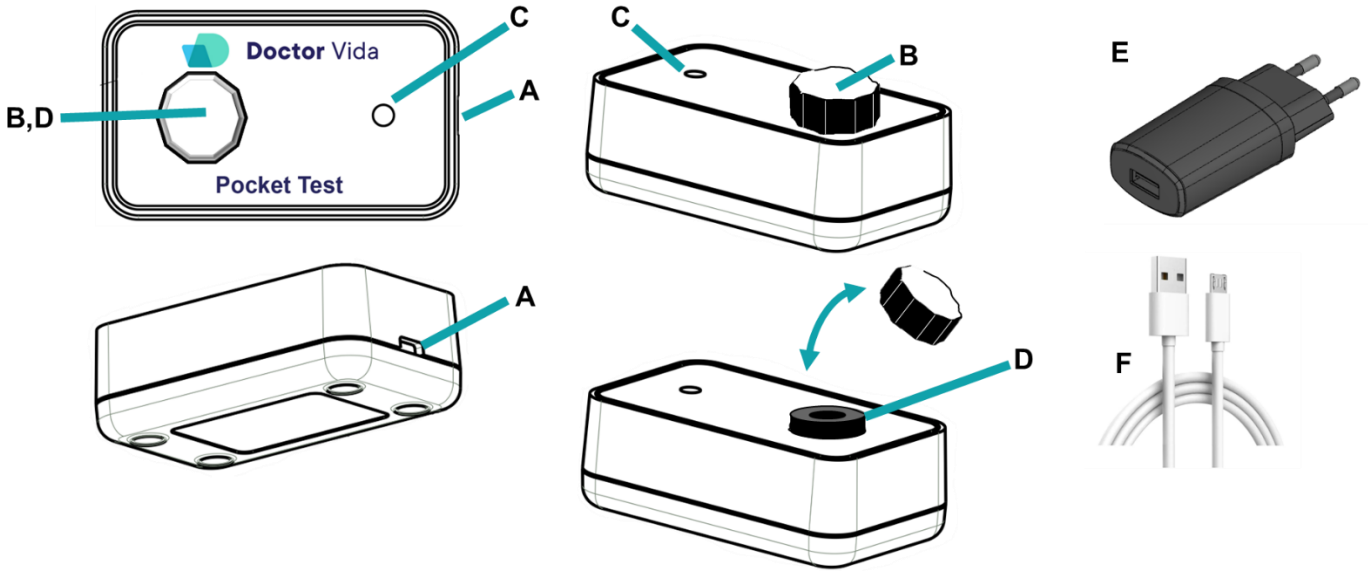
RoHS compliant

Before starting the trial

Check the contents of the package using the list of materials supplied. If any of the items are missing or damaged, contact the manufacturer immediately.

Materials provided

Description	Reference	Quantity	Storage conditions
Life Doctor Equipment (included power supply and micro cable USB-B)	133001002	1 unit	+15ºC to +30ºC



A► **Door** USB-B | **B►** Protective cover of the reaction chamber | **C►** Light indicator | **D►** Reaction chamber | **E►** Power supply | **F►** Cabro micro USB-B

Dr Vida Pocket PCR app (available on Google Play and iOS stores)	133001003	1 unit	Not applicable

Materials required but not provided

►Mobile phone with Bluetooth – to install and use the Dr Vida Pocket PCR application.

►Internet (wireless) – required to start and end the test (transfer of data to the server).

►Reagents - Test tubes. Ask for the list of tests available and compatible with the Doctor Vida equipment and *software*.

Performance characteristics

Refer to the performance characteristics information in the instructions for use provided with the Dr Vida tests compatible with the Doctor Vida equipment and *software*.

Sample collection, handling, preparation and analysis

Please refer to the information on sample collection, handling, preparation and analysis procedures in the instructions for use provided with Dr Vida tests compatible with Doctor Vida equipment and *software.*

Installation

Install the Doctor Vida equipment

Please read the following information carefully before attempting to use the machine for the first time.

Daily preparation of the workplace and the Doctor Vida equipment before starting trials

Important Note 1: If the equipment is not on a flat surface, the performance of the test may be affected.

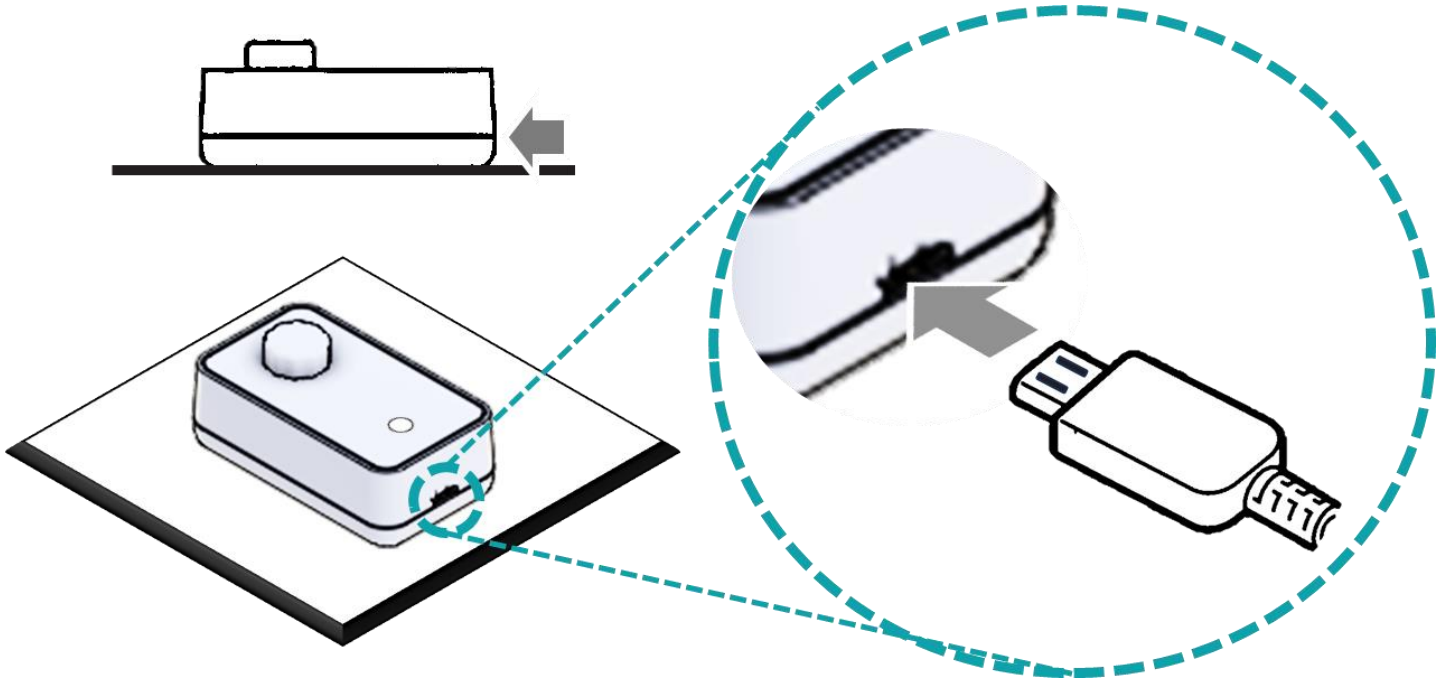
Important Note 2: Do not allow ethanol to enter the hole where the test tube is placed.

►Clean and disinfect the work surface with 10% bleach and 70% ethanol to control infectious hazards. After cleaning the surface, place the machine on a flat surface.

►Remove the cover from the equipment and clean it with paper moistened with 70% ethanol (do not spray). Let it air dry.

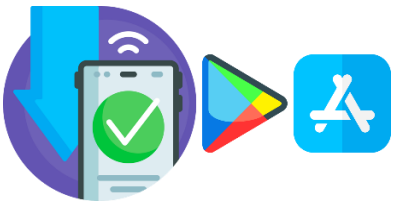
►Screw the lid onto the equipment and wipe the entire outside with paper moistened with 70% ethanol (do not spray).

► Connect the equipment to the electrical outlet with an output power 5VDC, 2A. The equipment may take a few minutes to stabilize the temperature.



►Remove the lid and leave the appliance on approximately 30 minutes before the first use of the day.

Install the software



The Dr Vida Pocket PCR application can be downloaded to the mobile phone, available on the App Store (Apple) and Play Store (Google).

Minimum hardware requirements for software to work as intended

Android phones: Operating system > 5.0

iOS phones: Operating system> 11.0

Make sure you have an internet connection and that Bluetooth is working before starting the test. It is recommended to have a Bluetooth version > 5.0 and a stable WiFi connection.

Check your device's hardware compatibility requirements with the software in the compatibility section within each store (Android/iOS).

Characteristics of computer networks and computer security measures

The design and maintenance of the software follows the internal procedure defined under ISO 13485.

Software

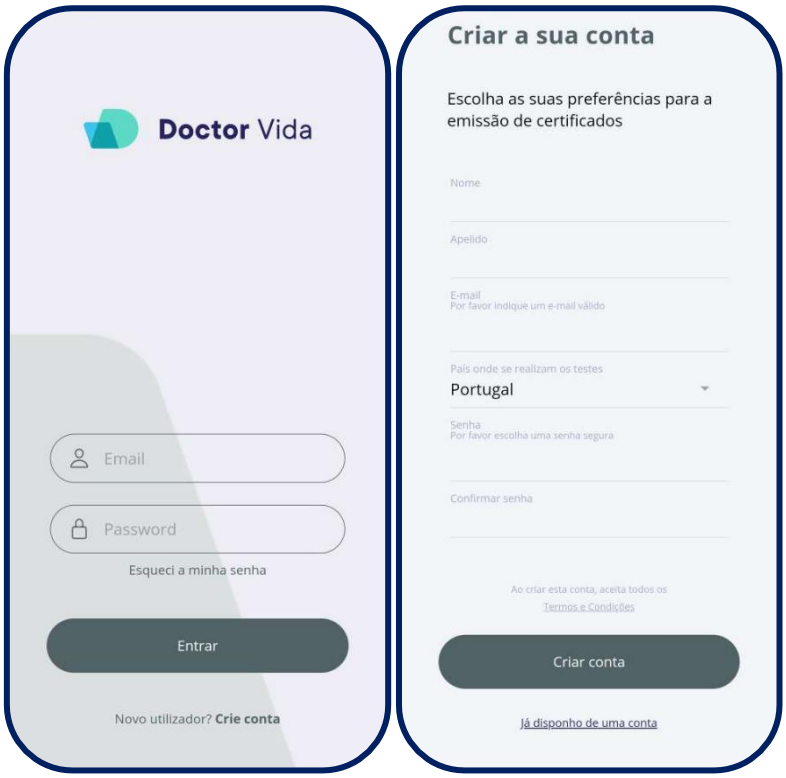
Permissions

To be able to use the Dr Vida Pocket PCR application, you must give permission for the use and storage of data, camera and location. See the privacy policy (https://www.doctorvida.com/privacy.html) for more details.

Account

If you don't have an account, create an account

Select "New user? Create account", fill out the form and select "Create account".



If you have an account.

Enter your registered email and password and click "Sign in".

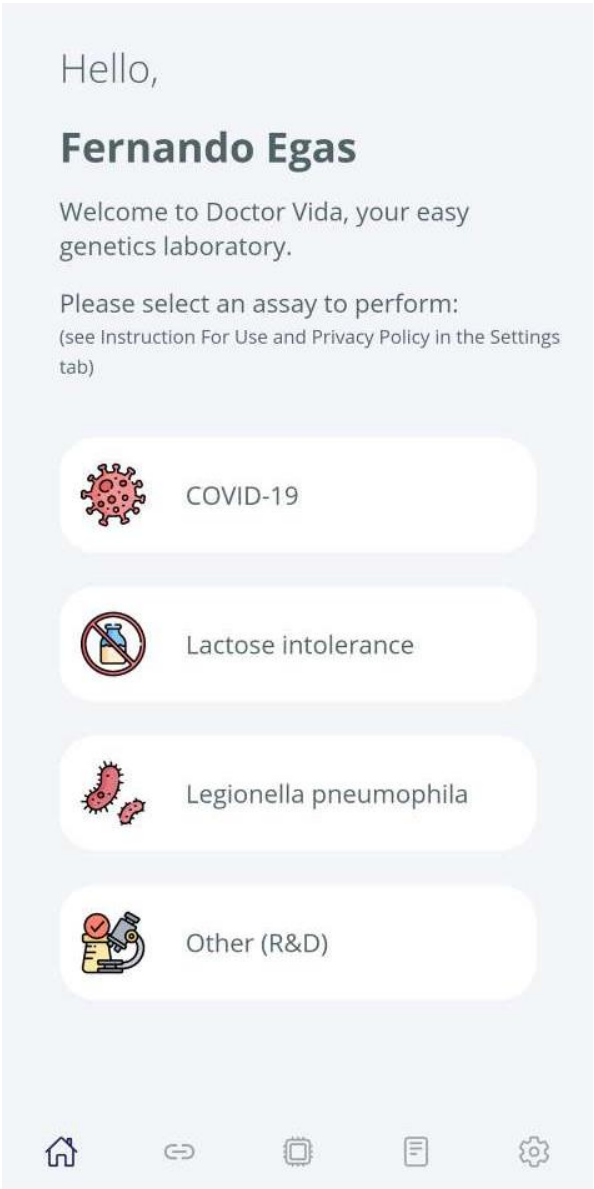
Note: Make sure the email is valid, otherwise you will not receive the test results.

Home Screen

Menu Bar

The menu bar consists of the **Devices, Tests in progress, Results, and Settings menus**.

Home



A► Menu Principal (Home)

B► Devices

C► Ongoing trials

D► Results

E► Definitions

Devices

In this menu you can check and select the devices available to perform the tests. Only devices recognized by Bluetooth and their current status will be shown.

Slide the button on the devices you want to pair. Click "Connect" and "Continue". The devices will be ready to take the test.

If one or more devices don't appear in the list, just refresh the list by swiping down on the screen.

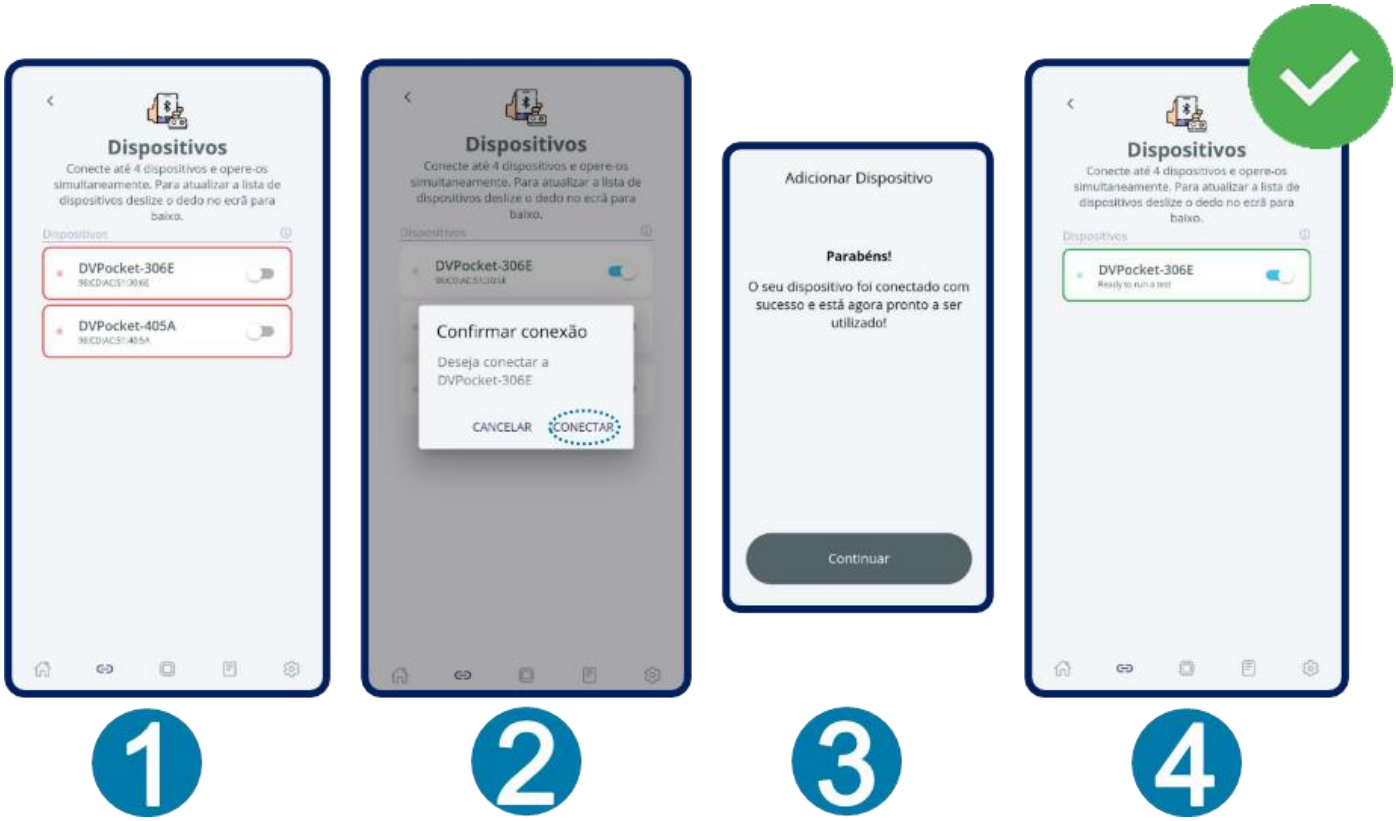
If not, make sure that:

The desired device is turned on and not connected to another phone, Bluetooth is enabled on the phone.

Otherwise, see the section: Troubleshooting.

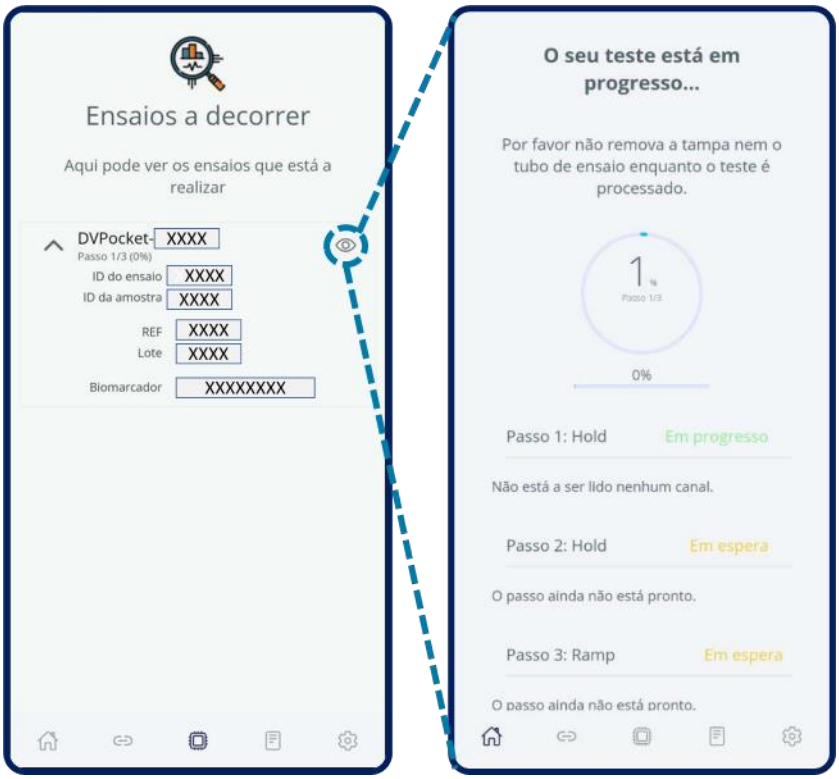
It is possible to connect up to 4 devices and operate them simultaneously.

Pay attention to the device status legend (click on the icon?):

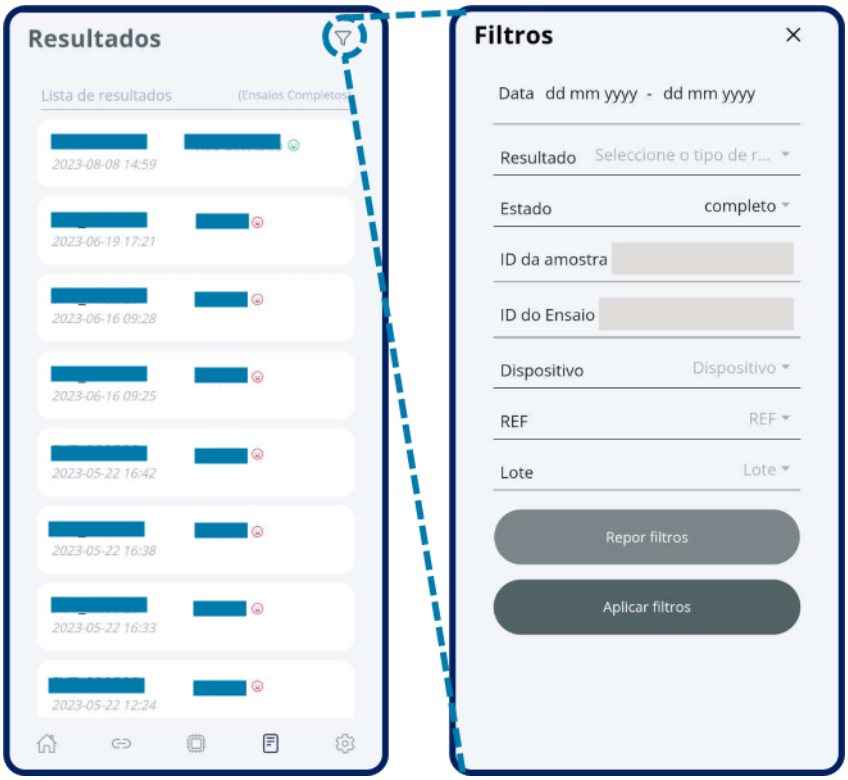


Ongoing trials

In this menu you can check and consult information about the tests that are in progress. You can operate and view the progression of 4 devices (maximum) at the same time for each phone. In this menu, you can filter by device and check the details of each test individually.



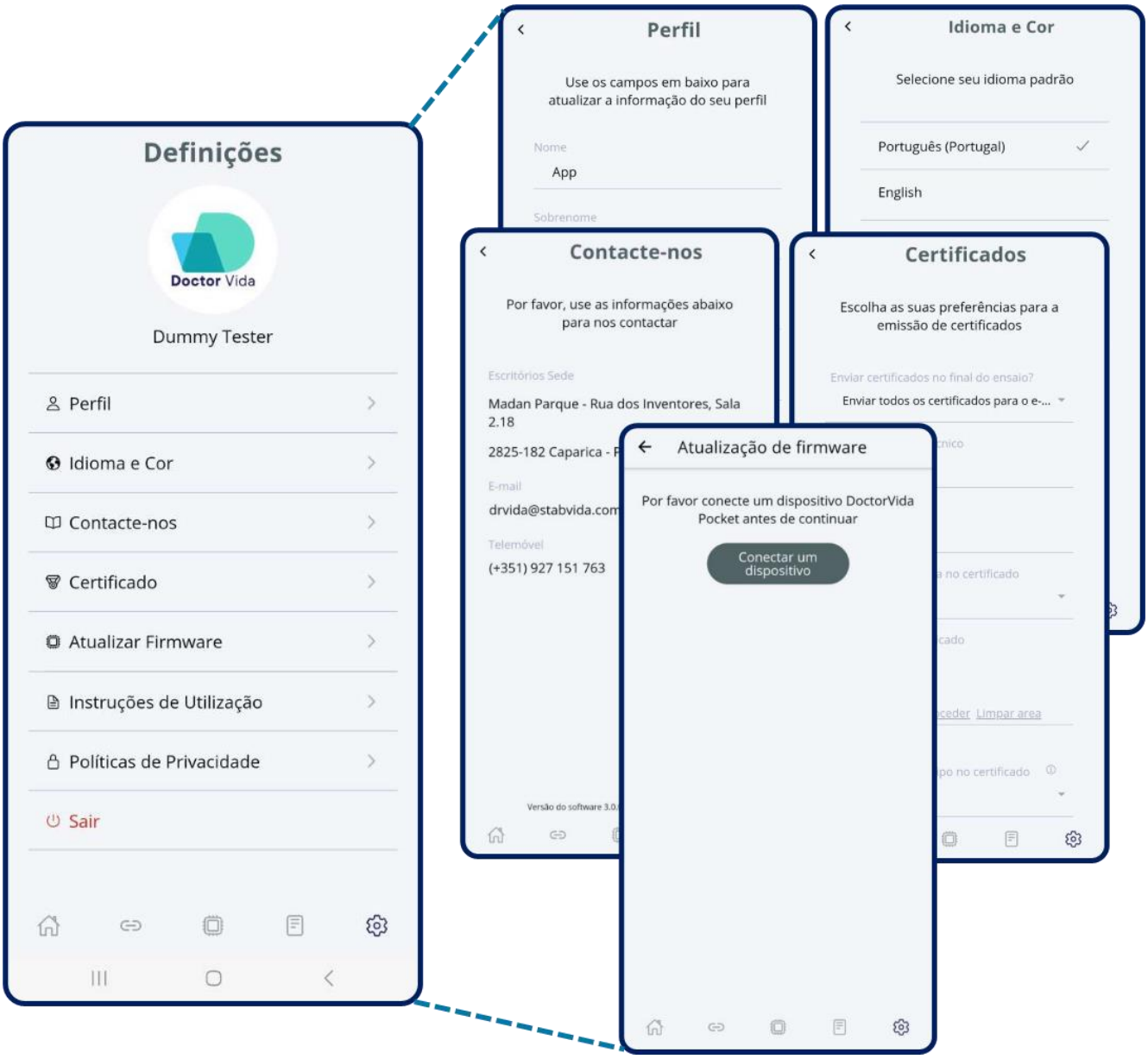
Results



In this menu you can check and consult information about the results of the selected tests.

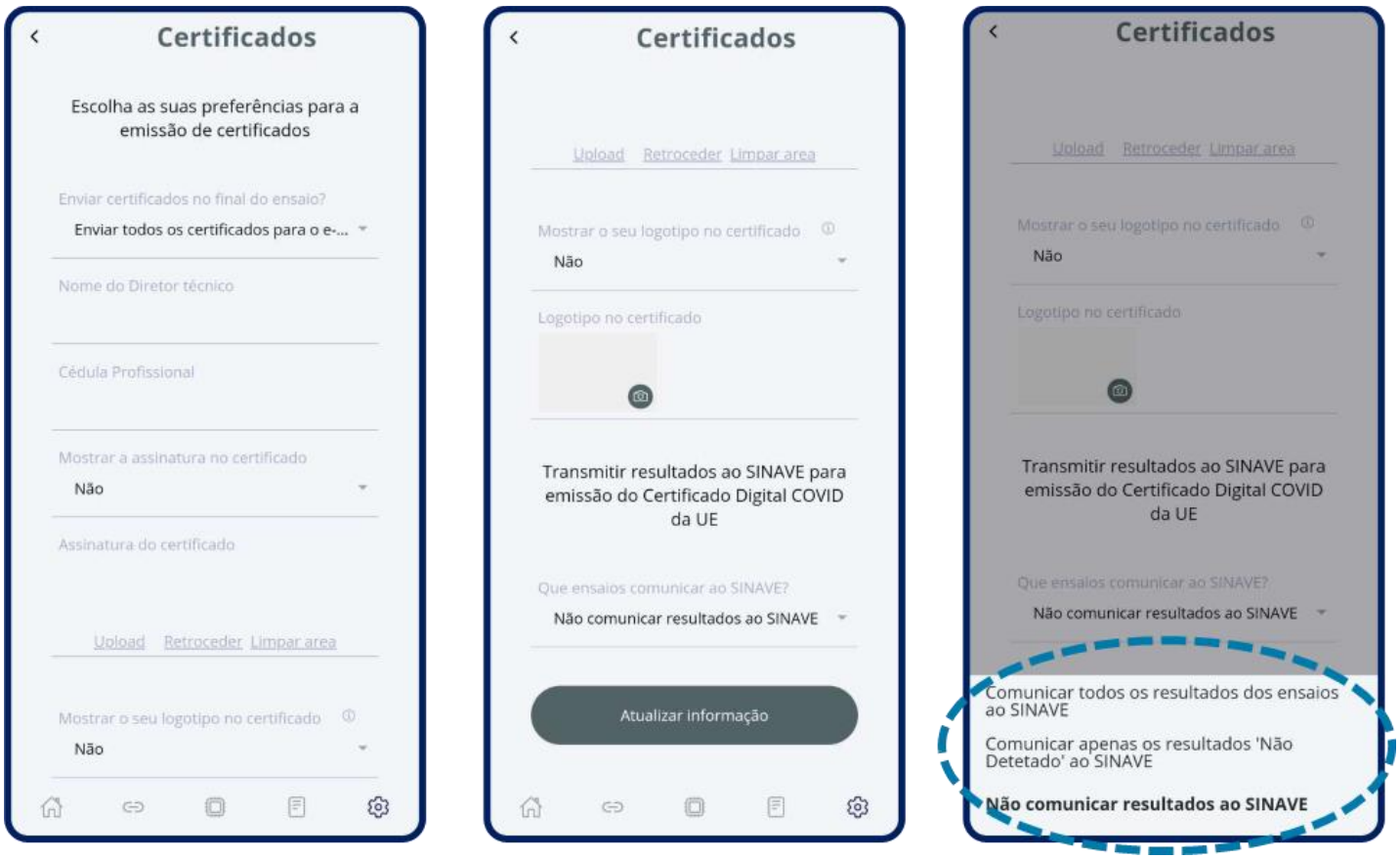
Definitions

In this menu you can check profile information, select the language and colour, the manufacturer's contacts, set the certificate options (test results report), instructions for use (also available in www.doctorvida.com) and privacy policy (also available in www.doctorvida.com)



Certificate

Before starting a test, you should define the information that will be included in the results report (Certificate).



Automatically send the certificate at the end of the tests?

There are three options available:

►Send all certificates to patients' email – Results will be automatically sent to the Account User (Operator) and to the patient's email after the end of the trial.

►Send only "Not detected" certificates to the patient's email – Only negative results will be automatically sent to the patient's email. Positive results must be validated at the end of the test by the Operator. After the validation of the results, the Operator can decide whether or not to send the certificate to the patient's email

►Never send certificates directly to the patient's email – The results will only be sent to the Operator.

Then, the Operator will decide at the end of the trial and after the validation of the results to send or not the results to the patient's email.

—Name of the Technical Director – Full name or first name and surname of the Technical Director of the organisation carrying out the trial.

—Professional Certificate – Certificate or License Number of the Health Professional and the Order of which the Health Professional is a member (e.g., 1234, Order of Biologists).

—Signature Display on Certificate – Yes, it means that the signature of the Technical Director (responsible for the validation of the test and submission of report results) will be presented on the Certificate

—Signature of the certificate – Signature of the Technical Director. It can be done directly on the mobile phone or submitted. The "Delete" option will allow you to delete the signature and replace it with another one.

—Logo on Certificate - You can upload the organization's logo to be displayed on the Certificate.

—Show logo on certificate – If you select the SIM option, the logo will be displayed on the certificate. If the option is NO, the logo will not be shown.

Transmit the test results to SINAVE for issuance of the EU DIGITAL COVID Certificate – Only valid for Portuguese operators. SINAVE is the Portuguese health system reporting COVID-19 tests. Results in other countries must be manually reported to the appropriate country's health system.

Which tests can you communicate with SINAVE?

There are three options available:

►Communicate all test results – All results will be automatically communicated to SINAVE.

►Report only "Not detected" results – Only negative results will be automatically communicated to SINAVE. The operator must manually communicate the positive results to SINAVE after internal validation.

►Do not communicate any test results – No results will be automatically communicated to SINAVE. The operator must communicate the results manually to SINAVE after internal validation.

Once you have selected the correct information to be displayed on the Certificate, select the "Update Information" button.

It is possible that the user decides not to submit the Certificate or changes the SINAVE communication options when starting a new test.

Update *firmware*

This feature allows you to check and update the latest *firmware* version of the device, follow the steps:

Turn on the equipment, perform the pairing in the "Devices" menu.

Go to the "Settings" menu and click on the "Update *firmware*" option and check if it requires an update.

If required, click on the update *firmware option*, it is possible to update one at a time. The application phase indicates the status of the update.

Only available for Android devices.

Doctor Vida equipment compatible with MAC ID prefix: AC:67:B2, E8:DB:84.

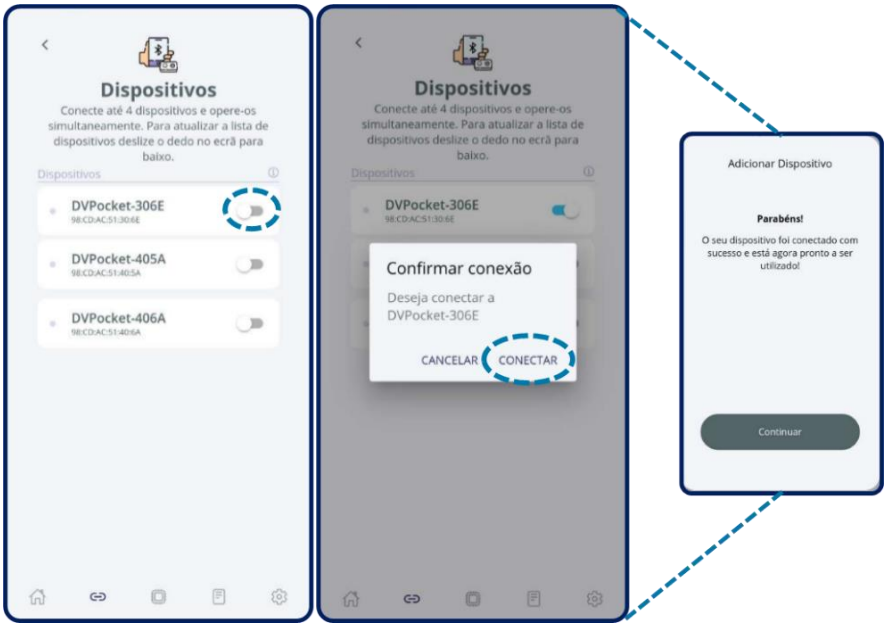
Operation of the software

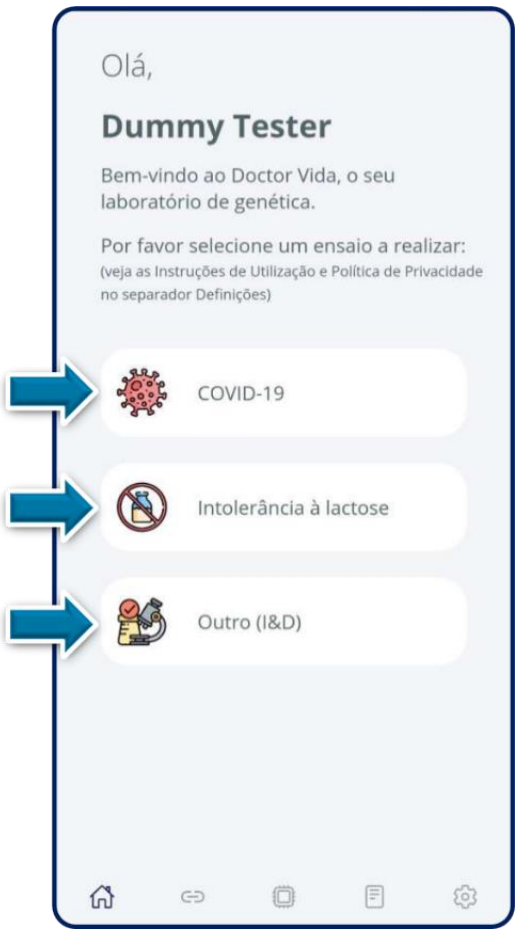
Open the app.

To start a trial, turn on the Doctor Vida equipment.

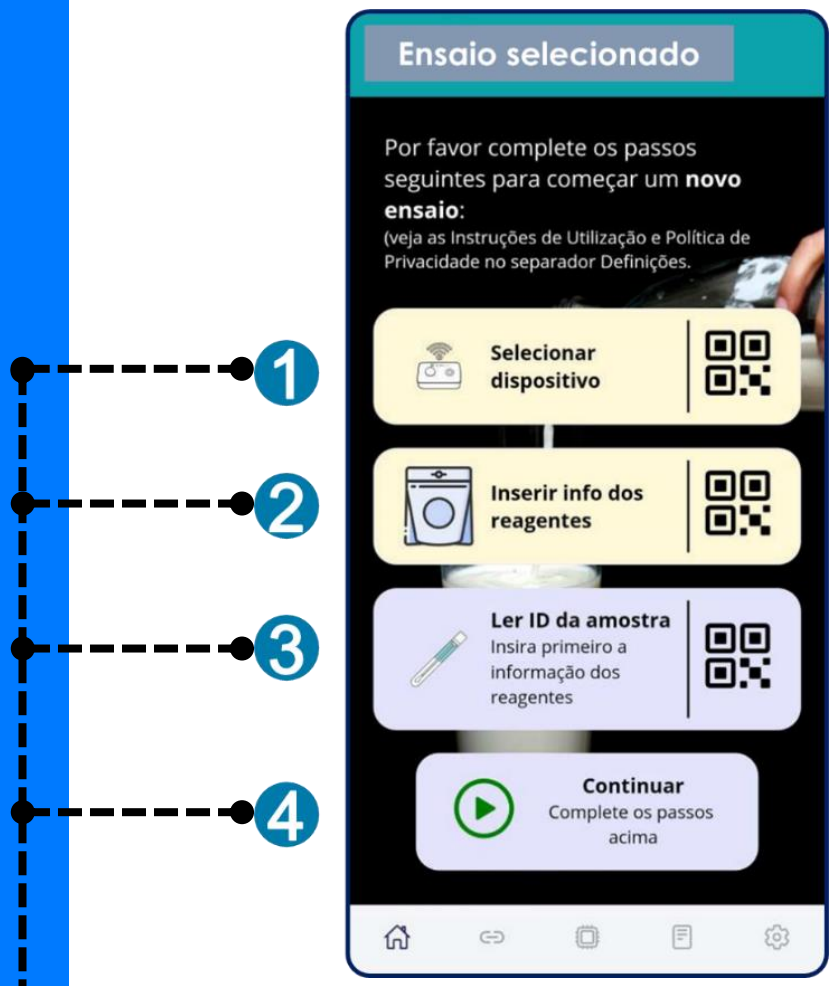
Connect the equipment to the mains, output: 5VDC, 2A. It may take a few minutes for the equipment to stabilize the temperature.

In the app, connect the equipment. On the home screen, click on "Devices" and slide the button on the devices you want to pair. Click "Connect" and "Continue". The equipment will be ready to do a test.





Select the "HOME" screen and choose the test you want to perform:



Once you have chosen the desired test, pay attention to the following screen that appears, check the color code.

Orange menu – information required

Lilac menu – you can't select until you fill in the information above.

There is the option to enter the data manually or scan the QR code with the mobile phone

1

Click the "Select Device" option or the QR code icon of the device

Select the device that is ready to perform a test by clicking on the device box or scan the device QR code on the device labeling.

The device QR code is on the labeling on the top or bottom of the device.

Once step 1 is fulfilled, the box turns green and the device ID will be shown in the green box.

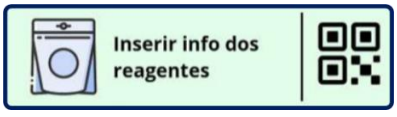
2

Click the option to enter the information or scan the QR code of the reagents

Enter the reference number (REF) and batch of the reagents (LOT) or scan the QR code present on the package labeling.

This will allow you to identify the test protocol and choose the analysis algorithm for the data collected while the new test is running.

The QR code of the reagents must have a standard format as mentioned in the App.



Once step 2 is fulfilled, the box turns green.

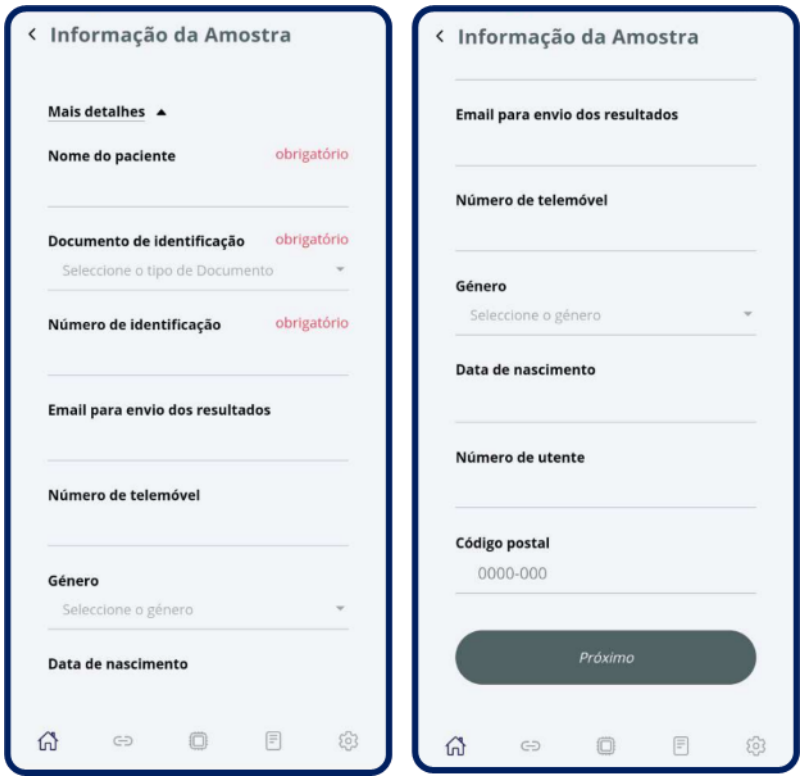
3

Click to enter the information or scan the sample QR code

Fill in the information or scan the sample QR code.

An anonymous alphanumeric code is recommended for sample identification.

The sample QR code should have a standard format as stated in the App.



If you select the test with certificate and/or to submit to SINAVE - there is mandatory information to fill in and confirm that the certificate information (in the Settings menu) is correct.

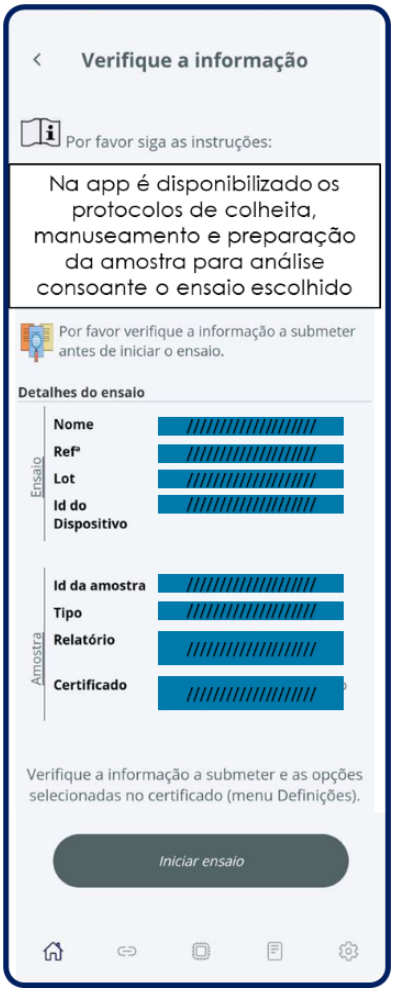
If you select the test without a certificate – only the sample ID is required.

After filling out the form, click "Next" and the "Read Sample ID" box turns green:

Once step 3 is fulfilled, the box turns green.

4

Click on "Continue" and follow the instructions provided in the Dr Vida Pocket PCR app regarding the protocol for collection, handling and preparation of the sample for analysis depending on the chosen assay.

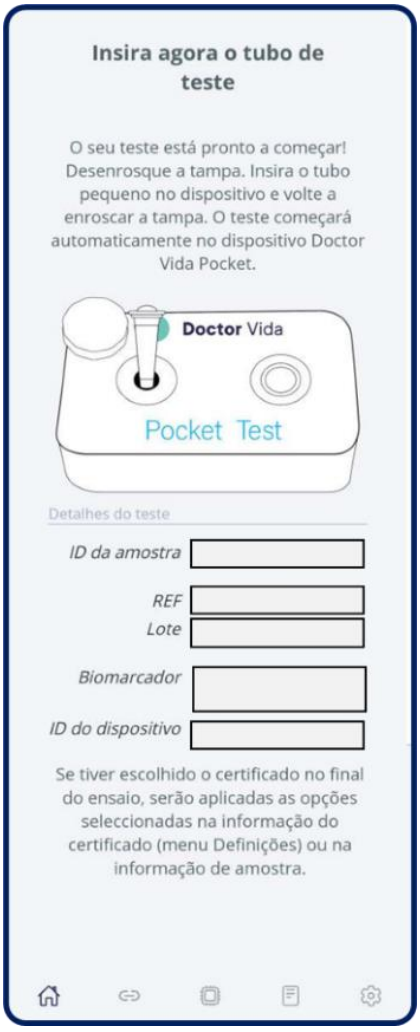


At the end, check the necessary information before starting the test, in case the information needs to be corrected, click on the arrow at the top left of the screen and return to the previous screen.

After selecting the "Start test" button, the system will check if the requirements necessary to start the test are met. Make sure that the device does not have any test tubes from the previous test. If so, you will hear a beep. Please take it off to continue.

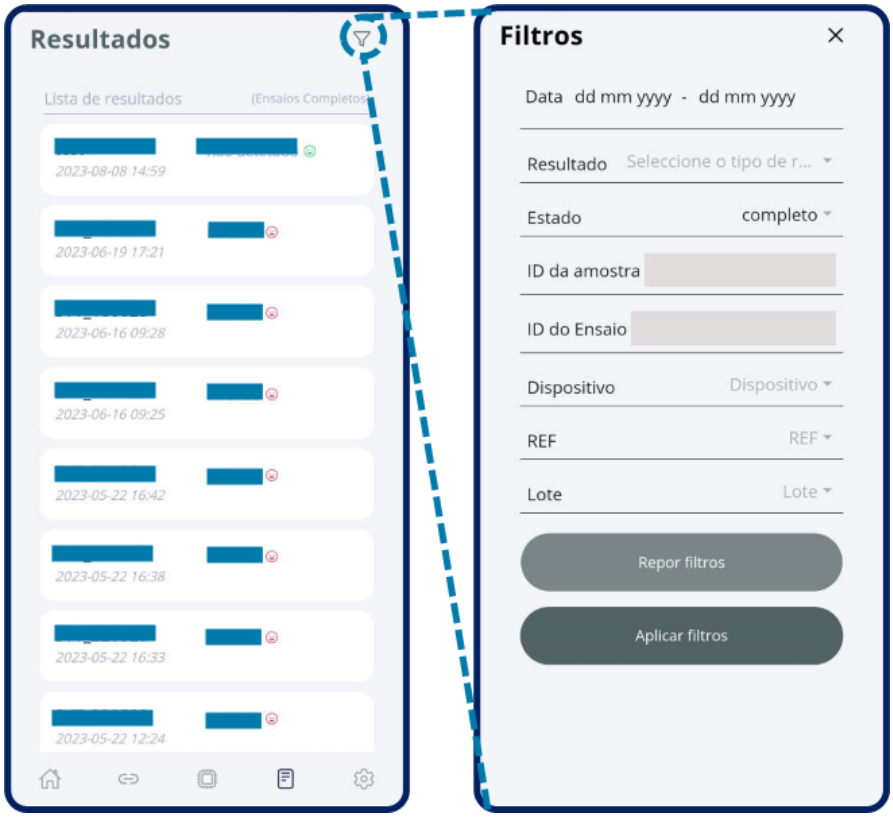
Important note: Do not touch or touch the device while the test is being processed, as this may affect the performance of the test.

Important note: If you lose Bluetooth or internet connection during tests, you do not lose the information. NEVER disconnect the device from the plug. Close the App, open the App again, and select the "Devices" screen to reconnect the devices that are in progress. Then click the device(s) again and click to "summarize tests" to resume the tests.



Now insert the test tube - Make sure that the tube is securely closed. Unscrew the cap (counterclockwise), insert the tube into the device and screw the cap on (clockwise). The test will start automatically.

Important note: Please do not move or move the device while the sample is being processed as it may compromise the reliability of the result.



Results

Click on "Results". When the test is finished, it may take up to 2 minutes for the device to transfer all the data to the App. If you want to select a specific test or a type of test, you can apply a filter by clicking on the top right side (red circle).

Click on each trial and the summary of the result will be displayed. Refer to the information on interpreting results in the Instructions for Use provided with the reagents used in combination with the Doctor Vida equipment and Software.

"Invalid result" – An "Invalid" result means that the test has not been successfully performed and that it is necessary to repeat the test or take a new sample.

You can resend the certificate by selecting the user and/or patient again and click on "Resend Certificate".

Doctor Vida

TESTE GENÉTICO MOLECULAR
DETEÇÃO DE INTOLERÂNCIA À LACTOSE PRIMÁRIA

Nome do utente:
Bruce Wayne
Número de utente de saúde:
839392
E-mail:
fernando.dominguez@stabvida.com

Referência da amostra: SVT_280423
Tipo de amostra: Exsudado oral
Documento de identificação: 270403030
Data do ensaio: 28-04-2023 10:13
Data da Emissão Relatório: 28-04-2023 11:36
Técnico responsável: Fernando Egas

Descrição do estudo
Deteção do polimorfismo -13910 C/T no gene MCM6 associado à persistência da lactase.

Indicação clínica
Suspeita de intolerância à lactose.

Genótipo
-

Conclusão
Um resultado "Inválido" significa que o teste não foi realizado com sucesso e é necessário repetir o teste ou fazer nova colheita de amostra.

Método

1. Amplificação por LAMP da região do gene MCM6 que contém a variante LCT-13910 C/T.

2. Hibridação de sondas específicas para a mutação com o fragmento amplificado.

3. Medição das alterações de fluorescência em tempo real durante a análise da curva de *melting*.

Bibliografia
Enattah NS *et al.* 2002. *Identification of a variant associated with adult-type hypolactasia*, Nature Genetics, vol.30

Comentários
1) A intolerância à lactose em adultos não é uma doença genética, mas sim uma característica ancestral.
2) Este teste não é um diagnóstico *in vitro*.
3) O teste é válido apenas para a população caucasiana.
4) Em crianças (em particular até aos 11 anos) a análise do polimorfismo LCT-13910 C/T produz um resultado preditivo, contudo o teste pode ser usado como método de rastreio para a intolerância à lactose na fase adulta.

Director técnico: Technical Dummy
Cédula profissional: 28423

Assinatura

Teste Molecular Rápido de Amplificação de Ácidos Nucleicos (TAAN) LAMP PCR: Deteção de Intolerância à Lactose Primária
ISENTA/IVDR. Lida, reprodução não autorizada
Em caso de dúvidas contactar o nº Mail: info@doctorvida.com

Issuance of certificates as shown in the example

The Certificate will be sent to the User and the patient, if selected.

Check that the information issued is always correct. Examples are shown below.

After the rehearsal

Maintenance

The equipment is designed and manufactured for a long life cycle with reduced maintenance requirements. The equipment does not contain internal components that require maintenance by the operator.

The following maintenance actions should be performed regularly:

Maintenance task	Periodicity
Equipment cleaning and disinfection	After each use
Cleaning and disinfection of the site	In accordance with applicable regulatory practices

Site and equipment cleaning

At the end of each test, ensure that the different locations are clean and ventilated as well as all the equipment used in the test, including the Doctor Vida equipment and ensure that the disposal of the reagent tubes and all inherent material is carried out in accordance with the rules of biological waste treatment and in accordance with the regulatory guidelines.

►After the analysis, open the lid of the Doctor Vida equipment, remove the reagent tube and dispose of it in the biological waste;

►Also dispose of consumables and accessories provided in the biological waste;

►Clean the outside of the Doctor Vida equipment with paper moistened with 70% ethanol (do not spray) as well as the lid and let it air dry;

Note: Be careful not to get ethanol into the hole where the reagent tube is placed.

►Clean and disinfect work surfaces with 10% bleach and 70% ethanol to mitigate the risk of contamination;

Keep the place clean and ventilated, daily natural ventilation;

Keep the lid of the equipment open until a new test;

Dispose of the papers and gloves used to clean the space and equipment for biological waste.

Note: Do not leave Doctor Life equipment on if you are not using it.

Waste disposal

Waste electrical and electronic equipment (WEEE) (Directive 2012/19/EU)

Equipment should not be disposed of like other household waste. It is your responsibility to dispose of the equipment properly for the recycling of waste electrical and electronic equipment. The collection and selected recycling of this equipment helps to conserve natural resources and protect human health and the environment. For more information on where you can dispose of the equipment, contact the manufacturer or the distribution company where you purchased the product.

Troubleshooting

Observed problem	Possible solution
—Electricity failure while the test is running. In this case it is not possible to complete the test.	►Turn off the machine and close the app. ►Open the Dr Vida Pocket PCR app. ►Discard the test tube that was in use and restart the process using a new test tube.
—Failed to start the test.	►Make sure you have an internet connection and that Bluetooth is working. ►Check the hardware compatibility requirements of your device with the Dr Vida software in the compatibility section within each store (Android/iOS). ►Turn off the app and reconnect to the device. ►Turn off the device and pair again in the App, in the "Devices" menu.
—Data transfer failed. **—The application takes too long to display results or the test appears to be stuck.**	►Close the Dr Vida Pocket PCR app. ►Check your internet connection and Bluetooth. ►Open the app in the "Devices" menu, reconnect the device. Press the device button again and click "continue". ►If it continues to fail, unpair the machine and pair again. It is important to check that the same device is not connected to more than one mobile phone. ►If you are able to start a new test with this machine, it means that a power failure has occurred or the machine has automatically restarted. In this case, the test becomes invalid. Discard the test tube that was in use. Turn the equipment off and on again and start the process using a new test tube. ►If the problem persists, please contact technical support. See the "Manufacturer Information" section.
—The device does not appear in the list of devices. **—The connection between the device and the mobile phone failed.**	►Check that the equipment is connected to the mains, that there is no electrical fault (e.g. the connection cable is damaged). ►In the phone's settings, check if Bluetooth is turned on, and if in the app you have given permission to access the device's location. ►Refresh the screen by swiping down.
—Failed to send the report with the results of the App to the customer's email.	► Contact technical support. See the "Manufacturer Information" section.
—The phone ran out of space to store the data.	►If your phone runs out of space before starting the test, you should free up space on your phone or use another phone. ►If your phone runs out of space during the test, the test continues, however, the results will not be available. In this case, do not turn off the equipment as the data is stored on the device. Free up space on your phone and the connection will be re-established.

Observed problem	Possible solution
	Important note: If you turn off the equipment you lose all data and you must repeat the test with a new test tube.
—Result with atypical/invalid graph.	►When the result is detected, but the growth of the curve is not as expected, the analysis must be repeated with a new test. This type of result can occur when: 1) There is current oscillation 2)When the lid is opened during the test. 2)When the equipment moves sharply or tilts.

Warranty Information

The product is covered by a two-year warranty period. This warranty is intended to protect you from the costs associated with problems resulting from manufacturing defects. The warranty period begins on the date of receipt of the product at the desired location. For assistance during the warranty period, contact the manufacturer.

Training

These instructions for use describe the correct use and operation of the device. Operators of the device should familiarise themselves with the applicable sections in the document before testing to ensure safe and efficient use of the document. Make sure you follow the training requirements in accordance with the applicable regulatory guidelines. If you need more information about training in the use of this product, please contact the manufacturer.

Manufacturer Information

Name: STAB VIDA- Research and Services in Biological Sciences, Lda.

Address: Madan Parque, Rua dos Inventores, Sala 2.18, 2825-182 Caparica, Portugal.

Sítio(s) web: https://www.stabvida.com

Technical assistance:

+351 938 437 766

In case of any problem, please contact us by email drvida@stabvida.com or phone 00351 938 437 766 (Call to national mobile network)

Monday to Friday from 8:30 am to 17:30 pm. (GMT time)

According to EU regulation 2017/746, any serious incident that occurs in connection with the device must be reported to the manufacturer and the competent authority of the EU Member State where the user and/or patient is established.

Revision history

Revision		Revised points	
N.º	**Date (dd/mm/yy)**	**N.º**	**Review Description**
1	04/11/2022	All	Issuance of the document considering the Equipment and Software set.
2	18/01/2023	All	Adaptation to the requirements of the standard (IEC/EN 61010-1)
3	18/01/2023	All	Adaptation to the requirements of the standard (IEC/EN 61010-1)
4	31/03/2023	All	Adaptation to the requirements of the standard (IEC/EN 61010-1)
5	28/04/2023	All	Compliance with Regulation (EU) 2017/746 IVDR
6	28/08/2024	-	Quality control: Inclusion of reagent considerations for quality controls of product-compatible tests. Manufacturer information: Updating the telephone contact number for technical assistance. Adding .of QR Code Added the list of used abbreviations. Added graphics and illustrative schemes. Added QR code for information relating (features) to Doctor Vida products. Change of technical support contact number Updated the troubleshooting list