OHMED

Instructions for Use

VerticaPlus App

ATTENTION! The VerticaPlus App is used together with the Vertica device. For detailed instructions on using your Vertica device to do a treatment, please refer to the Vertica/Vertica Instructions for Use or Quick Start Guide. This manual refers only to the operation of the VerticaPlus App.

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1 Preface

1.1 Important Notes

Important Information – **Please Read First**

- Read this entire manual carefully before using the VerticaPlus app.
- Keep this manual for future reference.
- This document refers to the Vertica app only. For information on using the Vertica device safely and effectively, please consult the separate *Instructions for Use (IFU)* included with your device.

1.2 Description of the user

- This document is intended for the home user of the Vertica device.
- The Vertica device is intended for adults only.

1.3 Conventions used in this manual

- The Vertica device is also referenced as 'device', 'Vertica', 'Vertica Plus' or 'product'.
- The VerticaPlus Application is also referenced as 'the App'.
- **Bold** indicates product elements.
- *Italic* indicates sections or publication titles referenced in the text.
- In the VerticaPlus App, the battery icon functions identically to the battery icon on the Vertica device.

2 Downloading and installing the VerticaPlus App

The Vertica app can only be used with a Vertica device. It offers exclusive features, including treatment quality tracking and progress monitoring.

For the best results, we recommend using the app alongside your device.

The VerticaPlus App can help improve treatment results by giving step-by-step video guidance on how to use the Vertica device and providing personalised feedback and sensory indications. It allows viewing of treatment duration and additional data to make the treatments as effective as possible.

The settings of the Vertica device can be modified with the App for personalisation of the parameters to improve the experience and treatment results.

2.1 Downloading and installing the VerticaPlus App

Depending on your device (Android or iOS operating system), the VerticaPlus App is installed from the Google Play Store or the Apple App Store. It can be found by searching for “VerticaPlus”.

GET IT ON Google Play

Download on the App Store

VerticaPlus

Download VerticaPlus on Google Play

Download VerticaPlus on the App Store

2.1.1 Downloading the App from the Apple App Store

1. On your iOS device, open the App Store application.
2. In the App Store application, use the search function to find VerticaPlus.
3. Tap the **Download button**.
   The app will download and install on your iOS device.

> You may be asked to enter your Apple ID password or use Face ID/Touch ID to confirm the download of the app.

App Store is a service mark of Apple Inc. registered in the U.S. and other countries and regions.

2.1.2 Downloading the App from the Google Play Store

1. On your Android device, open the Google Play Store application.
   In the search bar, type **VerticaPlus**
2. Tap the '**VerticaPlus for improving ED**' App in the list to open the page of the
   app.
3. Tap the Install button.
4. Review the app permissions and tap "Accept" to grant the necessary permissions.
   The app will download and install on your Android device.

Google Play and the Google Play logo are trademarks of Google LLC.

2.2 Setting up the app, and signing up

To access all features of VerticaPlus, we strongly recommend completing the questionnaire and signing up before using the app.

When using the app for the first time, you'll be asked to enter a few personal details to complete the sign-up process.

Scan the QR code to watch an explanation video about the VerticaPlus app

2.2.1 To set up the App and sign up:

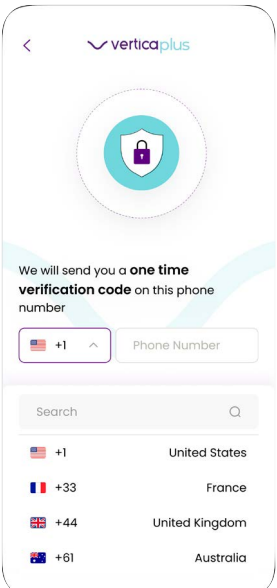
> Make sure to enable the location and Bluetooth permissions on Android and iOS devices.

1. Open the VerticaPlus App.
2. Select the desired language from the dropdown box and tap **Next**.
   The welcome screen opens.
3. If you have the Vertica device, tap **Yes, let's get started!** and continue with step 4.

> To go back to the previous screen, tap the **< button**.

4. Enter your mobile phone number:
   a. Select your country code from the dropdown list or use the search function.

b. Enter your mobile phone number in the **Phone Number field** and **tap Submit.**
A one-time passcode is sent to the mobile phone number, and the one-time password screen opens.



Your mobile phone number is verified with a one-time passcode (OTP). The OTP is sent by SMS to the phone number entered.

Please ensure you enter a valid mobile phone number during sign-up. If the one-time password (OTP) is entered incorrectly 15 times, the app will be locked for five minutes. If this happens, follow the on-screen instructions to proceed.

5. Check your SMS messages and copy the four-digit number into the password fields.

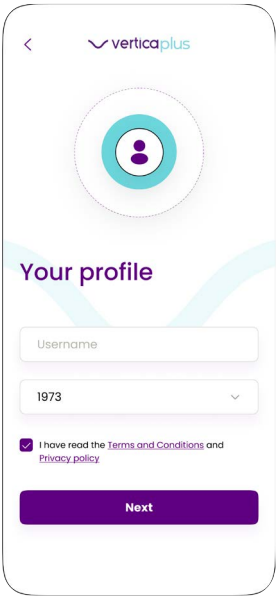
If you did not receive an SMS, tap **Send again**.

6. Select the **Remember me** checkbox and tap **Verify**. The OTP is verified and when correct, the 'Your Profile' screen opens.
7. Enter your name or a username in the **username field.**
8. Select your year of birth from the dropdown list.
9. Select the **Agree checkbox** to approve the Terms and Conditions.

> Before selecting the Agree checkbox, make sure to tap Terms and Conditions and read the contents.

10. Tap **Next**.
11. The VerticaPlus App shows the IIEF-EF* questionnaire.

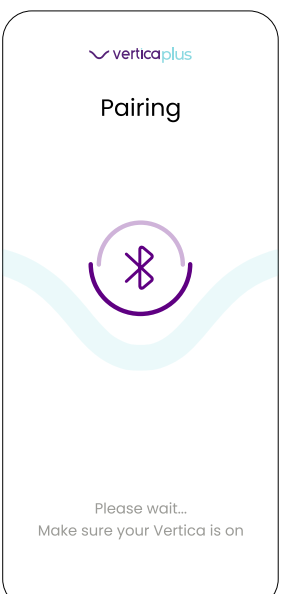
    Select one answer per question and tap **Confirm** to continue to the next question.



We highly recommend answering the IIEF-EF questionnaire* truthfully before starting the first treatment to make sure the treatment progress can be monitored as accurately as possible and improvement can be tracked.

*IIEF-EF questionnaire - International index of erectile function - Erectile function questionnaire

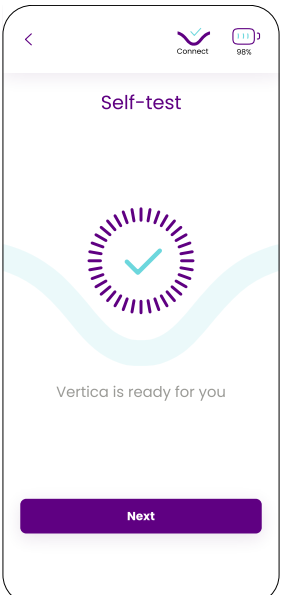
12. Pair the App with the Vertica device:
    a. Make sure Bluetooth on the mobile device is set to **on**.
    b. Set the Vertica device to **on** (see *Instructions for Use | Setting the device to on and off*).
    The App scans automatically for the nearest Vertica device.



If pairing fails, and the Vertica device is not found, make sure Bluetooth on your mobile device is on, the Vertica is set to **on**, and tap **Retry**.

If this does not solve the issue, tap Contact us to contact customer support.

13. When the Vertica device is found and paired, the App is set up, The sign-up is successful.
14. The Vertica device conducts a self-test. The device vibrates to indicate that the self-test is complete.
15. Wait until the self-test is completed and tap **Next** The main screen opens, and the Vertica device is ready for use.



If the self-test fails, tap **Retry** to try again. If the issue continues, tap **Skip** to proceed or **Contact Us** to get in touch with customer support.

3 Understanding the user interface

ID	Indicator & Controls	Function
1	**Vertica indicator**	Indicates that the Vertica device is connected to the App
2	**Battery indicator**	Indicates the battery status of the Vertica device
3	**Next button**	Navigates to treatment results
4	**Energy level indicator**	Indicates the energy level (1 to 6) of the Vertica device
5	**System messages**	Displays instructions or treatment feedback
6	**Treatment quality indicator**	Indicates the quality of the treatment based on actual delivery of RF energy
7	**Settings button**	Opens the settings
8	**More button**	Access more options
9	**Home button**	Return to the main screen
10	**Calendar button**	Opens the calendar of treatments
11	**Treatment timer indicator**	Indicates the duration of the treatment
12	**Treatment mode indicator**	Indicates that RING or RING+PAD mode is active on the Vertica device
13	**Tutorial button**	View tutorials (Tutorials can be viewed before, after or during the treatment. The treatment continues during the tutorials)
14	**Treatment indicator**	Indicates the treatment is active
15	**RF energy indicator**	Indicates the delivery of RF energy

4 Using the app during treatment with the Vertica Device

For the best experience and full functionality, we recommend using the Vertica app during each treatment session.

Doing so ensures:

- Treatment data is synced to the app immediately.
- Each session is recorded with the correct date and time. If multiple treatments are done in a single day, each is saved as a separate entry.

If the App is Not Open During Treatment:

- Data is not synced in real time.
- The device stores only basic treatment data, without specific dates or times.
- When the app is next opened and connected to the device, only the total treatment time since the last sync is transferred. This time is then added to the current date and time in the app's calendar.

Progress Monitoring:

Every month, the app will prompt you to complete the IIEF-EF questionnaire to help track treatment progress. If the questionnaire is not completed, the prompt will appear each time the app is opened until it is submitted.

- For security purposes, the app will request a one-time passcode (OTP) every three months. When prompted, follow the on-screen instructions and check your SMS messages for the OTP sent to your registered mobile number.
- If the OTP is entered incorrectly 15 times, the app will be locked for five minutes. In this case, simply follow the instructions provided within the app.
- After three hours of inactivity, the app will automatically log out.

4.1 Operating the app during treatment

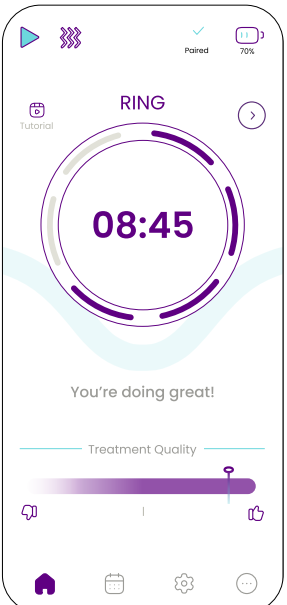
1. Make sure Bluetooth on your mobile device is set to **on**.
2. Set the Vertica device to **on** *(see Instructions for Use | Setting the device to on and off).*
3. Open the VerticaPlus app. The App shows the opening screen. The Vertica indicator and battery indicator illuminate when the Vertica device is connected.
4. The Vertica device starts a self-test. Wait for the self-test to complete.

If the Self-Test Fails

Tap **Try Again** to repeat the self-test. If the problem continues, tap **Skip** to proceed or **Contact Us** to reach customer support.

You can also press the power button on the Vertica device to go directly to the main screen.

5. The main screen opens and shows the message Vertica is ready for treatment.
   The App and Vertica device are ready for use.
6. You can now begin treatment. For further instructions on treatment delivery, please refer to the accompanying Vertica instruction guide.

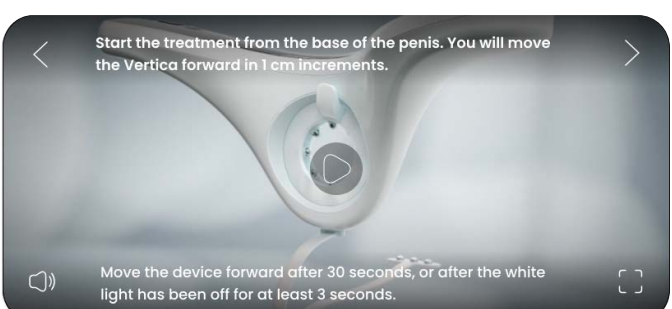


During the treatment, the App shows the following information:

- The **treatment indicator** comes on when the **energy button** on the Vertica device is pushed or double-clicked (can be managed in settings).
- The **RF energy indicator** comes on when RF energy is delivered.
- The **treatment timer indicator** shows the updated treatment time.
- The **treatment quality indicator** starts at 100% and is updated during the treatment based on the treatment quality.
- The App instructs when it is time to move the Vertica device to the next position on the penile shaft.

4.2 Viewing the tutorial video during the treatment

The App can assist the treatment with a tutorial video. The tutorial video can be viewed at any time during the treatment.



To open the tutorial video:

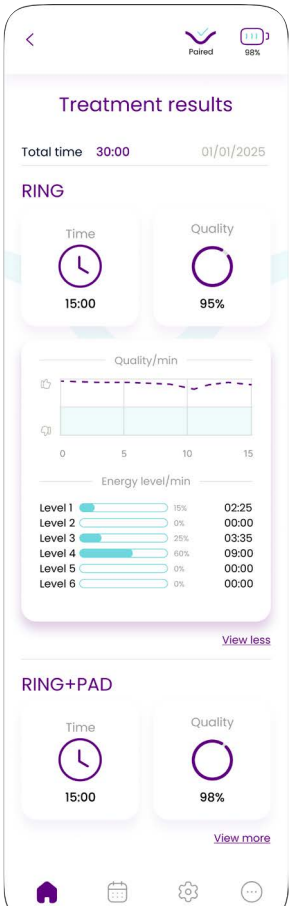
1. Click the **tutorial button.** The tutorial video opens.
2. Click the play button to start the video.
3. To skip the current step and go to the next or previous step in the tutorial video, click the arrow buttons.
4. To view the tutorial video full screen, click on the square.
5. To change the volume settings, click the speaker icon.

4.3 Treatment results

After a session, treatment results for the current session appear when you tap **Next** or swipe left on the main screen.

You can also view detailed results from past sessions by selecting a specific treatment from the calendar.

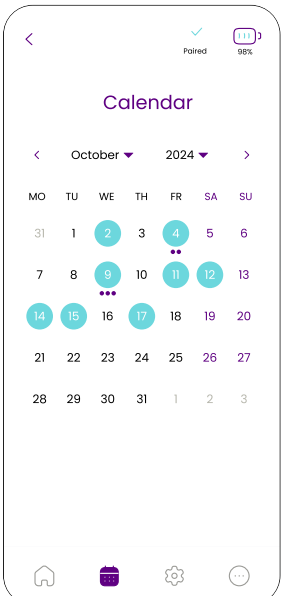
The screenshot is an example of a complete treatment summary from a session carried out with the app open.



Treatments that take place while the App is not open/in operation will not have a data-graphic or chart attributed to them.

5 Using the calendar

1. Tap the **calendar icon** in the bottom panel.
   The calendar opens in the current month.



- Days that have treatment data have a solid circle.
- Days that have more than one treatment are indicated with solid dots below the date.
- To see older treatment data, tap on the month or the year and make your selection from the drop-down menu.

2. Tap on a day with treatment data. The screen shows the treatment data.

If it is a day with multiple treatments, the screen shows a list of the treatment times on that day. Select a treatment time to see the specific treatment data.

A green dot indicates treatment data saved when the app was not used.

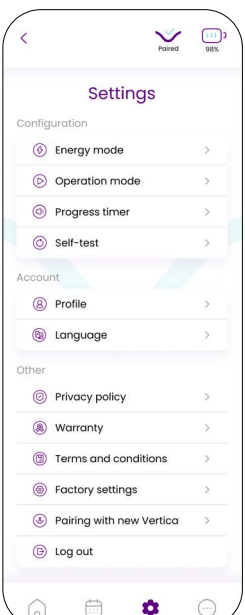
6 Changing the settings

Settings that affect the Vertica device can only be changed when the device is connected to the app. If the device is not connected, the app will prompt you to connect it.

Tap the information icon ⓘ next to each setting for a detailed explanation.

To change the settings:

1. In the App, tap the **settings button** in the bottom panel. The settings page opens.
2. Tap on a setting to expand it and see the options.
3. Select the desired option and tap **Confirm** or **Save** to set the selected option.



The following settings are available:

Configuration

- **Energy Mode**
  Set the energy mode of the Vertica device to Normal (default) or Adaptive mode, where energy is delivered with a higher sensitivity threshold.
- **Operation Mode**
  Set the lock function of the energy button to Double click (default) or Continuous press.
- **Progress timer**
  Set sound and/or vibration to indicate when it is time to move the Vertica device to the next position on the penile shaft.
- **Self-test**
  Initiates a self-test to ensure the device is functioning correctly.

Account

- **Profile**
  Set your nickname, year of birth, and mobile phone number.
- **Language**
  Set the language for the App, the data and time format, and the starting day of the week.

Other

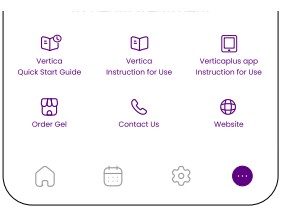
- **Privacy policy**
  Show the privacy policy.
- **Warranty**
  Show the warranty information.

- **Terms and conditions**
  Show the terms and conditions.
- **Default settings**
  Show information related to the App and the Vertica device.
- **Pairing with new Vertica**
  Pair a new Vertica device with the App.
- **Log out**
  Log out of the VerticaPlus App.

7 More options

Tap the '**More' Icon** to:

- View the Vertica/VerticaPlus Quick Start Guide
- View the Vertica/VerticaPlus Instructions for Use
- View the VerticaPlus app Instructions for Use
- Order RF conductive gel
- Contact customer support
- Visit the website



8 Explanation of in-app messages

The App shows messages on the screen during use. Follow the solutions below to solve any issues.

In-app message	Explanation/Solution
Vertica is ready for treatment	Indicates the self-test is completed successfully and the Vertica device is ready for treatment.
Keep going!/Great job!	Indicates the treatment is making good progress.
Vertica is ready to continue your treatment	Indicates the treatment is not yet completed. Continue with the treatment.
Start RING+PAD session	Indicates the RING+PAD treatment has not yet started. Start the RING+PAD treatment.
Start RING session	Indicates the RING treatment has not yet started. Start the RING treatment.
Please slide the Vertica to the next position	Move the Vertica device to the next position on the penile shaft.
Battery low, charge your Vertica	The battery of the Vertica device is low. Charge the Vertica device (see Instructions for Use | Charging the Vertica device)
Improve contact/ Add more gel	The contact between the RF electrodes and the skin of the penile shaft is not good. • Make sure the RF electrodes make good contact with the skin of the penile shaft. • Make sure enough gel is applied to the penile shaft.

In-app message	Explanation/Solution
No contact	There is no contact between the RF electrodes and the skin of the penile shaft. • Make sure the penis is inserted into the ring of the Vertica device. • Make sure the RF electrodes make good contact with the skin of the penile shaft. • Make sure enough gel is applied to the penile shaft.
To change the configuration, Vertica must be connected	The Vertica device is not connected to the App. • Make sure Bluetooth is set to On on your mobile device • Set the Vertica device to on. • Make sure the Vertica device is connected to the App. See Using the App during treatment with the Vertica device
To lock energy, press double-click on your Vertica	Press the energy button two times to lock the energy button.
To lock energy, press continuously for 5 seconds, and release	To lock the energy button in this mode, press the energy button continuously for 5 to 10 seconds and release it.
Please do not treat and contact us	Indicates there is an issue with the Vertica device. Stop the treatment and contact customer support.

9 Data privacy

When the VerticaPlus App is active, your treatment data is automatically synced to the cloud services used by Ohh-Med Medical Ltd.

The Vertica device and the VerticaPlus App use strong encryption algorithms to send and receive data between the Vertica device, the App, and the cloud servers. Your data is stored encrypted and anonymous. Access to your data is limited to authorised personnel for the purpose of customer support and device tracking only. To delete your user data or to update your phone number, send an email to service@vertica-labs.com.

The data is stored and used to:

- Personalise the treatment – The App uses the treatment data to provide cumulative feedback on treatment quality.
- Keep a history of the treatments – The App keeps a record of previous treatments, allowing users to review their treatment history and assess improvements over time.

The Vertica device and VerticaPlus App comply with the following security standards:

- EC 62304:2006 + AMD1:2015 CSV – Medical Device Software – Software Life Cycle Processes, Edition 1.1
- Guidance for the Content of Premarket Submissions for Software Contained in medical devices
- MDCG 2019-16 Guidance on Cybersecurity for medical devices

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- EN ISO 14971:2012 / ISO 14971:2019 Application of risk management
- IEC 62366-1:2015 Part 1: Application of usability engineering to medical devices

MANUFACTURER
Ohh-Med Medical Ltd.
Tsivonit St. 1, P.O. Box 89 Tiberias
1410002, Israel
Tel: +972-4-9036999

Email: service@vertica-labs.com
Website: www.vertica-labs.com

EU REPRESENTATIVE
G&D&Y
Tolstraat 112,
1077 EL Amsterdam,
The Netherlands

DISTRIBUTOR
OhhMed Medical UK Ltd.
107-111 Fleet Street, London, Greater London, EC4A 2AB, UK

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For further information about Vertica and VerticaPlus, scan the QR code:

Issue Date: May 2025 | OH_Misc0118_RevB

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