# OHHMED Instructions for Use

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ATTENTION! The Verticaplus App is used together with the Verticaplus device. For detailed instructions on using your Verticaplus device to do a treatment, please refer to the Vertica Instructions for Use or Quick Start Guide (P/N OH\_Misc008). This manual refers only to the operation of the Verticaplus App.

> These are the original English instructions. May 2024 | OH\_Misc0118\_RevA

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#### **1 PREFACE** 1.1 IMPORTANT NOTES

Congratulations on your new Verticaplus<sup>II</sup> device. For your safety and the success of treatments:

- Read and understand this entire user manual before using your Verticaplus device.
- Keep the Instruction Manual for future reference.
- Read and understand the Instructions for Use included with your Verticaplus device before using this product. It contains important safety information.

### **1.2 DESCRIPTION OF THE USER**

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

#### **1.3 CONVENTIONS USED IN THIS MANUAL**

- The Verticaplus device is also referenced as 'device', 'Verticaplus', or 'product'.
- The Verticaplus App is also referenced as 'the App'.
- Bold indicates product elements.
- *Italic* indicates sections or publication titles referenced in the text.
- The battery icon on the Verticaplus device, as shown in the table below, has the same functionality as the battery icon on the Vertica device

Battery icon Vertica device	Battery icon Verticaplus device
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### 2 DOWNLOADING AND INSTALLING THE VERTICAPLUS APP



Signing up with the App can only be done with the Verticaplus device. The App provides a range of features unique to the Verticaplus, including treatment quality and tracking. It is highly recommended to use the Verticaplus App with your Verticaplus device to gain all the benefits.

The Verticaplus App can help improve treatment results by giving step-by-step video guidance on how to use the Verticaplus device and providing personalized 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 Verticaplus device can be modified with the App to personalize 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 Google's Play Store or Apple's App Store. It can be found by searching for "Verticaplus".











Download Verticaplus on

Google Play

Download Verticaplus on the App Store

# 2.1.1 DOWNLOADING THE APP FROM APPLE'S 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 GOOGLE'S PLAY STORE

- On your Android device, open the Google Play Store application.
   In the search bar, type Verticaplus to find Verticaplus.
   A list of Apps shows on the screen.
- 2. Tap the Verticaplus 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

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It is strongly recommended to complete the questionnaire and sign up before using the App to enjoy all the benefits and the features of the Verticaplus.

When the app is used for the first time, a few personal details need to be entered to sign up.



#### To set up the App and sign up:

- 1. Open the Verticaplus App.
- 2. Select the desired language from the dropdown box and tap **Next**.

The welcome screen opens.

 If you have the Verticaplus, tap Yes, let's get started! and continue with step 4. If not, tap Visit store to order your Verticaplus device.

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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.

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



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

Your mobile phone number is verified with a one-time password (OTP). The OTP is sent by SMS to the phone number entered. Make sure you enter a working mobile phone number. After 15 attempts to enter the wrong OTP, the App is locked for five minutes. In that case, follow the instructions in the App.

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

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





- 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 nickname in the **Nickname field.**
- 8. Select your year of birth from the dropdown list.
- 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.
- The Verticaplus App shows the IIEF-EF\* questionnaire. Select one answer per question and tap **Confirm** to continue to the next question.

<	verticaplus
You	nr profile
1973	×
🔽 Lagr	ee to the <u>Terms and Conditions</u>
	Next

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.

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

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





When pairing fails, and the Verticaplus device is not found, make sure Bluetooth on your mobile device is on, the Verticaplus is set to on, and tap Retry. If this does not solve the issue, tap Contact us to contact customer support.

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



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In case the self-test fails, tap Retry to do the self-test again. If that does not solve the issue, tap Skip to continue or tap Contact us to contact customer support.

#### **3 UNDERSTANDING THE USER INTERFACE**





ID		Function
1	Vertica indicator	To indicate that the Verticaplus device is connected to the App
2	Battery indicator	To indicate the battery status of the Verticaplus device.
3	Next button	To navigate to treatment results
4	Energy level indicator	To indicate the energy level (1 to 6) of the Verticaplus device
5	System messages	To give instructions or treatment feedback
6	Treatment quality indicator	To indicate the quality of the treatment based on actual delivery of RF energy
7	Settings button	To open the settings
8	More button	To access a menu with more options
9	Home button	To return to the main screen
10	Calendar button	To open the calendar of treatments
11	Treatment timer indicator	To indicate the duration of the treatment
12	Treatment mode indicator	To indicate that RING or RING+PAD mode is active on the Verticaplus device.
13	Tutorial button	To see tutorials (Tutorials can be viewed before, after or during the treatment. The treatment continues during the tutorials).
14	Treatment indicator	To indicate the treatment is active
15	RF energy indicator	To indicate the delivery of RF energy

### 4 USING THE APP DURING TREATMENT WITH THE VERTICAPLUS

- To make full use of the App and its features, it is recommended to open the App to do the treatments to make sure:
  - The data of each treatment syncs to the App immediately.
  - The individual treatment data is stored with the date and time of the treatment. Multiple treatments on one day are stored as separate treatments.
- When the App is not open during the treatment:
  - The treatment data does not sync with the App. The Verticaplus device stores basic treatment data in its internal memory.
  - The Verticaplus device does not store the date and time of individual treatments. It only stores the total time of all the treatments combined since the last time it connected to the App.
  - The next time the App is open, and the Verticaplus is connected to the App, the total treatment time is synced to the App. The total treatment time is added to the calendar on the current day and time.
- Every month, the App will ask to complete an IIEF-EF questionnaire to measure the treatment progress. If the questionnaire is not completed, the App will show the questionnaire every time the App is opened.





• Every three months, the App requests to enter an OTP password for security reasons. In that case, follow the instructions in the App and check your SMS messages for the OTP password that is sent to the registered phone number.



- After 15 attempts to enter a wrong OTP, the App is locked for 5 minutes. In that case, follow the instructions in the App.
- After 3 hours of inactivity, the App will log out automatically.

# 4.1 USING THE APP DURING TREATMENT WITH THE VERTICAPLUS DEVICE

- Make sure Bluetooth on your mobile device is set to on.
- Set the Verticaplus 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 come on when the Verticaplus device is connected.
- The Verticaplus device starts a self-test. Wait for the self-test to complete.



In case the self-test fails, tap Retry to do the selftest again. If that does not solve the issue, tap Skip to continue or tap Contact us to contact customer support. Pressing the energy button on the Verticaplus device will directly open the main screen.

 The main screen opens and shows the message Verticaplus is ready for treatment.

The App and Verticaplus device are ready for use.

6. Start the treatment by following the steps in the Instructions for Use | Let's get started with the treatment!





During the treatment, the App shows the following information:

- The **treatment indicator** comes on when the **energy button** on the Verticaplus device is pushed or doubleclicked (depending on the 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 Verticaplus 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.
- To view the tutorial video full screen, click on the square.
- To change the volume settings, click the speaker icon.





#### **4.3 TREATMENT RESULTS**

The treatment results show on the screen for the current treatment when pressing the **next button** or swiping left on the main screen.

In addition, viewing the treatment data is possible by selecting a treatment from the calendar.

Example of a full treatment result after a treatment done with the App opened.

Treatment results of treatments done without the App do not have the quality graphic.

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Treatment results		
Treatment time: 30	<b>:00</b> 01/01/2024	
RING		
Time () 15:00	Quality O 95%	
Qualit	ulmin -	
©		
0 5	10 15	
Level 3 Level 4 Level 5 Level 6	16%         02:25           0%         00:00           24%         03:35           60%         09:00           0%         00:00           0%         00:00           0%         00:00           0%         00:00	
	View less	
RING+PAD		
Time	Quality	
15:00	98%	
	View more	
	\$ \$	

#### **5 USING THE CALENDAR**

- Tap the calendar button 1. 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 to change it.
- Tap on a day with 2 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 Verticaplus device can not be changed when the Verticaplus device is not connected to the App. The App gives a message to connect the Verticaplus device if it is not connected.
  - Tap the ?-icon for an explanation of a setting.

#### To change the settings:

- 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.
- 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 Verticaplus device to Normal (default) or Adaptive for greater sensitivity.

#### 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 Verticaplus device to the next position on the penile shaft.

#### Self-test

To let the Verticaplus device start a self-test.

#### Account

#### Profile

To set your nickname, year of birth, and mobile phone number.

#### • Language

To set the language for the App, the data and time format, and the starting day of the week.

Other

#### Privacy policy

To show the privacy policy.

#### • Warranty To show the warranty information.

#### • Terms and conditions

To show the terms and conditions.



Default settings

To show information related to the App and the Verticaplus device.

- Pairing with new Vertica
   To pair a new Verticaplus device with the App.
- Log out

To log out of the Verticaplus App.

#### **7 MORE OPTIONS**

#### Tap the More button to:

- View the Vertica Quick Start Guide
- View the Vertica 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	To indicate the self-test is completed successfully and the Verticaplus device is ready for treatment.
Keep going!/You're doing great!	To indicate the treatment is making good progress.
Vertica is ready to continue your treatment	To indicate the treatment is not yet completed. Continue with the treatment.
Start RING+PAD session	To indicate the RING+PAD treatment has not yet started. Start the RING+PAD treatment.
Start RING session	To indicate the RING treatment has not yet started. Start the RING treatment.
Please slide the Vertica to the next position	Move the Verticaplus device to the next position on the penile shaft.
Battery low, charge your Vertica	The battery of the Verticaplus device is low. Charge the Verticaplus device (see Instructions for Use   Charging the Vertica device)
Improve contact/ Add more gel	<ul> <li>The contact between the RF electrodes and the skin of the penile shaft is not good.</li> <li>Make sure the RF electrodes make good contact with the skin of the penile shaft.</li> <li>Make sure enough gel is applied to the penile shaft.</li> </ul>



In-app message	Explanation/Solution
No contact	<ul> <li>There is no contact between the RF electrodes and the skin of the penile shaft.</li> <li>Make sure the penis is inserted into the ring of the Verticaplus device.</li> <li>Make sure the RF electrodes make good contact with the skin of the penile shaft.</li> <li>Make sure enough gel is applied to the penile shaft.</li> </ul>
To change the configuration, Verticaplus must be connected	<ul> <li>The Verticaplus device is not connected to the App.</li> <li>Make sure Bluetooth is set to On on your mobile device</li> <li>Set the Verticaplus device to on.</li> <li>Make sure the Verticaplus device is connected to the App.</li> <li>See Using the App during treatment with the Verticaplus device</li> </ul>
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 on your Vertica	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	To indicate there is an issue with the Verticaplus 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 Verticaplus device and the Verticaplus App use strong encryption algorithms to send and receive data between the Verticaplus device, the App, and the cloud servers. Your data is stored encrypted and anonymous. Access to your data is limited to authorized 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:

- Personalize 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 Verticaplus 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

Always be ready with Vertica.

#### MANUFACTURER

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