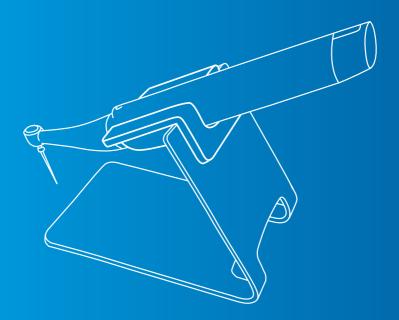


VDW.CONNECT Drive®



User Manual



www.vdw-dental.com

Dear customer,

Thank you for choosing VDW.CONNECT Drive.

By opting for VDW.CONNECT Drive, you have acquired a product that was developed and tested with maximum care to meet the highest standards in terms of performance and handling.

Instructions for Use are always kept up to date by VDW to bring them in line with the latest developments. You will find the current version on www.vdw-dental.com/manuals and in your VDW.CONNECT app.

In countries where the legal situation enables us to do so, we have decided not to produce a printed version of these instructions for use, for environmental reasons. Printed English instructions for use are always enclosed with your product.

If no printed version in your national language is enclosed and you wish to have a printed version of your instructions for use, we will be happy to send you a copy (free of charge within 7 calendar days to any address in the EU). Simply order your free copy at www.vdw-dental.com/manuals.

These instructions for use are available in other languages upon request.

The pictures in this user manual in chapter 10 Operation with VDW.CONNECT and iPad may vary slightly from the current VDW.CONNECT app.

This manual has been created with the greatest care, but even with all our efforts, errors can never be entirely excluded. Suggestions for improvements are welcome anytime. Please contact VDW GmbH directly with any related comments or suggestions.

VDW GmbH reserves the right to change the information and data contained in these instructions for use without prior notice.

VDW GmbH Bayerwaldstr. 15 • 81737 Munich • Germany Phone +49 89 62734-0 • Fax +49 89 62734-304 www.ydw-dental.com • service@ydw-dental.com

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- Technical Data

1. Symbols Used

1.1. In These Instructions for Use



If the instructions are not followed properly, operation may lead to hazards for the product or the user/patient.



Additional information, explanation of operation and performance.

CROSS REFERENCE

Points out where additional information on a certain topic can be found.

1.2. On the Product/Packaging

SN	Serial number	\$	IMPORTANT! Refer to Instructions for Use
REF	Catalogue number	X	Do not dispose of with normal household waste
	Manufacturer	ИМ05	PC Ghost Symbol (Russia)
	Date of manufacture	- 20° C	Temperature limits
	Safety class II device	20 <u>%</u>	Storage humidity range
*	Type BF applied part		Store in a dry place
CE 0123	CE marking	Ţ	CAUTION! Fragile!
	DC current	\sim	AC current
®	Bluetooth	ĺ	In EU countries the Instructions for Use are available in electronic form. Please consult the "Getting Started" brochure for more information.
2	Not for reuse	135°C	Can be autoclaved up to a maximum temperature of 135° Celsius
ĬĂ	Washer-disinfector	NON	Non-sterile
R)	Tap here (when using the VDW.CONNECT app)	ß	Swipe here (when using the VDW.CONNECT app)
•	ACPEIP (China RoHS)	106 kPa 50 kPa	Atmospheric pressure limitation

2. Intended Use

A cordless motor for dental root canal treatment using endodontic instruments in torque controlled continuous rotation and in reciprocating movement.

FOR DENTAL USE ONLY!

3. Contraindications

None known.

Safety and effectiveness have not been established in pregnant women and children.

4. Warnings

Read the following warnings before use:



4.1. User

The handpiece is intended for endodontic treatment and may only be used by trained and qualified professionals such as dentists.



4.2. Ambient Conditions

- The device must not be placed in humid surroundings or anywhere where it can come into contact with any type of liquids.
- Do not expose the device to direct or indirect heat sources. The device must be operated and stored in a safe environment.
- The device may be operated up to a maximum temperature of 35°C and up to an altitude of 2,000 m above sea level.
- Do not use the device in the presence of free oxygen, anaesthetics or flammable substances. The device must be operated and stored in a safe environment.
- The device can cause radio interference or interfere with the operation of equipment in the vicinity. If this happens, the interfering influence should be reduced by reorienting or repositioning the device or by screening off the immediate environment. The electromagnetic radiation emitted by this device is below the recommended limits specified by the applicable relevant provisions (EN 60601-1-2:2007 & EN 60601-1:2006).
- The device requires special precautions with regard to electromagnetic compatibility (EMC) and must be installed and operated in strict compliance with the EMC information. In particular, do not use the device in the vicinity of fluorescent lamps, radio transmitters, remote controls, portable or mobile RF communication devices, even if they meet CISPR 8 requirements.
- Do not charge, operate or store at high temperatures. Comply with the specified operating and storage conditions.
- Do not position VDW.CONNECT Drive in such a way as to make it difficult to disconnect the charge adapter.



4.3. During Treatment

- Gloves and a rubber dam are compulsory during treatment.
- If irregularities should occur in the device during treatment, switch it off. Contact VDW or your VDW authorised service partner.



4.4. Battery

- For charging purposes, always use the original charger with the charging cable. Use of nonoriginal chargers jeopardises the safety of both patient and user.
- If liquid should emerge from the handpiece, the batteries may be leaking. In such a case stop using the device immediately and contact VDW or your VDW authorised service partner.
- Never open the device yourself. Opening the device voids the warranty. Contact VDW or your VDW authorised service partner.
- A device with a faulty battery must not be sent by air freight (see Section 4.11.).



4.5. Contra-angle

- Never press the contra-angle pushbutton during use or if it is coming to a stop. This will lead to detachment of the instrument or cause the pushbutton to overheat.
- Never remove the contra-angle from the handpiece during operation.
- Only use undamaged root canal instruments. Please refer to the information provided by the manufacturer.
- Only insert the instrument when the contra-angle is stationary.
- Never place your fingers on the moving parts of the instrument while it is running or coming to a stop.
- Before treatment, check the contra-angle for any damage or loose parts.
- Only use the original VDW contra-angle.



4.6. Root Canal Instruments

- Before use, make sure the instrument is securely locked in place.
- Never use continuous rotary instruments in reciprocating mode.
- Never use reciprocating instruments in rotary mode.
- Use the torque and speed settings recommended by the instrument manufacturer.



4.7. iPad

- Use of the iPad is optional.
- Apple, the Apple logo and iPad are trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc.

- Ŵ
- Hygiene measures to prevent cross-contamination are absolutely essential. Use of the Sleeve for iPad mini is therefore compulsory (see Section 12.1.).
- The operating conditions and limitations specified by Apple must be complied with.
- When charging the iPad, maintain the minimum distances from the patient defined in Figure 1, as the iPad does not have a medical charger.

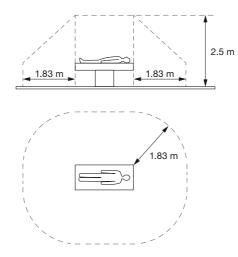


Figure 1 Minimum distance between iPad charger / iPad with plugged-in charger and patient



4.8. Accessories

• Only use original VDW components/accessories and spare parts:

Original VDW accessories	VDW REF
Handpiece	V041185000502
VDW 6:1 contra-angle	V041185000504
Charger with national adapters	V041185000501
Handpiece holder (stainless steel)	V041185000508
Plastic cradle (handpiece holder)	V041185000509
Spray adapter for manual lubrication (contra-angle)	V041185000506
Stand for iPad mini	V041185000500
Case for iPad mini	V041185000510
Sleeve for iPad mini	V041185000507
Handpiece sleeve	V041185000503

 Using other makes of accessories/spare parts can lead to increased emission of electromagnetic interference or to reduced electromagnetic interference immunity.



4.9. Apex Locator

• Only use apex locators approved by VDW.



4.10. Repairs and Defects

- Do not use the device if you suspect damage or defect.
- Repairs, alterations and modifications to the device are not permitted without the manufacturer's
 prior consent. VDW GmbH declines all responsibility if the device has been altered or modified. If
 a defect should occur, contact VDW or your VDW authorised service partner.
- Before opening the housing, the device must be disconnected from the power supply by unplugging the charger from the mains.



4.11. Transport

- Intact devices can be transported by land freight or air freight in the original packaging. The applicable requirements must be met (Table 1).
- Defective devices can also be transported by air freight or land freight in the original packaging. If the battery is defective, the device must not be transported by air freight under any circumstances.
 - Leaking liquid can be an indicator of a defective battery.

Table 1: Standards and regulations that apply to the transport of VDW.CONNECT Drive

	Air freight	Land freight
Intact device or defective device with intact battery	 UN 3481 Lithium batteries in equipment IATA Packing instruction/ 967 Part II Special regulations issued by airlines and national regulations must be complied with. 	 UN 3481 Lithium batteries in equipment ADR: Special provisions/ 188 f) and g)
Device with defective battery	• Not possible	 International, multilateral agreements M 228 and M 259 ADR SV 661 (international, road) Regulations issued by GRS (German Joint Battery Takeback System Foundation) for the transport of waste lithium batteries (FRG, road)

5. Precautions



5.1. VDW.CONNECT App

- Use of the VDW.CONNECT app is optional.
- VDW.CONNECT app updates are binding and serve to enable safe preparation. Install them as soon as possible (see Section 10.9.)
- Messages from other apps must be disabled. VDW recommends closing all other apps.

6. Adverse Reactions

None known.

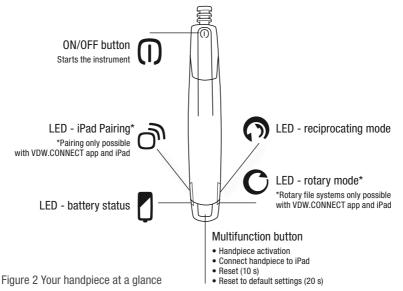
Safety and effectiveness have not been established in pregnant women and children.

7. Step-by-Step Instructions

You will find practical step-by-step instructions on getting started in the "Getting Started" brochure.

8. VDW.CONNECT Drive at a Glance

8.1. LEDs and Buttons

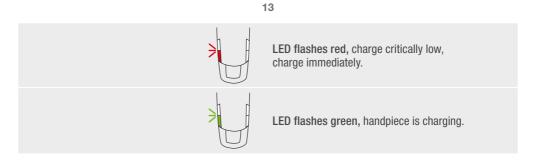


The handpiece switches into standby mode automatically (see chapter 8.3). You do not need a classic ON/OFF switch.

8.2. LED Colour Statuses

The various LEDs/buttons indicate the specific status of the handpiece by changing colours:

Symbol	Button/LED	Status	Meaning
(\mathbf{I})	ON/OFF button for starting the instrument	()	Handpiece ready for operation
		Flashes every 3s	Handpiece in energy-saving mode
		ົ	 Calibration (when using the VDW.CONNECT app with iPad) Flashes: ready for calibration Continuously lit: contra-angle is being calibrated
		\square	Possible error; see Section 11.2.
RO	LED - iPad Pairing	Flashes	Handpiece is connecting to the iPad
			LED continuously lit: handpiece connected to iPad (If you have selected a different colour scheme using the VDW.CONNECT app, the pairing LED is continuously lit in the colour selected)
()	LED - reciprocating mode		Reciprocating mode activated
0	LED - rotary mode		Rotary mode activated
	LED - battery status		Fully charged or still sufficiently charged to be able to perform treatment
			Connect with charging cable; for simultaneous acoustic signals see Section 8.4.



8.3. Standby Mode

To save energy, the handpiece switches to standby mode after a brief period. There are two different steps that can be indicated by the various colour statuses of the handpiece.

Mode	Status of LED/ button	Action to wake up
Standby mode 1 after 5 min of non-use	Flashes every 3 s	Pick up handpiece or press multifunction button
Standby mode 2 after 30 min of non-use		 Press multifunction button (if battery charge is low, connect with charging cable as required) Press multifunction button again to reactivate Bluetooth.

8.4. Acoustic Signals

Situation	Signal
Multifunction button has been pressed	Short confirmation tone (beep)
Battery status	One-time warning signal (beep) if battery status is weak (motor running)> Charge battery Dominant alarm signal (beep) lasting 3 s as soon as battery charge is critical (motor running)> Charge battery
Preparation in reciprocating mode	RECIPROC REVERSE function 2-step warning signal (for details see Section 8.5) in case the instrument is subjected to increased friction.
Preparation in rotary mode	 ASR (Auto-Stop-Reverse) comfort function Acoustic warning signal: beep if torque exceeds about 75% of the preset value
	Intermittent beep in the event of counter-clockwise rotation
	Recommendation: Clean the instrument, briefly adopt a brushing motion to create more space in the root canal, reduce pressure on the instrument; possibly recapitulate with a C-PILOT $^{\odot}$ FILE ISO size 10.

8.5. RECIPROC REVERSE Comfort Function

The RECIPROC REVERSE comfort function is a 2-step warning signal in reciprocating mode that draws attention to increased friction over the entire length of the instrument. This function is enabled by default.

RECIPROC REVERSE tones	Recommendation
First signal: (beep)	 Draws attention to increased friction over the entire length of the instrument. The tone continues as long as the increased friction continues. Therefore it is necessary to perform a lateral brushing motion to enlarge the canal. That relieves the instrument and preparation can continue with the usual motion.
Second signal: (interrupted beep)	 This indicates that the instrument is being subjected to even higher friction. The micromotor switches to clockwise rotation to relieve the instrument. That withdraws the instrument from the root canal. If the instrument is no longer subjected to friction, the motor comes to a stop. Perform steps 1-3 described below. If you press the ON/OFF switch again, the motor runs in reciprocating mode again. Perform steps 4 and 5 described below.
14	 Clean the instrument in the interim stand. Irrigate the canal. Check for accessibility with a C-PII OT[®] FII F

- 3. Check for accessibility with a C-PILOT® FILE ISO size 10.
- 4. Use a lateral brushing motion towards the coronal end (in order to enlarge the canal).
- 5. Then continue with a picking motion.

8.6. Battery Care



Please also follow the charging instructions in the "Getting Started" brochure and heed the warnings in Section 4.4.

The following instructions will help you to ensure that the battery has a long service life:

- If the battery LED on the handpiece lights up red, charge the battery. You can continue treatment during the charging process.
- Charge:
 - the battery no more than once a day.
 - the battery as soon as the battery LED turns red, at the latest when the LED starts flashing red.
 - the battery until it is completely charged every time, i.e. until the battery LED turns green.
- If the battery was completely flat, charging can take up to three hours.
- Continuous operation with the charger connected shortens the life of the battery. VDW recommends working without the charging cable connected.

9. Operation without VDW.CONNECT App



You will find details on getting started without the app in the "Getting Started" brochure.

- Reciprocating mode is preset by default.
 - The settings for operation without the VDW.CONNECT app are solely designed for original RECIPROC[®] instruments. In the event of non-compliance, misuse can occur. For working with instrument systems other than RECIPROC[®], the VDW.CONNECT app is required.
 - If later on you should decide to work with the free VDW.CONNECT app, it can be installed at any time. All you require is a compatible device, e.g. Apple iPad mini. The VDW.CONNECT app is available as free download in the App Store.

10. Operation with VDW.CONNECT App and iPad

In this section you will be quickly familiarised with all the setting options of the VDW.CONNECT app. You can download the VDW.CONNECT app free of charge in the App Store.





Apple, the Apple logo and iPad are trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc.

10.1. User Navigation of the VDW.CONNECT App at a Glance

To enable you to quickly familiarise yourself with the VDW.CONNECT app, here is a brief overview of the app navigation.

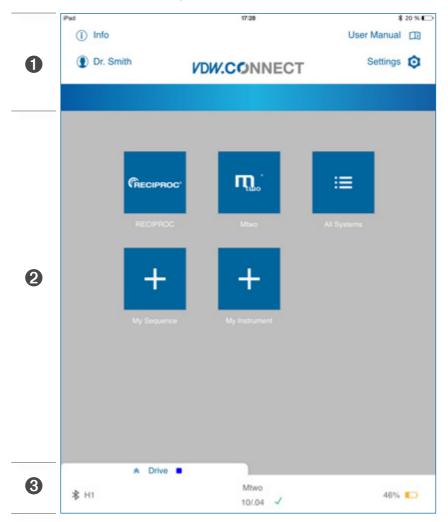
10.1.1. Symbols in the VDW.CONNECT App

Symbol	Explanation	Symbol	Explanation
\bigotimes	Close window or delete entry	<	One step back
公	Back to home screen	\star	Instrument system, instrument sequence or instrument added as a favourite
<u>[</u>]	Instructions for Use	$\overset{\wedge}{\bowtie}$	Instrument system, instrument sequence or instrument has not been selected as a favourite
i	Information about the manufacturer and the app	REV	Reverse rotation in rotary mode
Ø	Settings	↓ Ncm	Difficult canal
	User profile	CAL	Contra-angle: Calibration
	Edit	RR	RECIPROC REVERSE Comfort function
*	Bluetooth connected	*	Bluetooth not connected
	Delete profile		

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10.1.2. Home-Screen

When you start the VDW.CONNECT app on your iPad, the following home screen opens. It is divided into three navigation areas:



• Navigation bar:

- Info about app, connected devices, etc.
- User profiles
- Instructions for Use
- Settings

O Control panel:

- Shortcuts and favourites for instrument systems, sequences and instruments

Status bar:

- Connected handpieces
- Connection status
- Current instrument setting
- Handpiece battery charge status

10.1.3. Navigation Bar





Info

Manufacturer's contact data, version of the app and all connected devices.

Pat	***	10.40
C Back		
	From	
Manufacturier	VDW GmbH	
	Beyerwaldeln, 15 81737 Munioth Gentrary	
	+49 89 62734-0 +49 89 62734-304	
	service Brute-dental.com www.vde-dental.com www.vde-dental.com/comm	unity'
VOW CONNECT App	RC112015-01-21	
File Library	w0112014-11-24	
User Manual	v0.8012014-08-29	
Statistics	Send statistics to VDW	
Compatible With	VOWLCONNECT Drive **	
	IOS 8, iPad mini	
Connected With	VOWLCONNECT Drive TH	90110
Handpiece Firmware	0.4.3.T	
	_	_
A Drive .		
8.11	Niteo 10/04	78%



User profile

Select user profiles and create new ones

	Default Profile	
✓	Dr. Smith	

i

Instructions for Use Instructions for Use in your selected language





Settings

Select units, language and option: "Multifunction Button"

**	Home ()
Settings	
Language	German ())
UH .	tran 🔘
Wultivicion Button	
	Satings Largunge Lar

18

10.1.4. Control Panel: Shortcuts and Favourites

Shortcuts and Favourites provide you with fast access to all available instrument systems, sequences and instruments.



Preset Shortcuts (blue)

The following preset shortcuts (blue tiles) can be found on the control panel:



My Favourites (white)

You have the option of creating your own favourites for instrument systems, sequences and individual instruments. They are shown as white tiles on the control panel.

Favourites (example)	Description	Favourites (example)	Description
107.04 - 607.04	Example: Shortcut to Mtwo [®] sequence 10/.04 – 60/.04	T ,	Example: Shortcut to Mtwo [®] instrument 10/.04

10.1.5. Status Bar



Connection status

Current instrument setting

- Scanning
- Not Connected
- X Connecting
- Serial number (here: H1)
- 🖹 Re-connecting
- Demo Mode (displayed in demo mode only)

10.2.1. Connect Handpiece



You will find details on app installation and connecting of the handpiece to the iPad in the "Getting Started" brochure.

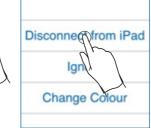
- Make sure Bluetooth is enabled on your handpiece (multifunction button). The pairing LED starts flashing. When the handpiece and the iPad are connected, the pairing LED is continuously lit (in the selected colour).
- Make sure Bluetooth is enabled on your iPad.
- Once you have connected to your handpiece, that handpiece will be automatically connected next time you start the app.

10.2.2. Disconnect Handpiece from the iPad

With the VDW.CONNECT app, you can disconnect a connected handpiece from the iPad. That is useful if you:

- only want to work with RECIPROC®.
- want to connect a new handpiece.
- 1. Tap Drive on the status bar.
- 2. Tap the menu item Disconnect from iPad.
- 3. The handpiece is disconnected from the iPad; the pairing LED is off.



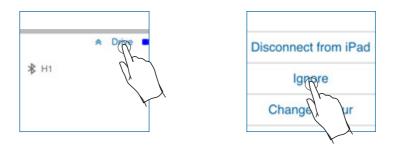


10.2.3. Ignore Handpiece

With the VDW.CONNECT app you can have a connected handpiece ignored by the iPad. That is useful if you do not want a certain handpiece to be automatically connected to the iPad. If you want to reconnect the ignored handpiece, perform the connection steps (pairing) again as described in the "Getting Started" brochure.

1. Tap Drive on the status bar.

2. Tap the menu item Ignore.

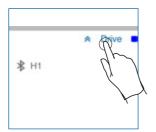


10.2.4. Change the Colour of the Pairing LED

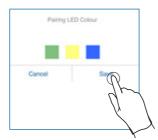
You have the option of changing the colour of the Pairing LED on your handpiece. This can help you if multiple handpieces are being used in your practice and you would like to visually distinguish them from one another (handpiece must be charged and connected to the iPad.)

1. Tap Drive on the status bar.





3. Select the desired colour and tap Save.





4. The Pairing LED of the handpiece and the icon on the status bar of the VDW.CONNECT app are now lit in the selected colour.

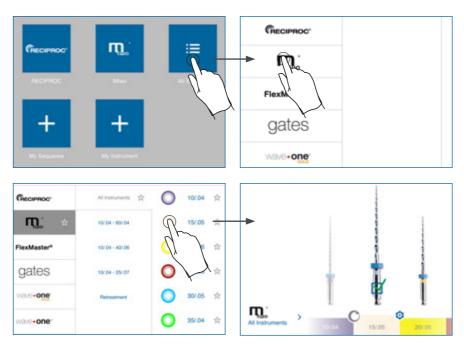


10.3. Working with Instruments

10.3.1. All Systems

With All Systems you can select all instrument systems, sequences and individual instruments.

Example: selection of Mtwo® instrument 15/.05



VDW reserves the right to update the instruments under All Systems. Therefore keep the VDW.CONNECT app up to date for the latest amendments.

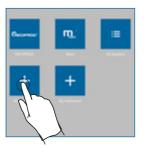
10.3.2. Create and Control My Sequence

With My Sequence you have the option of compiling your custom instrument sequence. Your customised sequence will then be shown as a favourite (white tile) on the control panel.

Create My Sequence

- 1. Tap the blue shortcut My Sequence on the control panel on the home screen.
- First select the instrument system. Then select the instrument that you wish to add to your sequence. The selected instruments appear on the bottom bar.
- 3. You can alter the order of instruments by moving the file entries (Drag & Drop).
- 4. You can delete instruments by clicking the Delete symbol.

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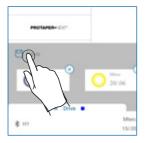
5. Tap Save.



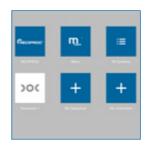
- 6. Give your sequence a name and tap Save.
- 7. Your sequence is shown on the home screen as a white tile.

Mart

15/.05







Change and Delete My Sequence



Remain on the white tile until the Edit pen and the Delete cross appear.

To edit, tap the Edit pen and proceed as described above.

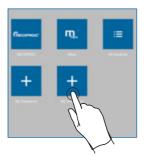
To delete, tap the Delete cross.

10.3.3. Create My Instrument

You have the option of creating a new instrument that is not stored under All Systems.

Comply with the instrument manufacturer's recommendations concerning torque and speed.

- 1. Tap the blue shortcut My Instrument on the control panel on the home screen.
- Enter the manufacturer, system and instrument.
 Select torque and speed settings and then tap Save.
 Please note that not every combination of torque and speed setting is possible.
- 3. Your instrument is shown as a white tile on the control panel.







10.3.4. Save and Delete Favourites

You have the option of saving an instrument system, instrument sequence or instrument as a favourite (white tile).

Save favourites

- 1. Select the desired instrument 2. Example: Selecting a sequence, an instrument system or instrument using All Systems (as described in the previous sections).
- favourite instrument: Tap the empty star opposite the desired instrument. The star now appears filled in colour. The instrument has been saved as a favourite.
- 3. The instrument is now shown as a white tile on the control panel.





Delete favourites

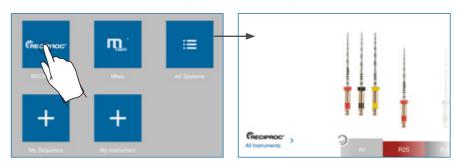
1. Remain on the white tile until the Delete cross appears. Tap the Delete cross to delete.



10.4. Working with Reciprocating Instruments (Taking RECIPROC $^{\mbox{\scriptsize \ensuremath{\mathbb{S}}}}$ as an Example)

10.4.1. Select RECIPROC® Instrument

Tap the blue shortcut RECIPROC[®] on the control panel of your home screen. No further settings are required. You can start with RECIPROC[®] preparation immediately.



Please follow the RECIPROC[®] Instructions for Use, which can be found at www.reciproc.com.

10.4.2. Enable/Disable RECIPROC REVERSE Comfort Function

The RECIPROC REVERSE comfort function is a 2-step warning signal in reciprocating mode that draws attention to increased friction over the entire length of the instrument.

- The RECIPROC REVERSE comfort function is enabled by default. For this purpose refer to Section 8.5.
- For optimal work with RECIPROC[®], VDW recommends having the RECIPROC REVERSE comfort function enabled at all times. If you nevertheless wish to disable the function, proceed as described below.

When you have selected a reciprocating instrument in the VDW.CONNECT app, the "RECIPROC REVERSE" button appears in the lower third of the screen.

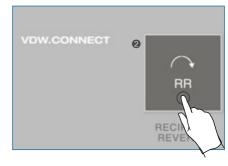
VDW.CONNECT*

• Tap the "RECIPROC REVERSE" button to

disable the RECIPROC REVERSE function

(button appears white).

Tap the "RECIPROC REVERSE" button again to enable the RECIPROC REVERSE function again (button appears grey).



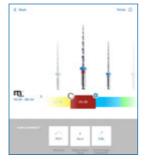
10.5. Working with Rotary Instruments

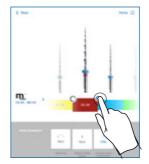
- Please refer to the instrument manufacturer's Instructions for Use.
 - VDW.CONNECT Drive has an Auto-Stop-Reverse function (ASR). If 75% of the preset torque threshold is reached, a warning signal (bleep) sounds. If the preset torque is reached, the ASR function prevents the instrument from being overloaded beyond the preset torque value.
 - The ASR function cannot be disabled.

10.5.1. Change Instrument Settings

You have the option of customising the default instrument settings in rotary mode.

- For safe use, VDW recommends not changing the default torque and speed values set by the instrument manufacturer. Those values are marked with a]-symbol.
- If you nevertheless wish to change the instrument settings, proceed as described below.
- 1. Select the desired rotary instrument.
- 2. Tap the settings wheel icon.
- 3. Select the desired torque and speed.





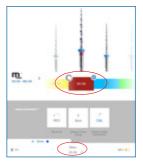
Bear in mind that not all combinations are possible.

At any time you can access the Restore default settings field to restore the settings recommended by the instrument manufacturer.

4. Tap Save to save the entry.

5. Your customised settings are displayed under the instrument name.

The handpiece is adjusted to your settings once a \checkmark appears opposite the instrument name on the status bar.

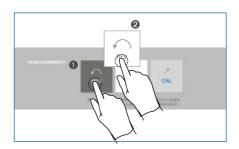


10.5.2. Reverse Rotation

When you have selected a rotary instrument in the VDW.CONNECT app, the REV Reverse Rotation button appears in the lower third of the screen.

• Tap REV to enable reverse rotation (button appears grey).

② Tap **REV** again to disable the function (button appears white).

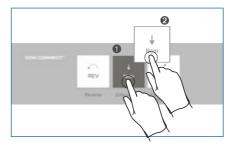


10.5.3. Difficult Canal

When you have selected a rotary instrument in the VDW.CONNECT app, the Difficult root canal button (Ncm) appears in the lower third of the screen.

• Tap Ncm to enable the function (button appears grey).

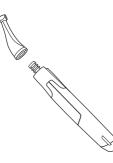
② Tap Ncm again to disable the function (button appears white).



10.5.4. Calibration

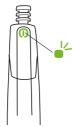
Do not insert an instrument for calibration purposes.

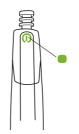
- 1. Attach the contra-angle to the handpiece.
- 2. Select any rotary instrument 3. Tap CAL. via the VDW.CONNECT app.





- 4. The ON/OFF button on the handpiece flashes green: The handpiece is ready for calibration.
- 5. Now press the ON/OFF button (note: after 30 s the handpiece is no longer ready for calibration).
- m)
- 6. You see a progress bar that disappears as soon as calibration has been completed successfully.







10.6. User Profiles

The following settings are assigned to your user profile:

- Favourites
- My Sequences
- My Instruments
- Customised torque and speed settings for individual instruments

In addition, the following settings that you make using Settings are also assigned to your profile:

- Language selection
- Indication of units (torque and speed)
- Option: Multifunction Button (see chapter 10.7.3.)

10.6.1. Create User Profile

1. Tap the profile symbol on the navigation bar 2. Tap New Profile. of your home screen.



3. Enter a name for your profile and tap Save.

	V Dr. S	mith
-	Dr. B	laur
My S		
	Ne	Select
100	d'	
	7	

4. Your user profile has been created and appears on the navigation bar. All the settings that you proceed to make in the VDW.CONNECT app are automatically

assigned to that profile.

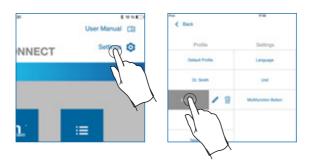
New Profile Dr. Karn



10.6.2. Delete User Profile and Change Profile Name

Before you delete a user profile or change the profile name, switch to any other user profile.

- 1. Tap Settings on the navigation bar of your home screen.
- 2. Tap and hold the desired profile until the Edit pen (change profile name) and the Garbage bin symbol (delete) appear.
- 3. Perform the desired action.



10.7. Settings

In Settings you have the option of selecting the language of the app, defining the units of torque and speed, and the option: Multifunction Button.

10.7.1. Language

- 1. Tap Settings on the navigation bar of your home screen.
- 2. Select the desired user profile.
- 3. Select Language and then the desired language.

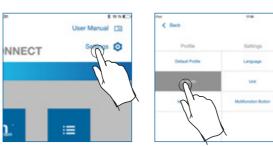






10.7.2. Units

- 1. Tap Settings on the navigation bar of your home screen.
- 2. Select the desired user profile.
- 3. Select Unit and then the desired unit.





10.7.3. Option: Multifunction Button

The option: Multifunction Button enables you to switch to the next file within a sequence by pressing the multifunction button, without having to operate the iPad.

- 1. Tap Settings on the navigation bar of your home screen.
- 2. Select the desired user profile.
- 3. Select Multifunction Button and then enable/disable the option: Next File.





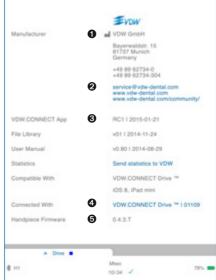


10.8. Info (VDW.CONNECT App and Handpiece)

1. Tap Info on the navigation bar.







No.	Information	
1	Manufacturer	
2	Email	Tap the email address to contact us directly via email.
	Homepage	Tap the web address to find out more about VDW.CONNECT Drive and our products.
3	Versions	
	VDW.CONNECT App	Version of the VDW.CONNECT app
	File library	Version of pre-set values under All Systems
	Instructions for Use	Version of the Instructions for Use
	Statistics	Instrument statistics can be sent to VDW. This is voluntary and statistics will never be sent out without your permission.
4	Compatible with	Devices that can be operated with the app, as well as compatible iPads and iOS versions
5	Connected to	On the list, tap the appropriate device and you will be given more information.
6	Handpiece firmware	Version of the handpiece firmware

10.9. Updates



To ensure safe use of VDW.CONNECT Drive, make sure you are always working with the latest version of the app and the latest handpiece firmware.

10.9.1. App

iPad Operating System

When installing the VDW.CONNECT app, the version of your iOS operating system should not be lower than 8.0.

VDW checks the compatibility of new iOS versions with the VDW.CONNECT app. Do not install an iOS update before VDW has approved it. Check the compatibility of an iOS update on the info page of the VDW.CONNECT app (see Section 10.8.).

Update of the User Manual

VDW reserves the right to change the user manual. In that case an update for your user manual will be available. The prerequisite for updating is an internet connection.

You will be informed whenever an update is necessary. In addition, you can always check under Info whether your user manual is the most current one. In case there is a new version available, the version number appears in blue. Tap the blue version number for updating your user manual.

10.9.2. Handpiece

The handpiece firmware is updated via the app. An update can take a few minutes.

- Before updating, make sure the battery in your handpiece is at least 80 % charged (or connect the handpiece with the charging cable).
- Before updating, make sure the battery of your iPad is at least 60 % charged (or connect the iPad with the charging cable).
- Place the handpiece 1 m from your iPad and only remove it when the update has been completed.
- VDW will inform you of upcoming firmware updates. In addition, you can check the info screen whether your version of the handpiece firmware is still current. If a newer version is available, the version number on the info screen appears in blue. By tapping the blue version number, you can start the update.

10.10. Demo Mode

In Demo Mode, you can test the VDW.CONNECT app and view all the setting options in the app. To do so, load the VDW.CONNECT app onto your iPad from the Apple App Store, start the app and tap Demo Mode.

Press multi-func VDW.CONNECT Dr demo m	ive or continue in
Demc Node	ОК

- • Settings with the VDW.CONNECT app can only be made when you connect the app to a handpiece.
 - Demo Mode is indicated on the status bar.
 - When you connect a handpiece, the app automatically quits demo mode.

11. Troubleshooting

If the device is not operating properly, read the following checklist. If you are unable to solve the problem by referring to the checklist, contact VDW GmbH or a VDW authorised service partner.

To remedy certain problems, it is necessary to perform a reset (reboot) or a factory reset (to restore factory settings) on the handpiece. In such cases, proceed as described below:

Reset (reboot)

- 1. Hold the multifunction button for approx. 10 seconds. While holding it down, all LEDs on the handpiece will extinguish first and then flash white briefly.
- 2. Let go of the multifunction button.

Factory reset (restore factory settings)

- 1. Hold the multifunction button for approx. 20 seconds. While holding it down, all LEDs on the handpiece will extinguish first and then flash white briefly. After another 10 seconds, all LEDs will briefly light up blue.
- 2. Let go of the multifunction button.

Problem	Possible error	Remedy
Running motor cannot be stopped during preparation.	The ON/OFF button is blocked or faulty.	Briefly press the handpiece mul- tifunction button once to stop the motor. Start and stop the motor again. If the error has not been re- medied, contact VDW GmbH or an VDW authorised service partner.
The handpiece cannot be switched on.	• The battery is completely flat (all LEDs off).	Connect handpiece to charger.
	• The handpiece no longer responds (the LEDs are lit but the motor does not respond when the button is pressed).	• Perform reset (see Section 11). The motor automatically switches to ready mode.
	• The multifunction button is faulty.	• Send the device to VDW GmbH or an authorised service partner.

11.1. Checklist

Problem	Possible error	Remedy
The handpiece cannot be connec- ted to the iPad.	The Bluetooth connection has failed.	 iPad: 1. Activate Bluetooth on your iPad under Settings. 2. Sign off the connected VDW.CONNECT devices. 3. Perform a reboot on your iPad. 4. Re-connect your VDW.CONNECT devices again by use of the VDW.CONNECT app. Handpiece: Perform a factory reset (see Section 11).
The contra-angle cannot be calibrated.	The calibration procedure may have been interrupted by increased resistance in the contra-angle.	 If calibration has been inter- rupted, calibrate the handpiece again to rule out the possibility of a motor fault. Clean and lubricate the contra- angle. Start the calibration procedure again.
Handpiece is getting hot	Overheating	The device switches off automatically if it overheats. Allow the device to cool down until it is cool enough to touch.
A RECIPROC [®] instrument has become jammed in the root canal	Treatment was not performed properly.	Remove the RECIPROC [®] instru- ment with pliers by rotating clockwise carefully.

Treatment was not performed properly.

Select reverse rotation, start the handpiece and rotate the instrument out of the root canal

carefully.

A rotary instrument has become jammed in the root canal

11.2. Error Messages

ON/OFF button	LED-Zustand	Possible error	Error number	Remedy
()		Total system failure	1	Perform a factory reset (see Section 11).
		The battery is flat.	2	Charge the battery.
()		The motor has overheated.	3	 Wait a few minutes. Press the multifunction button to reactivate the motor.
()		Motor hardware failure.	4	Perform reset (see Section 11).
()		The battery is faulty.	5	Send the device to a VDW authorised service partner.
()		General hardware failure	6	Perform reset (see Section 11).
()		The sensor of the ON/OFF button is not working properly.	7	Perform reset (see Section 11).
()		The Bluetooth connection is not working correctly.	8	Perform reset (see Section 11).
ົ		It was not possible to complete the calibration procedure.	9	 First remedy Lubricate and clean the contra- angle. Start the calibration procedure again.

			Second remedy1. Change the contra-angle.2. Start the calibration procedure again.
ົ	The battery is not sufficiently charged to perform an update of the handpiece firmware.	10	 Charge the battery until the battery LED is continuously lit green. Perform the software update again.
ເເ	General error in the handpiece firmware	11	Perform a reset (see Section 11).

12. Cleaning, Disinfection and Sterilisation

Regular maintenance of VDW.CONNECT Drive is essential to ensure that work performed is completely hygienic and that the device will have a long service life.

The components of VDW.CONNECT Drive have not been disinfected or sterilised upon delivery. Please perform the necessary steps before the first treatment.

In your responsibility for the sterility of the accessories, always make sure that only validated methods of cleaning/disinfection and sterilisation are used, that the equipment (disinfector, steriliser) is subjected to regular maintenance and inspections and that the validated parameters are maintained in every cycle.

Comply with your national guidelines, standards and requirements for cleaning, disinfection and sterilisation.

12.1. Single Use

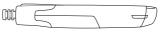
The following infection control measures are obligatory when working with VDW.CONNECT Drive:

- the cover for iPad mini and
- the handpiece sleeve.

Both products are designed for single-use and have to be disposed of and changed after every treatment. In the event of non-compliance, the contamination risk increases.

12.2. Disinfection

In addition to using the handpiece sleeve, clean and disinfect the handpiece regularly. The handpiece is NOT approved for device-based cleaning (washer-disinfector) and sterilisation.



Handpiece

The following components must be cleaned and subjected to disinfection **before the first treatment** and **immediately after every subsequent treatment**. They are not approved for device-based cleaning (washer-disinfector) and sterilisation.

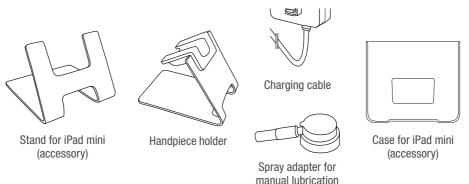


Figure 3 Overview disinfection

Disinfection:

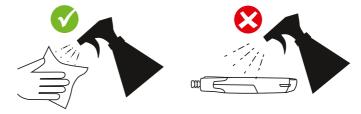
1. Separate the plastic cradle from the stainless steel base of the handpiece holder and take the case off the iPad mini.

aintenance

- 2. In the event of heavy soiling, pre-clean with disinfection wipes.
- 3. After any pre-cleaning, lightly soak a paper tissue or soft cloth in a mild, aldehyde-free disinfection and cleaning solution (bactericidal and fungicidal) and use it to clean/disinfect components. VDW recommends mikrozid[®] AF wipes manufactured by Schülke.
- 4. Thoroughly disinfect surfaces with a soaked wipe (min. 30 seconds), making sure the entire surface is wetted, and allow to act (contact time > 30 minutes). If large surfaces have to be treated, use more than one wipe where necessary.



If you use a disinfectant in the form of a spray, never spray directly onto the handpiece.



- Wear protective clothing
- Only use surface disinfectants that are certified by officially recognised institutes, do not contain chlorine and have been declared aldehyde-free.
- Please refer to the manufacturer's information on use of the disinfectant.
- When subjecting the handpiece to disinfection, ensure that the charging cable is not connected and that the charging socket is closed.

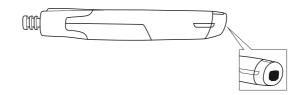


Figure 4 Closed charging socket for handpiece disinfection

• Never place the components in a washer-disinfector, autoclave or ultrasonic bath.

12.3. Cleaning, Disinfection and Sterilisation

The contra-angle must be cleaned, disinfected and sterilised **before the first treatment and after every subsequent treatment**. Clean and disinfect the contra-angle **immediately** after every treatment in order to prevent debris from clinging. According to a recommendation by the Robert Koch Institute, a distinction must be made between device-based and manual reprocessing, whereby device-based reprocessing is always preferable. In the following you will find instructions concerning device-based and manual reprocessing, lubrication and sterilisation.



Figure 5 Contra-angle

Comply with the following instructions before you commence cleaning, disinfection and sterilisation.

- VDW recommends device-based cleaning in a washer-disinfector. Please refer to the manufacturer's information concerning equipment, cleaning agents and rinsing agents.
- Sterilise the contra-angle after you have performed manual or device-based cleaning and disinfection as well as lubricate.



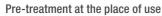
- preparation at the point of use
- and manual pre-cleaning.
- · Always wear protective clothing

Reprocessing limitation

• Frequent reprocessing has only minimal effects on the service life of contra-angles. The end of the product service life is normally dependent on wear and damage caused by use.



12.3.1. Pre-Treatment



- Remove the root canal instrument and separate the contra-angle from the handpiece.
- **Transport:** No special transport container is required for the contra-angle. Transport is not subject to any special requirements.
- Wear protective gloves when processing and transporting the contra-angle.



Manual pre-cleaning

- Manual pre-cleaning is required for an efficient cleaning procedure. Machine-based reprocessing of medical devices also begins with manual cleaning.
- In the event of heavy soiling, pre-clean with disinfection wipes immediately after use. Only use cleaning agents that do not have a protein-binding effect. Rinse the products under running water if necessary in order to remove any coarse soiling.
- It is not necessary to dismantle the contra-angle for this purpose.
- Do not place the contra-angle in a disinfectant solution or in an ultrasonic bath.

12.3.2. Manual Reprocessing

If you clean and disinfect the contra-angle manually, heed the instructions below and proceed as follows:

Manual cleaning

- Equipment: Cleaning tool (brush).
- For 5 minutes, rinse and brush under running, deionised water (DI) water, or water that has this degree of purity (<38°C).
- Remove any liquid residues (ultra-absorbent cloth, particle-free compressed air).



Manual disinfection

- For disinfection purposes VDW recommends the use of mikrozid® AF wipes manufactured by Schülke.
- Thoroughly disinfect surfaces with a soaked wipe (min. 30 seconds), making sure the entire surface is wetted, and allow to act (exposure time > 30 minutes). If large surfaces have to be treated, use more than one wipe where necessary.
- Make sure the surface is completely dry after disinfection.
- Only use surface disinfectants that are certified by officially recognised institutes, do not contain chlorine and have been declared aldehyde-free. Please refer to the manufacturer's information on use of the disinfectant.

12.3.3. Device-based Reprocessing

If you clean and disinfect the contra-angle in a reprocessing device, heed the instructions below and proceed as follows:



Automatic cleaning / disinfection

- Equipment: Washer-disinfector conforming to ISO 15883, e.g. Belimed WD, programme: neutral.
- Cleaning solution: e.g. 0.5% (v/v) deconex 24 LIQ, Borer Chemie
- Neutralising solution: e.g. 0.25% (v/v) deconex 26 plus, Borer Chemie
- Cleaning at 65°C, holding time 5 minutes
- Disinfection at 90°C, holding time 5 minutes
- The water quality to be recommended for cleaning is deionised (DI) water, or water that has this degree of purity.



• Drying is performed automatically during the drying cycle in the washer-disinfector. Make sure the contra-angle attachment is completely dry after thermal disinfection. Remove any liquid residues with particle-free compressed air.

12.3.4. Lubrication

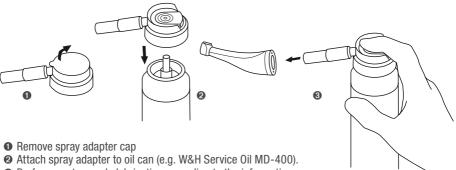
It is essential to subject the contra-angle to lubrication after every internal cleaning procedure, before every sterilisation or after 30 minutes of use, but at least once a day.

Lubrication

Lubricate the contra-angle immediately after thermal disinfection.

- When performing contra-angle lubrication, ensure that no oil penetrates the handpiece. Contamination of the handpiece with oil can damage it and have a negative impact on safety when it is being operated.
- Use the spray adapter included for manual lubrication
- VDW recommends the use of a fully automatic reprocessing device for the contra-angle, e.g. the Assistina from W&H.

Please perform the following steps for manual lubrication:



Perform contra-angle lubrication according to the information in the Instructions for Use of the oil spray can.

Contra-angle trial run after lubrication

- 1. Attach the contra-angle to the handpiece.
- 2. Hold the handpiece upside down.
- 3. Run the handpiece for 30 seconds to remove any excess oil.
- 4. If dirt emerges, repeat the entire hygiene and lubrication process.
- 5. Wipe the contra-angle with a paper tissue or a soft cloth.

Calibration of the contra-angle

- Always calibrate when the contra-angle has been subjected to lubrication or has been exchanged after sterilisation. For this purpose, use the calibration function in the VDW.CONNECT app (Section 10.5).
- Calibrate without any instrument attached.

If you only use the handpiece in reciprocating mode (without the app), no calibration is required.

12.3.5. Sterilisation

Packaging

Shrink-wrap the contra-angle in sterile barrier packages conforming to EN 868-5.

Sterilisation

- Please refer to the information provided by the device manufacturer.
- Clean and disinfect before sterilisation. The contra-angle should also be lubricated before sterilisation.
- Make sure you only remove dry sterile items.
- Maximum sterilisation temperature 135 °C (275 °F).
- The sterilisation validation procedure must be performed in compliance with ISO 17665 (valid Installation Qualification and Operational Qualification (IQ and OQ) and product-specific Performance Qualification (PQ)).

Approved Sterilisation Procedure

- Comply with your national guidelines, standards and requirements for cleaning, disinfection and sterilisation.
- Steam sterilisation with fractionated pre-vacuum method B, in accordance with EN 13060 or EN 285.
- Sterilisation holding time at least 4 minutes at 132 °C or at least 30 minutes at 121 °C.
- The fast sterilisation procedure and the sterilisation procedure with non-packaged accessories are not permissible. In addition, do not use hot-air sterilisation, radiation sterilisation or sterilisation with formaldehyde, ethylene oxide or plasma.

Storage

Store sterile items in a dry, dust-free place at room temperature.

Additional information

- Before resuming operation: wait until the contra-angle attachment has cooled down and is completely dry.
- Contra-angles must be checked for damage before they are reused. Damaged products must be replaced.



13. Disposal

Comply with your national regulations, guidelines and requirements for the disposal of end-of-life electrical equipment and batteries. Specialised dental dealers will be pleased to provide you with country-specific information concerning disposal.

Make sure the product or battery is not mixed with other types of waste when it is being disposed of. Prior to disassembly and disposal, your device must not be contaminated and must have been completely reprocessed (Cleaning/Disinfection/Sterilisation).

14. Warranty

- 1. VDW GmbH certifies that the device has been properly designed, that top-quality materials have been used, that all the necessary tests have been performed and that the device complies with the relevant laws and regulations.
- 2. Full performance capability of VDW.CONNECT Drive is covered by a 12-month warranty and that of the contra-angle is covered by a 24-month warranty that commences on the date of delivery to the customer (as indicated on the delivery documents bearing the serial number of the product, issued by the seller upon sale).
- 3. Only within the term of the warranty is the customer entitled to warranty services and only on condition that he informs VDW GmbH of the defect in writing within two months after the date when the defect was discovered.
- 4. In the event of a substantiated claim, the repair will be performed as soon as possible by VDW's Technical Service or a VDW authorised service partner.
- 5. This warranty only covers the exchange or repair of individual components or parts that are affected by manufacturing defects. The costs incurred by the dental dealer's technical personnel for visiting the customer and the customer's cost of packaging will not be reimbursed by VDW GmbH. The customer is not entitled to file claims with VDW GmbH that go beyond repair, e.g. indemnity claims. This warranty does not cover any compensation for direct or indirect personal injury or damage to property of whatever nature. The customer is not entitled to demand compensation for device outage times.
- 6. The warranty does not cover losses where VDW GmbH produces evidence that they have been caused by negligence on the part of the user with regard to normal maintenance (as indicated in the Instructions for Use), especially when: subjecting the battery to charging, discharging and maintenance in accordance with the Instructions for Use and with regard to careful and regular maintenance of the contra-angle.
 - The warranty explicitly excludes defects that: have been caused by damage in transit to VDW GmbH/ to a service partner authorised by VDW for the purpose of repair, have been caused by atmospheric events such as lightning strike, fire and moisture.
 - This warranty is automatically rendered void if the product has been improperly repaired, modified or otherwise tampered with by the user or unauthorised third parties.
- 7. The warranty is only valid if the device sent in for repair is accompanied by the invoice confirming the date of delivery of the product.
- 8. Legal claims, resulting from product-liability law for example, and claims filed with the person from whom the customer purchased the product, especially ones filed with the dental dealer, shall remain unaffected.

15. Exclusion of Liability

In the following cases the manufacturer declines all responsibility:

- 1. Use of VDW.CONNECT Drive for purposes and applications that differ from the specific requirements made in these Instructions for Use.
- 2. Cleaning, disinfection and sterilisation methods contrary to the directions in these Instructions for Use.
- 3. Contra-angle maintenance contrary to the directions in these Instructions for Use.
- 4. Work or repairs performed by unauthorised persons.
- 5. VDW accepts no liability for damage caused to or by the iPad.
- 6. Rights under the warranty or statutory guarantee are rendered void if the device is opened without permission.
- 7. Electrical installations in the room must meet the provisions of IEC 60364-7-710 ("Installation of electrical equipment in rooms used for medical purposes") and the regulations applicable in your country.
- 8. If you have any questions, contact your dealer or VDW GmbH.

16. Technical Data

Manufacturer	VDW GmbH - Bayerwaldstr. 15, 81737 Munich, Germany
Model	VDW.CONNECT Drive
Dimensions	206 mm x 24.6 mm x 24.8 mm
Material	PBT/PET, Stainless steel 316L, Silicone
Weight	180 g
Contra-angle	Contra-angle compatible with rotary and reciprocating instruments, equipped with a 2.35 mm shaft conforming to ISO 1797-1:2011, Type 1
Power supply	Lithium ion battery: 3.6 V, 2000 mAh
Charger power supply	100 - 240 V
Frequency	50 - 60 Hz
Charger nominal power input	5.5 VA
Torque range	5 mNm - 50 mNm (0.5 Ncm - 5 Ncm)
Speed range of the micromotor shaft	1200 - 5100 rpm (in rotary mode)
Electrical safety class	Class II
Applied part	BF (contra-angle)
Safety level in the presence of flammable anaesthetic gas mixtures or oxygen	Not suitable for use in the presence of flammable anaesthetic gas mixtures or oxygen.
Operating mode	Rotary and reciprocating
Ambient conditions	 Use: in enclosed spaces Ambient temperature: 15 °C / 35 °C Relative humidity: < 80 %; non-condensing at 0° Operating altitude < 2000 m above sea level Maximum housing temperature according to IEC 60601-1:2005
Medical device classification	Class IIa MDD/93/42, ANNEX IX, Rule 9
Transport and storage conditions	 Ambient temperature: -20 °C / +50 °C Relative humidity: 20 % - 80 %, non-condensing at > 40 °C Atmospheric pressure: 50 kPa - 106 kPa
Bluetooth	Bluetooth 4.0 low energy Device contains transmitter with: FCC ID: RFRMSR IC-ID: 4957A-MSR

17. EMC Tables



Manufacturer VDW GmbH • Bayerwaldstr. 15 • 81737 Munich • Germany Phone +49 89 62734-0 • Fax +49 89 62734-304 service@vdw-dental.com • www.vdw-dental.com