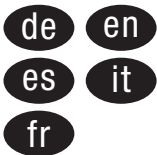


Instructions For Use



VDW.SILVER®

Electronic digital control system for Endodontics



Endo Easy Efficient®



Congratulations on your purchase of the **VDW.SILVER®** electronic digital control system for Endodontics.

This manual is supplied for safety reasons and must be considered an integral part of the system. We recommend always keeping it close at hand.

Changes to the content of these instructions are reserved without prior notice.

Please do not hesitate to contact VDW for help with any doubt or problem that may arise during consultation of this manual.

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1. Components

The **VDW.SILVER®** unit is made up of the components listed below.

1. Central unit
2. Micromotor with cable and connector
3. Foot control
4. External battery charger: Cincon Electronics Co. Ltd, model TR30RAM120
5. Instructions for Use
6. Reduction gear contra-angle: Sirona VDW 6:1

Note: The contra-angle, complete with Instructions for Use, is wrapped separately and packed with the **VDW.SILVER®** device. Refer to the contra-angle manual for instructions for use and statement of compliance with the Directive 93/42/EEC concerning Medical Devices.

2. Getting Started

2.1 General Warnings and Conditions for Operation

General Warnings

- Prior to installation, check the device for damage. Report any damage sustained during shipping to your retailer within 24 hours of receipt of the device.
- Do not install the device in damp places or in places where it will come into constant contact with liquids of any kind.
- Do not expose the unit to direct or indirect sources of heat.
- This device is designed to be used only by specialized personnel. Do not use the device for uses other than those for which it is specifically designed.
- Do not in any way alter or modify the product characteristics; VDW GmbH declines any and all responsibility in case of alteration or modification of the device.
- The device emits electromagnetic radiation at levels inferior to the limits recommended by the pertinent laws and regulations in force.


Ambient Conditions for Operation

- Use: indoors
- Altitude: less than 3000 m
- Ambient temperature: 15°C - 42°C
- Relative humidity: < 80%
- The original packing materials may be stored in ambient conditions of -20°C to +50°C with relative humidity of less than 90%.
- Do not use the system in the presence of free oxygen or flammable gas mixtures.
- Do not crimp the cable exiting the handpiece.
- Never place the **VDW.SILVER®** in autoclave or ultrasound tank.

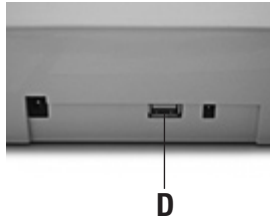


This symbol indicates that the product falls under the WEEE Directive (Directive 2002/96/EEC) concerning waste electrical and electronic equipment. This type of waste must be collected and disposed of correctly.

Warnings

- The warnings below are supplied for safety reasons. Read carefully before installing and/or using the system.
- It is of the utmost importance that this manual be preserved for future consultation. The manual must accompany the system in all cases of sale or other transfer in order that the new owner be aware of its operational characteristics and the relative precautions and warnings.
-  This symbol, found on the unit labels, reminds the user to consult this manual.
- **VDW.SILVER®** is a system for Endodontics. The system meets the requirements of Directive **93/42/EEC** concerning **Medical Devices**.
- The system may be used only in suitable locations and only by specialized physicians licensed to practice dentistry.
- **VDW.SILVER®** requires special precautions as regards electromagnetic compatibility (EMC) and must be installed and commissioned in strict conformity with the EMC information provided in this instruction manual.
- In order to avoid possible risks due to electromagnetic interference, do not use any electrical medical devices or electrical devices of any other kind in proximity to the **VDW.SILVER®** system. The electromagnetic radiation emitted by the device is inferior to the recommended limits set forth in pertinent regulations in force (**EN 60601-1-2**).
- Follow the manufacturer's instructions for use and disposal of the Endodontic files. Endodontic files are not supplied with the **VDW.SILVER®**.

- **Use only the Sirona VDW 6:1 contra-angle with VDW.SILVER®. The accuracy of the torque and rotation speed is guaranteed only when the Sirona VDW 6:1 contra angle is used.**
- The battery charger must be supplied at a voltage in the range: 100 – 240 V (+/- 10%), 47-63 Hz. Use only original parts.
- Should any anomalies arise during operation, suspend work and contact our technical service center.
- **Never install an external PC storage unit (hard disk) to the VDW.SILVER® (D) USB socket. Never use a commercial female-female USB cable to connect the VDW.SILVER® system to a PC.**
- **The USB socket is for exclusive use by authorized service centres for maintenance purposes.**



The manufacturer declines any and all responsibility in the case of:

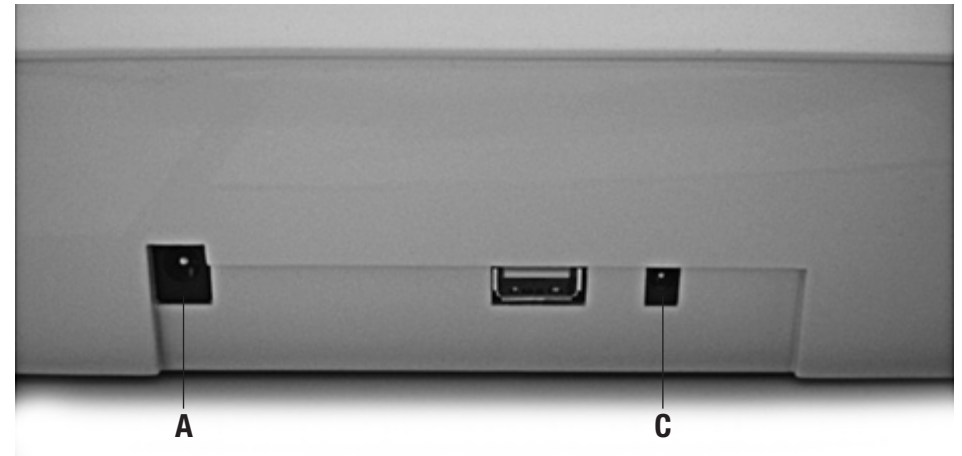
- use of the device for uses different from those specified in the instructions for use and maintenance.
- work or repairs performed by persons not authorized by the manufacturer or by the importer on their behalf.
- connection of the system to an electrical supply not in conformity with the provisions of the IEC 364 standard.
- **use of non-original components or components different from those specified in the STANDARD COMPONENTS section.**

2.2 Installation

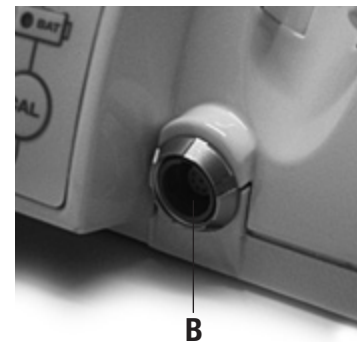
1. Carefully remove the unit and the accessories from their packing and place them on a flat surface.
2. Check that all the components listed in the STANDARD COMPONENTS section are present.
3. To charge the battery: insert the connector of the external battery charger in jack connector (A) on the back of the unit. (See 2.3 for battery charging).

⚠ Attention: Before using the **VDW.SILVER®** on battery power for the first time the batteries must be fully charged! Alternatively, the **VDW.SILVER®** can be used on mains power supply.

4. Insert the foot control connector in the jack connector (C) on the back of the unit.
5. Insert the micromotor connector into the 9-pin metal socket (B) on the front of the unit.



6. When disconnecting the cables, always grasp by the central part of the connector and pull outwards.
7. Attach the VDW 6:1 contra-angle to the micromotor. Please pay attention to the VDW 6:1 contra-angle instructions for use.
8. Disinfect the keypad and micromotor before the first use and before each use on a new patient.



2.3 Battery

VDW.SILVER® is equipped with a Nickel-Metalhydride (NiMH) battery. The battery should be fully charged before use.


Do not open the unit to replace the battery for any reason. The battery can be replaced only by an authorized service center.

When connecting for charging, check that the green LED on the charger is lit to show that the charger is properly connected to the power supply.

 LED (4) indicates battery condition:

Green: indicates that the battery has sufficient capacity.

Flashing red: indicates that the battery needs to be charged and the device can operate on battery power for only a few minutes. In the last seconds before the motor switches off, there is an acoustic warning signal and the following is shown in the display:

 In this case, connect the motor immediately to the battery charger. It is possible to use the **VDW.SILVER®** while it is charging! If the device has switched off, it is only possible to continue treatment when the device has been connected to the mains supply by means of the battery charger.




Flashing orange: indicates that the battery charger is correctly connected to socket A on the back of the unit and that the battery is charging. When charging is complete, the LED switches to green. If the battery is charged while the unit is switched off, the LED will remain green as long as the battery charger is connected to the supply socket. The unit can operate on battery supply for about 2 hours; battery charging requires about 3 hours. The unit may be used normally during battery recharging without appreciable increase in charging time since the **VDW.SILVER®** battery charger is sufficiently powerful to directly power the micromotor while the battery is charging.

Warnings

In order to ensure good battery life, we recommend always working with battery power and recharging the battery only when it is fully discharged. Do not allow the battery to charge for periods longer than that required to fully charge, and in any case never for more than 12 consecutive hours. Should any liquid exit the machine that may be attributed to battery leaks, interrupt work immediately and send the device to an authorized service centre for battery replacement. It is dangerous to use the device if the battery is leaking. Do not attempt to open the device to replace the batteries. This is dangerous due to the risk of short-circuit. Opening the device will invalidate the warranty.

3. Description

3.1 Keypad

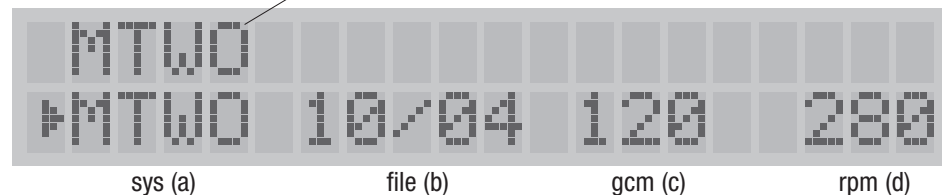
1. **POWER:** Switches the unit on and off.
2. **CAL:** Calibrates the contra-angle to ensure torque accuracy whenever the contra-angle is replaced or lubricated.
3. **ASR:** Activates the auto-reverse, and stop functions which occur automatically when the preset torque has been reached. Also activates reverse only function. The three functions are indicated by the colour of the integrated diode (see 4.3).
4. **BATTERY:** Signals that the battery requires recharging, that the battery is being charged and that charging is complete (see 2.3).
5.  **CONFIRM:** Used to confirm modifications to the torque and speed settings and to reload the default parameters when used together with the power button.
6. / 8.  : Scrolls right/left in the lower row of the display: through the file system, file, torque and speed fields in order to activate the fields which can then be changed by + / -. The field which is active is indicated by an arrow.
7. / 9. + / -: Scrolls through the selected display field (file system, file, torque and speed) and can be used to change torque and speed settings.



3.2 Display

When the unit is switched on for the first time, it will display a welcome screen and then it will show the information below. On following uses, it will display the first file in the system last used before switching the unit off or the last file used before switching into standby mode.

Description



Using **◀** and **▶** it is possible to move right and left through the following:

- sys (a) displays the selected NiTi System (MTWO®, FLEXMASTER®, Dr's Choice)
- file (b) displays the selected NiTi File (10/04, 15/05, 20/06, etc....)
- gcm (c) displays the preset torque limit. Torque is shown in g/cm (grams-force per centimetre. 1 g-cm = 0.0981 Nmm)
- rpm (d) displays the instrument rotation speed in rpm (revolutions per minute)

With the **+** and **-** keys the choice boxes for the NiTi systems and files can be navigated and the values for speed and torque can be changed.

3.3 Foot Control

The **VDW.SILVER®S** micromotor can be started with the foot control. The micromotor will remain in operation as long as the pedal is held down.

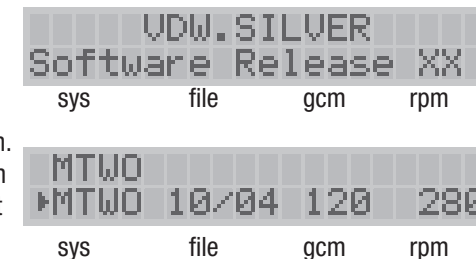
Alternative rotation of the file: the motor may be started by holding down the Confirm button **✓** (5) for 1.5 seconds. The motor can be stopped again by pressing any key or the foot control. As a safety measure, when started with the **✓** button, the motor will stop automatically after 5 minutes should it not be stopped by pressing a key or the foot control.

4. Operation

4.1. Switch-on, Standby Mode and Switch-off

Switch-on

Press the power button to switch on the unit. A welcome screen showing the software version will be shown for approx. 2 seconds. The first time it is turned on, the unit will automatically be set to the MTWO® file system. On following uses, it will display the first file in the system last used before switching the unit off or the last file used before switching into standby mode.



Standby Mode

After 10 minutes of non-use, the unit will automatically enter the standby mode to conserve battery power. The display will switch off and the green LED on the power switch will flash. To exit the standby mode, press any key or the foot control: the device will switch on and unit function will resume from the last screen displayed prior to entry in standby. After 30 minutes in standby mode, the device will switch off to conserve battery power. It can be switched on again by pressing the power button.

Switch-off

Press the power button to switch off the unit. The battery LED (4) will go out unless the battery is charging.

4.2 Calibration

Connect the 6:1 contra-angle to the micromotor and press the CAL button. The micromotor will turn to measure contra-angle inertia. Warning: during calibration, the micromotor will vary its speed from the minimum value (1500 RPM on the drive shaft) to the maximum value (6000 RPM on the drive shaft).

Note: the 6:1 contra-angle reduces the speed so that the instrument will rotate at the speed shown in the display.

Calibrate every time the contra-angle is lubricated or replaced after sterilizing.

Note: It is not necessary to insert a file into the contra-angle for calibration. However, if a file is inserted it will not disturb the calibration process.

During the calibration process the display will read:



When calibration has been completed, it will stop automatically.

Should you at any time wish to stop the calibration process, press any key or the foot control. The display will read:



Possible error warnings

Error 1: The micromotor is not properly connected to the unit. Check the connection.

Error 2: The contra-angle has a high resistance during rotation. Check the contra-angle. If necessary, lubricate.



4.3 ASR: Automatic Stop Reverse

On delivery, the ASR function is active (green LED). The function can be changed by pressing the ASR key. The LED will change colour according to the function selected:

- **Green LED.** When the preset torque is reached, the micromotor will turn automatically in reverse direction (anti-clockwise) until the file no longer encounters resistance, at which point it will automatically revert to forwards rotation (clockwise).
- **LED off.** When the preset torque is reached, the micromotor will stop. Release pressure on the foot control and then press down again to start the motor turning in reverse direction (anti-clockwise). When the file no longer encounters resistance it will automatically revert to forwards rotation (clockwise).
- **Red LED.** The micromotor will turn in reverse (anti-clockwise) with no torque control.

When the unit is switched off and then back on, it will return to the last setting used before it was switched off.

4.4 Audible Tones and Signals

VDW.SILVER® incorporates a series of audible tones and signals that facilitate use. The + and ►| keys have a high-pitched tone; the - and |◀ keys have a deep tone. An intermediate tone is emitted every time ASR is pressed.

All the audible signals are activated on delivery of the unit:

1. Warning signal when torque exceeds 75% of preset value.
2. Intermittent signal during reverse rotation of the micromotor.

To deactivate the audible signals

Press ►| and |◀ together: a double deep tone will sound and the following message will be displayed for 1 second.



To reactivate the audible signals, press ►| and |◀ together: a double high-pitched tone will sound and the following message will be displayed for 1 second:



4.5 Selecting a File System

See description of Keypad 3.1 and Display 3.2.

The file system shown in the upper row of the display is the selected file system. To choose a different file system (MTWO®, FLEXMASTER® or Dr's Choice), the file system field must be active.

The field which is active is indicated by an arrow ►|

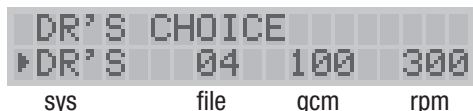
If the System Field is not active, use the |◀ key to scroll back to the System Field which will automatically activate it.

Then press the + and - keys until the display selects the desired system. It is not necessary to confirm the selection. The file system shown in the display is the selected system.

The display then reads, for example:



Or



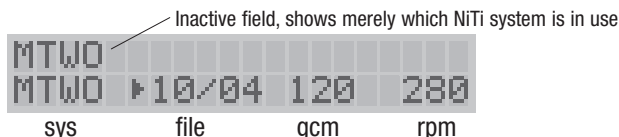
Each time the file system is changed the unit will display the first file in that system's sequence. It is sufficient to press the foot control which will activate the File Field and rotate the instrument. It is not necessary to confirm selection of the file. The setting shown in the display is the selected setting.

4.6 Selecting a File

When a file system has been selected, the first file in the sequence will automatically be shown in the display. There is no need to confirm selection. Simply press the foot control to rotate the file. This also activates the File Field (b).

To select the next file in the sequence, press the + key.

To select the previous file in the sequence, press the - key.



Note

Torque and speed can be individually adjusted through actuation of the + and - keys. If torque or speed values are changed, the corresponding displays blink. The available range of torque lies between 20 and 410 gcm, meaning 40 levels for each 10 gcm. The following speeds can be selected: 250, 280, 300, 500 and 1000 rpm.

4.7 Dr's Choice Individual programme

15 generic instrument settings can be saved in the Dr's Choice Programme. This permits the user to compile his own instrument sequence independently of file producer or recommended sequences.

Default Values

For convenience, **VDW.SILVER®** is delivered with 15 default values programmed into the Dr's Choice. To change these settings simply overwrite them as described on next page "Programming Dr'Choice".

To revert to factory default settings see 5.2.

The default values are:

| File Position | gcm | rpm | File Position | gcm | rpm |
|---------------|-----|-----|---------------|-----|-----|
| 01 | 30 | 300 | 09 | 220 | 300 |
| 02 | 50 | 300 | 10 | 250 | 300 |
| 03 | 70 | 300 | 11 | 270 | 300 |
| 04 | 100 | 300 | 12 | 300 | 300 |
| 05 | 120 | 300 | 13 | 320 | 300 |
| 06 | 150 | 300 | 14 | 350 | 300 |
| 07 | 170 | 300 | 15 | 400 | 300 |
| 08 | 200 | 300 | | | |

Programming Dr's Choice

The Dr's Choice system permits 15 torque/speed settings to be saved.

1. Select the Dr's Choice system by activating the System Field with the \leftarrow key if necessary and scrolling through the systems with keys + and - until "Dr's Choice" is shown in the display.
2. Press the \rightarrow key once to move to the File Field. The first file position will be shown. To select a different file position, use the + and - keys.
3. When the desired file position has been selected (indicated by an arrow), press the \rightarrow key to move to the Torque Field. The Torque Field will be indicated by an arrow. Use the + and - keys to select the desired torque setting. When the torque value is changed it will flash. The available torque range is from 20 to 410 g-cm; that is, 40 steps of 10 g-cm each.
4. After selecting the desired torque, it is necessary to save the setting by pressing the confirm key \checkmark once. The torque field will then stop flashing. If the \checkmark key is not pressed to save the setting, the setting cannot be used and will be lost once a different file setting is selected.
5. Press \rightarrow to move to the Speed Field. It will be indicated by an arrow. Use the + and - keys to select the desired speed setting. When the speed value is changed it will flash. The following speeds may be selected: 250, 280, 300, 500, and 1000 rpm.
6. After selecting the desired speed, it is necessary to save the setting by pressing the confirm key \checkmark once. The speed field will then stop flashing. If the \checkmark key is not pressed to save the setting, the setting cannot be used and will be lost once a different file setting is selected.

5. Standard Settings

5.1 Torque and Speed Settings

The following torque and speed settings are programmed in **VDW.SILVER®** for **MTWO®** and **FLEXMASTER®**.

| | gcm | rpm | ASR | | gcm | rpm | ASR |
|--------------------|------------|------------|------------|--------------------|------------|------------|------------|
| MTWO® | | | | FLEXMASTER® | | | |
| 10/04 | 120 | 280 | on | 06/25 | 90 | 280 | on |
| 15/05 | 130 | 280 | on | 06/20 | 60 | 280 | on |
| 20/06 | 210 | 280 | on | 06/15 | 40 | 280 | on |
| 25/06 | 230 | 280 | on | 04/40 | 130 | 280 | on |
| 30/05 | 120 | 280 | on | 04/35 | 100 | 280 | on |
| 35/04 | 120 | 280 | on | 04/30 | 90 | 280 | on |
| 40/04 | 160 | 280 | on | 04/25 | 60 | 280 | on |
| 25/07 | 200 | 280 | on | 04/20 | 30 | 280 | on |
| Retreatment | | | | 04/15 | 30 | 280 | on |
| 15/05 | 30 | 280 | on | 02/15 | 20 | 280 | on |
| 25/05 | 120 | 280 | on | 02/20 | 20 | 280 | on |
| | | | | 02/25 | 40 | 280 | on |
| | gcm | rpm | ASR | 02/30 | 50 | 280 | on |
| FLEXMASTER® | | | | 02/35 | 80 | 280 | on |
| IntroFile | 140 | 280 | on | 02/40 | 100 | 280 | on |
| 06/40 | 190 | 280 | on | 02/45 | 150 | 280 | on |
| 06/35 | 160 | 280 | on | 02/50 | 190 | 280 | on |
| 06/30 | 120 | 280 | on | 02/60 | 250 | 280 | on |
| | | | | 02/70 | 410 | 280 | on |

5.2 Factory Default Parameters

It is always possible to return to the original unit parameters (factory defaults). With the **VDW.SILVER®** switched off, press and hold down the **✓** key and press the power switch. The **VDW.SILVER®** will switch on and the display will read:



6. General Precautions

6.1 Undesired Effects

To date there have been reported no contra-indications or undesired effects deriving from normal use of the **VDW.SILVER®** in a clinical setting. VDW GmbH declines all responsibility for events deriving from clinical use of the equipment in question and in particular in the case of breakage of the file in the root canal space.

⚠ Attention: Do not touch the pins on any of the connectors or make connections with these connectors.

For transmitters whose maximum nominal output is not specified in the above table, the recommended working clearance *d* in meters (m) can be determined using the equation in the corresponding column, where *P* is the maximum nominal output of the transmitter in watts (W) specified by the transmitter manufacturer.

👉 Note: These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is influenced by their absorption and reflection by buildings, objects and persons.


6.2 Electromagnetic emissions

VDW.SILVER® is intended for use in the electromagnetic environment specified below. The customer or the user of the unit should assure that it is used in such an environment.

| | | |
|--|------------------------------------|---|
| RF emissions CISPR 11 | Group 1 | The device uses HF energy only for its internal function. The HF emission is therefore very low, and it is improbable that electronic devices in close proximity might be disturbed. |
| RF emissions CISPR 11 | Class B | The device is intended for use in all facilities, including residential areas and in any facilities connected directly to a public power supply providing electricity to buildings used for residential purposes. |
| Harmonic emissions IEC 61000-3-2 | Not applicable power output < 50 W | |
| Voltage fluctuation/ flicker emissions IEC 61000-3-3 | Compliant | |

6.3 Electromagnetic immunity

VDW.SILVER® is intended for use in the electromagnetic environment specified below. The customer or the user of the **VDW.SILVER®** should assure that it is used in such an environment.

| Immunity test | Test level ICE 60601 | Compliance level | Electromagnetic environment - guidance |
|--|--|--|---|
| Electrostatic discharge (ESD) according to IEC 61000-4-2 | ± 6kV contact discharge ± 8 kV air discharge | ± 6kV contact discharge ± 8kV air discharge | Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst according to IEC 61000-4-4 | ± 1kV for input and output lines ± 2kV for power cables | ± 1kV for input and output lines ± 2kV for power cables | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge voltages according to IEC 61000-4-5 | ± 1kV push-pull voltage ± 2kV push-pull voltage | ± 1kV push-pull voltage ± 2kV push-pull voltage | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and variations of the power supply according to IEC 61000-4-11 | < 5 % UT for ½ period (> 95 % dip of UT) 40% UT for 5 periods (60% dip of UT) 70 % UT for 25 periods (30 % dip of UT) < 5 % UT for 5 sec. (> 95 % dip of UT) | < 5 % UT for ½ period (> 95 % dip of UT) 40% UT for 5 periods (60% dip of UT) 70 % UT for 25 periods (30 % dip of UT) < 5 % UT for 5 sec. (> 95 % dip of UT) | Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires it to continue functioning following interruptions of the power supply, it is recommended to have the device powered by an uninterruptible power supply or a battery. |
| Magnetic field of power frequencies (50/60 Hz) according to IEC 61000-4-8 | 3A/m | 3A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Conducted HF interference IEC 61000-4-6 | 3Veff 150 kHz to 80 MHz1 | 3Veff | Portable and mobile radio equipment must not be used within the recommended working clearance from the device and its cables, which is calculated based on the equation suitable for the relevant transmission frequency. Recommended working clearance: $d = [1,2] \sqrt{P}$ $d = [1,2] \sqrt{P}$ at 80MHz to 800MHz $d = [2,3] \sqrt{P}$ at 800MHz to 2.5GHz where P is the nominal transmitter output in watts (W) specified by the transmitter manufacturer and d is the recommended working clearance in metres (m). The field strength of stationary radio transmitters is based on a local investigation for all frequencies 2 less than the conformance level for all frequencies 3. Interference is possible in the vicinity of equipment bearing the following Graphic  |
| Radiated HF interference IEC 61000-4-3 | 3V/m 80MHz to 800MHz1. | 3Veff | |
| | 3V/m 800MHz to 2.5GHz1. | 3Veff | |

Remarks: UT is the AC supply voltage prior to application of the test level.

1. The higher frequency range applies at 80MHz and 800MHz.

2. The field strength of stationary transmitters such as the base stations of radio telephones and land mobile services, amateur radio stations as well as AM and FM radio and television broadcasting stations cannot be accurately predetermined.

An investigation of the location is recommended to determine the electromagnetic environment resulting from stationary HF transmitters. If the field strength measured at the device location exceeds the conformance level specified above, the device must be observed with respect to its normal operation at each application site. If unusual performance characteristics are observed, it may be necessary to take additional measures such as reorientation or repositioning of the device.

3. A frequency range of 150kHz to 80MHz results in a field strength of less than 3V/m. Recommended working clearances between portable and mobile HF communication devices and the device.

The device is intended for operation in an electromagnetic environment, where radiated HF interference is checked. The customer or the user of the device can help prevent electromagnetic interference by duly observing the minimum distances between portable and/or mobile HF communication devices (transmitters) and the device. These values may vary according to the output power of the relevant communication device as specified below.

| Nominal transmitter output [W] | Working clearance according to transmission frequency [m] | | |
|--------------------------------|---|--|---|
| | From 150kHz to 80MHz $d = [1,2] \sqrt{P}$ | From 80MHz to 800MHz $d = [1,2] \sqrt{P}$ | From 800MHz to 2,5GHz $d = [2,3] \sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters whose maximum nominal output is not specified in the above table, the recommended working clearance d in meters (m) can be determined using the equation in the corresponding column, where P is the maximum nominal output of the transmitter in watts (W) specified by the transmitter manufacturer.

Annotation

These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is influenced by their absorption and reflection by buildings, objects and persons.

7. Cleaning, Disinfection, Sterilisation and Maintenance

Cleaning, Disinfecting and Sterilizing the Unit

Clean and disinfect the exterior surfaces of the unit, the micromotor, and the power cord using a clean cloth dampened with water or a disinfectant fluid.

Use only disinfectants tested and approved by national-level organizations or products with proven antibacterial, fungicide, and virucide power.

Warnings

- **The housing is not sealed.**
- **Do not immerse in ultrasound baths.**
- **NEVER spray the unit with liquids of any kind; in particular, do not spray the display or the electrical sockets.**
- **Never place the micromotor or any other unit component in autoclave: none of the components of the VDW.SILVER® unit may be sterilized (contra-angle excepted).**

Maintenance

Routine Maintenance

Inspect the micromotor cable at least once every six months. If any deterioration of the sheathing is noticed, have the power cord replaced by an authorized service centre.


Warnings

- **Do not lubricate the micromotor for any reason. When lubricating the contra-angle, check that no lubricant penetrates the micromotor.**
- **Lubricant contamination of the micromotor can have a strong negative effect on its safe operation. No replacement of the micromotor can be considered as repair under warranty if a condition of lubricant contamination exists.**
- **Never introduce any foreign objects into the micromotor.**

Special Maintenance

Contact the distributor, VDW GmbH, for any special maintenance that may be required.

8. Technical Specifications

| | |
|--|---|
| MODEL: | VDW.SILVER® |
| MATERIAL: | Shell: ABS Micromotor: aluminum |
| WEIGHT: | 1 kg |
| POWER SUPPLY: | battery-powered, 2000 mAh, 6V |
| BATTERY CHARGER POWER REQUIREMENT: | 100-240 V |
| VOLTAGE TOLERANCES: | ± 10 % MAX |
| FREQUENCY: | 47-63 Hz |
| BATTERY CHARGER RATED POWER: | 30 W |
| BATTERY CHARGER CURRENT RATING: | 2.5 A |
| TORQUE VARIATION: | 20-410 gcm at file |
| DRIVE SHAFT SPEED VARIATION: | 1500-6000 RPM |
| ELECTRICAL PROTECTION CLASS: | CLASS II |
| APPLIED PART TYPE: | BF (micromotor)  |
| SAFETY LEVEL IN PRESENCE OF FLAMMABLE ANESTHETIC MIXTURES OR OXYGEN: | NOT SUITABLE FOR USE IN THE PRESENCE OF FLAMMABLE ANAESTHETICS OR FREE OXYGEN |
| MODE OF OPERATION: | CONTINUOUS SERVICE |
| AMBIENT CONDITIONS FOR USE: | +15 °C /+42 °C; RH: < 80%; 700-1100 hPa |
| MEDICAL DEVICE CLASSIFICATION: | IIA, Annex IX 93/42/EEC |
| CENTRAL UNIT: MICROMOTOR | IP20 |
| PEDAL: | IP21 |
| CONDITIONS FOR SHIPPING AND STORAGE: | -20°C/+50°C; RH: 20-90%; 500-1100 hPa |

9. Troubleshooting

| | |
|---|--|
| THE UNIT DOES NOT OPERATE CORRECTLY | Check that during battery charging the battery charger is correctly connected to the power socket and that mains voltage is that reported on the battery charger data plate. Reload the factory default parameters (see 5.2). |
| THE DISPLAY DOES NOT OPERATE CORRECTLY | If the display tends to dim with the battery fully charged, the VDW.SILVER® unit is delivering full available power. Check-contrangle operation. The display will tend to dim when the battery charge is low. |
| THE MICROMOTOR DOES NOT START | Check that the motor connector is correctly inserted in the micromotor housing. Check that the contra-angle operates correctly. Remove the contra-angle and set maximum speed, then start the motor. Calibrate without the contra-angle, then reconnect the contra-angle and run calibration again. |
| THE FOOT CONTROL DOES NOT START THE MOTOR | Try to start the motor from the keypad (hold the Confirm [5] key down for 1.5 seconds). If the motor starts, call your service centre for foot control replacement. |
| THE BATTERY DOES NOT OPERATE CORRECTLY | If all the precautions for use have been observed and the battery discharges rapidly, it may be damaged. Send the unit to your service centre. If the unit does not operate under battery power but only when the battery charger is connected to the mains supply, the battery of the internal circuitry of the VDW.SILVER® may be damaged. Send the unit to your service centre. |
| ERROR 1 | Check motor connection. |
| ERROR 2 | Check contra-angle. Maintenance may be necessary. |

10. Declaration of Conformity

Manufacturer: Advanced Technology Research ATR s.r.l. Via S. Donato 1, 51100 Pistoia, Italy

Distributor: VDW GmbH 81709 Munich – Germany

Product: **VDW.SILVER®**

Standard accessories: Micromotor, pedal, external battery charger

The products described above meet the requirements of the following European Directives:

Electrical Medical Devices: Legislative Decree 46/97 of 24 February 1997 no. 46 as amended, implementing European Directive “93/42/EEC”.

June 2006

ADVANCED TECHNOLOGY RESEARCH
ATR srl
Jan Sicfert
Jan Sicfert-PRESIDENT



11. Warranty

In addition to the warranty applicable under the sales contract with the dental dealer, VDW directly offers customers the following service warranty:

1. VDW guarantees proper manufacturing of the product, the use of top quality materials, all required tests and adherence to all applicable pertinent laws and regulations relating to the product.

The full functionality of **VDW.SILVER®** is covered by a 36 month warranty, beginning on the date of delivery to the customer (according to the shipping papers with the respective product serial number, issued by the seller at the time of purchase).

The customer is only entitled to warranty services within the warranty period and under the condition that VDW has been informed of the defect in writing within a two month period from the date of discovery of the defect.

2. In the event of a warranty claim, the VDW Service Center in Munich, Germany will handle any repairs within 3 business days from receipt at the VDW facility in Munich plus transport time to return the shipment to the customer.

3. This warranty covers only the exchange or repair of individual components or parts affected by manufacturing defects. The cost for personnel to be dispatched for purposes of technical assistance from the dealer to the customer, and/or packaging expenses of the customer will not be covered by VDW.

Any customer claims beyond the realm of repair, such as claims for damages, will not be covered. This warranty does not include any compensation for direct or indirect personal injuries or material damage of any kind.

The customer will not be entitled to damages for down-time of the equipment.

4. The warranty does not extend to damage for which evidence can be provided by VDW that such damage has been caused by negligence on the part of the user as related to regular maintenance (see operating instructions), particularly during loading, unloading and maintenance of the battery unit in accordance with the user instructions, as well as regular careful maintenance of the contra angle in compliance with the separate user instructions for this component.

The warranty explicitly excludes any defects arising on the basis of:

- damage occurring during transport to VDW for the purposes of repair,
 - damage occurring through atmospheric events such as lightning strikes, fire and/or humidity.
- This warranty shall automatically become invalid if the product has been improperly repaired, modified or manipulated in any manner by the user, by non-authorized persons or by third party personnel.

5. This warranty is valid only if the device sent for repair includes the invoice with confirmation of the product's shipping date.

6. Legal claims, such as through product liability law or claims against sources from whom the customer has purchased the product, in particular the dental dealer, remain unaffected.

Hersteller/Manufacturer:

ATR s.r.l. • Via S. Donato, 1 • 51100 Pistoia • Italy



Vertrieb/Distributor:

VDW GmbH • Postfach 830954 • D-81709 München

Tel. 089/627 34-0 • Fax 089/627 34-190

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