

ToothWave

H7001

USER MANUAL

Patent protected
technology by

TOOTH
WAVE™

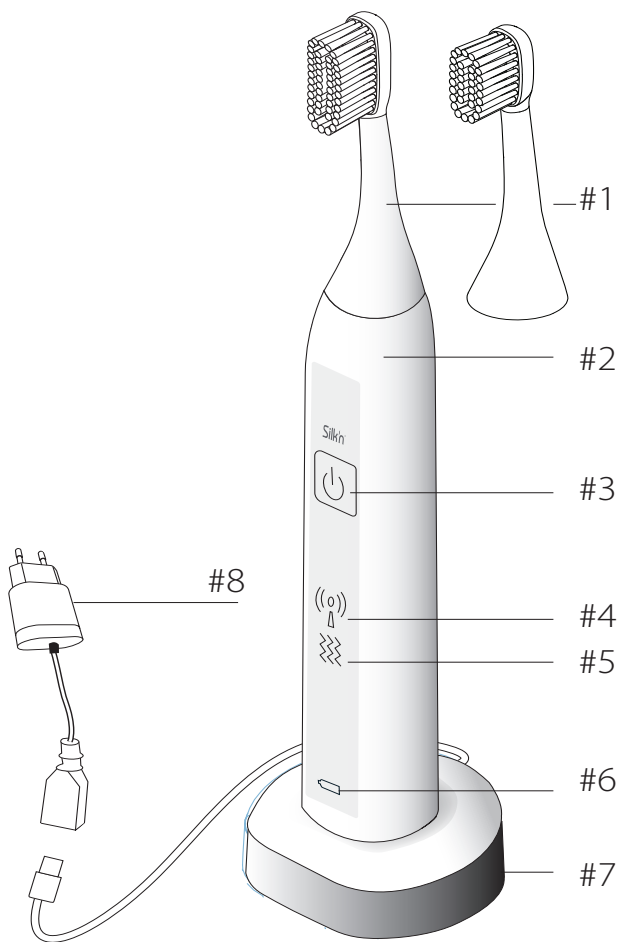
SCIENCE DRIVEN ORAL CARE



DentalRF™
Technology

Silk'n®

Silk'n ToothWave



(i)

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1. Warnings and precautions

- Read the manual in full before use, and refer to it if you are in any doubt about how to use the device safely.
- The device is for home-use. The handle may be used by multiple persons, but for reasons of hygiene, each user must have their own brush head (see section [7.4 Replacing the brush head](#)).
- The device is not intended for use on multiple patients in a dental practice or institution. Do not use for any purpose other than as described in this manual.
- Always ensure that your hands are dry before connecting the charging cradle to the electricity supply.
- Do not place or store the USB wall adapter where it can fall, or be pulled into any liquid.
- Do not use the USB wall adapter if it has fallen into liquid.
- For the purpose of recharging the battery, only use the USB wall adapter provided with this device.
- If the charging cradle malfunctions, unplug immediately.

- ⦿ Never use the charging cradle or the USB wall adapter if they are damaged or aren't working properly.
- ⦿ Keep the device, all parts and accessories away from heated surfaces.
- ⦿ Do not attempt to modify, open or repair the device. You may expose yourself to an electric shock.
- ⦿ Do not use if the parts or accessories are not supplied by the manufacturer as defined in this manual, or if they are damaged in any way, do not appear to be working properly, or if you see or smell smoke. In such cases, stop using the device, and contact customer service.
- ⦿ The manufacturer accepts no liability for damage or injuries caused by improper or incorrect use.
- ⦿ Do not clean any of the parts in the dishwasher.
- ⦿ Keep the device out of the reach of children or pets.
- ⦿ This device contains batteries that are non-replaceable.

- ⦿ Do not dispose of the device or the battery with household waste! The law requires that you dispose of this electrical device (including all accessories and parts) at a designated recycling collection point for electrical devices.
- ⦿ Dispose of the battery safely.
- ⦿ If the product reaches its end of life, or you no longer wish to use it, the battery must be removed before disposal (see section 12. Disposal).

Precautions

Consult your physician before use if you:

- ⦿ have concurrent conditions, such as cardiac disorders, epilepsy, uncontrolled hyper-tension, and liver or kidney diseases.
- ⦿ have poorly controlled endocrine disorders, such as diabetes or thyroid abnormality.

Consult your dentist before use if you:

- ⦿ have had oral or gum surgery in the last two months.
- ⦿ have severely injured gums.

 **Additional precautions:**

- Do not bite the brush head.
- Do not touch or apply pressure to the brush head when you use, clean or maintain the device. Applying pressure to the bristle area of the brush head can pose a risk of injury.
- The safety and effectiveness of the device for uses other than those indicated are not known.

2. Contraindications

This device including all its parts must not be used by the following people: children, adults below the age of 18, those with limited physical, sensory or psychological capacities, those lacking experience or knowledge in how to use the device in a safe way, or those who do not understand the hazards involved.

 **Do not use the device if you:**

- have a pacemaker, internal defibrillator, another active implanted device, or if you have any medical concerns about using this device.
- have a history of oral cancer or oropharyngeal cancer, or have any other type of cancer, or have pre-malignant lesions.
- have an impaired immune system due to immunosuppressive diseases such as HIV, or you use immunosuppressive medication.
- are pregnant or nursing.

3. Get to know the device

3.1 Indications for use

The device is intended to promote good oral hygiene, including reduction in plaque and calculus (tartar), and prevention and treatment of gingivitis. The device is intended for over-the-counter use.

i The device is not a substitute for regular visits to the dentist for routine dental care.

3.2 Clinical summary data

A single-blind, randomized, double arm, prospective study was performed with 86 subjects. The purpose of the study was to test the safety and efficacy of the ToothWave toothbrush.

Subjects were randomized into one of two study groups, receiving either the ToothWave RF powered toothbrush (n=45), or a control powered toothbrush (n=41). The subjects performed twice daily brushing for a test period of 6 weeks. Plaque (RMNPI), calculus (V-MI), gingival inflammation (MGI) and bleeding (GBI) were assessed at baseline, after 4 and 6 weeks.

After 6 weeks of tooth brushing, the measured mean plaque, calculus and gingivitis scores in the ToothWave group were significantly lower than those of the control group. Furthermore, the improvements from baseline in plaque, calculus and gingivitis reported in the ToothWave group were significantly greater than those calculated for the control group, following 6 weeks of brushing. Remarkably, there was a calculus reduction following 6 weeks of brushing using the ToothWave toothbrush, whereas there was a calculus accumulation following 6 weeks of brushing in the control group. Both toothbrushes were well-tolerated and no device-related adverse events were reported.

The study demonstrated that the ToothWave toothbrush provides significant benefits in the reduction of plaque and calculus and the prevention and treatment of gingivitis compared to the control group which used a powered toothbrush with an American Dental Association (ADA) Seal of Acceptance.




3.3 Package contents







Refer to the diagram on page (i) at the front of the manual.

- 2x Brush heads with extra soft bristles (small, large) (#1)
- 1x Handle (#2)
- 1x Charging cradle with USB cable + transparent base (#7)
- 1x USB wall adapter (#8)
- 1x Warranty booklet
- 1x User manual

3.4 Device controls & settings

Refer to the diagram on page (i) at the front of the manual.

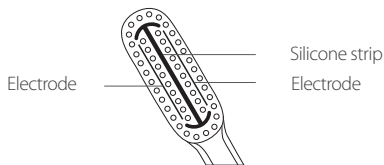
Control	Function / Mode
Control button (#3) 	Long press: turns the device on or off Short press: each press moves to the next mode
DentalRF mode indicator light (#4) 	DentalRF is active for all modes 

Control	Function / Mode
Vibration mode indicator light (#5) 	Mode 1: Low vibration 
	Mode 2: Medium vibration 
	Mode 3: High vibration Recommended mode 
	Mode 4: No vibration 
Battery indicator light (#6) 	Green blinks - battery is charging No light - battery is charged Orange blinks - battery is low Orange constant - battery is empty

i When the battery is fully charged, the light will be constant green for 30 seconds, then it will go out.

3.5 The brush head

The brush head (#1) is an innovative and special feature of the device. It contains bristles, 2 DentalRF electrodes and a silicone strip that lies between the electrodes. The silicone strip enables the DentalRF current to flow across the teeth. It also ensures that the toothpaste and the DentalRF energy interact effectively. For this reason, we recommend that the bristles are always in good contact with the teeth.



- ⚠ Always check that the brush head (#1) is not damaged. If you are in any doubt about its condition, replace with a new one. Naturally, you may contact Customer Service at any time for specific queries or questions.

Some signs of damage to the brush head (#1) include but are not limited to:

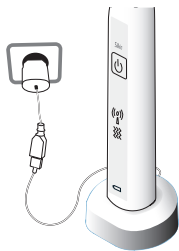
- a significant change in shape or appearance;
- excessive wear showing on the bristles;
- a bend or tears in the silicone barrier.

- ⚠ Do not use the brush head (#1) if the bristles, silicone strip, or electrodes become loose, bent, damaged, or crushed. Damaged electrodes, bristles or a damaged silicone strip may break off while brushing. If it is damaged, replace with a new brush head (#1). Refer to section [7.4 Replacing the brush head.](#)

3.6 Device charging

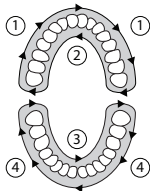
- Check that the battery is not low before each use.

First charge 
hours



4. Treatment plan

- Use for 2 minutes, morning and evening.
 - Clean between the teeth and gently massage gums.
 - Brush each section (1,2,3,4) for 30 seconds.
- i** The device is suitable for use with dental implants.



For details, refer to section [6. Get started!](#)

5. What to expect with the device

During or after using the device you may:

- feel pain, if you have cavities or any teeth condition that requires dental treatment. If you do feel pain, consult your dentist.
- i** Stop using the device if you experience excessive bleeding after use, or if bleeding continues after one week of regular use.

6. Get started!

1. Rinse the bristles under lukewarm water.
2. For best results, apply a generous amount of toothpaste. You can use any commercial toothpaste.
3. Hold the handle (#2) firmly, and turn on the device. Short press the control button (#3) as many times as needed to select your treatment mode.

4. Gently press the bristles against the teeth, and move the brush in circular movements, slowly and systematically from tooth to tooth, gently massaging the gums. Make sure the bristles are always in good contact with your teeth.

i The device comes with soft bristles to protect your teeth and gums. Brush gently, and apply only light pressure when brushing. Do not scrub.

5. Brush all surfaces of the teeth for 2 minutes. You will feel a slight vibration every 30 seconds (1 vibration at 30 seconds, 2 vibrations at 60 seconds and so on). After the vibration(s), you can move to another section of the mouth (refer to section 4. [Treatment plan](#)). After 2 minutes, the device will shut down automatically.
6. Clean the device with warm water, and store in open air whilst it is wet.


7. Cleaning & maintenance

7.1 Routine cleaning

- After use, wash the brush head under running water to remove any toothpaste or debris.

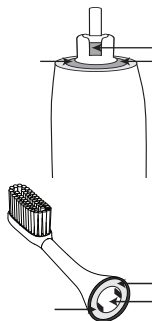
 Do not wash with soap or chemicals.

- If debris or toothpaste accumulates on the handle (#2) wash under running water and dry with a clean dry cloth.

 Do not try to remove any stuck debris from the brush head (barrier and/or electrodes). In such cases, replace the brush head (#1). Refer to section [7.4 Replacing the brush head](#).

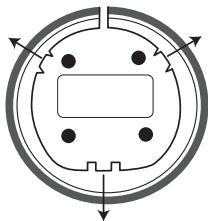
7.2 Maintenance of the RF contact

- Once a month, remove the brush head (#1) from the handle (#2). Clean the groove in the handle (#2) to remove any toothpaste or debris that may have accumulated. Use a cotton bud, rinse and dry with a clean dry cloth.
- Remove debris and excess toothpaste from the brush head (#1) and handle (#2). Clean the underside of the brush head using a cotton bud.



7.3 Cleaning the charging cradle

1. First disconnect the charging cradle (#7) from the electricity supply and remove the toothbrush from the charging cradle (#7).
2. Next, remove the transparent base. To do this, turn the charging cradle (#7) upside down. Remove the transparent base by pressing the clips outwards.



3. Clean both parts with a damp cloth and dry them. Place the charging cradle (#7) back, and press down firmly. You will hear it click into place.

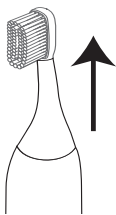
7.4 Replacing the brush head

Replace the brush head (#3) when any of these apply:

- another person wishes to use the device
- you've used the same brush head (#1) for 3 months
- the bristles are damaged or worn.

To replace the brush head:

1. Switch off the device.
2. Shake off any excess water from the brush head (#1).
3. Remove any toothpaste or debris from the handle (#2) and wipe with a clean cloth.
4. Detach the brush head (#1) from the handle (#2). Hold it straight (don't twist it), and pull it from the handle (#2) Then replace with a new brush head (#1).



- i** If you have replaced the brush head (#1) temporarily, (because another person wishes to use the device), cover the brush head (#1) you have just removed with the transparent protective cover provided with the brush head refill packs.

8. Parts & consumables

You can purchase replacements from where you purchased the device, or online. Refer to the customer service section for details.

9. Troubleshooting

Do not attempt to open or repair your device. You may expose yourself to dangerous electrical components and cause serious harm to yourself. It will also void your warranty.

Problem	Checks
My device does not start.	Make sure the battery is not low. Refer to section 3.6 Device charging .
The device is charged but it does not work.	Press the control button (#3) to restart the device. If the problem persists, contact customer service.
All indicator lights (#3, #4, #5) blink.	There is a system error. Press the control button (#3) to restart the device. If the problem persists, contact customer service.

i For problems or queries, please contact Silk'n customer service.

10. Customer service

For more information, visit our website www.silkn.co.il. In the event of a problem with the device, please contact customer service by email at contact@silkn.co.il, or telephone 1-700-700-309.

11. Warranty

Please refer to the separate product warranty booklet for complete information.

i The manufacturer accepts no liability for damage or injuries caused by improper or incorrect use.

12. Disposal

Be sure to follow your country's laws for the disposal of electrical items. Contact your local council for information on recycling points and/or disposal services for lithium batteries and electrical devices.

12.1 Battery removal

At the product's end of life, you are required to remove the battery before disposal. To do this, the device must be opened up. The device will no longer function after this procedure, nor can it be repaired. Any warranty will be void when the device casing is opened and the battery is removed. Home Skinovations Ltd is not liable for any physical or material damages as a result of performing this procedure.

Refer to the diagrams at the end of this section for steps 5-8.

1. Remove the device from the charging cradle (#7).
2. Make sure that the battery is completely empty. Turn on the device to fully drain the battery.
3. Remove the brush head (#1) from the handle (#2).
4. As a protective measure, wear safety goggles for the rest of the process.
5. **Open the casing:** Put the flat-head screwdriver into the slot at the bottom of the handle (#2) and gently swing the bottom cover gently until you see a gap - see diagram.
6. Place the flat-head screwdriver into the gap and pry the bottom section out of the handle (#2) - see diagram.

7. **Remove the inner section:** Place the handle (#2) upside down on a sturdy table covered with a towel. Use the flat-head screwdriver to move the clips inwards. As the clips release, push down to release the inner part of the handle (#2) - see diagram.

8. **Remove the battery:**

⚠ If the battery is damaged or leaking, wear rubber gloves before touching it.

⚠ Make sure the exposed red and black wires do not touch each other. Cut each wire separately.

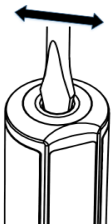
⚠ If the red and black wires touch each other, separate them immediately.

- With cutters, cut the red wire of the battery close to the printed circuit board (PCB). Seal the exposed end (battery side) with insulating tape - see diagram step 8.
- Again with cutters, cut the black wire of the battery close to the PCB. Seal the exposed end (battery side) with insulating tape - see diagram step 8.
- Carefully remove the battery from the casing.

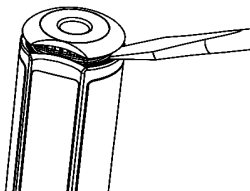
9. **Place the battery in a plastic bag:** This prevents the battery from coming into contact with other items.

10. Dispose of the battery and the device as advised by your local council.

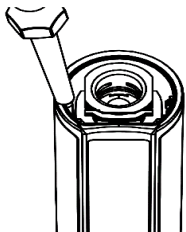
⚠ If the battery is damaged or leaking, wear rubber gloves before touching it.



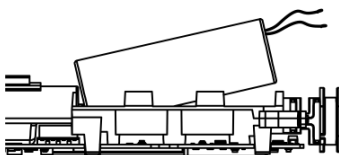
Step 5



Step 6



Step 7



Step 8

12.2 Packaging

Dispose of the packaging separated into single type materials. Dispose of cardboard and carton as waste paper and film via the recyclable material collection service.

12.3 Device

Do not dispose with household waste! The WEEE directive requires that you dispose of this electrical device (including all accessories and parts) at a designated recycling collection point for electrical devices. This ensures that the device is recycled professionally, and prevents the release of harmful substances* into the environment. Remove the battery and dispose of it safely before disposing of the device.









* Products labeled with Cd = cadmium, Hg = mercury, Pb = lead.

13. Specifications

Model no.	H7001
Technology	DentalRF™ and vibration
Vibration	0; 275Hz; 300Hz or 400Hz (± 5%)
Radio frequency	3.3MHz ±0.3MHz; up to 3W
Package size	(W)165 (H)227 (D)80 [mm]
System weight	115g
Transport & storage between uses and storage condition	Temperature: - 40 to 70°C Relative humidity : 10 to 90%rH Atmospheric pressure: 500 to 1060hPa
Operating conditions	Temperature: 5 to 40°C Relative humidity: 15 to 90%rH Atmospheric pressure: 700 to 1060hPa
Time from minimum storage temperature between uses to minimum operating temperature with ambient temperature of 20°C	30 minutes

Time from maximum storage temperature between uses to maximum operating temperature with ambient temperature of 20°C	30 minutes
Protection against electric shock	Class I medical equipment type BF applied part
Adapter	HNAE050060UB (Europe)
Input: Output:	100 – 240V; 50/60Hz; 0.2A 5.0Vdc; 0.6A
Mode of operation	Non-continuous
Waterproof rating: USB adapter (IPX4)	Protection assured against water splashing
Charging cradle (IPX7) Handle (IP67)	Protection assured against water immersion at a depth of up to 1 meter, for a maximum of 30 minutes.
The device was tested and complies with	IEC 60601-1 (Safety) IEC 60601-2-2 (RF Safety) IEC 60601-1-2 (EMC) IEC 60601-1-11 (Environment)
Service life of the equipment	5 years

14. Signs & symbols

	Important information about using or maintaining the device.
IP67	Protected from immersion in water with a depth of up to 1 meter (or 3.3 feet) for up to 30 minutes.
 	Do not dispose with household waste. Dispose in accordance with your country's laws and help protect the environment. In accordance with the WEEE Directive.
 Li-Ion	Lithium inside.
	Degree of protection against electric shock: type BF applied part.
	Follow the operating instructions.
	The built-in rechargeable battery contains substances that may pollute the environment. Always remove the battery before you discard at an official collection point for batteries.
	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
	Manufacturer
	Recycle the packaging.
	Worldwide warranty.

15. Labeling

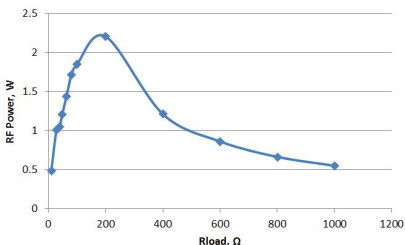


This device is not suitable for use in the presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide.

16. Output power curves

The Rload (impedance) is the resistance of the toothpaste and saliva medium through which the RF current flows. The RF power is the rate per second at which the RF energy is transferred by the RF generator into the impedance. During brushing, the toothpaste density is changed, as the toothpaste is foamed and mixed with saliva, this change in density changes the impedance respectively.

The curve shows the device RF power (for all modes of operation) versus the toothpaste and saliva medium impedance.



17. EMC Technical results

EMC requirements

IEC 60601-1-2 Edition 4.0 (2014)

Environment of intended uses:

Home Healthcare Facility Environment

Summary of Test Results

Test	Standard	Class/ Severity level	Test result
Emission (IEC 60601-1-2 section 7)			
Radiated emission Freq. range: 30 - 1000 MHz	CISPR 11	Group 1 Class B	Complies
Immunity (IEC 60601-1-2 section 8)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3	3.0; 10.0 V/m; 80 MHz ÷ 2.7 GHz, 80% AM, 1 kHz	Complies
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3	List of frequencies, from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies
Immunity from power frequency magnetic field	IEC 61000-4-8	30 A/m @ 50 Hz	Complies

18. Legal notice

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