

Silk'n®

Beautiful Technology

Tightra

H2401



EN USER MANUAL

Silk'n Tightra

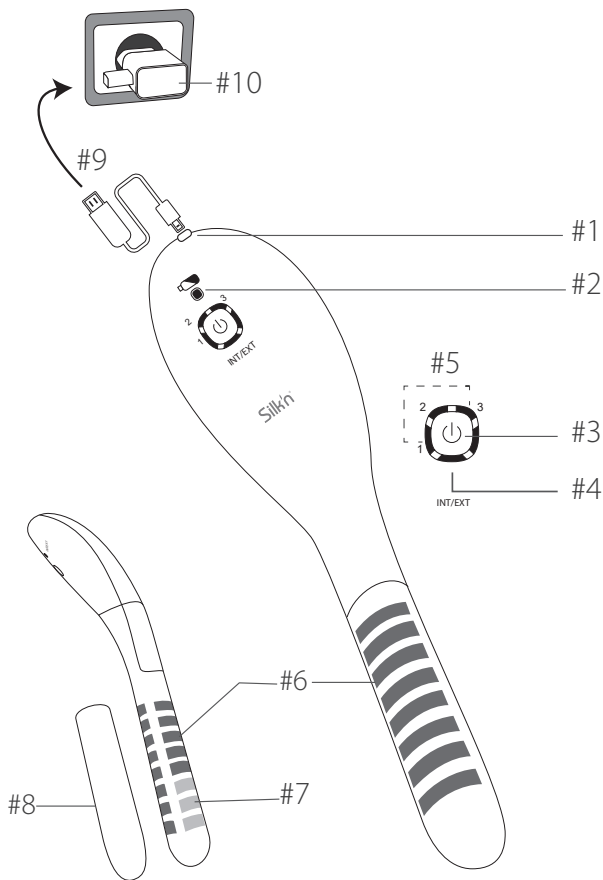


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1. Warnings



Before first use, please read this user manual in full, and keep it for future use. We recommend you refamiliarise yourself with the instructions before each treatment.

- Keep the device, USB cable and adapter dry at all times.
- Do not use the device while bathing or taking a shower.
- Always ensure that your hands are dry before connecting the device to the electricity supply.
- Never use the adapter if it has a damaged cable or plug, or isn't working properly, or has been submerged in water. If that happens, unplug the adapter immediately before touching it. Failure to unplug the adapter may result in an electric shock!
- Do not operate the device in environments where there is a risk of explosion. Keep the device and all its parts away from open flames and hot surfaces.

- Keep the adapter accessible at all times, so it can be removed from the electricity supply easily in case of emergency.
- Disconnect the device from the electricity supply after charging.
- Never pull the adapter out of the socket by the cable. Always remove it by taking hold of the adapter.
- Place the adapter cable in such a way that it does not pose a tripping hazard.
- Do not use if the parts or accessories are not supplied by the manufacturer as defined in this manual, or if the device is damaged or does not appear to be working properly. In such cases contact Customer Service.
- Ensure there are no unintended rough surfaces, sharp edges or protrusions which may cause harm before each use.
- Do not attempt to modify, open or repair the device. You may expose yourself to dangerous electrical components and may cause serious harm to yourself. It will also void the warranty.
- Children shall not play with the device. Cleaning and user maintenance shall not be made by children.

- ⦿ Children must not play with the packaging. They may injure themselves with the packaging material, or swallow small parts and choke.
- ⦿ This unit has been designed and tested to meet the requirements of electromagnetic, electrostatic, and radio frequency interference standards. However, the possibility of electromagnetic or other interference may still exist. Relocating the device may help to eliminate interference.
- ⦿ If your device reaches its end of life stage, take the device and all its parts to a recycling point designed for electrical devices. Refer to section 12. Disposal.

2. Contraindications

This device including all its parts is suitable for women aged 18 and above who wish to improve the firming and tightening of pelvic floor organs, reduce stress urinary incontinence, or vaginal symptoms.

The device must not be used by the following people: children, transgender women, adults with limited physical, sensory or psychological capacities, or 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 if you:**

- are pregnant or nursing.
- have had any surgical procedure in the vaginal or pelvic area within the last 12 months, or before complete healing.
- have an active electrical implant/device in any region of the body, a pacemaker or internal defibrillator.
- have a metal implant, including a metal intrauterine device (IUD), in the treatment area.
- have severe concurrent conditions, such as cardiac disorders, sensory disturbances, epilepsy, uncontrolled hypertension, liver or kidney diseases.
- have a history of skin cancer and genital area cancer, or current condition of any other type of cancer, or pre-malignant moles.
- have an impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use immunosuppressive medications.
- have poorly controlled endocrine disorders, such as diabetes, or thyroid dysfunction and hormonal virilization.
- have any active condition in the treatment area, such as sores, psoriasis, eczema, rashes, open lacerations, abrasions, or lesions.
- have received treatment with light, laser, RF, or other devices in the treated area for either non-ablative procedures, or ablative fractional laser resurfacing (according to treatment severity) within 3 months prior to treatment.
- have used Isotretinoin (Accutane®) within 6 months prior to treatment.
- have a sexually transmitted disease.

- have a current urinary tract infection, pelvic or pelvic tract infection.
- have received radiation therapy or chemotherapy treatments within the past 3 months.
- cannot sense heat properly because of an illness, or other health related issue.
- are menstruating.
- have any other condition which in your physician's opinion would make it unsafe for you to use the device.



Consult your physician before use if you:

- have received an abnormal result from a PAP smear or pelvic exam within the last 2 years.
- have a history of diseases stimulated by heat, such as recurrent Herpes Simplex, in the treatment area.
- have had vaginal surgery, or you have been told you have a vaginal prolapse.
- have a history of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- have a history of bleeding coagulopathies, or use of anticoagulants except for low-dose aspirin.
- have an implanted mesh.
- have a non-metal intrauterine device (IUD).
- have used medications, herbs, food supplements, and vitamins known to alter healing in the treatment area within the last two weeks.
- have a uterine prolapse, cystocele, or rectocele.
- have received drugs from your physician for a skin condition within the past 6 months.

- have uterine fibroids (myomas), endometrial or uterine polyps, or any other abnormal condition in the uterus or cervix.

3. Safety features

With Silk'n safety comes first. The device has these safety features:

- **Heat stabilizer:** To prevent overheating, each of the 16 electrodes (**#6**), (**#7**) has a built-in heat stabilizer. When a rise in the treated skin temperature is detected, the stabilizer automatically stops emitting RF energy, until the skin temperature lowers enough for the stabilizer to resume heating.
- **Touch sensor:** The touch sensor ensures that the RF Energy will only pass through the electrodes (**#6**), (**#7**) when the electrodes (**#6**), (**#7**) are in good contact with the skin.
- **Movement sensor:** When you use the device in external mode, the device will only emit RF Energy when you move the device across the skin.

4. Get to know your device

4.1 Device description

The device uses Bi-Polar RF Energy that flows between the electrodes (**#6**), (**#7**). The Bi-Polar RF energy works to promote the formation and reconstruction of vaginal collagen and elastin fibers.

The device has LED lights to indicate different energy levels and treatment modes. It has a rechargeable battery which is charged using a type C USB cable (**#9**).

Refer to the illustration on page (i) at the front of the manual to see the location of each feature.

4.2 Intended use

This electric device is intended to improve the firming and tightening of pelvic floor organs, reduce stress urinary incontinence or vaginal symptoms, and improve sexual functioning.

The device is intended for self-treatment only, and is not suitable for commercial or therapeutic use. Do not use for any purpose other than as described in this manual.


4.3 Package contents


- The device
- USB cable & adapter
- Silk'n Intimate Gel
- User manual
- Warranty card
- Storage case


4.4 Device parts


- USB port **(#1)**
- Battery indicator light **(#2)**
- Control button **(#3)**
- Treatment mode indicator light **(#4)**
- Energy level indicator lights **(#5)**
- Electrodes - internal mode **(#6)**
- Electrodes - external mode **(#7)**
- Protective cover **(#8)**
- USB cable - type C **(#9)**
- USB adapter **(#10)**

4.5 Device controls

Control	Action	Description
Control button (#3) 	Long press	<ul style="list-style-type: none"> • Device activated - internal mode, energy level 1 (low); treatment mode indicator light (#4) is off (no light) • Once active, long press shuts the device down; 1 vibration.
	Short press x1	Internal mode - energy level 2 (medium)
	Short press x2	Internal mode - energy level 3 (high).
	Short press x3	External mode - energy level 1 (low); treatment mode indicator light (#4) is on (white constant)
	Short press x4	External mode - energy level 2 (medium)
	Short press x5	External mode - energy level 3 (high)

Treatment mode indicator light (#4) 	Off: no light	Internal mode
	On: white constant	External mode
	On: white blinks	There is a system error. The light blinks and alternates with blinking energy level indicator lights (#5)

Control	Action	Description
Energy level indicator lights (#5) 	Green - constant	1 light - level 1 (low) 2 lights - level 2 (medium) 3 lights - level 3 (high)
	Green - blinks	There is a system error. The lights blink and alternate with the blinking treatment mode indicator light (#4)

Control	Action	Description
Battery indicator light (#2) 	Green - blinks	Device charging
	Green - constant	Device charged
	Orange - blinks	Low charge in battery
	Orange - constant	No charge in battery, treatment mode inactive

4.6 Device shutdown

The device shuts down in one of 3 situations:

- You have completed a 20 minute treatment session.
 - The device has not had firm contact with the skin for more than 2 minutes.
 - The battery is too low.
- i** There is one vibration when the device shuts down.

4.7 Treatment modes

The device has 2 treatment modes: internal and external.

- **Internal mode:** Use this mode to tighten the vaginal tissue and muscles of the pelvic floor to increase muscle tone and reduce incontinence.
- **External mode:** Use this mode to tighten the external vulva skin tissue for an improved vaginal appearance.

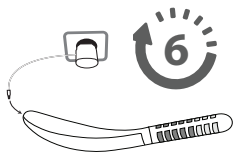
- **To change treatment modes:** Turn off the device and then turn it on. To access the mode you want, see step 2 in sections [6.2 Internal mode treatment](#) or [6.3 External mode treatment](#)).

4.8 Energy levels

- Each treatment mode has 3 energy levels: level 1 (low), level 2 (medium), level 3 (high). In general, the higher the energy level, the better the results.
- Each treatment mode starts at energy level 1.
- **To change the energy level:** Cycle through the energy levels by short pressing the control button (**#3**) until you get the level you want.

4.9 Device charging

Always charge the device before first use. The initial charge should take approximately 6 hours.



- Place the USB cable (**#9**) into the device. Place the other end of the cable into the USB adapter (**#10**) and connect to the electricity supply. The battery and treatment mode indicator lights (**#4**, **#2**) will go on and off, and then the battery indicator light (**#2**) will blink green.
- Recharge the device fully after each 20 minute treatment, and check the battery level before you start a new treatment.

5. Treatments

5.1 Treatment plan

- Each internal or external treatment lasts for 20 minutes.
- Use the device in one or both modes 2 or 3 times a week for 4 weeks.
- After that, reduce the use gradually to once a week, then to every 2 weeks or less frequently, to meet your specific needs.



5.2 What to expect with the device

During a treatment session it is normal to experience and feel:

- **A sensation of heat:** both during internal and external treatments.
- **Some redness or slight swelling of the skin:** This may occur around the vagina following an external treatment. These reactions should last no more than 24 hours.
- i** If you experience these reactions, we recommend that you apply aloe vera gel on the affected skin.
- **A short vibration:** During a treatment, you will feel a vibration every few minutes. This is normal, and indicates that the device is active.
- **Temporary increase in incontinency:** When using the internal mode, some users might experience the need to pass water more frequently. Don't worry, this will go away in a few days. The effects of incontinency will start to reduce, and you will see an improvement as a result of the treatments.

⚠ Stop use immediately if you see full redness of the skin, blistering or burns.


⚠ Stop use immediately if you have any pain, or if the skin or the device becomes too hot.


5.3 Possible side effects

When used according to the instructions, side effects and complications associated with the use of the device are uncommon. Below are some recommendations should you experience any of the possible side effects.

<p>Minor discomfort (Internal/external modes)</p> <p>Some users may feel mild discomfort during use. This is best described as a mild stinging sensation on the skin around the vagina. The stinging sensation may last during or after treatment.</p>	<p>Recommendation: Use a lower energy level and wait until you have no discomfort before your next treatment.</p>
<p>Excessive heat sensation (Internal /external modes)</p> <p>If you have pain, severe discomfort or a very unpleasant feeling, reduce the energy level until you feel OK.</p>	<p>Recommendation: Use a lower energy level and wait until the effect has cleared before your next treatment.</p>
<p>Allergic reaction (Internal /external modes)</p> <p>In rare cases, you may experience an allergic reaction after the treatment.</p>	<p>Recommendation: Stop treatment, and consult your physician if the reaction remains for more than 24 hours.</p>
<p>Excessive redness and swelling (External mode)</p> <p>In rare cases, the skin around the vagina may become very red and swollen. The redness and swelling should subside within 2 to 5 days.</p>	<p>Recommendation: Treat with frequent applications of aloe vera cream. Wait until the effect has cleared before your next treatment. Consult your physician if the redness does not go away within 5 days.</p>

<p>Blisters or burns (External mode)</p> <p>In very rare cases, you may experience some blistering or burning of the skin around the vagina.</p>	<p>Recommendation:</p> <p>Cool the affected area and apply anti-burn cream. Wait until the effect has cleared before your next treatment and use a lower energy level.</p> <p>Consult your physician if the skin does not return to normal within a week.</p>
<p>Spotting (Internal mode)</p> <p>In rare cases, you may experience slight spotting immediately after a treatment.</p>	<p>Recommendation:</p> <p>Consult your physician if the effect continues for more than 24 hours.</p>

 Stop use immediately if any of these effects are more severe.

 See your physician if the effects do not go away within 2 to 3 days.

6. Get started!

6.1 Pre-treatment

- Make sure the device battery is not low (see section [4.9 Device charging](#)).
- Empty the bladder before treatment.
- Check that the gel expiry date has not passed.
- Remove the protective cover (**#8**) that is over the electrodes (**#6**), (**#7**) before use.
- Before use, clean the electrodes (**#6**), (**#7**) with a vaginal wipe, and dry with a clean paper towel.

- Never use flammable liquids such as alcohol (including perfumes, sanitizers, or other applications containing alcohol), or acetone to clean the skin before use.
- Remove all piercing or metal from the treatment area before use.

6.2 Internal mode treatment

1. Apply a small amount of the gel supplied with the device to all the electrodes **(#6)**, **(#7)**. There is no need to apply gel internally.
 2. For internal mode treatments, turn on the device by long pressing the control button **(#3)**. The internal mode will be active, and the device will be set to energy level 1. The treatment mode indicator light **(#4)** will be off (no light). You will feel a vibration and the device is ready for use.
 3. Lie down and make yourself comfortable. Start your treatment at energy level 1.
 4. Insert the electrodes **(#6)**, **(#7)** into the vagina as far as is comfortable for you. When the device is inside the vagina you need to make sure that the device is supported during treatments:
 - If your legs are splayed out on the bed, close your legs slightly to hold the device in place.
 - If you lie with your legs bent (and feet on the bed), place a cushion under the device to hold the device in place.
 - You might also wish to hold the device, if you find that helps to keep the device in place.
- i** During the treatment, you will feel a vibration approximately once a minute.

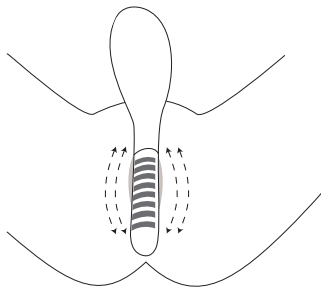
5. If after 5 minutes you feel comfortable with the heat, move to energy level 2 by short pressing the control button **(#3)**. To use energy level 3 (high), short press the control button **(#3)** one more time.
6. Keep the device in place for 20 minutes. We recommend that you lie still and do not move about. However, it's good to rotate the device from time to time so that the energy keeps flowing across the electrodes **(#6)**, **(#7)**. After 20 minutes the device will shutdown.
 - i** In cases of pain or discomfort:
 - If you are using energy levels 2 or 3, reduce the energy by pressing the control button **(#3)** 1 or 2 times. Wait 5 minutes for the heat to reduce.
 - If you are already using energy level 1, remove the device and wait until you feel OK before using the device again.
7. At the end of the treatment, remove the device, and wipe the external skin around the vagina with a clean dry towel, or wipes specifically for the vaginal area, to remove any gel residue.
8. Clean the device (see section 7. Cleaning, maintenance & storage).

6.3 External mode treatment

Before use, the skin should be shaven, clean, dry and free of any powders, antiperspirants or deodorants. Also, be sure that the skin is not red or inflamed.

1. Apply a small amount of the gel supplied with the device to the 3 silver-colored electrodes **(#6)**, **(#7)**. There is no need to apply gel internally.

- For external mode treatments, turn on the device by long pressing the control button **(#3)**, then short press it 3 times. The external mode will be active, and the device will be set to energy level 1. The treatment mode indicator light **(#4)** will be on (constant white). You will feel a vibration and the device is ready for use.
- Lie down and make yourself comfortable. Start your treatment at energy level 1.
- Hold the base of the device and place the 3 silver-colored electrodes **(#6)**, **(#7)** on the labia. The triangular shape of the side with the silver-colored electrodes **(#6)**, **(#7)** will help you position the device correctly.



- When the electrodes **(#6)**, **(#7)** are in good contact with the skin, and you are moving the device, you will feel heat emitted from the electrodes **(#6)**, **(#7)**. Keep moving the device slowly but firmly across the skin. If there is no movement, the Bi-Polar RF energy will not work.
- i** During the treatment, you will feel a vibration approximately once a minute.

6. If after 5 minutes you feel comfortable with the heat, move to energy level 2 by short pressing the control button **(#3)**. To use energy level 3 (high), short press the control button **(#3)** one more time.
 - i** If the energy level is right for you but it feels too hot now and again, increase the area you are treating and/or keep moving the device around the treatment area.
 - i** If you find it difficult to move the device across the skin, you may apply another small amount of gel on the 3 silver-colored electrodes **(#6), (#7)**).
7. Continue to glide the device across the labia. After 20 minutes the device will shutdown.
 - i** In cases of pain or discomfort: remove the device, and wait until you feel OK before using the device again.
8. At the end of the treatment, remove the device, and wipe the external skin around the vagina with a clean dry towel, or wipes specifically for the vaginal area, to remove any gel residue.
9. Clean the device (see section [7. Cleaning, maintenance & storage](#)).

6.4 After treatment

After internal or external mode treatments, we recommend that you:

- avoid very hot water for 2 days after the treatment.
- contact your physician if there is any indication of infection, excessive swelling, redness, pain, or any other unusual symptom.

7. Cleaning, maintenance & storage

- Use a vaginal wipe to remove any gel residue off the device including the treatment surface. This prevents any gel from solidifying or damaging the device.
 - Then dry the device with a clean paper towel.
 - After cleaning, we recommend you store the device in the storage case. You may wish to put the protective cover **(#8)** over the electrodes **(#6),(#7)**, but it is not essential.
- i** You may use cleaning fluids with up to 70% alcohol but never use acetone or other abrasive fluids, because they will damage your device.

 Never immerse the device or any of its parts in water.

8. Troubleshooting

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

Problem	Explanation / what to do
My device does not start.	<ul style="list-style-type: none"> • Check that the device is charged. Restart the device.
I don't feel any heat from the device.	<ul style="list-style-type: none"> • No heat is emitted if the electrodes (#6), (#7) are not in good contact with your skin. This is a safety feature. Make sure the device is tightly pressed to the skin before starting treatment. • No heat is emitted if you have not applied gel, or if previously applied gel has dried up. Be sure to apply the gel directly before treatment.

Problem	Explanation / what to do
The treatment mode indicator light (#4) and the energy level indicator lights (#5) blink alternately.	<ul style="list-style-type: none"> • There is a system error. Restart the device.
The device does not charge.	<ul style="list-style-type: none"> • Make sure the adapter is connected to the device and the electricity supply. Unplug the adapter (#10) and then reconnect it again to reset the device. • Check that the USB cable (#9) is not damaged.
The device has stopped working during a treatment.	<ul style="list-style-type: none"> • Make sure the device is fully charged. The device will shutdown automatically during a treatment if the battery is too low, or if there is a system error.
The device has stopped working.	<ul style="list-style-type: none"> • Restart the device.

If any of the problems persist, contact Customer Service.

9. 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.

10. Consumables

You can purchase more Silk'n Intimate Gel from our website: www.silkn.co.il.

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

If your device reaches its End of Life stage, be sure to follow your country's laws for the disposal of electrical items.

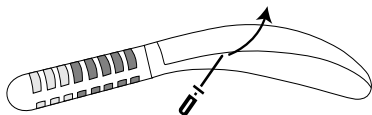
12.1 Packaging

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.

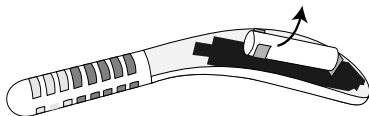
12.2 Battery removal

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.

1. **Disconnect the device:** Remove the device from the electricity supply, remove the USB cable (#9) and make sure the battery is empty.



2. **Open the casing:** Use a small tool (e.g., screwdriver or utility knife), to open the device casing.
3. **Remove the battery:** Place the device on a sturdy table. Hold the printed circuit board (green) with one hand, and remove the battery carefully with the other hand. Do not damage the battery.



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. Make sure that the device is in an uncharged state before disposal.

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



13. Specifications

Model	H2401
Technology	RT™
Bi-Polar RF (frequency; maximum output power, maximum output current)	1MHz \pm 30%; 10W max
Operation & safety	Temperature sensor to prevent skin overheating Touch sensor and movement sensor
Transport & storage between uses and storage condition	Temperature: - 40 to +70°C Relative humidity: 90%rH max Atmospheric pressure: 500 - 1060hPa
Operating conditions	Temperature: 5 to 40°C Relative humidity: 15 to 90%rH Atmospheric pressure: 700 - 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 II - charging mode internally powered medical equipment - treatment mode Type BF applied part
Protection against harmful ingress of water or particulate matter	IP23

Mode of operation	Continuous
Adapter	KSA-10D-050200HE
Adapter input; output	100-240V; 50/60Hz; 0.3A; 5.0V - 2.0A
Expected service life of the equipment	5 years

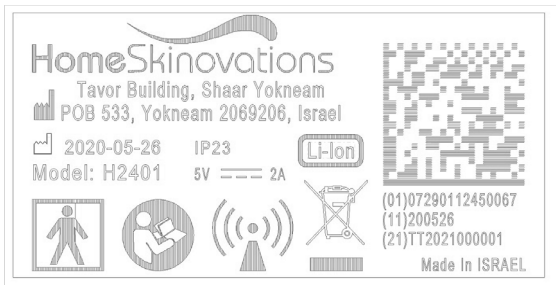
14. Signs & symbols

	A statement or event that indicates a possible or impending danger when using the device.
	Important information about using or maintaining the device.
IP23	The device is protected against spraying water when tilted up to an angle of 60°.
	Degree of protection against electric shock: type BF applied part.
	Interference may occur in the vicinity of the equipment.
	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.
	Follow the operating instructions.
	Lithium battery inside.
	Date of manufacture.

	Manufacturer.
	Product serial number.

- i** This device is not suitable for use in the presence of flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

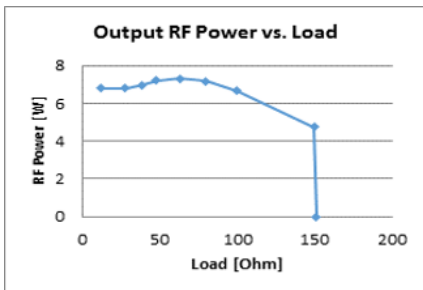
15. Labeling



16. Output power curves

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The curve shows the changes for each mode at specific power settings.



17. EMC Technical results

Test	Standard	Class/ Severity Level	Test Result
Emission (IEC 60601-1-2 section 7)			
Conducted emission Freq range 150 kHz – 30 MHz	CISPR 11	Group 1 Class B	N/A
Radiated emission Freq range 30 – 1000 MHz	CISPR 11	Group 1 Class B	Complies
Harmonic current emission test	IEC 61000-3-2	AC mains	N/A
Voltage changes. Voltage fluctuations and Flicker test	IEC 61000-3-3	AC mains	N/A
Immunity (IEC 60601-1-2 section 8)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15kV 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, 1kHz	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 @ 50Hz & 60Hz	Complies

FCC Declaration

This device complies with part 15 of the FCC Rules. Operation is subject to both of the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

18. Legal notice

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