

# medisana®

**Radiance Chill IPL Hair Remover HR 350**

User manual

# User Manual

## Radiance Chill IPL Hair Remover

The Radiance Chill IPL Hair Remover is an over-the-counter device intended for removal of unwanted hair such as but not limited to small areas such as underarm and facial hair below the chin line and large areas such as legs, in patients with Fitzpatrick Skin Phototypes I-V.

### 0 Welcome

Thanks for choosing Radiance Chill IPL Hair Remover. In order to get better effect for the device, we suggest you:

- Please read through the User Manual before using and keep this User Manual.

#### Notice:

- This user manual guide you how to use the Radiance Chill IPL Hair Remover.
- We follow sustainable development strategy. So we keep the right that we will not notify customers when we change product function, interface and appearance.
- If there is difference between description and actual product due to upgrade, please refer to actual product.
- Please use device according to correct operation steps and treatment setting.

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## 1. Safety Instructions



Please first read these safety precautions carefully and then follow the user manual to operate. These safety precautions are to ensure the operation of product is correct and safe, to prevent users or other people from personal injuries or property damage, and please make sure to follow them.

### 1.1 Warnings

•The Radiance Chill IPL Hair Remover shall not be serviced or maintained while in use with a PATIENT. The PATIENT is an intended LAY OPERATOR.

•The isolated power supply is considered as part of the device.

•Hair removal by lasers or intense pulse light sources can cause increased hair growth in some individuals. Based upon currently available data, the highest risk groups for this response are females of Mediterranean, Middle Eastern, and South Asian heritage treated on the face and neck. This group should be careful.

•DO NOT expose treated areas to the sun. Wait at least 24 hours after treatment before you expose treated skin to the sun or tan with artificial light. Even after 24 hours, make sure that the treated skin is not red from the treatment before you expose it to the sun. Be sure to carefully protect the treated skin with sunscreen throughout the hair removal period. Failure to follow this warning could result in skin swelling, blisters, or permanent skin discoloration or skin whitening.

•DO NOT continue with the treatment if the treated area feels very hot, very sensitive or burns. Such use can result in burns or other skin injury. Stop treatment and contact service centre.

•DO NOT use if you have received radiation therapy or chemotherapy treatments within the past 3 months.

•DO NOT use if you have a history of skin cancer or areas of potential skin malignancies.

•DO NOT use if you have a disease related to photosensitivity, such as porphyria, polymorphic light eruption, solar urticaria, lupus, etc.

•DO NOT use if you have an active implant, such as a pacemaker, incontinence device, insulin pump, etc.

•DO NOT use if you have a history of herpes outbreaks in the area of treatment.

•If your skin blisters or burns, STOP USE IMMEDIATELY! Continued use can result in burns or other skin injury.

•The device should not be used on the face above the cheek line: around the eyes, eyebrows, or eyelashes, as this could cause serious eye damage.

•Since the device is powered by the external power adapter, do not use the device by placing it in a location away from the electrical outlet.

•Do not use the device together with electronic devices such as cell phone, electrotome, MRI device. Otherwise, it may affect the performance of the device or cause electric shock to the patient.

•The applied part (AP) of the device is treatment window. In the process of use, the temperature of the AP may reach up to 45 °C. The operator can control the temperature by limiting the contact time, which is recommended to be less than one minute per session.

•Keep out of the reach of children under 18 years of age.

•If the power cable of the adapter becomes tangled, it may lead to strangulation, especially with excessive cable length.

•Do not treat exactly the same area multiple times during one session to avoid skin redness.

•Do not leave the equipment unattended when it is switched on to avoid the risk of fire or burns.

•This equipment is not intended for use by persons with reduced physical, sensory or mental capabilities, or lack of experience and knowledge, unless they have been given supervision or instruction concerning use of the equipment to avoid the risk of fire or burns.

•This equipment is not intended for use by children. Children should be supervised to ensure that they do not play with the equipment to avoid the risk of fire and burns.

•If the mains cord is damaged, you shall have it replaced by a service Centre authorized by Shenzhen Mlay Intelligent Technology Co., Ltd. or similarly qualified persons in order to avoid risk of electrocution.

•Manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to service personnel in parts repair.

•Water and electricity are a dangerous combination! To avoid risk of electrocution,

- Do not use this equipment in wet surroundings (e.g. in the bathroom or near a shower or swimming pool).

- Do not let water run into the appliance.

•Check if the voltage indicated on the equipment corresponds to the local mains voltage before you connect the equipment to avoid risk of electrocution or permanent damage to the equipment.

•If the wall socket used to power the equipment has poor connections, the plug of the equipment becomes hot. Make sure you plug the equipment into a properly installed wall socket to avoid the risk of fire and burns.

•The lay operator or lay responsible organization should contact the manufacturer or manufacturers representative:

-for assistance, if needed, in setting up, using or maintaining the Radiance Chill IPL Hair Remover, or

-to report unexpected operation or events.

## 1.2 Precautions

•It is recommended to use this device in a well-lit indoor environment to avoid affecting the operation of the device.

•When the Radiance Chill IPL Hair Remover is removed from the maximum or the minimum storage temperature environment to a room temperature environment (20 °C), the device is expected to take five minutes to be ready.

•When the treatment window of the device has been closely and correctly fitted to the expected skin area and the device fails to respond accordingly, the operator needs to restart the device. If the same problem still occurs after restarting, the built-in skin sensor may be loose or damaged; in this case, please contact our customer service.

•During the operation, do not shield the air intake and ventilation holes to impact heat dissipation.

•Do not throw away the device with the normal household waste at the end of its life, but hand it in at an official collection point for recycling in accordance with the regulations in force in your city or county. By doing this, you help to preserve the environment.

•Do not subject the equipment to heavy shocks to avoid risk of damage to the lamp;

•Always unplug the appliance after use and in case of a power failure to avoid risk of damage to the equipment.

•Keep the skin of the treated area clean, dry and free of any cosmetic residues before each operation.

•During the treatment, the flash button can only be triggered when the

treatment window is in good and correct contact with your skin. If the above specified conditions are not met and the flash button can be triggered, please turn off the device immediately and contact our customer service.

•The treatment level of the device will be initially set to Level 1. Adjust the energy level from low to high level. Please follow the recommended level protocol provided in the manual to choose the level that is suitable for your skin. After treatment, it is normal to have skin redness, suggest to use ice pad after treatment;

•It is recommended to clean the treatment window after every session by using a clean cloth or cotton swab to gently wipe. This can avoid hair and sebum of carbon sticking glass and affecting energy of shooting light;

•If necessary, only use a dry clean cloth to gently wipe the outer shell of the device. Never immerse the device or any of its parts in water and do not rinse it under the tap.

•Do not use the device in wet surroundings (such as near bathtubs, showers, basins or other vessels containing water). If the device becomes wet, it is prohibited to be used.

•Please store the device and its accessories in ventilated and dry environment and keep them dry and far away from pets, pests or children and lint, dust, light (including sunlight), etc.

•Please do not put metal object into heat emission hole. Otherwise, there will be risk of electric shock.

•In case the device is soaked please send it back to the factory for examination to determine whether it is repairable. In case the device is electrified when it is soaked, please power off before touching the device for your safety;

•DO NOT disassemble, repair, or transform the device without authorization. If device cannot be operated normally, please send the device and accessories back manufacturer. Our qualified maintenance personnel will overhaul it.

•This device is not needing special skills, training, and knowledge required of operator or responsible organization and environmental restrictions on locations of use.

•People with reduced physical, sensory or mental capabilities or lack of experience and knowledge, may use the device if they have been given supervision or instruction concerning the safe use of the device and understand the hazards involved.

•Regularly inspect the treatment window for damage: Do not use if the glass filter is cracked or missing. Do not use if the built-in reflector is missing or not in correct place.

•Precautions to be taken in the event of changes in the performance of the device.

•Precautions to be taken regarding the exposure of the device to reasonably foreseeable environmental conditions (e.g.to external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources).

•Instructions for installation, maintenance, pre-use checks and safe use, including clear warnings concerning precautions to avoid possible exposure to HAZARDOUS radiation or risk of fire.

•If you find that the device's treatment window is damaged, please do not use the device. When the device emits UV-A, UV-B or UV-C, warning about the risks that PATIENTS will suffer from future potential carcinogenic occurrences.

•To minimize visual disturbances to personnel, such as increasing the level of ambient light, applying spot lighting of the target area and use of protective eyewear.

•Eye safety:

The Radiance Chill IPL Hair Remover emits flashes of Intense Pulsed Light. Through the Device has been tested and passed the international standards to ensure that its output is safe for your eyes, direct exposure is still potentially harmful to your eyes. The Device can only be flashed (light emitted) if both skin sensor (inside the treatment window) detect a valid skin reading. However:

--DO NOT look directly into the treatment window of the Device when the Device has electrical power and is switched on.

--DO NOT attempt to flash (emit light) the Device towards the eyes.

--DO NOT treat area around the eyes (eyebrows or eyelashes)

--ONLY attempt to flash the Device when the treatment window is in good contact with the area you wish to treat.

--WE RECOMMEND you look away from the Device when firing into your skin.

--WE RECOMMEND that you use protective glasses that comply with ISO 12609 when operating the device.

## 1.3 Contraindications

•DO NOT use if you are under the age of 18. The effects of using the system in this age group are unknown.

•DO NOT use if the skin, in the area you want to treat, is tanned or burned. Use of the device on tanned or burned skin may result in temporary or even permanent whitening or darkening for the skin.

•DO NOT use if you are pregnant, trying to become pregnant (conceiving) or breast-feeding. Hormonal changes occur during pregnancy or breast-feeding and could increase the risk of skin injury or skin sensitivity.

•DO NOT use if you have epilepsy or light-induced seizures or migraines. The energy flashes might cause severe headaches and migraines.

•DO NOT use on tattoos, dark brown or black spots (such as dark freckles, birthmarks, moles or warts). Tattoos or dark spots may absorb too much light energy which could cause skin swelling, temporary or permanent blisters or discoloration of the skin or whitening of the skin

•DO NOT use on the face, head, ears, necks, nipples, genitalia, or around the anus. Use in these areas could cause skin swelling, blisters, or temporary skin discoloration or whitening of the skin.

•DO NOT use if you have any active skin condition in the treatment area, including acne, sores, psoriasis, eczema, burns, herpes simplex, wounds or a rash. These conditions can make the skin more sensitive to the light treatment and could make the treatment uncomfortable or cause skin swelling, blisters or infection. If your skin condition has healed enough to use the device, then please consult with your doctor.

•DO NOT use the device if you have a history of keloidal scar formation, a known sensitivity to light (photosensitivity) or are taking medication that makes the skin more sensitive to light, including non-steroidal anti-inflammatory agents, (e.g., aspirins, ibuprofens, cetaminophen), tetracyclines, phenothiazines, thiazide, diuretics, sulfonamides, DTIC, fluorouracil, vinblastine, griseofulvin, Alpha- Hydroxi Acids(AHAS), Beta-Hydroxi Acids(BHAS),Retin-A, Accutane and/or topical retinoids.

•DO NOT use if you have a disease related to photosensitivity, such as porphyria, polymorphic light eruption, solar urticaria, lupus, etc. These conditions make the skin more sensitive to the light treatment and could make the treatment uncomfortable or cause skin swelling, blisters or infection.

•The Radiance Chill IPL Hair Remover is MR Unsafe. Do not enter an MRI scanner room or an MR system. Doing so may result in severe injury or death.

## 1.4 EMC Statements

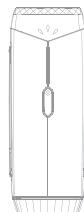
- The Radiance Chill IPL Hair Remover conforms to EMC requirements.
- User shall install and use in accordance with EMC information described in attached materials.
- During the use of the product, some of these RF emitters (e.g. RFID) in the intended environment of use might be concealed and give a potential harm to users. So, it needs to pay attentions to the followings:
  - The portable RF communications equipment including antennas can affect medical electrical equipment, and it is used to no closer than 30cm (12 inches) to any part of the Radiance Chill IPL Hair Remover;
  - Do not use the device in the present of or close to several common RF emitters (RF emitters that are known sources of electromagnetic disturbance such as diathermy, electrocautery, and RFIDs, walk-through metal detectors, and security systems (e.g., electromagnetic anti-theft systems, and metal detectors), these RF emitters have not been evaluated for electromagnetic compatibility with the subject device and it may be a source of electromagnetic disturbance and affect the safety of the device.
  - Do not apply the device in the presence of electronic monitoring equipment (e.g. cardiac monitor, ECG alarms), which may not operate properly when the electrical stimulation device in use.
  - The portable and mobile RF communication equipment may affect the performance of the device, so please avoid strong electromagnetic interference when using, such as do not use it near phone, microwave and so on.
- Manual and manufacturer's statement details are in the end of the article (Annex I).

## 2. Introduction

The Radiance Chill IPL Hair Remover is powered by Intense Pulsed Light (IPL) derived from professional IPL technology and it has the cooling function that effectively cools the skin. The Radiance Chill IPL Hair Remover is an over-the-counter device indicated for the removal of unwanted hair such as but not limited to small areas such as underarm and facial hair below the chin line and large areas such as legs. The device is also indicated for the permanent reduction in hair regrowth, defined as the long term, stable reduction in the amount of hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

### 2.1 Packing List

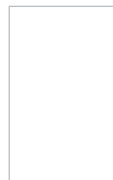
Please check first of all that the device is complete and is not damaged in any way. In case of doubt, do not use it and contact your supplier or your service centre. The following parts are included:



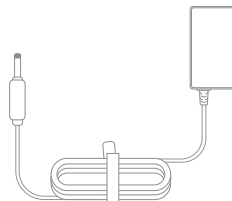
IPL main device



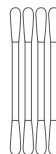
Protective glasses



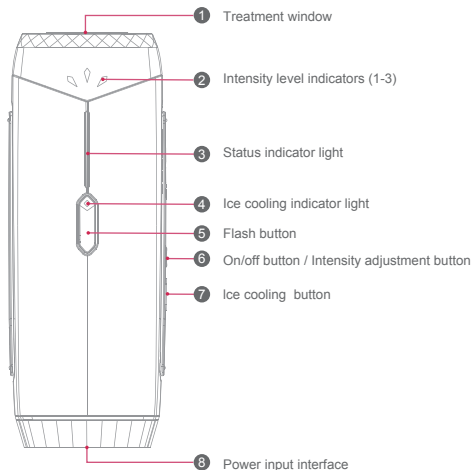
User manual



AC adapter



Cotton swab



Remark: the treatment window belongs to non-removable part, and it is the treatment panel and light-emitting window of the device.

The Radiance Chill IPL Hair Remover's Activation Buttons and Status Indicators:

- Pressing the on/off button **6** for over two seconds (after the device is connected to the power supply) will turn on the device at treatment Level 1.
- Each press of the on/off button **6** will change the level, from the lower level to the higher, for a total of 3 different treatment levels.
- Pressing the on/off button **6** for over two seconds again, it will turn off the device.
- Short press the ice cooling button **7** to turn on ice cooling function. If no need ice cooling function, then short press the button.

Note: the ice cooling function is used for skincare after or during the hair removal, which has no other medical therapeutic effect and just for cooling down the skin temperature to make the whole treatment more comfortable.

• When the treatment window is in full contact with the skin, short press the flash button **5** to activate the flash lamp in a single pulse.

• Press the flash button **5** about 3 seconds will active auto pulse mode, and the level icon will blink at the same time.

• Short press the flash button **5** to stop auto pulse, and it will back to single pulse mode.

Note: Move the device about the distance of one window each time.

• Status indicator light **3** indicators:

| Indicator                  | Mode               | Meaning                                                                                        |
|----------------------------|--------------------|------------------------------------------------------------------------------------------------|
| No Light                   | OFF                | Device not working (Not connected to the AC adapter).                                          |
| Slow "flashing" blue light | Activation/Standby | Device is in standby state (Device is activated after connected to the power supply).          |
| Fast "flashing" blue light | Charge             | Device is charging for energy storage.                                                         |
| "Steady" blue light        | Hair removal       | Device can deliver a pulse (You can conduct "Hair Removal") due to only the full skin contact. |

### 3. How It Works

#### 3.1 How Does IPL Work

Radiance Chill IPL Hair Remover uses Intense Pulsed Light (IPL) technology to emit a specific wavelength of the light and delivers to the skin. The device is designed to help break the cycle of hair regrowth. Light energy is transferred through the skin's surface and is absorbed by melanin present in the hair shaft. The absorbed light energy is converted to heat energy (below the surface of the skin), which disables the hair follicle preventing further growth, so as to achieve effective hair removal.

#### 3.2 What To Expect

##### Immediately Post-Treatment

You should not see any significant side effects from treatment (Refer to section 5.2 for more information on side effects).

In the first few weeks following initial treatments, you will still see some hair growing. These are likely to be hairs that were missed during treatment i.e. they were lying dormant and not in their growth phase (Anagen) during treatment; when IPL is most effective.

##### 6 weeks into the 12 week plan

You should see a reduction in hair growth. However, many hairs may still not have been treated in their growth phase. It is important to continue the weekly treatments.

##### After the 12 week plan

Immediately after you have completed the 12 weeks plan you should see a significant reduction in hairs within the treated area. Any remaining hairs should be finer and lighter in colour. Continued monthly treatments, or treatments as required, should keep your skin hair-free.

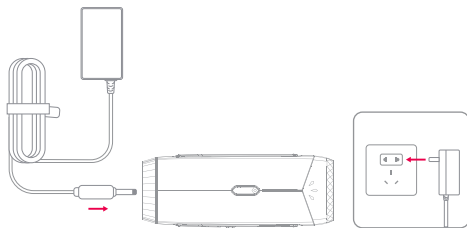
### 4. How To Use

#### Preparation

The Radiance Chill IPL Hair Remover should ideally be used on the small areas such as underarm and facial hair below the chin line, large area such as the legs.

#### 4.1 Device Set-up

- 1) Remove all components from the gift box;
- 2) Make sure the device is clean, dry and intact before beginning the treatment: You can clean the lamp cap's treatment window with clean cloth or cotton swab. This is done in order to remove hairs and dust from the treatment window;
- 3) Before each treatment, inspect the treatment window, AC Adapter cord for damage;
- 4) Plug AC adapter end into an electrical outlet and the cord into the device socket , the blue LED indicator will be lighted up and blinked slowly;



Radiance Chill IPL Hair Remover is now ready to be used.

#### NOTE:

•Place the device on a table or area near an electrical wall outlet. Move away any liquids from the area.

#### 4.2 Preparing Yourself

- 1) On the basis of Fitzpatrick Photo typing Scale, identify your skin tone whether is suitable for; the details please refer to "4.4 Recommended Treatment Protocol" in this article.
- 2) Prior to use, make sure your skin is in good condition without any injury and wound; as well as your skin is shaved, clean and dry (free of any residue such as powders, creams, makeup, antiperspirants, or deodorants);



#### 4.3 Skin Sensitivity Test

If you are using the device for the first time or on a new body area, choose a small area close to the area you intend to treat, for the purpose of performing a skin sensitivity test. Use the LOW treatment level. Follow the treatment instructions below but make sure to emit only 2-3 pulses. After the skin test, wait 6 hours and check your skin for any reaction. If after 6 hours the skin appears normal and there is no redness or other skin reaction, then you are ready to perform a full treatment.

#### 4.4 Recommended Treatment Protocol

Applications:

Lip hair, armpit hair, body hair and legs, hair on places that affecting looks such as hair line on forehead and bikini area.

| Skin color<br>Hair color | White | Ivory | Beige | Light Brown | Brown | Dark Brown |
|--------------------------|-------|-------|-------|-------------|-------|------------|
| Black                    | ✓     | ✓     | ✓     | ✓           | ✓     | ✗          |
| Dark brown               | ✓     | ✓     | ✓     | ✓           | ✓     | ✗          |
| Brown                    | ✓     | ✓     | ✓     | ✓           | ✓     | ✗          |
| Golden                   | ✓     | ✓     | ✓     | ✓           | ✓     | ✗          |
| Red                      | ✗     | ✗     | ✗     | ✗           | ✗     | ✗          |
| White                    | ✗     | ✗     | ✗     | ✗           | ✗     | ✗          |
| Gray                     | ✗     | ✗     | ✗     | ✗           | ✗     | ✗          |

✓:Indicates applicable

✗:Indicates not applicable

NOTE:

•Choose the comfortable level according to your skin tolerance and increase level from one to three levels gradually. If there isn't unsuitable or reaction, you could increase level gradually.

•The colour of your skin may change, for example because your skin has been tanned: it may then be darker than the skin tone during the previous treatment. Therefore, it is important that you check the settings to be used before each treatment and set the settings according to different treatment areas. Some areas may be darker than others.

•Don't hold the main device's window still over one spot on the skin and flash multiple pulses on the skin. Doing so may cause too much heat and may result in skin swelling, blisters, or other discomforts of your skin.

•After each flash, move treatment window slowly to a neighboring skin spot.

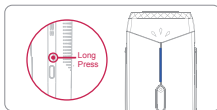
Treatment Schedule:

•For optimal results, the Radiance Chill IPL Hair Remover should be used once a week for 12 weeks to ensure all hair follicles are treated.

•After the initial treatment phase (12 weekly treatments), we recommend to use the device is used once a month, or as required to maintain the results.

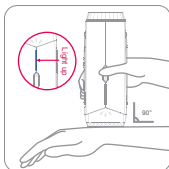
## 4-5 Getting Started

1) Press and hold the on/off button **⑥** for two seconds to start the device, the fan will operate.



2) After turning on the device, the ice cooling function will be turned on automatically. At this time, the ice cooling indicator light **④** will light up, and the hardware around the light outlet will feel the ice cooling.

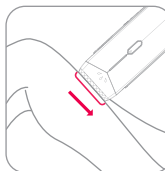
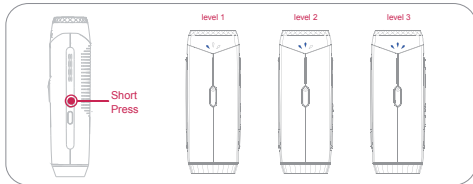
Short press the ice cooling button **⑦** to turn off the ice cooling function, and the ice cooling icon will go out.



3) Make the treatment window **①** of the device perpendicular to the skin at 90 degrees. When the window and the skin are fully fitted, when the indicator light changes to a blue solid light, it means that the device has correctly identified the skin in the treatment area and has completed the treatment. Energy reserve, equipment is ready for irradiation operation.

4) After turning on the device, the treatment level enters level 1 by default; short press the intensity adjustment button **⑤** to switch the treatment level in turn. When the skin adapts to the irradiation effect, the treatment level can be freely selected according to the skin's tolerance.

Note: Each time you press the flash button **⑤**, the device will emit a flash; at the same time, you will feel a slight warming and tingling sensation, which are normal symptoms of using this device.



5) Press the flash button **⑤** to start hair removal, and after each emission, move the position of the light outlet one by one until the entire hair removal area is operated. Individuals can rest for a while according to different energy levels and the skin's ability to withstand heat. After the skin cools down, repeat the above steps for one or two times on the depilated area, but please do not repeatedly irradiate the same skin in a short period of time to avoid burning the skin.

6) When performing hair removal, you can press the flash button **⑤** for 3 seconds to enter the automatic light emitting mode to start hair removal. When entering the automatic light emitting mode, the intensity level indicators **②** will flash. When operating in the automatic light emitting mode, you can short press the flash button **⑤** to exit the automatic light emitting mode. The levels icon will stop flashing.

Note: Duration of use: When using a single continuous treatment, avoid repeated use for more than three times on the same part.

7) After hair removal, press and hold the on/off button **⑥** for more than two seconds to turn off the power (the fan will stop running after a delay of 10 seconds), and remove the power adapter.

Note: If the device is inactive for five minutes, the device will go into standby, its indicator light will blink blue, and the fans will stop.

Note: Plug is a technical for the mains isolation.

8) After the device cools down, please clean the treatment window **①** according to the prescribed cleaning method to prevent residual hair or dust (see the product maintenance and maintenance chapter of the manual for the cleaning method). After cleaning, put the device and its accessories into the box and store in a dry and cool place.

## 4-6 ERROR reminder function

1) Fan error: When the fan appears error, the 2nd and 3rd intensity level indicators **②** flash.

2) Temperature alarm: When the device overheats, the 1st and 2nd intensity level indicators **②** flash.

Solution: When the above error reminder appears, please turn off the device and disconnect the power, and then restart the device.

## 5. Aftercare

### 5.1 Possible Side Effects

When using the Radiance Chill IPL Hair Remover according to the instructions for use, side effects are rare. However, every aesthetic procedure including the usage of home use devices may cause some degree of side effects. If any of the following conditions (refer to section 5.2 Side Effect Table) appear and last more than 24 hours, you should consult your physician.

### 5.2 Side Effect Table

It is possible that the following side effects have emergence during use.

| Degree of Side Effects     | Side Effects                                                      |
|----------------------------|-------------------------------------------------------------------|
| Minor Side-Effects         | Irritation / Redness / Sun Sensitivity                            |
| Rare Side-Effects          | Burns / Scarring / Pigment Changes / Excessive Redness / Swelling |
| Extremely Rare Side-Effect | Infection / Bruising                                              |

### 5.3 Cleaning, inspection, maintenance & storage

After each treatment, inspect the treatment window for damage. Do not touch or clean the treatment window immediately after use to allow it to cool down.

#### Cleaning

- Make sure to turn off and unplug main device before cleaning.
- Wipe the treatment window with a dry, lint-free cloth if any marks or black spots are visible.
- Never use acetone or other abrasive fluids, because they will damage your device.
- Keep the device dry. Never submerge the device or any of its parts in water as it may lead to an electrocution risk.

#### Inspection

- After wiping, visually inspect the device. If the black spots remain, please wipe several times until no visual contamination.

#### Maintenance & Storage

- To avoid breakage or missing device and its parts, we recommend you store the device in its original box after each use.
- Clean the device before you store it and store it in a safe and protective place.

### 5.4 Troubleshooting

If you experience any problem with the the Radiance Chill IPL Hair Remover, please refer to below information to try to resolve it:

| Problem                                                                          | Solution                                                                                                                                                                                                                                                                          |
|----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| If the Radiance Chill IPL Hair Remover does not turn on.                         | Make sure that the power supply is plugged properly into the device and the electrical outlet.                                                                                                                                                                                    |
| If the Radiance Chill IPL Hair Remover does not trigger a pulse.                 | <ol style="list-style-type: none"><li>1. Verify there is full contact with the skin. The flash button will activate a flash pulse only when the device is in full contact with the skin.</li><li>2. In the case of a safety issue, the device will not trigger a pulse.</li></ol> |
| If you feel heat and hurt during the use of the Radiance Chill IPL Hair Remover. | <ol style="list-style-type: none"><li>1. Shave and clean the hair in the expected treatment area before use.</li><li>2. Choose one comfortable treatment level for yourself.</li><li>3. DO NOT treat the same area repeatedly at the same time.</li></ol>                         |

If you still have problems with your device, please contact customer service.

## 6. Information

### 6.1 Technical Specifications

| Basic Specifications                           |                                               |
|------------------------------------------------|-----------------------------------------------|
| Name and Model                                 | Radiance Chill IPL Hair Remover HR 350        |
| Level of Protection                            | BF Type, Class II                             |
| Service life of the device                     | 500,000 times (the maximum shot time)         |
| Shelf life of the device                       | 3 years                                       |
| Method(s) of sterilization                     | N/A                                           |
| Suitability for use an OXYGEN RICH ENVIRONMENT | N/A                                           |
| Mode of operation                              | Continuous operation                          |
| Output Specifications                          |                                               |
| Type of Light                                  | Intense Pulsed Light (IPL)                    |
| Energy Medium                                  | Xenon Arc flashlamp                           |
| Light Wavelength Range                         | 510~1200nm                                    |
| Pulse Duration                                 | 4.0~8.0milliseconds                           |
| Spot Size (Window size of IPL)                 | 3.5cm <sup>2</sup>                            |
| Treatment Level                                | Level 1 to 3                                  |
| Max Energy                                     | 12J±20%                                       |
| Energy Density                                 | 1.37J/cm <sup>2</sup> ~ 4.11J/cm <sup>2</sup> |
| Pulse Interval                                 | 0.7~2.5s                                      |
| Risk Group                                     | Exempt                                        |

In the course of constant product improvements, we reserve the right to make technical and design changes.

Caution: Use of controls or adjustments or performance of procedures other than those specified herein may result in HAZARDOUS radiation exposure.

The product fulfills the requirements of IEC60601-2-57:2011 and IEC 60601-2-83:2019/AMD1:2022.

### Power Specifications

| Adaptor Model         | J482B-1204000IX            |
|-----------------------|----------------------------|
| AC/DC Adapter Input   | AC 100-240V, 50/60Hz, 1.5A |
| AC/DC Adapter Output  | DC 12V/4A                  |
| Usage Specifications  |                            |
| Operation Temperature | 0°C~30°C (32°F~86°F)       |
| Operation Humidity    | 25%~75%                    |
| Atmospheric Pressure  | 80kPa~106kPa               |
| Storage Temperature   | 0°C~50°C (32°F~122°F)      |
| Storage Humidity      | 25%~75%                    |
| Atmospheric Pressure  | 80kPa~106kPa               |

### 6.2 Disposal



This device must not be disposed of with domestic waste. Metals are reusable or can be recycled into raw materials. Dispose of a device that is no longer needed at a collection point in your town/city so that it can be disposed of in an environmentally friendly way. Please contact your local authority or retailer with regard to disposal procedures. Remove the battery before you dispose of the device. Do not dispose of spent batteries in domestic waste, rather in special waste or at a battery collection point at your retailer!

## 6.3 Warranty

In case of warranty please contact your specialist shop or the service centre directly. If you need to return the device, please indicate the defect and enclose a copy the purchase receipt. The following warranty conditions apply:

1. All medisana products are guaranteed for one year from the date of purchase. The date of purchase is to be proven in case of warranty by the purchase receipt or invoice.
2. Defects due to material or manufacturing defects shall be eliminated free of charge within the warranty period.
3. A warranty service does not extend the warranty period for either the equipment or any replacement parts.
4. The following are excluded from the guarantee:
  - a. any damage caused by improper handling, e.g. by non-observance of the instruction manual.
  - b. Damage due to repair or intervention by the purchaser or unauthorised third parties.
  - c. Transport damage that has occurred on the way from the manufacturer to the consumer or when sending it to the service centre.
5. Liability for direct or indirect consequential damages caused by the device is also excluded if the damage to the device is recognised as a warranty case

## 7. Relevant Symbol, Explanation and Marking

| Symbol                                                                            | Explanation                                           | Symbol                                                                             | Explanation                        |
|-----------------------------------------------------------------------------------|-------------------------------------------------------|------------------------------------------------------------------------------------|------------------------------------|
|  | Keep dry                                              |  | Fragile handle with care           |
|  | This way up                                           |  | Manufacturer                       |
|  | Type BF applied part                                  |  | Class II equipment                 |
|  | Indoor installation equipment                         |  | Cautions, warnings                 |
|  | WEEE (Waste Electrical and Electronic Equipment) mark |  | Follow instructions for use        |
|  | Date of Manufacture                                   |  | Serial number                      |
|  | Unique device identifier                              |  | MR Unsafe                          |
|  | Medical device                                        |  | Warning: OPTICAL RADIATION         |
|  | Do not stare at light source                          |  | Opaque eye protection must be worn |

## Annex I: Manufacturer's EMC Statement

Proper light energy output is defined as ESSENTIAL PERFORMANCE of this device by the manufacturer. If the device is placed firmly on the skin and completed energy-storage, and then the device does not flash after the trigger button is pressed, the device has malfunctioned. If this occurs, contact customer service.

Warning: Don't use near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 in (30 cm) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

| Guidance and Manufacturers Declaration - Electromagnetic Emissions |            |
|--------------------------------------------------------------------|------------|
| Emissions test                                                     | Compliance |
| RF emissions CISPR 11                                              | Group 1    |
| RF emissions CISPR 11                                              | Class B    |
| Harmonic emissions IEC 61000-3-2                                   | Class A    |
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3        | Complies   |

| Guidance and Manufacturers Declaration - Electromagnetic Immunity                                   |                                                                                                                                     |                                                                                                                                     |
|-----------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| Immunity Test                                                                                       | IEC 60601-1-2 Test level                                                                                                            | Compliance level                                                                                                                    |
| Electrostatic discharge (ESD) IEC 61000-4-2                                                         | ±8 kV contact<br>±2 kV, ±4kV, ±8 kV, ±15 kV air                                                                                     | ±8 kV contact<br>±2 kV, ±4kV, ±8 kV, ±15 kV air                                                                                     |
| Electrical fast transient/burst IEC 61000-4-4                                                       | ±2 kV for power supply lines<br>±1 kV for input/output lines                                                                        | ±2 kV for power supply lines<br>±1 kV for input/output lines                                                                        |
| Surge IEC61000-4-5                                                                                  | ± 1 kV line(s) to line(s)<br>± 2 kV line(s) to earth                                                                                | ± 1 kV line(s) to line(s)<br>± 2 kV line(s) to earth                                                                                |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | 0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°<br>0 % UT ; 1 cycle<br>70 % UT; 25/30 cycle<br>0% UT; 250/300 cycle | 0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°<br>0 % UT ; 1 cycle<br>70 % UT; 25/30 cycle<br>0% UT; 250/300 cycle |
| Power frequency magnetic field IEC 61000-4-8                                                        | 30 A/m<br>50Hz/60Hz                                                                                                                 | 30 A/m<br>50Hz/60Hz                                                                                                                 |
| Conducted RF IEC61000-4-6                                                                           | 3 V r.m.s.<br>150 kHz to 80 MHz<br>6 V RMS in the ISM and amateur bands between 0.15 MHz and 80 MHz                                 | 3 V r.m.s.<br>150 kHz to 80 MHz<br>6 V RMS in the ISM and amateur bands between 0.15 MHz and 80 MHz                                 |
| Radiated RF IEC61000-4-3                                                                            | 10 V/m<br>80 MHz – 2.7 GHz<br>80 % AM at 1 kHz                                                                                      | 10 V/m<br>80 MHz – 2.7 GHz<br>80 % AM at 1 kHz                                                                                      |
| NOTE U <sub>r</sub> is the a.c. mains voltage prior to application of the test level.               |                                                                                                                                     |                                                                                                                                     |

Guidance and Manufacturer's Declaration - IMMUNITY to proximity fields from RF wireless communications equipment

| Immunity test                   | IEC60601 test level              |                                     |               |                | Compliance level |
|---------------------------------|----------------------------------|-------------------------------------|---------------|----------------|------------------|
|                                 | Test frequency                   | Modulation                          | Maximum power | Immunity level |                  |
| Radiated RF<br>IEC<br>61000-4-3 | 385 MHz                          | **Pulse<br>Modulation:<br>18Hz      | 1.8 W         | 27 V/m         | 27 V/m           |
|                                 | 450 MHz                          | *FM+ 5Hz<br>deviation:<br>1kHz sine | 2 W           | 28 V/m         | 28 V/m           |
|                                 | 710 MHz<br>745 MHz<br>780 MHz    | **Pulse<br>Modulation:<br>217Hz     | 0.2 W         | 9 V/m          | 9 V/m            |
|                                 | 810 MHz<br>870 MHz<br>930 MHz    | **Pulse<br>Modulation:<br>18Hz      | 2 W           | 28 V/m         | 28 V/m           |
|                                 | 1720 MHz<br>1845 MHz<br>1970 MHz | **Pulse<br>Modulation:<br>217Hz     | 2 W           | 28 V/m         | 28 V/m           |
|                                 | 2450 MHz                         | **Pulse<br>Modulation:<br>217Hz     | 2 W           | 28 V/m         | 28 V/m           |
|                                 | 5240 MHz<br>5500 MHz<br>5785 MHz | **Pulse<br>Modulation:<br>217Hz     | 0.2 W         | 9 V/m          | 9 V/m            |

Note\* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Note\*\* - The carrier shall be modulated using a 50 % duty cycle square wave signal.

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