

SMOOTH SKIN
bare^{fit}

IPL USER GUIDE
10 minutes and *voilà!*

Welcome to SmoothSkin Bare Fit!

Congratulations! You've opened up a world of unparalleled beauty, smoothness and convenience. Come and join in the conversation at www.smoothskin.com where you can find expert advice and support throughout your treatment.

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1. THE SMOOTHSKIN BARE FIT SYSTEM

Package Contents

Inside the packaging of the SmoothSkin Fit you will find the following:

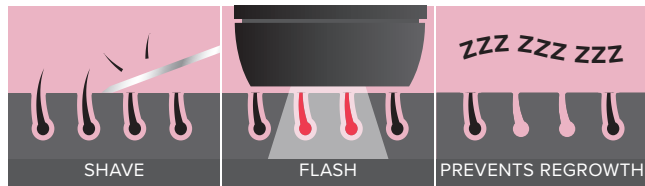
- Handset and Power Supply
- Mains Power Cable
- Precision Head
- User Manual



2. HOW DOES SMOOTHSKIN BARE FIT WORK

HOW DOES IPL WORK

SmoothSkin Bare Fit is designed to help break the hair cycle. Light energy is transferred through the skin's surface and is absorbed by melanin present in the hair shaft. That light energy is converted to heat energy (below the surface of the skin), which stops the hairs from growing back. Now you can look forward to seeing the treated hairs naturally fall out over the course of a few days to 1-2 weeks.



3. IMPORTANT SAFETY INFORMATION

Contraindications

DO NOT use SmoothSkin Bare Fit if you have very dark skin. The skin tone sensor located near the output window of the device will determine the tone of your skin. If the skin tone sensor determines that your skin is too dark for safe use, operation of SmoothSkin Bare Fit will be prevented.



DO NOT use SmoothSkin Bare Fit if your skin has been artificially or naturally tanned or is burned from sun overexposure. Your skin may be extra sensitive following sun exposure and particularly susceptible to burning, blistering, discolouring or scarring if you use SmoothSkin Bare Fit. Wait 1 week until sunburn or tan disappears before using SmoothSkin Bare Fit.

DO NOT expose treated areas to the sun. Wait at least 7 days after treatment before exposing treated skin to direct sunlight. Your skin may be extra sensitive following SmoothSkin Bare Fit treatment and particularly susceptible to sunburn. Apply sunscreen (SPF 15 or greater) to the treated area or cover the treated area with suitable clothing.

DO NOT use SmoothSkin Bare Fit directly on the nipples, genitals or around the anus. These areas may have a darker skin colour and/or greater hair density. Using the device in these areas may cause discomfort/pain or injure (burn, discolour or scar) your skin.

DO NOT use SmoothSkin Bare Fit if you have a history of skin cancer or pre-cancerous lesions (e.g. nevi or a large number of moles).

DO NOT use on blisters and scars

DO NOT use SmoothSkin Bare Fit if you are pregnant, lactating, as this device has not been tested with these individuals.

DO NOT use SmoothSkin Bare Fit on dark brown or black spots such as birthmarks, moles or warts in the area you wish to treat. Using SmoothSkin Bare Fit may injure your skin or make existing conditions worse. You may experience side effects such as burns, blisters and skin colour changes or

scarring.

DO NOT use SmoothSkin Bare Fit if you have any skin condition in the treatment area, including psoriasis, vitiligo, eczema, acne, herpes simplex or active infections or wounds.

DO NOT use SmoothSkin Bare Fit if you are under the age of 18 as this device has not been tested on these individuals.

Warnings

EYE SAFETY



SmoothSkin Bare Fit emits flashes of Intense Pulsed Light. Direct exposure is potentially harmful to your eyes. Take care to follow the safety precautions below.

WARNING: Possible eye injury (Potentially leading to loss of vision) or skin injury if instructions are not followed. Read and follow the instructions.

The handset can only be activated (flashed) if the skin tone sensor (next to the treatment window) detects a valid skin tone reading and is in full contact with the treatment area. However:

DO NOT look directly into the treatment window of the handset when the

system has electrical power and is switched on.

DO NOT attempt to activate (flash) the system towards the eye.

DO NOT treat areas around the eye (eyebrows or eyelashes). Misuse can lead to eye damage, protect eye from exposure. **DO NOT** use the appliance over the eye lids or close to the eye.

ONLY attempt to activate (flash) the system when the front of the handset is in good contact with the area you wish to treat.

WE RECOMMEND you look away from the handset when firing onto your skin.

ELECTRICAL AND SAFETY

As with any electrical device, certain precautions must be taken in order to ensure your safety.

DO NOT try to open SmoothSkin Bare Fit, as this may expose you to dangerous electrical components.

DO NOT use if SmoothSkin Bare Fit is damaged; for example, cracked Handset, cable damage (internal wires visible), cracked or broken glass on the handset, etc.. This may result in injury.

DO NOT use near bathtubs, showers, basins or other vessels containing water. If SmoothSkin Bare Fit becomes wet, it should not be used.



DO NOT use if SmoothSkin Bare Fit becomes uncomfortably hot to touch. This may indicate that the unit is damaged.

DO NOT use a power supply or other component, other than those provided for use with SmoothSkin Bare Fit. This may damage the unit and cause it to stop working.

DO NOT attempt to activate (flash) SmoothSkin Bare Fit onto any surface other than skin.

WARNING: no modification of this equipment is allowed.

DO NOT position SmoothSkin Bare Fit so that it is difficult to disconnect from the mains supply.

GENERAL SAFETY

DO NOT use if you have had a skin peel treatment on the area you wish to treat. Please wait 30 days after a skin peel before treating with SmoothSkin Bare Fit.

Treating tanned skin with Intense Pulsed Light (IPL) may result in permanent Hyperpigmentation (Darkening) or Hypopigmentation (lightening) of the treated skin.

DO NOT use on areas where you have tattoos or permanent make up.

DO NOT use If you have a known sensitivity to sunlight (photosensitivity) or are taking medication that makes the skin more sensitive and causes photosensitivity, e.g. Retin A, Accutane and/or other topical retinoids. Always check the instruction leaflet that comes with your medicinal product, to see if photosensitivity is listed as a side effect. Use of SmoothSkin Bare Fit on photosensitive skin could result in skin damage such as swelling or blisters. Seek medical advice prior to application of the appliance as use may harm the skin.

This appliance is not intended for the treatment of medical conditions. Medical advice should be sought to address, for example, moles, skin rash, itchy skin, skin fungus or infection, skin bumps, or skin tags.

SmoothSkin Bare Fit should not be used over any fillers or botox.

SmoothSkin Bare Fit should be kept out of the reach of children under 18 years of age. Children should not use, play with, maintain or clean the

device. There are a number of potential risks – exposure to the light output causing burns or eye damage, electrocution, strangulation from the cables, choking from the removable front.

SmoothSkin Bare Fit should be kept out of reach of pets and pests which could damage the device. Potential risks include reduced function and electrocution.

SmoothSkin Bare Fit is not intended for use by persons with reduced physical, sensory or mental capabilities. Unless they have been given supervision or instruction concerning safe and proper use of the device by a person responsible for their safety.

The SmoothSkin Bare Fit glass filter is a critical component that will get hot during use. **DO NOT** touch the filter during or directly after use. Regularly inspect the filter for damage.

DO NOT use SmoothSkin Bare Fit if the filter is cracked or missing.

Ensure that SmoothSkin Bare Fit treatment window is clean and free from debris. Any debris on or around the treatment window during operation may result in temporary skin changes such as redness or swelling.

WARNING: Damage of the skin may occur after prolonged or repeated

surface application on one site. **WARNING:** Damage of the skin may occur after prolonged or repeated surface application on one site. Avoid over-usage which included excessive passes, stacking of pulses and/or increased frequency of use.

WARNING: Do not override the safety mechanisms inherent to the device.

DO NOT exceed the usage specified in the treatment regime.

Precautions

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.

DO NOT use SmoothSkin Bare Fit on any area where you may want hair to grow back.

DO NOT use your SmoothSkin Bare Fit device on man's face, jaw, or neck. The hair in a man's beard area is too dense, and using SmoothSkin Bare Fit device in these areas may result in skin injury.

SmoothSkin Bare Fit is not recommended for use on red, grey, white or blonde hair. SmoothSkin Bare Fit is not effective on these hair colours.

4. POTENTIAL RISKS, SIDE EFFECTS AND SKIN REACTIONS

Use of the SmoothSkin Bare Fit could result in side effects.

The table below lists the known skin reactions that may occur following treatment with the SmoothSkin Bare Fit.

POSSIBLE SIDE EFFECTS	HOW TO ASSESS AND REACT
Mild pain / discomfort in the area being treated.	This is expected and is normal for all IPL treatments. You can keep on using the device as instructed, and the pain should diminish with continued use.
Warm feeling or tingling sensations during treatment, which typically disappear after a few seconds to a minute and decrease with continued use.	This is expected and is normal for all IPL treatments. You can keep on using the device as instructed.
Itchiness in the treatment area.	This is quite common for IPL treatments, and should subside after a short period. You can keep on using the device as instructed. Do not scratch the area.
Skin redness during or after treatment which disappears within minutes.	This is expected and is normal for all IPL treatments. You can keep on using the device as instructed once skin redness has disappeared.
Skin redness which does not disappear within minutes and lasts 24-48 hours.	Stop using the device immediately and consult your physician before using it again.
Pain or discomfort that is intense during treatment or persists after a treatment.	Stop using the device immediately and consult your physician before using it again.

IN VERY RARE CASES	HOW TO ASSESS AND REACT
Swelling and redness that does not disappear within two to three days.	Stop using the device immediately and consult your physician before using it again.
Temporary changes in skin colour (lightening or darkening).	If your skin colour changes, stop using the device immediately and consult your physician.
Blistering, scarring or burning of the skin.	Stop using the device immediately and consult your physician before using it again. Apply a cold pack to the area. Treat with antiseptic or burn cream.

In a clinical trial of 50 subjects, each subject received 12 weekly treatments. The recorded effects were:

- Itchiness – Four subjects experienced mild itchiness after treatment.
- Slight Redness – This was reported by 1 subject.
- Mild Stinging Sensation – Five subjects reported mild discomfort following treatment.
- In-growing Hair – One subject reported experiencing an in-growing hair following treatment.
- Follicle Redness – One subject reported a red spot at the treatment site following treatment.

In all cases, the treated skin returned to normal within 7 days.

5. BENEFITS OF USING SMOOTHSKIN BARE FIT

The SmoothSkin Bare Fit is indicated for the permanent reduction of unwanted hair.

A clinical trial was performed to assess both the safety and efficacy of the SmoothSkin Bare Fit. The key features of the clinical trial were:

- All treatments were performed by non-medically trained operators at a single location using devices identical to the SmoothSkin Bare Fit provided in this package;
- All subjects were required to complete questionnaires related to their general health and those who could not be treated, e.g. those who had one or more of the contraindications as listed in Section 3 of this User Manual were excluded. In addition, all subjects were required to provide Informed Consent as per international clinical trial requirements;
- A total of 53 female subjects, aged between 19 and 45 years old, commenced the trial;
- Three subjects left the trial during the treatment period for personal reasons. No subjects left the trial due to problems associated with the use of the SmoothSkin Bare Fit;
- Each subject received 12 weekly treatments to their chosen body location. A typical treatment consisted of shaving the site then applying the SmoothSkin Bare Fit following the same process as outlined in Section 8., Step 3 of this user manual;
- Hair counts were used to measure the change in the amount of hair 6 months after the last treatment and 12 months after the last treatment. The hairs in the treatment sites were counted via high resolution photography and the difference in hair counts was calculated as a percentage change;

- When used as directed, the clinical trial participants showed on average 44% less hair 6 months after their last treatment and 36% less hair 12 months after their last treatment when compared to hair counts taken before treatment (See Table below). Actual results did vary from person to person;

SmoothSkin Bare Fit	
Number of Subjects at 6 Months Post Treatment	50
Hair Reduction at 6 Months Post Treatment	43.9%
Number of Subjects at 12 Months Post Treatment	33
Hair Reduction at 12 Months Post Treatment	36.0%
% of Subjects met success (>30% hair reduction) on all body areas at 12 months post-treatment. Subject Success is defined as greater than 30% hair reduction at all treatment sites at 12 months.	66.7%

- The incidence of side effects during the clinical trial was minimal (as outlined in Section 4 above) and the majority of subjects (48 out of 50) would recommend the SmoothSkin Bare Fit to their friends.

6. WHAT IS THE INTENDED USE OF SMOOTHSKIN BARE FIT

INTENDED USE

SmoothSkin Bare Fit is intended for the permanent reduction in unwanted hair.

7. YOUR SUITABILITY

BODY AREAS

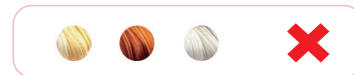
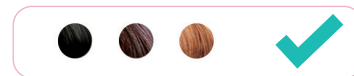
SmoothSkin Bare Fit is suitable for use on body hair and female facial hair below the cheekline.

SKIN COLOUR

SmoothSkin Bare Fit is suitable for use on light, medium and dark skin tones up to and including skin tone 5. SmoothSkin Bare Fit incorporates a Skin Tone Sensor that measures the colour of your skin and will prevent use if your skin tone is too dark.

HAIR COLOUR

SmoothSkin Bare Fit is suitable for use on naturally black or brown hair. It may not be as effective on white, grey, blonde or red hair.



8. HOW TO USE SMOOTHSKIN BARE FIT

WARNING: Follow each step in the treatment process ensuring you complete all aspects of each step before progressing to the next.

Step 1: PREPARE the area to be treated

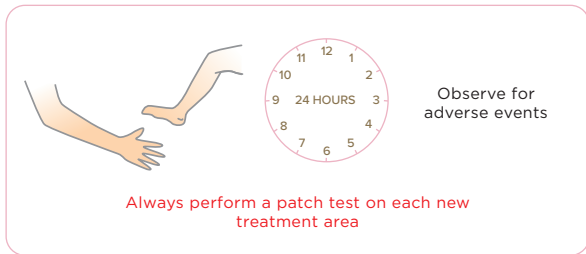
Remove all visible hair by shaving. Make sure there is no hair remaining above the surface of the skin as this may cause injury. This also prevents debris from covering the front of your device.

Cleanse the treatment area and pat dry. Remember, don't use any gels or creams with this device!

Step 2: Doing a TEST PATCH

Before your first treatment on each new body area, we RECOMMEND you test your skin in that area for a reaction to SmoothSkin Bare Fit. The patch test area should be approximately 3cm x 2cm in size (equivalent to 2 flashes applied to the skin side by side). Follow Step 3 to treat the area.

Wait 24 hours following the patch test, to ensure your skin is suitable for treatment and there is no adverse reaction to the light energy. If there is no reaction after 24 hours, you may treat the area around the patch test. The 'patch tested area' should NOT be re-treated for at least 1 week.



Step 3: Treating with SmoothSkin Bare Fit

- Plug the Power Supply into an Electrical Outlet using the provided Power Cable. The Skin Tone Sensor on the front of the Handset will illuminate blue and the fan will start up.

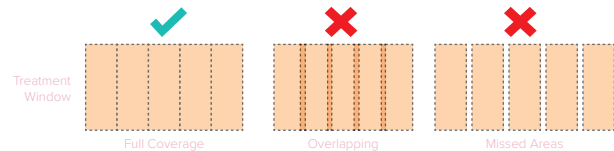
STANDBY MODE Timeout

When the unit is left "inactive" i.e. no buttons are pushed for 10 minutes then the unit will revert to STANDBY mode, and the STS lights will switch off. To return to READY mode for treatment, press the Activation Button.

- Press the Handset firmly against the area to be treated ensuring the Skin Tone Sensor is in contact with the skin. If the Skin Tone Sensor does not detect a valid skin tone, then the Handset cannot be activated. When the Skin Tone Sensor measures a valid skin tone, the lights around the Activation Button will illuminate WHITE to indicate the device is ready to flash.



- c) Press the ACTIVATION BUTTON. The device will flash, and a warm sensation should be felt.
- d) Move the Handset to the next area to be treated and repeat. The device needs to recharge between flashes. This will only take about 0.6 seconds.
- e) Ensure that the ENTIRE AREA receives treatment, and treat any stubborn areas (such as underarms) with multiple passes (running your device over the same area a maximum of 3 times).



WARNING: Make sure not to cover the vents on the device whilst treating, as this can lead to the device overheating.

SmoothSkin Bare Fit is an extremely fast and powerful device, allowing you to complete a whole body treatment in under 10 minutes.

TREATMENT METHOD - STAMP OR GLIDE?

Stamp Method

This method is recommended for small areas such as the underarm and bikini line. Place the Handset on the skin, press & release the Activation Button. Remove from the skin before carefully re-applying to the next treatment area.

Glide method

This method is recommended for larger areas such as legs. Place the Handset on the skin, hold down the Activation Button (press down continuously), then glide the Handset along the skin between flashes. Try to move the Handset at a steady speed that gives full coverage without overlap or missed areas.

Step 4: Your SmoothSkin Bare Fit Treatment Schedule

SmoothSkin Bare Fit should be used WEEKLY until the desired results are achieved.



Step 5: Switching Off the SmoothSkin Bare Fit

When the treatment is finished, SmoothSkin Bare Fit should be unplugged from the Electrical Outlet. Refer to **section 11** for details of how best to look after your SmoothSkin Bare Fit.

9. THE SKIN CONTACT SENSOR

SmoothSkin Bare Fit is fitted with a skin contact sensor that checks your skin contact before each flash, making sure the device is safe to operate! This makes the device compliant with the most stringent safety regulations..

The skin contact sensor also ensures you get the best results from your device. The sensor must be in full contact with the treatment area in order for the device to flash.

This full contact with your skin means that all the light energy emitted from the device reaches the treatment area to deliver the best results. If the device is not in full contact with the treatment area, the device will not fire. Try adjusting the positioning of the device to ensure full contact is achieved, particularly on more awkward areas like arms and shins.



10. THE PRECISION HEAD

SmoothSkin Bare Fit comes with a detachable precision head that is perfect for smaller, tricky areas (like upper lip, fingers, and toes). This has the benefit of giving you even more flexibility during each treatment.

Using the precision head will slow your device down a little, so we only recommend using when needed, to ensure you get the fastest treatment possible.

The precision head simply attaches on to the front of your device via an internal magnet inside the front of the main device. This magnet holds the head in place whilst you treat the area. Simply unclip or re-attach depending on what area you're treating.

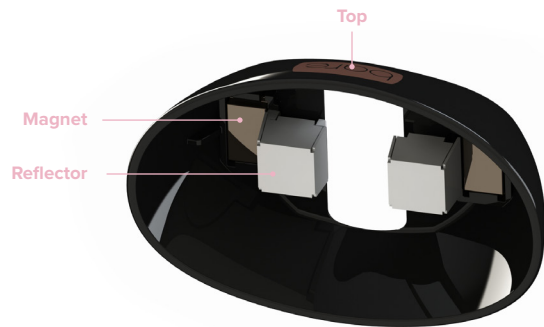


If the precision head is damaged or missing any parts (e.g. magnet or reflector), then **do not use**.

If the precision head becomes uncomfortably hot during use, then stop treatment until it has cooled down.

Follow all EYE SAFETY warnings (Section 3) when the precision head is fitted.

Follow the cleaning instructions (Section 11) for the precision head.



11. CLEANING, MAINTENANCE, STORAGE

After treatment, always switch off SmoothSkin Bare Fit by unplugging from the electrical outlet.

After use, the handset, skin tone sensors and treatment window should be inspected for damage and wiped down with a dry, lint free cloth.

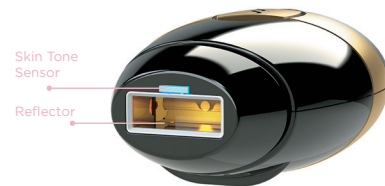
WARNING: The glass filter can get hot during use. **DO NOT** touch or clean the filter for at least 5 minutes after use to allow it to cool down.

NEVER use water or other cleaning fluids, as these can damage the device leading to a potential safety hazard.

If necessary, the Reflector and Skin Tone Sensor can be carefully cleaned by using a slightly damp cotton bud.

Store SmoothSkin Bare Fit in a cool, dry place. Make sure that the treatment window and skin tone sensor on the handset are protected from damage.

Regularly check the device (including cords) for visible signs of damage. In case of damage or cracks, stop using the device - and visit the website for support details.



12. TRAVELLING WITH SMOOTHSKIN BARE FIT

The Power Supply unit of the SmoothSkin Bare Fit is universal and will work with all commonly encountered mains supplies. Providing you have a suitable adaptor for the mains power cable plug, the SmoothSkin Bare Fit will operate as normal.

13. TROUBLESHOOTING

PROBLEM	SOLUTION
The Activation Button Lights on the Handset do not light up when placed against your skin.	Make sure the power supply is plugged in. Ensure the skin tone sensor is fully pressed against the skin. Your skin could be too dark for treatment. Check against the skin tone chart in the front of this user guide.
The Activation Button on the Handset lights up white when placed on the skin, but the Handset fails to flash when the Activation Button is pressed.	There could be a fault with the device. Unplug the device and restart. If the problem persists, visit the website for support details.
The Activation Button Lights on the Handset are illuminated red continuously, and the device will not function.	This indicates that there is a fault with the device. Stop using the device and visit the website for support details.
The SmoothSkin Bare Fit handset, treatment window, power supply or cable are damaged, broken, cracked or appear defective.	DO NOT USE. If you are in any doubt about the safety of SmoothSkin Bare Fit or suspect it is damaged in any way, it must not be used, and you should visit the SmoothSkin website for more information.

14. WARRANTY

We grant a 2 year warranty on the product starting on the date of purchase. Within the warranty period, we will check faults in materials or workmanship free of charge and replace the complete device, at our discretion.













This warranty extends to every country where this device is supplied by CyDen or its appointed distributor.

This warranty does not cover damage due to improper use, normal wear or use as well as defects that have a negligible effect on the value or operation of the appliance. The warranty becomes void if repairs are undertaken by unauthorised persons and if original SmoothSkin Bare Fit parts are not used. To obtain service within the warranty period, please visit our website: www.smoothskin.com

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15. LABELS AND SYMBOLS

SmoothSkin Bare Fit is marked with the following symbols:

	Type BF Applied Part		FCC EMC compliance for North America
	Class II Equipment		Australia Regulatory Compliance Mark
	Follow Instructions for use		Trefoil compliance mark for Ukraine
	WEEE waste disposal mark of the European Union		China RoHS environmental protection use period
	European Conformity Marking		Warning Optical Radiation from device may cause eye injury
	Keep Dry		
	NRTL Certification marking		

FCC Statement:

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

16. TECHNICAL SPECIFICATIONS

The SmoothSkin Bare Fit is a filtered broadband Intense Pulsed Light system with the following technical specifications:

- **Repetition Rate:** Manually pulsed every 0.6 seconds. Continuous operation
- **Max Optical Output:** 4J/cm²
- **Pulse Length:** 0.8 – 1.0msec FWHM
- **Wavelength:** 510-1100nm
- **Power Line Input:** 100-240V-, 50/60Hz,1.7-0.91A
- **Operating temperature:** Between 5°C and 40°C
- **Operating humidity:** Up to 93%R.H. non condensing
- **Operating Pressures:** 700hPa to 1060hPa
- **Treatment area (spot size):** 3 cm² (30mm x 10mm)

The area directly around the treatment window is classified as the Applied Part, and can reach a maximum temperature of 52degC. Ensure SmoothSkin Bare Fit is used as directed in Section 8.

Transport Conditions:

- **Temperature:** -25°C to +70°C
- **Humidity:** Up to 93%R.H. non condensing
- **Pressures:** 500hPa to 1060hPa

If the device has been stored at temperatures outside of the stated operating range, then please allow at least 30 minutes before use to allow the device to acclimatise.

SmoothSkin Bare Fit has unlimited flashes and is intended for a single user. Minimum expected service life is 10 years when following the recommended regimen.

EMC

SmoothSkin Bare Fit complies with the latest EMC Standards and Amendments applicable to Household and Medical Devices. These are: EN 60601-1-2:2014 Ed 4.0, EN 55014-1:2017 and EN 55014-2:2015, EN 61000-3-2:2014 & EN 61000-3-3:2013, FCC CRF 47 Part 15B 15.107 & 15.109

Safety

SmoothSkin Bare Fit complies with the latest Safety Standards and Amendments applicable to Household and Medical Devices.

These are: IEC 60335-1:2010, IEC 60335-2-23 :2003, IEC 60601-1:2015 , IEC 60601-1-1:2005, IEC 60601-2-57:2011, IEC 60601-1-6:2010, IEC 62366-1:2015, IEC 62366-1:2015, IEC 62304:2006, CAN/CSA -C22.2 No 60601-1:2008 and 2014, ANSI/AAMI ES 60601-1:2005 + AMS

CE marking certifies that this appliance conforms to the following EU Directives:

- Low Voltage Directive 2014/35/EU
- Electromagnetic Compatibility Directive 2014/30/EU
- Energy-Related Product Directive 2009/125/EC

For further details contact CyDen Ltd

DISPOSAL (end of life)

This product is a medical device.

In order to minimize hazards to health and the environment and ensure that materials can be recycled, this product should be disposed of at a separate collection facility for waste electrical and electronic equipment.

The WEEE symbol marked on the product is there to remind you.

You can reach us via our SMOOTHSKIN web page at
www.smoothskin.com

CyDen Limited
Block A,
Bay Studios Business Park
Fabian Way,
Swansea
SA1 8QB
UK

*Product may vary from illustrations
shown throughout this guide



CM12-1743-01
Type: SSB1/1

SMOOTHSKIN
bare^{fit}