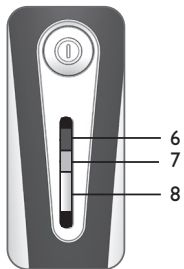
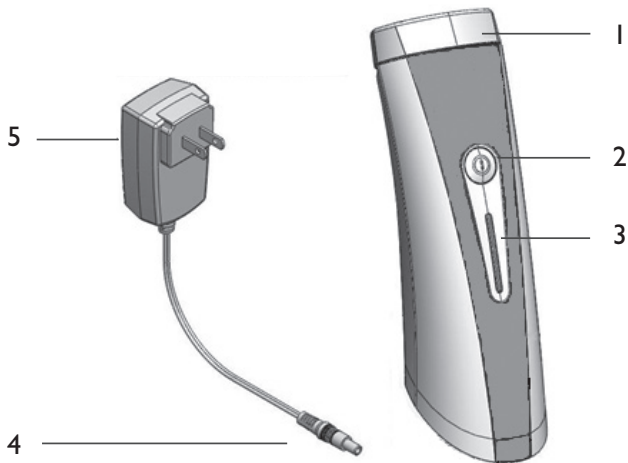




Blue
SKIN CARE

EN INSTRUCTIONS FOR USE





What is Blue™?

Silk'n Blue device overview (Fig. 1)

- 1 Treatment surface
- 2 On/off switch
- 3 Indicators panel
- 4 Plug
- 5 Adaptor
- 6 standby - indicator light
- 7 System error - indicator light
- 8 Ready/treatment - indicator light

Package contents

Upon opening the Silk'n Blue package, you will find the following parts:

- SILK'N BLUE APPLICATOR
- ADAPTOR
- User's Manual

Silk'n Blue - Indications For Use

Silk'n Blue intended use

Silk'n Blue is indicated as an over the counter phototherapy device for the treatment of mild to moderate acne.

Phototherapy is a form of treatment using optical energy with a wavelength of 415nm, which

manages to destroy the bacteria causing the acne.

Mild acne is marked by mostly blackheads and whiteheads. There may also be a few small pimples that lie under the surface of the skin – with no big permanent lesions and lesions which are not visible from 2.5m away, on your skin.

Moderate acne is more serious. It is marked by large swollen pimples and painful lesions - inflamed red lesions, which are as large as 1-2cm and inflammatory or non-inflammatory lesions visible at a distance of 2.5m also.

Silk'n Blue intended users

Silk'n Blue is intended for the use of young adults from the age of 12 years and up to the age of 55 years.

Contraindications



Risk of skin injury!

- **DO NOT USE SILK'N BLUE** except for its indications for treatment of mild to moderate acne.
- **DO NOT USE SILK'N BLUE** If you have any skin condition including brown or black spots, birth marks, moles, warts, eczema and psoriasis.
- **DO NOT USE SILK'N BLUE AGAIN** and **CONSULT YOUR PHYSICIAN OR DERMATOLOGIST** if after using Silk'n Blue you experience skin redness or discomfort that lasts for over three days.
- **DO NOT USE SILK'N BLUE** if you have open wounds or active infections, such as cold sore.
- **DO NOT USE SILK'N BLUE** if you ever had herpes in the area of treatment, unless you have consulted your physician and received preventative treatment before using Silk'n Blue.
- **DO NOT USE SILK'N BLUE** if your skin has been treated with a physician-prescribed drug within the past 6 month. Please consult with your physician!

- **DO NOT USE SILK'N BLUE** if you have sensitivity to light. To determine if you have such sensitivity, please follow the skin test instructions in Directions for Use chapter 6.

Failing to comply with the above contraindications could cause skin redness, burns or pigmentation changes!

Warnings



Risk of electrocution!

- ALWAYS keep Silk'n Blue out of the reach of children.
- ALWAYS keep SILK'N BLUE out of the reach of persons with reduced physical, sensory or mental capabilities.
- NEVER use the SILK'N BLUE or the Wall Power Supply when bathing or standing in water.
- NEVER use the SILK'N BLUE or the Wall Power Supply if you think they may have been immersed in water; may have become wet, or if you have spilt any liquids on them.
- NEVER remove any covers from the SILK'N BLUE or the Wall Power Supply. Opening or removing covers may expose you to dangerous voltages or other risks. Incorrect reassembly could cause an electric shock when the Silk'n BLUE is subsequently used.
- NEVER attempt to operate SILK'N BLUE with any Wall Power Supply other than the one provided.
- NEVER use SILK'N BLUE if it is damaged in any way.
- NEVER use the Wall Power Supply if it is broken or if its cord or plug is damaged.

Failing to comply with the above warnings may expose you to dangerous voltages and electrocution!



Risk to pregnancy!

- DO NOT use the SILK'N BLUE if you are pregnant. The safety of the treatment for pregnant women has NOT been tested in clinical trials.

Failing to comply with the above warning may harm your pregnancy!

Precautions

Device damage risk!

- DO NOT cover the air vents in SILK'N BLUE. They are provided for ventilation. Be aware of objects, items of clothing or material that may accidentally block the air vents.
- DO NOT replace the ADAPTOR with another plug! The ADAPTOR contains a dedicated transformer.
- DO NOT cover the ventilation slots during use. Remove any obstruction to air flow through the ventilation slots.

Failing to comply with the above Precautions may damage your device and void its warranty!

Risks - Possible Side Effects of using Silk'n Blue

I. Normal reaction of using Silk'n Blue

Silk'n Blue treatments are generally very well-tolerated, and reported as such by 93 out of 100 study subjects. Most users sense the moderate heat applied by the device during use, with no further discomfort.

- **Minor Skin Discomfort Skin Redness**

Typically, when using SILK'N BLUE, your skin may become slightly red right after using SILK'N BLUE. For all users - skin color should return to normal after treatment.

- **Burns or pigmentation changes**

Previously published studies indicate that contact heat of 41°C and light exposure of 415nm (as in the Silk'n Blue treatment) may cause burns and pigmentation changes.

- **Risk to pregnancy**

Using Silk'n Blue during pregnancy may harm your pregnancy.

Clinical Data Summary

Clinical trials were performed in 3 clinics.

50 subjects participated in the trials, (62% female, 38% male) with mild to moderate acne conditions who received the device for the purpose of the study.

The trials' subjects treated themselves with Silk'n Blue 2 times a week for 4 weeks, (8 treatments in total).

In each session the subject used the device for 10 minutes on each treatment area.

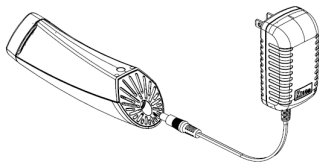
A clinical study conducted with Silk'n Blue shows that:

- A vast majority of SILK'N BLUE users experienced reduction in the number of lesions.
- 47 out of 50 users (male and female alike) experienced at least 40% reduction in the number of lesions (with average reduction of 56.7%) after 1 month.
- 48 out of 50 users (male and female alike) experienced at least 40% reduction in the number of lesions (with average reduction of 57.7%) after 3 months.

Using Silk'n Blue

1. Silk'n Blue Setup

- A. Plug the adaptor plug into the APPLICATOR socket.
- B. Plug the ADAPTOR into an electrical outlet.
A **STANDBY** - indicator light (6) will illuminate to indicate that your SILK'N BLUE ready to use.



Before using the device, make sure it kept at least 30 minutes at operational temperature specified in "Specification" section.

2. Directions for Use

2.1 Silk'n Blue treatment course:

SILK'N BLUE is intended to be used twice a week over a period of four weeks (a total of 8 treatments). The expected improvement in the appearance of acne was validated in clinical trials that followed this treatment plan. Additional use has not been tested.

To achieve the expected results, use Silk'N BLUE according to the treatment time specified below:

Condition / Injury	Treatment Guidelines
Treatment test spot	4 minutes, one spot
Facial area (cheek) covered with many acne pimples	Slowly move the applicator to cover the whole area for 10 minutes

2.2 Prepare your skin for treatment

Wash your face with water and dry with a clean towel to assure that your skin is clean, dry and free of any powder, gel or cream.

2.3 Prepare your Silk'n Blue device for treatment

Press the ON/OFF Switch. The STANDBY - indicator light will come on and the READY/TREATMENT - indicator light (8) will be lit steadily.

Your SILK'N BLUE is ready for treatment.

2.4 Skin test

Before treating with SILK'N BLUE for the first time, we recommend that you carry out a skin test on your forearm, to verify that your skin is not sensitive to the effect of SILK'N BLUE.

- Hold the SILK'N BLUE applicator and apply its Treatment surface on your forearm skin constantly for 3 minutes.
- Make sure that the treatment surface is in full contact with the skin. (The LED light will automatically activate.)
- If during the 24 hours following this test, no adverse reaction appears, you may start the treatment course.

2.5 Perform the treatment

- Attach the TREATMENT SURFACE to your skin. The LED light will automatically activate.
- Note that the device will not activate without skin contact and will deactivate when removed from the skin.
- Perform the treatment according to the treatment protocol on each target area.
- After 5 minutes of nonuse the device is automatically go into STANDBY mode. To reactivate the device, push the ON/OFF switch.



DO NOT treat the affected area for longer than the recommended time at each session. If you treat the affected area for longer than the recommended time the effectiveness of the treatments may be reduced.

DO NOT treat the affected area more often than recommended. If you treat the affected area more often than recommended the effectiveness of the treatments may be reduced.

- When SILK'N BLUE session has been completed, turn the device off by pressing the ON/OFF Switch. All indicator lights will be turned off.
- Finally, unplug the ADAPTOR from the AC electrical outlet, and unplug the Plug (4) from the APPLICATOR.

2.6 After the Silk'n Blue treatment

- After each session clean your SILK'N BLUE device, especially the treatment surface at the tip of the APPLICATOR (See Section: "Cleaning SILK'N BLUE").
- Store SILK'N BLUE according to the instructions (See Section: "STORAGE").



Contact your healthcare professional as soon as possible, if you suspect that you have had an adverse reaction from use of SILK'N BLUE.

What can go wrong?

Please see section: Risks - Possible Side Effects of using SILK'N BLUE

When to call a doctor?

After the treatment, in case you experience over 2 hours of heat sensation, crusting of skin or burns in the treated area, please contact your physician.

Care and Maintenance

I. Cleaning Silk'n Blue

After each session, it is recommended to clean your SILK'N BLUE device, and especially its TREATMENT SURFACE.

- Turn Silk'n Blue off by pressing the ON/OFF SWITCH.
- Unplug Silk'n Blue from the electrical outlet
- Allow cooling down of its TREATMENT SURFACE.
- The exterior of the SILK'N BLUE unit may be cleaned by wiping it with a dry cloth or isopropyl alcohol wipe. Please refrain from using any other cleaning products as these may damage the plastic parts.



- Never immerse SILK'N BLUE or any of its parts in water!
- Never clean the SILK'N BLUE or any of its parts under the tap or in the dishwasher.

2. Silk'n BLUE Storage

- Clean SILK'N BLUE according to the instructions (See "Cleaning SILK'N BLUE")
- Store the clean device and all its parts in a dry clean place free of dust.

3. Disposal

Dispose of the packaging at a recycling point which sorts materials by type.



Products marked with this symbol should not be disposed of along with household refuse! You are legally bound to dispose of old appliances separately from household refuse. Information about where old appliances can be disposed of free of charge is available from your local authorities.

4. Silk'n Blue Troubleshooting

This chapter summarizes the most common problems you could encounter. If you are unable to solve the problem with the information below, contact your local Silk'n customer Service center for further support.

Problem	Possible cause	Solution
Silk'n Blue does not work	The ADAPTOR is not connected	Plug the adaptor to AC electrical outlet, and connect the PLUG (4) to the APPLICATOR
	The APPLICATOR is broken	Contact your local Silk'n customer Service center
Silk'n Blue suddenly switches off	The ADAPTOR is not connected properly	Plug the adaptor to AC electrical outlet, and connect the PLUG (4) to the APPLICATOR
Device temperature rises during use.	This is normal	No action is required

Problem	Possible cause	Solution
READY/TREATMENT MODE - INDICATOR LIGHT (8) does not illuminate when pressing the ON/OFF SWITCH	The APPLICATOR needs to be reset	Press the ON/OFF SWITCH twice to switch the Applicator off and on again. If READY/TREATMENT MODE - INDICATOR LIGHT (8) does not illuminate again, contact your local Silk'n customer Service center
The Yellow SYSTEM ERROR - INDICATOR LIGHT (7) is lit.	Malfunction of the APPLICATOR	Press the ON/OFF SWITCH twice to switch the Applicator off and on again. If SYSTEM ERROR - INDICATOR LIGHT (7) illuminates again, contact your local Silk'n customer Service center

User Assistance and Customer Service


For more information about Silk'n™ products please enter your local Silk'n™ website, www.silkn.eu or www.silkn.com.

If your device is broken, damaged, in need of repair, or for any other user assistance, please contact your local Silk'n™ Customer Service:








For USA and Canada customers: 1-877-DO-SILKN / 1-877-367-4556, contact@silkn.com

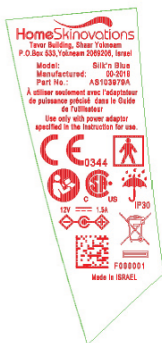
For customers in other countries: info@silkn.com

Specifications

Rated voltage (Adaptor)	100V - 240V
	Model: KSA24A1200150HE
Rated frequency (Adaptor)	50Hz/60Hz
Rated (Adaptor)	12Vdc; 1500 mA
Applied part	 Type BF
Protecting rating	IP30 (EN60529)
Storage condition	Temperature: -40°C to 70°C / -40°F to 158°F
	Relative humidity: 10% - 93%
Classified standard	IEC 60601-1-2:2007
	EN 60601-1-2:2007
Operating condition	Temperature: 10°C to 35°C / 50°F to 95°F
	Relative humidity: 15% to 90%
	Atmospheric pressure: 700 to 1060 hPa
Light source	Light Emitting Diodes
	Wavelengths peak emission wavelength: 415nm
Degree of protection against electric shock	Class II.

Labeling

Degree of protection against electric shock: type BF applied part	
WEEE - Waste Electrical and Electronic Equipment	
CSA Mark	
Keep dry	
CE Mark	
Manufacturer	
Authorized Representative in the European Community	



This label is for reference only.

Degree of protection against ingress water: IP30 ordinary

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

The symbol  on the label affixed to this device means "Follow the instructions for use".

Test	Standard	Class/Severity level	Test result
Documentation (IEC 60601-1-2 sections 4 and 5)			
General requirements General requirements for EMC	section 4.1.1.	--	Complies
External labels	section 5.1	--	Complies
Conformity of Users' Manual	section 5.2.1	--	Complies
Accuracy of Technical Description	section 5.2.2	--	Complies
Emission (IEC 60601-1-2 section 6.1)			
Conducted emission Freq. range: 150 kHz - 30 MHz	sec. 6.1.1 & CISPR 11	Group 1 Class B 230, 120 & 100 VAC mains	Complies
Radiated emission Freq. range: 30 - 1000 MHz	sec. 6.1.1 & CISPR 11	Group 1 Class B	Complies
Harmonic current emission test	sec. 6.1.3.1 & IEC 61000-3-2	230AC mains	Test NA
Voltage changes, Voltage fluctuations and Flicker test	sec. 6.1.3.2 & IEC 61000-3-3	230AC mains	Complies
Immunity (IEC 60601-1-2 section 6.2)			
Immunity from Electrostatic discharge (ESD)	sec. 6.2.2 & IEC 61000-4-2	6 kV contact discharges & 8 kV air discharges	Complies
Immunity from radiated electromagnetic fields	sec. 6.2.3 & IEC 61000-4-3	3.0 V/m 80 MHz \pm 2.5 GHz, 80% AM, 1kHz	Complies
Immunity from Electrical Fast transient (EFT)	sec. 6.2.4 & IEC 61000-4-4	\pm 2 kV on 230 & 100 VAC mains; Tr/Th - 5/50 ns, 5 kHz	Complies
Immunity from Surge	sec. 6.2.5 & IEC 61000-4-5	\pm 1.0 kV DM/2.0kV CM on 230 & 100 VAC mains (PA); Tr/Th - 1.2/50 (8/20) μ s	Complies
Immunity from conducted disturbances induced by radio-frequency fields	sec. 6.2.6 & IEC 61000-4-6	3.0 Vrms on 230 VAC mains (PA) 0.15- 80 MHz, 80% AM, 1 kHz	Complies
Immunity from power frequency magnetic field	sec. 6.2.8 & IEC 61000-4-8	3 A/m, 50 Hz & 60 Hz	Complies
Immunity from Voltage interruptions	sec. 6.2.7 & IEC 61000-4-11	230 & 100 VAC mains (PA); > 95% - 10 ms; 60% - 100 ms; 30% - 500 ms; > 95% - 5sec	Complies

Electronics and Telematics
Laboratory
5 November 2013

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