

SMOOTHSKIN

DuoLux™ Mini Collagen+

LED Eye Patch

USER MANUAL



It is mandatory that users of this device read and comprehend all information in this User Manual prior to use of the **DuoLux™ Mini Collagen+** device. You must follow all the instructions in the User Manual.

Please contact us if you have any comments about the device or this User Manual or if you experience any side effects that are not mentioned in this guide or are more severe than those described.



smoothskin.com



help@smoothskin.com

DuoLux™ Mini Collagen+ is a trademark of SMOOTHSKIN



Manufactured by:
iSMART Developments Limited, 129 Green Lanes,
Wylde Green, Birmingham, B73 5LT United Kingdom

RP: Certainty IP Ltd, Dublin, D18 CV48. +353 1582 9003



Emergo Australia, Level 20 Tower II,
Darling Park, 201 Sussex Street, Sydney,
NSW 2000, Australia



The information in this document is proprietary to iSMART Developments Limited, and supplied on the understanding that it shall be kept confidential to recipients and that it shall not be reproduced and/or used for commercial purposes without the written consent of iSMART Developments Limited.

Contents

Who should use DuoLux™ Mini Collagen+	5
Device Description	5
Intended Use	7
Contraindications, Warnings and Precautions	7
Contraindications	7
Warnings	9
General Safety	11
Precautions	11
Risks and Benefits	12
Potential Risks	12
Potential Benefits	13
First Time Setup	13
Unpacking and charging your DuoLux™ Mini Collagen+	13
Charging your DuoLux™ Mini Collagen+	13
Charging Status of the DuoLux™ Mini Collagen+	14
Sensitisation test	14
Using DuoLux™ Mini Collagen+	16
Treatment Recommendations	16
Carrying out a treatment	16
How to use the Hydrocolloid Patches	18
Care and Maintenance	21
Cleaning the DuoLux™ Mini Collagen+ Device	21
Disposal/Recycling	22
Troubleshooting	22
Labelling	24
Technical specification	24
Explanation of symbols	25
Warranty	27
Standard Warranty	27
Warranty exceptions	27
What to do if your product is faulty	27



Before using the DuoLux™ Mini Collagen+ you must carry out a sensitisation test and wait 6 hours.

Who should use DuoLux™ Mini Collagen+

Thank you for choosing the DuoLux™ Mini Collagen+. The device is suitable for adults wishing to treat facial wrinkles.

If you have purchased the device and find that it is NOT suitable for you, please contact your supplier to return the device within 30 days with proof of purchase.

Device Description

The DuoLux™ Mini Collagen+ is a battery operated, cordless wearable Light emitting diode (LED) device intended to emit light in the red (630nm) and near-infrared (830nm) regions of the light spectrum for the treatment of facial wrinkles and help reduce the appearance of eyebags and puffy skin.

The device system consists of the following key components.

1. 2 x Silicone LED Patches
2. 2 x Magnetic 2 pin, 4mm to USB A Charging Cables
3. 24 x Individually Wrapped Hydrocolloid Patches including 1 to be used as a Sensitisation Test
4. 1 x User Manual

DuoLux™ Mini Collagen+ is a silicone flexible patch containing LEDs. The LEDs generate the light.



The LEDs produce Red: (630nm +/- 10nm) and Near-Infrared (830nm +/-10nm) light in the visible spectrum. The device works through non-thermal mechanism called Photobiomodulation.

The LEDs are driven by an integrated 3.7V, 37mAh Lithium Polymer battery.

The battery is charged via a magnetic 2 pin, 4mm to USB A connector that plugs into a standard 5V USB A power adaptor. The device cannot be operated while in charging mode.

The charging status of the device is indicated by a single indicator LED on the rear of the device patches and the treatment LEDs.

In charging mode.

- i.  **Solid green** - battery is fully charged.
- ii.  **Solid orange** - battery charging.

The LED eye patch contains a simple ON/OFF button (⏻) on the rear of the patch that switches the LEDs ON/OFF. The treatment time is 10 minutes. The device automatically turns OFF after the 10-minute treatment cycle. The user may stop the treatment program during the 10 minutes by pressing the ON/OFF button.

The LED patch is worn on the face and held in place by an adhesive hydrocolloid patch. The adhesive hydrocolloid patch is impregnated on both sides with an elastomer and hydrogenated petroleum resin that acts as an adhesive. The hydrocolloid contains Cellulose Gum, Styrene/Isoprene coPolymer, Polyisobutene, Hydrogenated rosin, Parffinum Liquidum, Polyethylene terephthalate, Niacinamide, Sodium Hydroxide, Sodium Hyaluronate, Pentaerythrityl tetra-di-T-butyl hydroxyhydrocinnamate, Oligopeptide-10.

You are supplied with 24 adhesive hydrocolloid patches for treatment, one of which must be used to carry out a Photosensitivity patch test before starting your treatment course.

The equipment is not used to make measurements of any sort, or to draw any conclusions regarding the indication to treat. The equipment does not require checks on the light output as the LEDs do not dim with age to any practical extent.

Intended Use

The DuoLux™ Mini Collagen+ is an over-the-counter device intended to emit energy in the Red and Near-Infrared region of the light spectrum and is intended for use in the treatment of facial wrinkles.

The device is intended to be used in the home by adults.

Contraindications, Warnings and Precautions



Contraindications

- **DO NOT** share the device with any other person. The device is for single person use only.
- **DO NOT** reuse the hydrocolloid patches between treatment sessions. The hydrocolloid patches are for single use only.
- **DO NOT** use the device to treat any other conditions apart from those listed in the intended use. The device has not been tested for any other conditions than those listed, and the risk is unknown.
- **DO NOT** use the device if you are pregnant, planning on becoming pregnant or breastfeeding. The device has NOT been tested on pregnant or breast-feeding women and therefore the risk to the foetus, neonate or pregnant women is unknown.
- **DO NOT** use the device if you have an allergy to Silicone or Polyethylene terephthalate. The treatment surfaces of the device contain medical grade silicone and Polyethylene terephthalate.

- **DO NOT** use the device if you have an allergy to Hydrocolloid bandages or any of the ingredients in the hydrocolloid patches outlined above. The LED patch fixes to your face using an adhesive hydrocolloid patch.
- **DO NOT** use the device if you suffer from light induced headaches.
- **DO NOT** use the device if you suffer from any genetic conditions of the eyes. If you are unsure about any related eye condition and using the device, contact a health care professional.
- **DO NOT** use the device if you suffer from lupus erythematosus, photosensitive eczema, or albinism. If you use the device to treat lupus erythematosus, photosensitive eczema, or albinism you may cause a severe skin reaction.
- **DO NOT** use the device if you suffer from any photosensitive disorder (sensitisation to light). If you use the device and you suffer from a photosensitive disorder; you may cause a severe skin reaction.
- **DO NOT** use the device if you are taking any medication that can cause photosensitivity. If you use the device and you are taking any medication that can cause photosensitivity you may cause a severe skin reaction.
- **For a full list of drugs that can cause photosensitivity, please visit: smoothskin.com**



Photosensitivity is a common side effect of various medications. These can include certain antibiotics, chemotherapy drugs, and diuretics. If you are unsure about any medication, you may be taking consult your healthcare provider.



Other substances not listed above can also cause photosensitivity.

- Common examples of these substances are: St John's Wort, coal tar, deodorants, antibacterial soaps, artificial sweeteners, naphthalene (mothballs), petroleum products, brightening agents found in laundry detergent, and cadmium sulphide (a chemical injected into the skin during tattooing).



Warnings

- Before using the device you must carry out a sensitisation test. Please read the section "**Sensitisation test**" on page 14 on how to carry out the test.
- **DO NOT** over flex the device. Although it is flexible, it is not designed to withstand excess bending or folding.
- Keep the device away from sharp objects.
- **DO NOT** use the device in any way that is not exactly as specified in this User Manual. Use of the device other than exactly as specified in this User Manual has not been tested and the risk is unknown.
- **DO NOT** use the device in an environment that is NOT specified by the manufacturer as this may cause damage to the device or harm to the user.
- **TURN OFF** and **REMOVE** the device immediately if it feels hot or your skin feels uncomfortably warm. **DO NOT** continue treatments and contact customer services.
- **STOP** using the device during a treatment if you experience headaches or changes in vision. **DO NOT** continue treatments and contact customer services.

- **DO NOT** use the device without first removing creams, lotions, or make-up **BEFORE** treatment. Some ingredients in these products may cause light sensitisation or may reduce the effect of the treatment. If you use the device without removing these products, you may cause a skin reaction, or may reduce the effect of the treatment.
- Only use the adhesive hydrocolloid patches recommended. Other adhesive patches are available but have not been tested with the device and may block light penetration and reduce the effects of the treatment.
- **DO NOT** use the hydrocolloid after its expiry date.
- **NEVER** use the device near water or where water can be spilt onto the equipment. **DO NOT** use the device if you think it has come into contact with water.
- Keep the device away from HOT surfaces or direct sunlight.
- **DO NOT** attempt to modify the device in any way. Modifying the device will void your warranty. Opening up the device could cause an electric shock or burns. The system contains no serviceable parts.
- **DO NOT** use the device if the Patch, Cable or Packaging are damaged in any way.
- **DO NOT** use the device any longer if it shows any signs of damage to the material through wear and tear.
- Keep away from Children and Pets. Electrical cables can present a strangulation hazard.
- **DO NOT** leave the device unattended when it is switched on. Accidental mishandling of the device could lead to the risk of fire or burns.



General Safety

The DuoLux™ Mini Collagen+ is an electrical device, which under certain circumstances could present an electrical shock hazard to the user. Please read this User Manual thoroughly and follow directions stated in the manual to assure maximum safety during operation.

The device may only be charged with the charging cable that is supplied with the device. Use of other charging cables may not be safe and could lead to electric shock.



For implanted devices such as pacemakers keep the device at least six inches away from implanted medical devices. Stop using the device and talk to your health care provider if you are experiencing any symptoms or have questions about the device and implanted medical devices.



Precautions

- **DO NOT** stare directly at the LED light source.
- **DO NOT** use the device without a Hydrocolloid.
- The device cannot be used in charging mode.
- Unplug The 2-pin charging cable from the USB charging port when not in use.
- Before each use, with the device switched off, clean the device. All surfaces of the device may be cleaned by following the cleaning instructions on page 21.
- **DO NOT** use any other cleansing products other than those stated in the cleaning instructions on page 21. Use of other cleansing products may damage the device.
- Store the device at room temperature in dry conditions, away from direct sunlight.

- **DO NOT** use the device in Direct Sunlight.
- Take care when removing the patch and hydrocolloid, as there is a risk of damaging the top layer of the skin if it is removed too vigorously.
- **DO NOT** charge the device if the USB socket or wall adapter you are using has poor connections or becomes hot. Make sure you plug the device into a high quality, CE certified USB charging socket or adapter to avoid the risk of fire and burns.
- **DO NOT** subject the device to heavy shocks or vibrations to avoid risk of damage to the device, if you damage the device, do not use it any longer.



Risks and Benefits

Potential Risks

This list although not exhaustive, lists what are considered to be among the mostly likely adverse effects that could occur with use of the device.

Immediately after treatment skin may appear red. Skin should return to normal within 1-2 hours.

Some users have reported pigmentation, skin flaking or peeling, associated pruritis and dryness. This is transient and fades within a few days.

Temporary headaches may occur immediately following the light treatment.

Although this device emits levels of visible and near-infrared light that are considered to be safe for the skin, if you have adverse reactions after using the device that do not resolve, you should stop using the device immediately.

If you experience a side effect that is not described above or is of greater severity than described above, please **STOP** using the device immediately and contact a Healthcare Professional and iSMART Developments Limited or your provider and your representative Competent Authority if you deem it applicable.

Potential Benefits

People who have undergone a course of 3-5 treatments per week for 6 weeks using the device report a reduction in facial wrinkles and eyebags.

First Time Setup

Unpacking and charging your DuoLux™ Mini Collagen+

Unpack the device and check off the parts described in Device description on page 5.

Visually inspect the parts and connections. Return the device to your supplier if you think the device or connecting parts or components are damaged or have been previously used.

DO NOT use the device if you notice device or connecting parts or components are damaged.

Charging your DuoLux™ Mini Collagen+

Before use, fully charge the device.

The device uses an integrated lithium-ion polymer battery. When the LED patch is connected to the power supply do not attempt to use the device as the LEDs will not illuminate.

1. To charge the device connect the 2-pin connection cable to the port on the upper side of the LED patch.

2. Insert the USB A connector into a suitable USB power supply or laptop port.
3. The indicator LED on the upper surface of the patch will illuminate Orange to show that the patch is charging. The patch is fully charged when the indicator LED is solid green.
4. When fully charged the battery will deliver 3-4 treatments before recharging. The lifetime of the Lithium battery can be maximized by allowing it to fully charge and then fully discharge during regular use.
5. Always ensure the LED patch is fully charged before commencing a treatment session.
6. Unplug the 2-pin charging cable from the USB A charging port when not in use.

Charging Status of the DuoLux™ Mini Collagen+

The device uses a single display LED on the rear of the LED patch and treatment LEDs to indicate the status of charging.



Solid Green – Battery is fully charged.



Solid Orange – Battery is charging (Charging Mode).

Low Battery Mode – When there is insufficient battery capacity to complete a full treatment, the Treatment LEDs will flash and the device will turn OFF – You will need to recharge the patch.

Sensitisation test



Before carrying out your first treatment you must first carry out a sensitisation test to see if you are sensitive to light or the adhesive hydrocolloid patch. Follow the step-by-step guide below.

DO NOT attach the device to your face, the sensitisation test should be carried out on your inner arm.

1. Ensure the device is fully charged.
2. Remove one of the adhesive hydrocolloid patches from its packaging.
3. See the “**How to use the Hydrocolloids**” section for a step-to-step guide to using the hydrocolloids.
4. Unpeel the device side of the backing paper off the adhesive hydrocolloid patch.
5. Place the sticky side of the adhesive hydrocolloid patch onto the LED side (white) of the device. Ensure the adhesive hydrocolloid patch aligns with the shape of the device.
6. Press down across the entire surface of the adhesive hydrocolloid patch.
7. Peel the face side of the backing paper from the adhesive hydrocolloid patch.
8. Attach the device to the inside of your left or right forearm and push down gently.
9. Switch ON the device and allow it to run for a full treatment (10 minutes).
10. At any time if your skin feels HOT or uncomfortable **STOP** using the device immediately.
11. After the treatment, carefully remove the device and adhesive hydrocolloid patch from the treatment area. Discard the test adhesive hydrocolloid patch in the general waste.
12. Wait at least 6 hours. If your skin on your inner arm is red or itchy, then the treatment is unsuitable for you. Return the device to the retailer within (30) days of purchase.

Using DuoLux™ Mini Collagen+



Regarding electromagnetic compatibility (EMC) and electromagnetic fields (EMF), in and around the home environment the device should be kept away from radio frequency (RF) equipment and pacemakers to avoid interference.

Treatment Recommendations:

For the treatment of facial wrinkles, the best results are seen by treating for 3-5 times a week for 6 weeks.

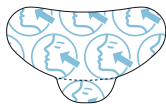
Maintenance treatment should be carried out as required, according to lifestyle and skin condition.

Carrying out a treatment

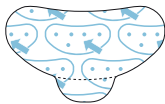
- **DO NOT** over flex the device. Although it is flexible, it is not designed to withstand excess bending or folding.
 - **DO NOT** use the device without a Hydrocolloid.
1. Ensure the device is fully charged before commencing a treatment session.
 2. Cleanse or exfoliate the skin to remove any traces of skincare.
 3. Use a new hydrocolloid every treatment session.
 4. See the “**How to use the Hydrocolloids**” section for a step-to-step guide to using the hydrocolloids.
 5. Unpeel the device side of the backing paper off an adhesive hydrocolloid patch.
 6. Place the sticky side of the adhesive hydrocolloid patch onto LED side (white) of the device. Ensure the adhesive hydrocolloid patch aligns with the shape of the device.

7. Press down across the entire surface of the adhesive hydrocolloid patch.
 8. Peel the face side of the backing paper from the adhesive strip.
 9. Using a mirror position the device over the treatment area.
 10. Switch ON the device. The device will automatically switch OFF after 10 minutes. You may stop the treatment at any time by pressing the ON/OFF button.
 11. After the treatment, carefully remove the device and adhesive hydrocolloid patch from the treatment area.
 12. Remove the adhesive hydrocolloid patch from the device and discard in general household waste. If you would like to keep the hydrocolloid patch on the treatment area after the LED treatment cycle has finished, press the hydrocolloid patch onto the face using the tab and carefully peel the LED device from the hydrocolloid patch.
 13. Clean the device by following the instructions in “**Cleaning the DuoLux™ Mini Collagen+ device**” on page 21. Ensure that the device is **NOT** being charged when cleaning.
 14. You may treat more than one treatment area in a treatment session.
- DO NOT** repeat a treatment on the same treatment area in the same treatment session.

How to use the Hydrocolloid Patches



FACE SIDE



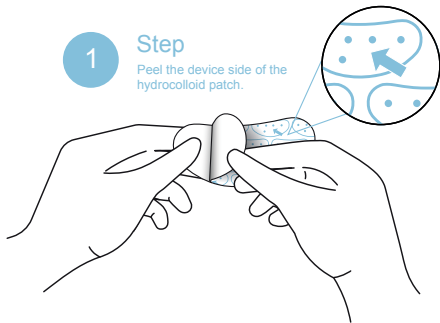
DEVICE SIDE

Step-to-step diagram for using the Hydrocolloids

1

Step

Peel the device side of the hydrocolloid patch.

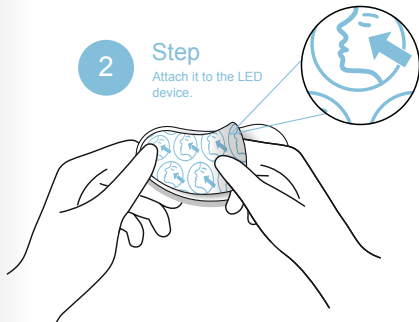


18

2

Step

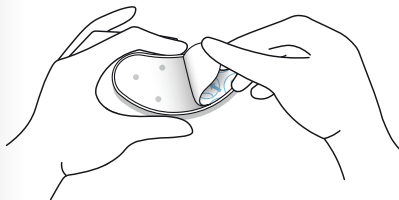
Attach it to the LED device.



3

Step

Once secured to the device, peel the face side of the hydrocolloid patch.



19

4

Step

Press firmly on the face
in the desired treatment
area.

**Re-order**

Refill Adhesive Hydrocolloid patches can be purchased from smoothskin.com

Part number	Description	Quantity
HCR01	DuoLux™ Mini Collagen+ adhesive hydrocolloid patches	20 per Box

Care and Maintenance

- The lifetime of the Lithium battery can be maximized by allowing it to fully charge and then fully discharge during regular use.
- Store the device at room temperature in dry conditions.
- Avoid storing the device in dusty conditions, in direct sunlight or in damp and humid conditions.
- The device contains no serviceable parts.
- Before each use, with the device switched off, clean the device following the cleaning instructions below.
- **DO NOT** use the device any longer if it shows any signs of damage to the material through wear and tear.
- **DO NOT** use the hydrocolloid after its expiry date.
- **DO NOT** use the device if it has been exposed to environmental conditions outside of those specified in the Technical Specification on page 24.

Cleaning the DuoLux™ Mini Collagen+ Device

- Before cleaning ensure that the charging cable is disconnected from the device and that the device is not charging.
- Clean the device with a water-based wipe. Stubborn stains or adhesive residue can be removed by wiping gently with 70% alcohol.
- Place the device on a clean surface and allow to air dry.
- **DO NOT** use water to clean the device.
- **DO NOT** use the device if you think it has come into contact with water.

Disposal/Recycling



DO NOT dispose of the DuoLux™ Mini Collagen+ patch or charging cable at a domestic waste facility (2006/66/EC). The adhesive hydrocolloid patch can be disposed of in general household waste.



The device contains a Lithium-ion polymer battery. For protection of the environment, please package and return this unit to the manufacturer or their representative at the end of its working life or safely dispose of the device following your local guidelines.



The adhesive hydrocolloid patch can be disposed of in general household waste.

Troubleshooting

Problem	Possible Cause	Action
Indicator light is not illuminated.	Battery drained.	Connect the 2-pin connection cable to the port on the upper side of the LED patch. Insert the USB A connector into a suitable USB port power supply or laptop and charge until indicator light turns from orange to green.
No red or near-infrared light from the device.	The device is connected to an electrical outlet.	Ensure that the indicator light is solid Green. Remove the magnetic charging connector from the device and ensure that the charging cable is unplugged from the charging source.
When the device is switched on the Treatment LEDs flash.	Insufficient battery to complete a treatment.	Connect the 2-pin connection cable to the port on the upper side of the LED patch. Insert the USB A connector into a suitable USB port power supply or laptop and charge until indicator light turns from orange to green.

Problem	Possible Cause	Action
During charging, the indicator light is not illuminated and does not illuminate during charging. No red or near-infrared light from the device.	The device is faulty.	If your device is within warranty, return your device to the point of purchase or contact the SMOOTHSKIN Customer Service email: help@smoothskin.com
Treatment LEDs do NOT turn OFF after 10 minutes.	The device is faulty.	If your device is within warranty, return your device to the point of purchase or contact the SMOOTHSKIN Customer Service email: help@smoothskin.com
Treatment LEDs flicker continuously during treatment.	The device is faulty.	Ensure that the device is fully charged, and the green light is illuminated. If the green light is illuminated and the LEDs continue to flicker contact your place of purchase to arrange a return or contact the SMOOTHSKIN Customer Service email: help@smoothskin.com

If the actions suggested fail to fix the problem, or the problem reoccurs, and your device is within the warranty period, please return to your place or purchase or contact the SMOOTHSKIN Customer Service email: help@smoothskin.com



- **DO NOT** attempt to investigate any further.
- **DO NOT** attempt to modify the device in any way. Modifying the device will void your warranty. Modifying the device could cause an electric shock when the system is used again. The device system contains no serviceable parts.

Labelling

The labelling supplied with the device contains the following information

- Date of manufacture
- Model number and batch code
- Manufacturers information
- Operating environment

Technical specification

- Model Number: TN2189
- LEDs: Red: 630nm +/-10nm. NIR 830nm +/-10nm
- Total Intensity: 30mW/cm²
- Total Device Dimensions:
Approx 68mm max (L) x 36mm max (W)
- Program time: 10 minutes +/- 11 Seconds
- Operating Temperature: 0°C to 30°C
- Storage and Transport Temperature: -5°C to 55°C
- Operating Humidity: 30% to 95% without condensation
- Storage and Transport Humidity: 20% to 85% without condensation
- Mains Electrical Input for charging: Any USB A Charger (5V)
- IP25

Explanation of symbols

There are several safety warnings on the device and associated packaging and in the User Manual. Not following these warnings may result in one or more of the following hazards: electrical shock and/or fire.



Warning.



It is Mandatory to read and comprehend the information in the User Manual prior to using the device.



Refer to the User Manual for Guidance on using the device.



Applied part type BF.



The DuoLux™ Mini Collagen+ is single patient multiple use.



Conforms to certain EC Directives on health, safety, and environmental protection standards. CE stands for 'Conformité Européenne'.



Conformity to UK Directives on health, safety, and environmental protection standards. UKCA stands for UK Conformity Assessed.



Manufacturers information.



Date of manufacture.



Keep dry.

	Serial number.
	Model Number for DuoLux™ Mini Collagen+ - TN2189
	Batch Code.
	Unique device identifier.
	DuoLux™ Mini Collagen+ is a Medical Device (USA and Australia Only).
	Made in China.
	Keep away from direct sunlight.
	Shows the lower and upper temperature limits.
	Shows the lower and upper humidity limits.
	The box materials and paper packaging is recyclable.
	Product shall not be disposed of with normal household waste (2012/19/EU).
	Input- 5V (USB A).
	Emergo Australia, Level 20 Tower II, Darling Park, 201 Sussex Street, Sydney, NSW 2000, Australia

Warranty

To start a claim against the warranty, you will need to show proof of purchase within 2 years. To start a claim contact, help@smoothskin.com.

Standard Warranty:

Under normal use this product is guaranteed for 2 years after its original purchase date against manufacturing defects in materials or workmanship.

Warranty exceptions:

This warranty extends only to the original purchaser. This warranty does not cover damage caused by the following:

- Accident, misuse, abuse or alteration
- Servicing by unauthorized persons
- Connection to incorrect power sources
- Use with unauthorized accessories

What to do if your product is faulty

If the product should become faulty within the warranty period, contact your place of purchase.

CyDen Limited or iSMART Developments Limited or its authorised distributor reserves the right to replace a defective product with the most compatible product currently available.

CyDen Limited or iSMART Developments Limited or its authorised distributors shall not be responsible for any incidental, special or consequential damages resulting from the use of this product. All implied warranties, including but not limited to implied warranties of fitness and merchantability are limited in duration to one year from date of original purchase.

This warranty gives you specific legal rights, and you may also have other rights that vary from country to country. Some countries do not allow the exclusion or limitation of incidental or consequential damages, or limitations on how long an implied warranty lasts, so some of the above limitations and exclusions may not apply to you.

This warranty is given in lieu of all other warranties, written or oral, whether expressed by affirmation, promise, description, drawing, model or sample. Any and all warranties other than this one, whether expressed or implied, including implied warranties of merchantability and fitness for a particular purpose are hereby disclaimed.



Manufactured by:

iSMART Developments Limited

129 Green Lanes
Wylde Green
Birmingham
B73 5LT
United Kingdom

Distributed by:

CyDen Limited

Block A
Bay Studios Business Park
Fabian Way
Swansea
SA1 8QB
United Kingdom