

LumiFem™
Nursing Without Pain



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LumiFem™ operating instructions

Your LumiFemTM

You have chosen a high-quality, state-of-the-art medical product from Reimers & Janssen, one of Europe's leading manufacturers of low-level laser and LED light therapy devices.

LumiFem light therapy offers an alternative treatment method, free of side effects, for sore and cracked nipples. An easing of the pain and healing of cracking should become noticeable soon after even just a few treatments.

Contents

Delivery contents	4
General information	4
Safety information and warnings	5
Withdrawal from use and Liability disclaimer	6
Action	8
Use	9
Instructions for use	10
Start-up	11
Starting treatment	12
Changing the therapy program	13
Cleaning and disinfection	14
Changing the batteries	16
Warranty and disposal	17
Technical data	18

Delivery contents

- LumiFem control unit
- 2 LED holders with connecting cable
- 2 batteries (AA type)
- 10 x 2 nipple covers

General information

Read these operating instructions thoroughly before operating the device.

The operating instructions describe the proper use of the LumiFem and indicate hazards associated with its use. All individuals who use, care for, service, or inspect this device must read and follow the instructions. These operating instructions must always be kept with the device and must be included with the LumiFem if given to others.

Safety information and warnings

- The nipple covers are designed as disposable items and should be discarded after use
- The LED holders must be cleaned and disinfected before use
- The nipple covers must only come in contact with intact, healthy skin
- Do not look directly at the light beam
- People who are sensitive to light should consult their doctor before treatment
- Store the device in a safe place out of the reach of children
- Do not operate the LumiFem in wet environments or with wet hands
- Risk of strangulation: do not coil around the throat
- For use only on sore and cracked nipples or for prevention of mastitis (inflammation of the breast)
- In the case of an elevated temperature over 37.5°C, consult a doctor or midwife immediately to rule out the possibility of mastitis
- If there is no improvement in the soreness or cracking after two days, consult a doctor or midwife immediately

Withdrawal from use in the event of a hazard

If it appears likely that the device can no longer be operated without risk, withdraw it from use, secure it to prevent further use and send it to your distributor for repair or maintenance.

This must be done if:

- the device no longer functions properly
- the LumiFem has been stored or transported for a long period under adverse conditions

Liability disclaimer

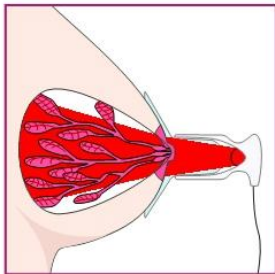
The LumiFem must be used only for the purpose described in this user manual. The LumiFem must be operated only together with original accessory parts. The manufacturer is not liable for the device and the consequences resulting from operation or applications that are not described within these operating instructions. The manufacturer reserves the right to make changes based on technological improvements.

Legal notice from the German Advertising of Medicines Law

For legal reasons we hereby advise that none of the information given is intended to create the impression that a cure is promised here or that alleviation or improvement in afflictions and diseases are guaranteed or promised.

Action

Sore nipples frequently lead to inflammation of the mammary glands (mastitis) which can often only be treated with antibiotics. That carries the risk that the medication could enter the breast milk, placing increased stress on the infant. LumiFem regenerates the nipples by stimulating cell metabolism, preventing inflammation in a natural way without any side effects or stress on your baby.



The cells of sore nipples often have an energy deficiency, making them susceptible to infection. They require an input of energy for regeneration. In LumiFem light therapy, a light-emitting diode releases the required energy in the form of red light directly at the site of inflammation. This stimulates cell metabolism and also allows damaged tissue to be removed more easily and new, healthy tissue to form more quickly.

Use

With LumiFem light therapy, you can prevent interruptions to breastfeeding due to the pain of sore or cracked nipples. Timely therapy can also minimise the risk of mastitis (inflammation of the breast) and the possibility of abrupt weaning.

If used early, treatment will normally take two to four days. If irritation recurs when your baby resumes suckling on the nipple, use should be resumed and continued until the nipples have regenerated.

LumiFem can also be used as a preventive measure so that soreness and cracking do not appear in the first place. The risk of infection from mastitis pathogens will also be reduced from the outset.

One use takes 5 minutes and should be repeated 3-4 times daily, ideally directly after breastfeeding so that your breast has time to regenerate before your next feed.

Instructions for use

If you are using only one nipple cover, set the other LED holder aside, making sure that its light-emitting diode (LED) is covered.

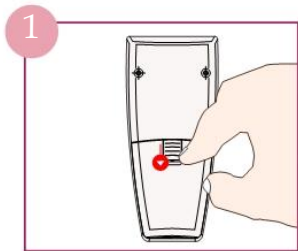
When applying the nipple cover, make sure that neither the cover nor the LED in its holder come in direct contact with injured skin.

After every use, the LED adapters should be cleaned with a sterile wipe. Never pass on used nipple covers for another person to use.

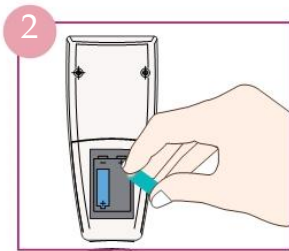
If there is no improvement in the soreness or cracking after two days, consult a doctor or midwife immediately.

Start-up

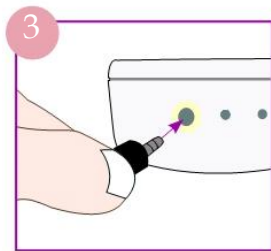
The LumiFem does not require a particular start-up procedure. You simply need to insert the batteries included with the device. If you are hiring the unit, the batteries may already be inserted. If so, you can begin treatment immediately, as described on the following page.



Unlatch the lid on the back of the unit, fold it up and remove.

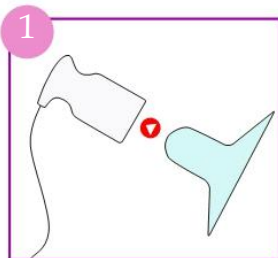


Insert the batteries, put the lid back in position and latch it in place.

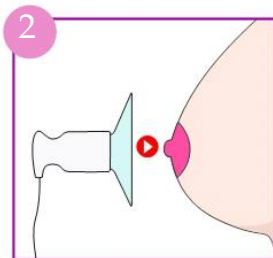


Plug the connecting cable from the LED holders into the socket on the front of the unit.

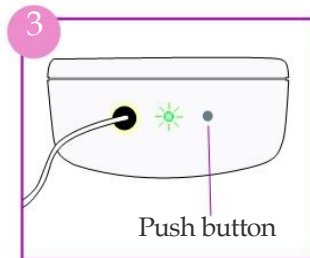
Starting treatment



Separate a pair of nipple covers and fit an adapter onto each cover you wish to use. You may use one cover or two, as needed.



Apply the cover to your breast, avoiding direct contact with injured skin as much as possible. The LED should not touch the nipple.





Start the treatment program simply by pressing the button. The LED indicator will light up green. The therapy will stop automatically after 5 minutes.

If the LED indicator does not light up or flashes red, change the batteries.

Changing the therapy program

The preset therapy program is a continuous wave program, where the LED is lit continuously and emits maximum energy.

The LumiFem is also equipped with a “frequency program” where the LED lights up repeatedly in quick succession. These biofrequencies are programmed according to the findings of acupuncture specialists Dr. Elias, Dr. Nogier and Prof. Bahr. The energy emitted is half as much as with the continuous light program. This therapy is activated simply by pressing the button a second time. The LED indicator will flash.

Operating instructions	Operating mode	LED indicator on unit
Button pressed 1 x	Continuous wave mode —	LED lights up green ●
Button pressed 2 x	Frequency mode ∨∧	LED flashes green 
Button pressed 3 x	Sleep mode z ^{zz}	LED off ●
Occurs automatically	Battery charge low	LED flashes red 

Cleaning and disinfection

The nipple covers are designed as disposable items and should be replaced after use. We hereby explicitly draw your attention to the risk of infection if covers are re-used.

However, if you do re-use the nipple covers, rinse them out first with cold water and then with hot water. For best treatment results, new covers should be used each day.

After every use, the LED adapters should be wiped with a sterile wipe.

Never pass on used nipple covers for another person to use.

When wiping clean the LumiFem control unit, always use a sterile wipe.

Changing the batteries

When the battery charge is low (shown by the LED indicator flashing red), the batteries must be changed. This prevents treatments taking place with a lower light intensity. Use only high-quality AA batteries (non-rechargeable) in order to prevent damage which can be caused by the batteries leaking. To change the batteries, see the instructions for inserting them as given on page 11.

One set of batteries contains enough charge for about 200 treatments (or for 6 months in sleep mode). If you do not need to use the unit for more than 2 weeks, take the batteries out.

Warranty and disposal

Manufacturer's warranty

The manufacturer's warranty is valid for 24 months. The manufacturer is responsible for the features of the LumiFem as warranted by the operating instructions if the device has been operated carefully and in accordance with the operating instructions. The warranty does not cover the disposable/hygiene-sensitive items included with the product such as the nipple covers and carry bag.

Readjustment, calibration, and maintenance or repairs may only be performed by the distributor, otherwise the warranty is void. Any alterations to the device by unauthorised third parties void the warranty.

Disposal

The LumiFem must be disposed of in accordance with legal requirements. If you have any questions regarding these, please contact your distributor.

Technical data

Device: LumiFem

Battery operation: 2 x AA batteries 1.5V

IP rating: IPXO

Mass: 180 g

Dimensions: 18 x 12 x 8 cm

Wavelength: 625-630 nm

Power output: 15 - 30 mW per LED

Light intensity: 4000 - 8500 mcd per LED






Half-angle of beam: 40°

Functions and safety standards





The LumiFem conforms to the following European safety standards:

EN 14971:2007	Medical devices - risk management
EN 60601-1-6:2007	Medical electrical equipment Parts 1-6
EN 62471:2009	Photobiological safety of lamps
EN 13485:2007	Quality management systems

Nameplate

LumiFem Phototherapiegerät	
Serial-No.:	11430-07
LED Data:	625-630 nm, P < 30 mW
Battery: 2 x 1,5V AA	 12-2011  ^{IPX0}   
 Reimers & Janssen GmbH Fabrikstraße 22 D-79183 Waldkirch www.LumiFem.de e-mail: Kontakt@LumiFem.de	

Explanation of symbols

	The device meets the requirements of Directive 93/42/EEC concerning medical devices.
IPX0	No rating against harmful ingress of water as defined in IEC 529
	Observe the accompanying documentation.
	Device provides special protection from electric shocks, especially in relation to permitted leakage current
 12-2011	Date of production Month - Year

Distributor

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