



 **KFH Novo**

*Next Generation wound healing*

# User Manual

KFH NOVO

## Contents

Introduction .....	3
About KFH Novo .....	4
Indications .....	5
Description .....	6
How to use your device .....	8
Precautions .....	12
Specifications.....	13
Maintenance .....	14
Warranty .....	15
Declaration of conformity .....	16

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## Introduction

Thank you for choosing KFH Novo. You have purchased a state-of-the-art medical device of the highest quality, which has improved the lives of many people.

We are proud of our product and its beneficial effects, and we always welcome constructive feedback that might help us to improve the present generation of devices or develop new products for the future. Please send any comments you may have to: [info@kfhealth.com](mailto:info@kfhealth.com), or contact your local distributor.



**Please make sure you have read this User Manual before using your KFH Novo device**



Type B Applied Part protection against electric shock. This equipment is internally powered only

Not protected against ingress of water IPX0

Not protected in case of use with a flammable anaesthetic mixture with air or with oxygen or nitrous oxide

Mode of operation: continuous use

When necessary, this device and the batteries should be disposed of carefully, according to local regulations



## About KFH Novo

Your hand-held medical device delivers a very specific form of bio-stimulation, known as micro current or BEST (Bio-Electric Stimulation Therapy). BEST works by enhancing the physiological processes at cellular level, documented effects include:

- an increase in ATP, the molecule that delivers energy to all cells in the body
- increased synthesis of proteins, the building blocks of the body

Your KFH Novo device has several unique features to ensure optimal effects, as well as ultimate ease of use. Some examples are:

### Superior Design

- ☑ Sleek and modern – no knobs or old-fashioned buttons
- ☑ By an award-winning specialist design team from Germany

### Ease of Use

- ☑ Very simple to operate (touch screen, 1 finger)
- ☑ Intuitive Timer indicator, (6 green LED's in vertical line)

### State-of-the-art Technology

- ☑ Patented, interactive touch screen front panel
- ☑ Unique output parameters to optimize tissue repair and wound healing

### Safe

- ☑ Automatic switching off after 60 or 30 minutes
- ☑ Visual and audible disconnection alarm

## Indications

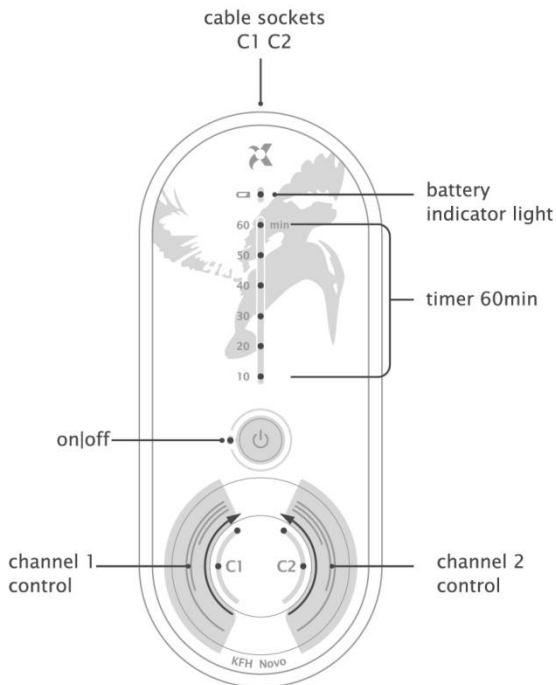
- Your KFH Novo can be used for the treatment of chronic wounds where conventional therapies have failed.

### Treatment Protocol

- It is recommended to use your KFH Novo device for one hour per day, five to seven days a week. If time allows, two sessions of one hour per day may produce quicker results. Results may not be apparent for several weeks of therapy although pain relief is often a lot quicker.
- For more information see [www.kfhealth.com](http://www.kfhealth.com)

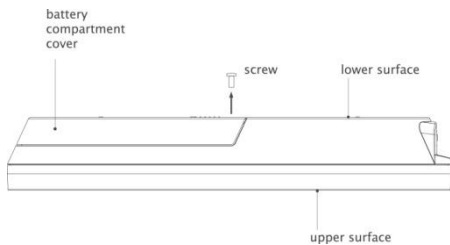
## Description

- front view

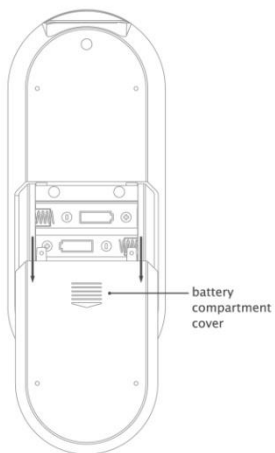


## Description

- side view

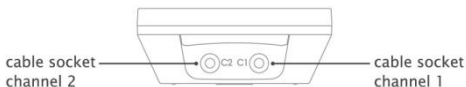


- back view



## Description

- top end view



## How to use your device

### Starting for the 1st time

- Check the equipment for damage before use.
- Insert 4 AA (1.5 V Energizer) batteries after removing the battery cover from the back of your device. To open, first remove screw from the top of the battery lid, then slide battery lid backwards. Alkaline batteries are recommended.

### Cables and Electrodes

- Insert a cable into the outlet for channel 1 on the top of your KFH Novo device indicated as C1. The cable has two wires ending in one grey and one white connector pin. These can be separated by gently pulling them apart. (You may need to move the slider along the cable first.)
- Attach these connector pins to the 2 adhesive electrodes as follows
  - White pin to the large electrode
  - Grey pin to the smaller electrode

## How to use your device

- Channel 2 gives you the option of treating two wounds simultaneously. In this case, insert a cable into both channels and connect a second set of electrodes as described above.

### Electrode placement

- Your normal wound care regime and dressings do not have to be changed for BEST treatment.
- To ensure proper function of the electrodes:
  - the skin must be clean and free from moisturizers and creams
  - place on intact skin only
  - ensure good skin contact over the whole area of the electrode

### Leg Ulcers

The electrode patches should be placed just outside the dressing as shown in the diagram. Place the smaller electrode on the upper surface of the foot. Make sure it is in good contact with the skin and that it is connected to the grey cable end. Place the larger electrode just above the knee on the front of the thigh making sure it is flat and making good contact with the skin. Ensure this is connected to the white cable end.

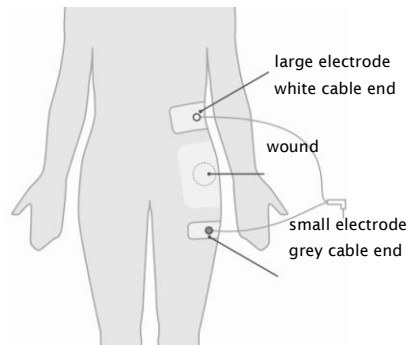
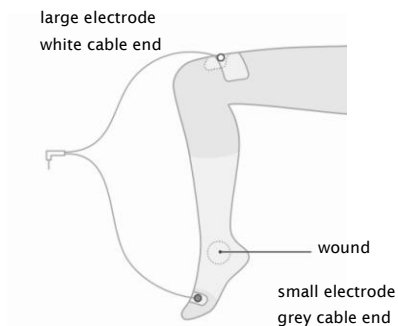
### Wounds at other sites

It is possible to treat a wound anywhere on the body surface except the head and neck. As a general rule the electrodes should be placed on either side of the lesion, just outside the dressing so that the electric current will pass through the wound. A straight line joining the two electrodes should pass directly through the wound.

- For more information on electrode placement consult the website [www.kfhealth.com](http://www.kfhealth.com) or your healthcare practitioner.

## How to use your device

- Examples of electrode placement



## How to use your device

### Switching on, setting timer

- Put your finger on the ON/OFF area for two seconds. You will hear a bleep and all 6 green timer LEDs will light up. Your KFH Novo device is now switched on and the timer has been set for 60 minutes.
- If you want a treatment time of 30 minutes, press the ON/OFF area for a second time. The timer has now been set to 30 minutes, and only the lower 3 green timer LEDs will be on.
- Pressing it a third time will switch the whole device off.
- Each LED represents 10 minutes of treatment and will switch off one by one until the treatment period is finished. At the end of the session you hear a bleep and the device will automatically turn itself off.

### Controlling Channels

- Channel 1: Place finger over the 6 o'clock position on the wheel, then slide it slowly and firmly upwards and to the left. You will first hear a bleep (indicating the channel is now on) and then a green LED will come on (indicating the optimal treatment setting).
- Channel 2: Exactly as for channel 1, except slide your finger upwards and to the right. It is only necessary to switch on channel 2 if two wounds are treated simultaneously.
- To switch off a channel switch the device off by placing a finger on the ON/OFF area once or twice. Wait 3 sec. then switch on again. The channels will be reset to zero current.

### Bag

- The device can be placed in the bag during use. Use the shoulder strap or belt attachment to hold the device safely during a treatment session.
- The device and all accessories can be stored in the bag for security and convenience. Do not place accessories directly against the glass panel.

## How to use your device

### Low battery

- Replace the batteries when the orange LED next to the battery symbol is on.

### Disconnection warning

- When a cable becomes disconnected or faulty, a repeated bleep will be heard and the green LED of the affected channel will flash on and off. This warning will be continuous until the channel is switched off or the continuity restored.
- Note: Usually you feel nothing during treatment. This is due to the very low current levels and is quite normal. For this reason your device has a disconnect alarm to warn you if the treatment is not being delivered.

## Precautions

Treatment with KFH Novo is very safe, and is continuously being evaluated by medical professionals in many countries.

As a precautionary measure we advise the following:

- Do not use KFH Novo, unless medically advised:
  - if you have a demand style cardiac pacemaker
  - during pregnancy
  - if you have cancer
- Do not place the electrodes:
  - near the eyes
  - over the carotid sinus (upper side of neck, behind the jaw)
  - directly on the open wound
- Electrode pads are for single patient use only
- For effective treatment, the electrode pads must be replaced after 10 hours of use or when their stickiness is reduced.
- Do not immerse the device in water or any other liquid.

## Precautions

- Never connect the device directly to a mains power supply.
- Keep out of reach of children.
- If, for whatever reason, you feel uncomfortable during treatment, you can switch off the device by pressing the ON/OFF area with your finger. As an additional safety measure, your KFH Novo device will automatically switch off at the end of the selected treatment period.
- KFH Novo complies with the requirements of EN 60601-1-2. However, the manufacturer recommends that the device is not used together with other equipment to avoid potential electromagnetic or other interferences.
- Only use cables (part no. H3.8PP150) and electrodes (part no. Novo L and Novo S) as supplied by Kingfisher Healthcare, or accessories that are CE marked.

## Specifications

Power Source	4 AA (LR6) batteries.
Timer	60 or 30 minutes treatment duration
Waveform	biphasic, rectangular with decay
Current	580 $\mu$ A (range : 300 to 800 $\mu$ A)
Frequency	100 Hz
Physical dimensions	190mm x 80mm x 30mm
Weight	350 grams with batteries

The manufacturer will make available, on request, circuit diagrams, component part lists, descriptions, calibration instructions, etc which will assist the User's appropriately qualified technical personnel to repair those parts of equipment which are designated by the manufacturer as repairable.

## Maintenance

- Replace the batteries when the orange LED next to battery symbol is on.
- Wipe the surface periodically with cloth dampened with clean water.
- Do not use cleaning sprays or solutions.
- After treatment, replace your electrodes on the plastic backing to maintain their stickiness.
- Remove batteries if not in use for any extended period of time. (> one month).
- Use and store at temperatures between 0°C and 40°C, humidity < 90% and between 0,9 and 1,1 atm pressure.
- No preventive inspections necessary.

## Warranty

KFH warrants this product against defects in workmanship and materials to the original purchaser for a period of 2 years from the date of purchase.

The liability of KFH under this limited product warranty does not extend to any misuse or abuse such as immersing the unit in water or other liquid substance, tampering with the unit or normal wear and tear. Any evidence of tampering will nullify this warranty. This warranty does not apply to any accessories. In no event shall KFH's liability under any cause of action relating to the product exceed the original purchase price.

Guidance and Manufacturer's Declaration		
KFH Novo is intended for use in the electromagnetic environment specified below.		
Electromagnetic emissions		
Test	Compliance	Guidance
RF emissions CISPR 11	Group 1	KFH Novo is unlikely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	KFH Novo is suitable for use in domestic establishments.

Electromagnetic immunity			
Test	IEC 60601 test level	Compliance	Guidance
IEC 61000-4-2	±6 kV contact ±8 kV air	pass	For synthetic floors, use in humidity > 30%
IEC 61000-4-8	3 A/m	pass	Use in normal magnetic field environments

## Declaration of conformity

On behalf of Kingfisher Healthcare NV, Interleuvenlaan 62, 3001 Leuven.

I hereby declare that the KFH Novo is a Class IIa, Type B medical device. It has been independently tested by outside agencies in order to confirm conformity to applicable standards for medical equipment safety and electromagnetic compliance.

KFH Novo complies with the following standards:

EN ISO 9001:2000

EN ISO 13485:2003

MDD 93/42/EEC



H. Snyman

Chief Executive Officer

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Signed at Leuven, Belgium in November 2007

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