

Instructions for Use

bite away®

Product Description

The bite away® is a patented handheld device that allows the user to apply a therapeutic dose of heat directly to an insect sting or bite and is clinically proven to provide temporary relief of the resulting itching, pain and swelling. If the device is applied immediately after the sting or bite, the symptoms can usually be prevented completely. Even if the device is used slightly later, the symptoms can still subside sooner.

bite away® works solely by concentrated heat and is thus completely free from chemicals (also suitable for pregnant women, allergy sufferers and children).

The bite away® allows the user to choose either a 3 second heat dose or a longer 5 second heat dose. The ceramic contact surface is heated up to 122 - 127°F (50 - 53°C) by an integrated micro-processor and maintained for 3 or 5 seconds according to the button selected.

The bite away® is provided with two AA LR6 1.5V batteries to power the device, which have to be placed into the battery compartment before the first use (see illustration below).

Indications for Use

The bite away® is indicated for use to provide temporary relief of the itching and pain resulting from insect stings and bites such as bees, wasps and mosquitoes by temporarily increasing localized blood flow.

User group/patient group:

adults and children aged 12 years and older in self-application / under 12 years only in third party application by adult person

Environment:

all environments except oxygen rich environment

Contraindications

- Not for use on mucus membranes (e.g. inside of the mouth, nose, etc.).
- Not for use on or near the eyes. Do not simultaneously use with medication and/or cosmetics.
- Not for use in case of heavy or chronic skin inflammation or severe internal diseases, in which the use could cause deterioration, such as:
 - open wounds, damaged skin
 - scalded or burnt skin
 - frostbite
 - small-fiber neuropathy, allodynia, hyperalgesia
 - tumors and malignant changes of the skin
 - people with reduced sensitivity due to physical or medical complaints.

Directions of Use

- Remove the stinger before applying the bite away® to the site of the sting.
- Place the contact surface (round ceramic disc at the tip of the device) directly onto the skin where the bite or sting had occurred and gently press it against the skin.
- Choose either:
 - 3 second treatment time (left button) for the initial treatment and sensitive skin (e.g. patients under 12 years of age in third party application) or
 - 5 second treatment time (right button) for regular application.
- Press the button and release immediately. The ceramic contact surface is heated up to a temperature of around 124°F (51°C). Once this temperature is reached, the LED will light up. The LED will go off once the device automatically shuts down after the end of the chosen treatment time. At the start of the heating-up phase and at the end of the treatment, you will hear an additional acoustic signal.
- For successful treatment, do not interrupt the indicated duration of the treatment. The treatment of the same insect sting or bite may be repeated as required. Please leave a treatment interval of at least 2 minutes between each application. Do not exceed a maximum number of 5 applications per hour on the same insect sting or bite.
- The device packaging includes two batteries (2x AA LR6 1.5V). Empty batteries of the bite away® are indicated when LED flashes 3 times and triple acoustic signal is heard.

Warnings

- Use carefully - may cause serious burns. Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of the bite away® by children or incapacitated persons may be dangerous.
- To avoid contamination to other person, the bite away® is intended to be used by only one person. Do not apply one bite away® to more than one person.
- The heated ceramic surface may reach a maximum temperature of 127°F (53°C).
- If you may use the device repeatedly on the same sting or bite, insure a pause of at least 2 minutes before repeated application. Do not exceed a maximum number of 5 applications per hour on the same insect sting or bite.
- The bite away® is not intended to replace medical advice or treatment. If symptoms (e.g. pain) are severe or persistent, consult a physician.

In the event of severe hypersensitivity reactions after an insect sting or bite (anaphylactic reaction), bite away® is not a replacement for emergency treatment. You should immediately call a doctor at the first signs of any such reaction (e.g. increased itching, reddening, swelling or formation of a welt, dizziness, nausea, difficulties breathing, hypotension or hypertension).

Medical advice should be sought in the following cases:

- persistent symptoms while using bite away®.
- worsening symptoms while using bite away®. Until these symptoms have been clarified, you should stop using the device.
- Do not use on or near the eye area or on mucus membranes (e.g. inside the mouth or nose).
- Individuals with impaired sensitivities due to physical or medical conditions should use extreme caution when using the bite away®. If in question, consult a physician prior to use.
- Do not use the bite away® if damaged or in case of obvious malfunction. Do not use damaged batteries.
- For external use only.
- The use of other accessories as listed in this IFU may negatively affect the EMC performance or lead to noncompliance.
- If you intend to not use the bite away® for a longer time, please remove the batteries to prevent them to leak out.
- The bite away® is not intended to be used in oxygen rich environment.
- Please keep away the bite away® from young children or babies, because small parts (like a disassembled battery cap) could be swallowed.
- Electromagnetic interference (EMI) from common household products such as security systems, metal detectors, diathermy equipment, MRI devices, RFID (Radio Frequency Identification) emitting devices may interfere with the bite away® device. The bite away® should not be used adjacent to or stacked with other electromagnetic equipment. If the bite away® device is adjacent or stacked with other electromagnetic equipment, assure that the bite away® operation is normal by verifying that the LED light illuminates and the device emits a 'beep' when the left and or right button is pressed prior to contacting the device with the skin. You can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the bite away®.
- Contact with liquids: Do not soak in water, wash or lubricate the bite away®, this may damage it. Do not use water, chemicals or other cleaning solutions to clean the bite away®. Furthermore, the device must not be used on moist skin.

Precautions

- Not recommended for children under the age of 2 years.
- The bite away® is indicated only for self-administration by adults and children aged 12 years and older. Children under the age of 12 years should only use the device under the supervision of an adult.
- The bite away® is intended for the relief of itching and pain immediately after an insect sting or bite. In case of an allergy to these insects (or in the case of continuous pain), consult a physician immediately.
- The bite away® is not effective against venom from spiders, scorpions or snakes.
- The use of bite away® may cause reddening of the skin.
- The use of bite away® may cause a burn blister if used on the same skin area more than once within a short period of time.
- The use of bite away® may cause a stinging sensation or a transient hot feeling.

Maintenance

A periodic maintenance is not defined. Please clean the bite away® or replace the batteries if necessary.

Cleaning and Storage

- Please clean the outside of bite away® by wiping it with a clean cloth.
- Do not soak in water, wash or lubricate the bite away®, this may damage it.
- Do not use water, chemicals or other cleaning solutions to clean the bite away®.
- Clean off dirt and dust with a dry cloth.
- Please store the bite away® on a safe place, dry, clean, no extreme heat and without direct sunlight.
- Please do not drop the bite away® on hard surface.

Warranty

2 years (valid from date of purchase)

Technical data

Heating times initial treatment and persons with sensitive skin child (12 – 18 years of age)* or child (under 12 years of age)** or adult (over 18 years of age)*	3s
regular application child (12 – 18 years of age)* or child (under 12 years of age)** or adult (over 18 years of age)*	5s
Range of ceramic tip temperature target treatment temperature	122°F (50°C) – 127°F (53°C) 124°F (51°C)
Internal voltage	2.4 + 3.0 V (2x AA LR6 1.5V batteries) shelf life of battery: please refer to battery labeling ! Only original batteries containing labeling for shelf life are allowed for use with the bite away®!

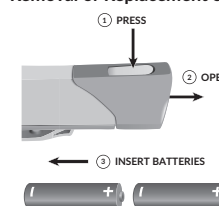
* self-application

** only in third party application by adult

Accessories

- 2x AA LR6 1.5V batteries (no rechargeable batteries allowed)
- The use of other accessories as listed in this IFU may negatively affect the EMC performance or lead to noncompliance!

Removal or Replacement of Batteries



2x AA LR6 1.5V batteries included in delivery. Before the first use, place the batteries into the battery compartment as shown in the illustration.

Please remove the batteries when you intend to not use the bite away® for a longer time, to prevent the batteries to leak out.

A storage of the batteries at cool temperatures (<30°C) will obtain their lifetime.

If the bite away® indicates empty batteries, please replace them.

Environmental Conditions

The bite away® is intended for storage and operation in a room-temperature environment.

Condition	Temperature	Humidity	Pressure (Altitude)
Operating	08°C – 40°C	15% – 93%	700 hPa – 1060 hPa
Storage	08°C – 40°C*	15% – 93%	700 hPa – 1060 hPa
Transport	08°C – 40°C	15% – 93%	700 hPa – 1060 hPa

* in case of longer storage without batteries (please remove the batteries and store them cool < 30°C)

Symbols

	Refer to manual		Caution: Consult instructions for use
	Type BF Applied Part		CLASS II equipment
	Batch Code		Manufacturer
	Charge clock		Protect against UV rays
	Operating temperature Storage temperature		Protect against liquids Keep away from rain
	Protection against Ingress of Solids and Liquids		Disposal of waste products
	Humidity conditions		MRI Unsafe – Keep away from magnetic resonance imaging (MRI) equipment

Trouble shooting

bite away® is not heating up	<ul style="list-style-type: none"> try an application on another spot and try to feel the heat replace battery and try again
bite away® without function	<ul style="list-style-type: none"> replace battery and try again
bite away® battery empty	<ul style="list-style-type: none"> replace battery
bite away® LED flashes 3 times and device beeps simultaneously	<ul style="list-style-type: none"> replace battery
bite away® LED flashes 5 times and device beeps simultaneously	<ul style="list-style-type: none"> replace battery and try again if the error occurs again contact distributor or manufacturer

Disposal of bite away® or batteries

Please do not use the bite away® in case of malfunction, visual defects or in reach of the shelf life. The shelf life of the bite away® is defined up to 5 years. The shelf life of the batteries is indicated on the batteries. Please dispose the bite away® without batteries concerning the national regulations for electronic disposals. Batteries must be disposed separately as hazardous waste.

Complaint & Service

In case of complaint or service please contact the distributor or the manufacturer.

Manufacturer

mibeTec GmbH
Münchener Straße 15
06796 Brehna
Germany

Distributor

mibeTec U.S.
801 Barton Springs Rd.
Austin, TX 78704
USA
e-mail: support@mibe-tec.com

Information on Electromagnetic and Other Interferences

The bite away® has been evaluated and deemed compliant with the requirements in EN60601-1-2 Class B for Electromagnetic Compatibility (EMC). Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this User Manual.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment. The bite away® should not be used adjacent to or stacked with other electromagnetic equipment. If adjacent or stacked use with other electromagnetic equipment is necessary, verify that the bite away® operation is normal in the configuration(s) in which it will be used.

The medical equipment bite away® needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this section of the manual.

Portable and mobile RF communications equipment can affect the medical equipment bite away®.

The bite away® may be interfered with by other equipment, even if that equipment complies emission requirements.

Guidance and manufacturer's declaration - electromagnetic emissions

The bite away® is intended for use in the electromagnetic environment specified below. The customer or the user of the bite away® should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The bite away® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The bite away® is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity


The bite away® is intended for use in the electromagnetic environment specified below. The customer or the user of the bite away® should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6kV contact +/- 8kV air	+/- 6kV contact +/- 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output	Not applicable	
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity

The bite away® is intended for use in the electromagnetic environment specified below. The customer or the user of the bite away® should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not Applicable 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the bite away®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance Not Applicable $d = 1.17 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.33 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz		

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the bite away® is used exceeds the applicable RF compliance level above, the bite away® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the bite away®.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the bite away®

The bite away® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the bite away® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the bite away® as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	Not applicable	0.1	0.23
0.1	Not applicable	0.4	0.74
1	Not applicable	1.2	2.3
10	Not applicable	3.7	7.4
100	Not applicable	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.