

# Instructions for use for Bliss One

Medical device, Class I

**The purpose of these instructions for use is to ensure that Bliss One is used correctly. Please read this information carefully and follow the instructions it contains.**

You should always use Bliss One by strictly following the information provided in this leaflet or by your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

The Butterfly Therapeutics support team will be happy to answer any questions you may have.

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## WHAT BLISS ONE IS AND WHEN TO USE IT

Bliss One is part of the Bliss DTx solution for pain and anxiety management.

### Class of this medical device

Bliss One is a class I reusable active medical device.

Bliss One is a medical device compliant with regulation (EU) 2017/745 art.2.

### Intended use

Bliss One is a medical device for reducing pain and anxiety before, during and after painful medical procedures.

Bliss One may only be used with the support of a healthcare professional trained in the use of this medical device. Bliss One is intended for use in patients aged 12 and over.

The Bliss One device can be used alone or in addition to a local anaesthetic, in the following applications (this list is not exhaustive):

- during diagnostic or sampling procedures such as endoscopies, punctures (pleural, ascites, lumbar, myelogram) and biopsies.
- during surgical procedures in oncology (catheter port insertion), urology (bladder surgery), vascular surgery (varicose vein surgery), orthopaedics (knee surgery, hand surgery, hallux valgus), oral surgery (wisdom tooth avulsion), etc.
- during painful post-surgical care (re-dressing, burns, mobilisation, etc.).

## HOW TO USE BLISS ONE

### Instructions for proper use

The Bliss One software is installed on a virtual reality headset.

It is recommended to use Bliss One in a quiet environment to ensure best results from the medical device.

Before using the virtual reality headset, check the battery level. There must be sufficient charge to prevent any sudden stoppage during the session.

If using Bliss One away from a power source, make sure you have a spare external battery.

Place the virtual reality headset on the head in the patient's field of vision a few minutes before the medical procedure.

Then place the headphones over the patient's ears.

At the end of the session, to avoid a sudden shutdown, first press the "exit the environment" button, then remove the headphones, and finally the virtual reality headset.

### Treatment duration

The different durations of the virtual reality programmes that come with Bliss One are pre-programmed. There is no limit to the frequency of sessions. The period of use of Bliss One is defined by the medical procedure and the associated protocol. The recommended period of use is around 45 minutes. However, this may be extended up to 2 hours with medical advice and depending on the medical procedure being performed.

### Environment for use

Should it be necessary to interrupt a Bliss One session, the healthcare professional should move around quietly and speak softly, to maintain the effects of Bliss One and then resume therapy under optimal conditions.

## 1 | STARTING THE DEVICE



Press the on/off button (1) for 3 seconds (the blue LED lights up) to switch on the VR headset (3). Press again for 3 seconds to switch it off.



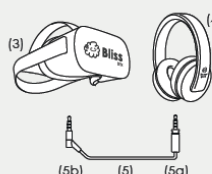
The indicator light next to the on/off button (1) shows the **charge level** (2) when the headset is plugged in:

- - green/high,
- - blue/medium,
- - red/low.



Check the battery level and the status of the licence or tokens.

## 2 | PREPARING THE DEVICE FOR USE



Connect the headphones (4) to the VR headset (3) using the **lead for this purpose** (5).

Use the **straight connector** (5a) with the headphones (4) and secure it with a quarter turn.

Use the **curved connector** (5b) on the lead and insert it into the VR headset (3).



Next, adjust the volume using the + and - buttons (6) on the VR headset.

## 3 | RUNNING THE APPLICATION



Menu items are selected by moving the head. An **animated icon** (7) gradually appears for the selected item.



**Back / Exit** (8) from the environments.



**Confirm** (9) avoids waiting for the animated icon.



**Recenter** (10) the user's point of view (in the event of a change of position).



**Home** button (11) to go back to the start.



**Back** button (12) to go back to the previous choice.



When available, **choice of solutions** (13):

- Bliss One (pain and anxiety)
- Bliss O2 (cardiac coherence)
- Wild Immersion (recreational/optional)



**Choice of viewing position** (14) for the patient depending on the procedure/posture.



**Choice of environment** (15) from the available options (Forest, Meadow, Space, Seabed).

## POSSIBLE ADVERSE EFFECTS

Bliss One may cause slight discomfort at the start of the session, as the patient adapts to the medical device. This possibility of discomfort should be explained to the patient.

Adverse effects linked to the use of Bliss One are limited to the three symptoms that may be caused by the virtual reality headset: headaches, dizziness and nausea. These are infrequent and can be dealt with by temporarily interrupting the virtual reality session.

If the patient experiences any of the above symptoms:

Until the above symptoms have completely disappeared, it is recommended not to drive, operate machinery or undertake visually or physically demanding and potentially hazardous activities (i.e. any activity during which the occurrence of such symptoms could result in death, bodily injury or damage to property), or any activities requiring a good sense of balance or hand-eye coordination (sports or cycling, etc.). Wait several hours after complete resolution of the symptoms before resuming a session that has been interrupted due to the onset of the symptoms described.

If you experience any side effects from using Bliss One, please email [app@bliss-dtx.com](mailto:app@bliss-dtx.com).

Any serious incident relating to the use of the product must be reported to the manufacturer and to the responsible authority in the country in which the patient and/or user is established.

There are currently no known interactions.

In addition to these warnings, no adverse effects have been reported since the market launch of Bliss One.

## WARNINGS AND CONTRAINDICATIONS

The use of Bliss One needs to be explained by trained staff to ensure its analgesic/anxiolytic effects are produced.

For people with impaired vision, the use of Bliss One must be approved by a healthcare professional. Bliss One is not recommended for patients with poor vision and/or hearing (glaucoma, very young patients under the age of 6), or for patients with photosensitivity and/or epilepsy.

### Driving vehicles and using machines

If the patient is driving after a session with Bliss One, make sure that they are sufficiently alert. You can check the patient's state of alertness using the Glasgow scale. If the Glasgow score is 15, the patient is sufficiently alert.

### Precautions for use and handling



Keep away from open flames.

## HOW TO STORE AND CARE FOR BLISS ONE

Do not expose Bliss One to a source of heat or bright light, as this may burn the screen, which will have to be replaced.

Particular care and attention must be paid to the headset lenses.

The virtual reality headset and the headphones used with Bliss One are fully cleanable and disinfectable. After each use, clean with disinfectant wipes such as surface safe wipes or similar (standard 14476).

Cleaning the virtual reality headset:

- Use a special microfibre lens cloth moistened with a little water to clean the optical lenses.
- Use the disinfectant wipes to gently wipe down the foam padding on the headset and the areas around it in contact with the skin, until the surface is slightly damp and can dry for at least 5 minutes. Leave to dry before use.

Cleaning the headphones:

- Use the disinfectant wipes to gently wipe down the headset pads and straps until the surface is slightly damp and can dry for at least 5 minutes. Leave to dry before use.

## MINIMUM SYSTEM REQUIREMENTS

Bliss One must only be used with the virtual reality headset and headphones supplied with Bliss One. In the event of malfunction or damage to either of these products, please contact BUTTERFLY THERAPEUTICS.

## MANUFACTURER

BUTTERFLY THERAPEUTICS  
106 Avenue Pierre de Coubertin  
53000 LAVAL, FRANCE  
Email: [app@bliss-dtx.com](mailto:app@bliss-dtx.com)



## SOFTWARE VERSION

The current version of the Bliss One software is V3.

## INFORMATION UPDATE

Version v05  
26-06-2024


## OTHER INFORMATION

### Disposal

Products used in combination with Bliss One must be disposed of in accordance with the applicable regulations for waste electrical and electronic equipment at the end of its life.

If you have any technical questions, please email [app@bliss-dtx.com](mailto:app@bliss-dtx.com).


If you would like to receive a printed copy of these instructions for use free of charge, please send a request to the Technical Support e-mail address given above. We will send you the paper version within 7 calendar days.

 22-10-2018

The UKCA mark consists of the letters "UK" stacked above "CA" in a bold, sans-serif font.



## MEANING OF SYMBOLS

 Manufacturer

 Medical device

