Instructions for use for Bliss DTx

Medical device, Class I

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

You should always use Bliss DTx 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 Neo DTx support team will be happy to answer any questions you may have.

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WHAT BLISS DTX IS AND WHEN TO USE IT

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

Class of this medical device

Bliss DTx is a class I reusable active medical device.
Bliss DTx is a medical device compliant with regulation (EU) 2017/745 art.2.

Intended use

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

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

The Bliss DTx 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 DTX

Instructions for proper use

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

It is recommended to use Bliss DTx 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 DTx away from a power source, make sure

you have a spare external battery.

Positioning Before Launching the Experience:

The device offers 6 starting positions:

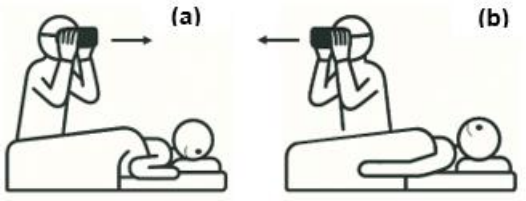
(1) **Lateral decubitus:** lying on the side.
(2) **Prone position:** lying face down.
(3) **Seated position with anterior tilt (~30°):** seated, slightly leaning forward.
(4) **Neutral seated position:** seated upright.
(5) **Seated position with posterior tilt (~30°):** seated, slightly leaning backward.
(6) **Supine position:** lying on the back.

Before launching the experience, select the position corresponding to the patient's posture.

- For positions (1) (3) (4) (5), the "Recenter" button can be used to adjust the patient's viewing angle after the experience has started.
- For the prone (2) and supine (6) positions, the recentering function is not available.

The healthcare professional must therefore:

1. Position the virtual reality headset in the correct orientation, corresponding to the patient's orientation, before launching the experience.
   a) Select the **Prone position (2)**.
   Stand laterally to the patient as shown in diagram (a).
   b) Select the **Supine position (6)** in the application.
   Stand laterally to the patient as shown in diagram (b).
2. Look **straight ahead**, then **adjust the headset by holding it in front of the eyes while maintaining this position**.
3. Then launch the program without using the "Recenter" function.
4. Once the program has started, **place the headset on the patient's head**.



A misalignment at startup may result in an incorrect perception of the virtual environment.

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.

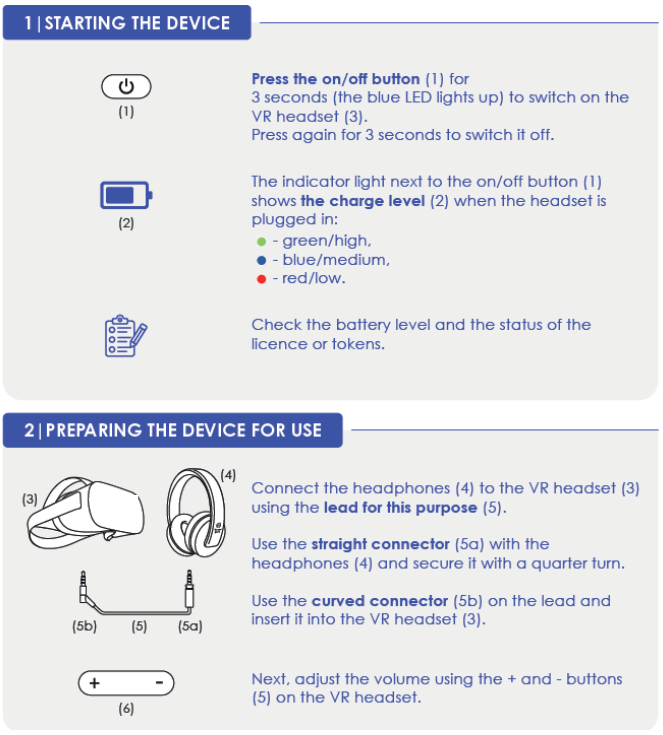
At the end of the session, to avoid a sudden shutdown, first press the "exit the environment" button, then remove the headphones, and finally the virtual reality headset.

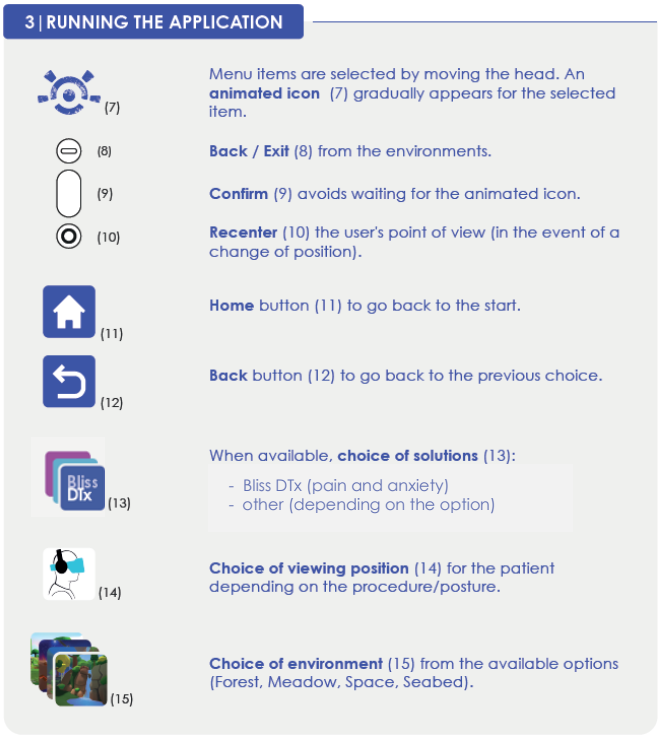
Treatment duration

The different durations of the virtual reality programmes that come with Bliss DTx are pre-programmed.
There is no limit to the frequency of sessions.
The period of use of Bliss DTx 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 DTx session, the healthcare professional should move around quietly and speak softly, to maintain the effects of Bliss DTx and then resume therapy under optimal conditions.





Note:
The Recenter function (10) depends on the headset model used, which can be identified by its color:
• Pico G3+ headset (white, see diagram): Recentering by a brief press on the "Recenter" button

(< 1 second).

• Pico G2 headset (black, see diagram): Recentering by pressing and holding the "Recenter" button for approximately 3 seconds.



Pico G3+ headset *Pico G2 headset*

POSSIBLE ADVERSE EFFECTS

Bliss DTx 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 DTx 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 DTx, please email support@neodtx.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 DTx.

WARNINGS AND CONTRAINDICATIONS

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

For people with impaired vision, the use of Bliss DTx must be approved by a healthcare professional.
Bliss DTx 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 DTx, make sure that they are sufficiently alert. You can check the patient's state of alertness using the Glasgow scale provided at the end of the leaflet. 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 DTX

Do not expose Bliss DTx 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 DTx 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 DTx must only be used with the virtual reality headset and headphones supplied with Bliss DTx. In the event of malfunction or damage to either of these products, please contact NEO DTX.

MANUFACTURER

NEO DTX
874 Route de Change
72530 YVRE-L'EVEQUE, FRANCE
Email : support@neodtx.com

SOFTWARE VERSION

The current version of the Bliss DTx software is V3.

INFORMATION UPDATE

Version v8
14-01-2026

OTHER INFORMATION

Disposal

Products used in combination with Bliss DTx 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 support@neodtx.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.

CE 25-09-2025

UK CA

MD

MEANING OF SYMBOLS

Manufacturer

MD Medical device

Glasgow Coma Scale: Follow this method

Method steps

CHECK
- Factors reducing communication
- Ability to respond
- Other injuries

OBSERVE
- Eye opening
- Verbal responses
- Movements on the right and left sides

STIMULATE
- Verbally: give a command by speaking normally or shouting
- Physically: apply pressure to the nailbed, the trapezius muscle, or the supraorbital notch

ASSESS
- Assign the score according to the best response observed

Eye Opening

Criterion	Observed	Evaluation	Score
Opens before stimulation	✓	Spontaneous (normal)	4
After verbal request or shout	✓	To speech	3
After nailbed pressure	✓	To pressure	2
No eye opening at any time, no interfering factors	✓	None	1
Eyes closed due to local problem	✓	Not testable	N/A

Verbal Response

Criterion	Observed	Evaluation	Score
Gives correct name, place, and date	✓	Oriented	5
Not oriented but coherent communication	✓	Confused	4
Understandable single words	✓	Words	3
Only moaning or groaning	✓	Sounds	2
No audible response, no interfering factors	✓	None	1
Communication prevented by external factors	✓	Not testable	N/A

Motor Response

Criterion	Observed	Evaluation	Score
Performs two simple, opposite commands	✓	Obeys commands	6
Hand reaches above clavicle after trapezius or supraorbital notch stimulation	✓	Localizing	5
Rapid arm flexion without abnormal features	✓	Normal flexion	4
Arm flexion with abnormal features	✓	Abnormal flexion	3
Arm extension	✓	Extension	2
No movement of arms or legs, no interfering factors	✓	None	1
Paralysis or other limiting factor	✓	Not testable	N/A

Sites for Physical Stimulation

- Nailbed pressure
- Pinching the trapezius muscle
- Pressure on the supraorbital notch

Characteristics of Flexion Responses

- **Abnormal flexion:** slow, stereotyped movement; arm drawn toward chest; forearm rotation; thumb flexion; leg extension
- **Normal flexion:** rapid, non-stereotyped movement; arm abducts