

START HERE

INSTRUCTION MANUAL



FLOW

NEUROSCIENCE

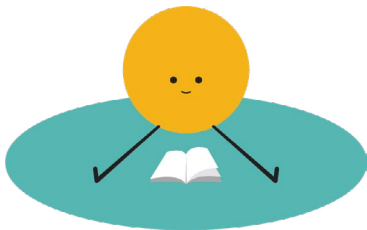


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Instruction for Use (IFU) – Flow

- Instructions on how to use the Flow headset and the accompanying smartphone app.
- IFU Version and Issuing date:
Ver 01 - Date: 2018-10-10
- Product model: FL-100

1. Manufacturer

Flow Neuroscience AB
Bredgatan 4; 211 30
Malmö; Skåne län, Sweden

2. Intended Use

The Intended use of the Flow device is for home-based treatment of adults (18+) diagnosed with Major Depressive Disorder (MDD).

3. Box Contents

Flow Headset	1
Pad Holder Rings	2
Micro-USB Charger incl. cord	1
Instructions for Use (IFU)	1

After each use put the headset and other parts back in the box. The Headset should also be delivered together with a box of 20 bags of Headset Pads. More Pads can be ordered at flowneuroscience.com.

4. The Treatment Program

- The Flow treatment program consists of 18 sessions over 6 weeks, as shown in the table below.
- After this main treatment period, 1–2 sessions could be done as follow-up sessions.
- Each session lasts about 30 minutes, plus a few minutes of preparation time.

WEEK	W1	W2	W3	W4	W5	W6	W7+
No. of sessions	5	5	2	2	2	2	1-2

5. Prerequisites

- A smartphone or other device running Apple iOS 11+.

6. First Time Use

- Download the Flow MDD App from the Apple App Store to an iOS device.

- Create an account in the downloaded Flow MDD App using your email address and password.

7. Charging the Battery

- Charge/ recharge if LED indicator on the front of the headset does not blink when pressing the button.
- Remove the USB cover and charge/ recharge using the supplied Micro-USB cable and charger.
- The LED indicator blinks during charging and shows a steady light when the headset is fully charged.
- Recharging a fully flat battery takes approximately an hour.
- Be sure to replace the USB cover in its place after charging.

8. How to Perform a Treatment Session

- Ensure your forehead is free from any makeup or hair products. Clean your forehead.
- If you have a fringe it is recommended you use a hair tie to remove it from your forehead.
- Take out the headset from the box.

- Press the button on the headset and make sure it blinks twice. If not, charge the headset.
- Start the Flow MDD App and log in with your email address & password.
- Press the “Start treatment” button in the app.
- Follow the instructions given by the virtual therapist in the App.
- Follow the instructions on how to prepare the headset, as below:
 - » Take a new pair of Flow Pads and attach them to the electrodes using the Pad Holder Rings.
 - » Place the headset on your head.
 - » The App guides you how to correctly position the headset using the camera of your device.
 - » Start the stimulation by pressing the “Start stimulation” button in the App.
- The current will now slowly increase to its maximum of 2 mA, as shown in the App.
- You can at any point press the pause button in the App or on the headset to decrease the current.
- Do not remove the headset before the app indicates that the stimulation has stopped.

- The headset also gives a “beep” signal when the stimulation has finished.
- Follow the instructions in the app during the rest of the session. The session will last for 30 minutes.
- When the time’s up (30 mins) the headset will automatically start decreasing (ramp down) the current.
- Wait until the simulation has come to a complete stop before removing the headset.
- After the session, dispose of the Flow pads and put the Pad Holder Rings and headset back in the box.

9. Cleaning of the Device

- It is recommended to clean the headset and especially the electrodes after each use.
- To clean the device, ensure Micro-USB cable is not connected, and remove the pads.
- Dampen a soft cloth or paper towel with ethanol alcohol, and clean the headset unit.
- Clean the electrodes using a circular motion.
- Use an IPA (isopropanol) Wet Wipe (70% is a good choice).

10. Precautions

- Use the device **ONLY** if you have been diagnosed with Major Depressive Disorder, otherwise known as unipolar depression.
- **DO NOT** use the device if you are under the age of 18 years old.

DO NOT use the device before consulting a physician if you:

- are under the active care of a physician;
- have a history of hypomanic/manic switches or episodes;
- have been diagnosed with Bipolar Disorder;
- have a history of seizures;
- are suspected of having or have been diagnosed with epilepsy;
- have open wounds, or broken or damaged skin at the stimulation site (this might create further irritation and/or damaged skin);
- are pregnant or may be pregnant;

- have a pre-existing neurological or neuropsychiatric condition;
- have an active implanted medical device such as a cardiac pacemaker or neurostimulation device such as a spinal cord stimulator, vagal nerve stimulator, auricular stimulator, or deep-brain stimulating electrodes, or implanted defibrillator, or other implanted metallic or electronic device;
- have a defect in neurocranium, an implant inside the skull, a cochlear implant, or an implanted hearing aid;
- are suspected of having or have been diagnosed with heart disease;
- have recently had a surgical procedure.

11. Warnings

- Apply the headset **ONLY** on the head as directed and not on other body parts.
- Keep the headset dry and out of sunlight.
- Keep the headset out of the reach of children.
- Do not apply the headset over areas of skin that lack normal sensations.


- Do not apply the headset while outside or close to water.
- Do not apply the headset while driving.
- Do not apply the headset during any activity creating a significant risk of injury.
- Do not apply the headset while intoxicated or incapacitated.
- Do not apply the headset in an environment with strong magnetic fields.
- Do not apply the headset without the supplied Headset Pads.
- Do not apply the headset with dried-out Headset Pads (Pads are single use).
- **Worsening of symptoms:** Patient **MUST** consult a physician if he/she experiences a significant worsening of depression while using this device before continuing the treatment.
- **Suicidal thoughts:** Patient **MUST** consult a physician before starting or continuing the treatment if he/she experiences suicidal thoughts or fantasizing about ending his/her life.

12. Possible Adverse Reactions

- Some skin redness under the electrode or near the electrode sites is normal, due to increased local blood flow, and will subside within approximately an hour of the end of use.
- DO NOT apply the device over open wounds, or broken or damaged skin. This might create further irritation and/or skin damage.
- Skin irritation might be experienced beneath the stimulation electrodes. In this case, electrodes should NOT be reapplied to the irritated skin.
- Discontinue treatment if the sensation of tingling, itching or burning under electrodes becomes severe (mild sensation of tingling, itching or burning is normal).
- Discontinue treatment if you experience a mild headache, that does not pass within an hour after the end of a session.
- Discontinue treatment if you experience tinnitus (noise or ringing in the ears) during or after using the device.
- Discontinue treatment in case of any other adverse reaction from the device.

13. Device Specifications

PERFORMANCE	
PARAMETER	NOMINAL VALUE
MAX. STIMULATION CURRENT	2.0 + 0.05 mA
MAX. STIMULATION VOLTAGE	24 V
MICRO-USB CHARGER	5 V D.C.
BATTERY	RECHARGEABLE LiPo 3.7 V; 250 mAh
ELECTRODE SIZE	22.9 cm ² (5.4 cm diameter)
DEVICE WEIGHT	~110 g
WATER INGRESS PROTECTION	IP22
DEVICE EXPECTED LIFETIME	3 YEARS
OPERATING ENVIRONMENT	5 to 35°C (41 to 95°F)
OPERATING TEMP. RANGE	5 to 35°C (41 to 95°F)
STORAGE/ TRANSPORT TEMP. RANGE	-10 to 40°C (14 to 104°F)
OPERATING HUMIDITY RANGE	10% to 93%, NON- CONDENSING
STORAGE/ TRANSPORT HUMIDITY RANGE	10% to 93%, NON- CONDENSING
OPERATING ALTITUDE RANGE	0 - 3000 m
STORAGE/ TRANSPORT ALTITUDE RANGE	0 - 3000 m

MARKINGS	
ICON	DEFINITION
	Consult Instruction for Use (IFU)
	Caution: Consult Accompanying Documentation
	Separate collection for electrical and electronic equipment per EC Directive 2012/19/EU. Waste Electrical and Electronic Equipment (WEEE).
	Type BF Applied part
	Manufacturing Year
	Keep Dry
	Manufactured by Flow Neuroscience AB Bredgatan 4 211 30 Malmö, Sweden Web: flowneuroscience.com
IP22	Water ingress protection: 22
	Notified Body No.

ACCESSORIES	
ITEMS	DEFINITION
ACCESSORIES	CHARGER, HEADSET PADS (SINGLE USE)

EMISSION MEASUREMENT			
ITEMS	DEFINITION	TEST METHOD	STATUS
RADIATED EMISSION	IEC 60601-1-2: 2014	CISPR 11: 2015+A1: 2016	PASS
CONDUCTED DISTURBANCE (0.15-30 MHz)	IEC 60601-1-2: 2014	CISPR 11: 2015+A1: 2016	PASS
HARMONIC CURRENT	IEC 60601-1-2: 2014	IEC 61000-3-2: 2014	N/A
VOLTAGE FLUCTUATION & FLICKER	IEC 60601-1-2: 2014	IEC 61000-3-3: 2013	PASS

IMMUNITY MEASUREMENT			
ITEMS	DEFINITION	TEST METHOD	STATUS
ELECTROSTATIC DISCHARGE	IEC 60601-1-2: 2014	IEC 61000-4-2: 2008	PASS
RF FIELD STRENGTH SUSCEPTIBILITY (80-2700 MHz)	IEC 60601-1-2: 2014	IEC 61000-4-3: 2006 + A1: 2007 + A1: 2010	PASS
ELECTRICAL FAST TRANSIENT/ BURST TEST	IEC 60601-1-2: 2014	IEC 61000-4-4: 2012	PASS
SURGE TEST	IEC 60601-1-2: 2014	IEC 61000-4-5: 2014	PASS
CONDUCTED SUSCEPTIBILITY TEST	IEC 60601-1-2: 2014	IEC 61000-4-6: 2013	PASS
POWER FREQUENCY MAGNETIC FIELD SUSCEPTIBILITY TEST	IEC 60601-1-2: 2014	IEC 61000-4-8: 2009	PASS
VOLTAGE DIPS AND INTERRUPTIONS TEST	IEC 60601-1-2: 2014	IEC 61000-4-11: 2004	PASS

14. Warranty

TBD

15. Return and Refund Policy

TBD

16. Contact Us

If you have any questions regarding Flow, don't hesitate to contact customer support at support@flowneuroscience.com

Flow Neuroscience AB
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211 30 Malmö
Skåne Län, Sweden



