

INSTRUCTION MANUAL

START HERE



FLOW
NEUROSCIENCE

Don't forget to
download the app!

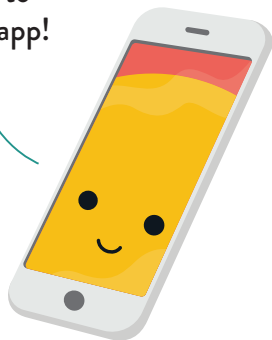


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Instruction for Use (IFU) – Flow

- Instructions on how to use the Flow headset and the accompanying smartphone app.
- IFU Version and Issuing date:
Ver 01 - Date: 2018-11-12
- 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

1. Instructions for Use (IFU)
2. Micro-USB Charger & cord
3. Two Pad Holder Rings
4. Flow Headset

After each use put the headset and other parts back in the box.



4. Accessories

ACCESSORIES	
ITEMS	DEFINITION
FLOW PADS	A BOX OF FLOW PADS CONTAINING 20 POUCHES (SINGLE USE)
MICRO USB CHARGER	A LXCPI2-005 CHARGER AND CORD

More Pads can be ordered at <https://flowneuroscience.com>.

5. 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 devices;
- 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.

6. 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).
- Do not charge the headset with any other charger than the one supplied with the Headset.
- **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.

7. Possible Adverse Reactions

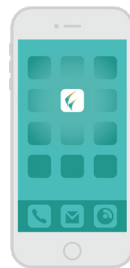
- Some skin redness under the electrode or near the electrode sites is normal, due to increased local blood flow, and will subside within approximately an hour of the end of use.
- DO NOT apply the device over open wounds, or broken or damaged skin. This might create further irritation and/or skin damage.
- 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.

8. Prerequisites

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

9. First Time Use

- Download the “Flow - Depression” app to your smartphone.
- Create an account in the downloaded “Flow - Depression” app using an email address you have access to and a new password of your choosing.

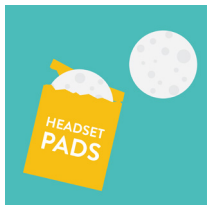


10. How to Perform a Treatment Session

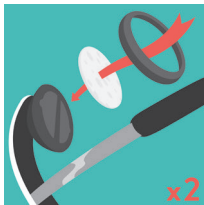
- Ensure your forehead is free from any makeup or hair products. Clean your forehead.
- If you have a fringe it is recommended you use a hair tie to remove it from your forehead.
- Take out the headset from the box.
- Press the button on the headset and make sure it blinks twice. If not, charge the headset.
- Make sure Bluetooth is enabled on your smartphone.
- Start the Flow app and log in with the email address & password you choose in 9 above.
- 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:

1.

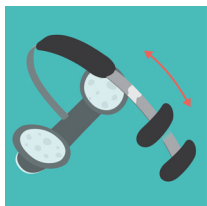


Take a new pair of Flow Pads from a pouch.



Attach them to the electrodes using the Pad Holder Rings.

2.



Adjust the length of the metal arch by sliding the back piece.



The end of the arch should sit comfortably on the back of your head.

3.



Place the headset on your head.

The App guides you how to correctly position the headset using the camera of your device.

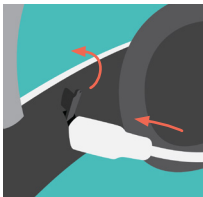
4. Start the stimulation by pressing the “Start stimulation” button in the App.

- 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 the button on the headset to stop the stimulation.
- 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.

11. Charging the Headset

- 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.

12. Cleaning of the Headset

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

13. 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

14. 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	HOME OR CLINICAL ENVIRONMENT
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

15. 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
 0086	Notified Body No.
	Bluetooth Low Energy

16. Contact Us

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

Flow Neuroscience AB
Bredgatan 4
211 30 Malmö
Skåne Län, Sweden

17. EMC - Test Results

EMISSION LIMITS & MEASUREMENT

PHENOMENON	STANDARD	TEST METHOD	TEST LEVELS	RESULT
RADIATED RF EMISSION	IEC 60601-1-2	CISPR 11 ETSI EN 301 489-1	30-1000 MHz ; 1-3 GHz & 3-6 GHz (Measurement Uncertainty 4.24 dB)	PASS
CONDUCTED RF EMISSION	IEC 60601-1-2	CISPR 11 ETSI EN 301 489-1	0,15-30 MHz (Measurement Uncertainty 3.35 dB)	PASS
VOLTAGE FLUCTUATION & FLICKER	IEC 60601-1-2	IEC 61000-3-3	EUT VALUES & LIMITS Pst: 0.028 ; Limit 1.00 Plt: 0.028 ; Limit 0.65 dc [%]: 0.0000 ; Limit 3.30 dmax [%]: 0.053 ; Limit 4.00 dt [s]: 0.000 ; Limit 0.50	PASS

IMMUNITY MEASUREMENT

PHENOMENON	STANDARD	TEST METHOD	TEST LEVELS	RESULT
ELECTROSTATIC DISCHARGE	IEC 60601-1-2	IEC 61000-4-2	±2 kV, ±4 kV, ±6 kV, ±8 kV - Contact Discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV - Air Discharge	PASS
RF ELECTROMAGNETIC FIELDS	IEC 60601-1-2	IEC 61000-4-3	10 V/m 80 - 2700 MHz 80 % AM at 1 kHz	PASS
EL FAST TRANSIENTS COMMON MODE / BURSTS	IEC 60601-1-2	IEC 61000-4-4	±2 kV for A.C. Power Lines 100 kHz Burst Frequency	PASS
SURGES LINE TO LINE	IEC 60601-1-2	IEC 61000-4-5	±0.5 kV & ±1 kV At 0°, 90°, 180°, 270° ; Repetition Rate: 60 S	PASS
SURGES LINE TO GROUND	IEC 60601-1-2	IEC 61000-4-5	±0.5 kV, ±1 & ±2 kV At 0°, 90°, 180°, 270°	PASS
RF COMMON MODE	IEC 60601-1-2	IEC 61000-4-6	3 & 6 V for A.C. Main Port ; 80%, 1 kHz Amplitude Modulation Frequency: 150kHz to 80MHz	PASS
VOLTAGE DIPS & INTERRUPTIONS	IEC 60601-1-2	IEC 61000-4-11	0 % UT; 0,5 Cycle At 0°, 45°,90°,135°,180°, 225°, 270°, 315°, 0 % UT; 1,0 Cycle 70 % UT; 25/30 Cycles	PASS



