

START HERE

# INSTRUCTION MANUAL



**FLOW**

NEUROSCIENCE



## **Flow Neuroscience AB**

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## Instruction For Use (IFU) - Flow

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

### 1. Manufacturer

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

### 2. Intended Use

Intended Use of the Flow device is for home base 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

### 4. The Treatment Program

- The Flow treatment program consists of 18 sessions over 6 weeks as shown in below table.
- After this main treatment period, 1-2 sessions could be done as follow up sessions.
- Each session is 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 that runs Apple iOS 11+.

### 6. First Time Use

- Download Flow MDD App from Apple App Store to an iOS device.
- Create an account in the downloaded Flow MDD App using your email 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 & charger.
- LED indicator blinks during charging and shows a steady light when the headset is fully charged.
- Recharging a fully flat battery takes approximately about an hour.
- Ensure putting back 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 bangs it is recommended you use a hair tie to get it out of 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 email & 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 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.
- Don't remove the headset before the app indicates that the stimulation has stopped.
- The headset also gives a “beep” signal when the stimulation has stopped.

- Follow the instructions in the app during the rest of the session. The session will last for 30 min.
- When the time's up (30 min) the headset will automatically start decrease (ramp down) the current.
- Wait until the simulation has gone to a complete stop before removing the headset.
- After the session, dispose the Flow pads and put the Pad Holder Rings and headset back in its 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 in a circular motion.
- Using an IPA (isopropanol) Wet Wipe 70% is a good choice.

## 10. Precautions

- ONLY use the device, if you are diagnosed with Major Depressive Disorder otherwise known as unipolar depression.
- DON'T use the device if you are under the age of 18 years old.

DON'T 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.
- Are diagnosed with Bipolar Disorder.
- Have a history of seizures.
- Are suspected or diagnosed with epilepsy
- Have open wounds, broken or damaged skin at the stimulation site. It 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, cochlear implant, or implanted hearing aid.
- Are suspected or diagnosed with heart disease.
- Recently have 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.
- Don't apply the headset over areas of skin that lack normal sensations.
- Don't apply the headset while outside or close to water.
- Don't apply the headset while driving.

- Don't apply the headset during any activity creating a significant risk of injury.
- Don't apply the headset while intoxicated or incapacitated.
- Don't apply the headset in an environment with strong magnetic fields.
- Don't apply the headset without the supplied Headset Pads.
- Don't 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.
- DON'T apply the device over open wounds, broken or damaged skin. It might create further irritation and/or skin damage.
- Skin irritation might be experienced beneath the stimulation electrodes. In this case- electrodes should NOT be applied on the irritated skin over again.
- 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 250mAh
ELECTRODE SIZE	22.9 Cm <sup>2</sup> (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: <a href="http://flowneuroscience.com">flowneuroscience.com</a>
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

## EMISSION MEASUREMENT

ITEMS	DEFINITION	TEST METHOD	STATUS
ELECTROSTATIC DISCHARGE	IEC 60601-1-2: 2014	IEC 61000-4-2: 2008	PASS
RF FIELD STRENGTH SUSCEPTIBILITY (80-2700MHZ)	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 & Refund Policy

TBD

## 16. Contact Us

If you have any questions regarding Flow don't hesitate to contact the customer support at [support@flowneuroscience.com](mailto:support@flowneuroscience.com)

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