Flow Neuroscience
User Manual

Model FL-100

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Get started by downloading the app
“Flow - Depression Treatment”

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Instruction for Use (USA only)

- Instructions on how to use the FL-100 Headset and the accompanying smartphone app.
- Instructions for Use (IFU) Version and Issuing date: Ver 02 - 2026-07-16
- Product model: FL-100.
- The latest version of this manual is also available to download from flowneuroscience.com.

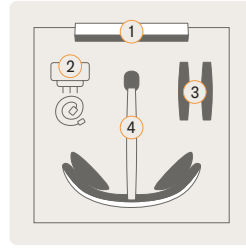
1. Manufacturer

Flow Neuroscience AB
Södra Tullgatan 3
21140 Malmö, Sweden

2. Intended Use

- The FL-100 Headset is intended for the treatment of moderate to severe major depressive disorder in the current episode, either as monotherapy or as an adjunctive treatment, in patients 18 and older who are not considered treatment refractory to medication.
- For prescription use only (Rx only).

3. Box Contents & the Headset





1. Instructions for Use
2. USB Charger & micro-USB cable
3. Pad Holder Rings
4. Headset
5. Metal arch
6. Headset Pad
7. Electrode
8. Power Button
9. LED indicator
10. Charger port cover
11. Back piece



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

4. Accessories

ITEMS	DEFINITION
HEADSET PADS	A BOX OF HEADSET PADS (SINGLE USE)
USB CHARGER	A USB CHARGER & MICRO-USB CABLE

Reuse of Headset Pads may cause skin damage. Always start a stimulation session with a new pair of Headset Pads.

5. Contraindications

Do NOT use the device in case you have:

- Open wounds, broken skin, or damaged skin at the electrode site.
- Metallic skull reconstruction at the electrode site.

6. Precautions

The device should only be used by people at least 18 years old who are diagnosed with depression (Major Depressive Disorder or MDD), whose clinical course is supervised by a medical provider.

Take extra precaution and discuss with your clinician the following circumstances, if applicable:

- You are pregnant, think you might be, or become pregnant while using the device.
- You currently have thoughts about suicide or harming yourself.
- You have been told there is a problem with your skull or if you have metal parts in or around the brain, like brain surgery clips, metal plates or screws in the skull, cochlear implants, or brain pacemakers such as those used for Parkinson's disease. It is fine to use the device if you have dentures.
- You have been diagnosed with "epilepsy", "seizure(s)", "seizure disorder", unexplained loss or alteration of consciousness, or, according to a medical provider, you have had symptoms of a possible seizure.
- You have a chronic skin condition affecting your forehead or scalp, such as psoriasis.

There is a risk that the device is ineffective for the individual patient. The device should only be used by patients whose clinical course is supervised by a medical provider.

Ensure your forehead is free from any makeup or hair products before you start stimulation. Not doing so can result in skin damage.

7. Warnings

- Never change your treatment for depression (major depressive disorder) prior to discussing it with your medical provider.
- The FL-100 Headset should never be applied to open wounds, damaged, or irritated skin. If the skin is irritated, red, or abnormal in any way since the device was last used, wait for the skin to heal completely before using the device.
- New FL-100 Headset Pads should be used each time, and these Headset Pads should not be dry.
- Clean your forehead before using the device.
- Never use tap water to wet Headset Pads.
- Apply the FL-100 Headset only on the head as directed. Do not apply the headset anywhere except the head.
- When using the FL-100 Headset, avoid activities that may cause the headset to move or change position.
- Keep the FL-100 Headset dry.
- Keep the FL-100 Headset out of the reach of children.
- The FL-100 Headset should not be used around very strong magnetic fields, e.g., near an MRI machine. However, house appliances cause no risk.

8. Possible Adverse Reactions

- Some skin redness under the electrode or near the electrode sites is normal due to increased local blood flow. The redness will normally subside within approximately an hour after the end of use.
- DO NOT apply the FL-100 Headset over open wounds, or damaged or irritated 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. If you experience any dryness of the skin/skin irritation after stimulation, it is recommended to apply moisturizer to the area.
- In rare cases, the stimulation can cause skin burns. Always let the skin heal before continuing treatment. Not cleaning the forehead or reusing Headset Pads increases the risk of skin damage.
- Discontinue treatment if the sensation of tingling, itching or burning under electrodes becomes severe (mild sensations of tingling, itching or burning are normal).
- Discontinue treatment if you experience persistent or worsening headaches.
- Discontinue treatment if you experience persistent tinnitus (noise or ringing in the ears) during or after using the FL-100 Headset.

If you have questions about adverse reactions, please talk with your medical provider or contact Flow Neuroscience.

NOTE: Any serious incident that has occurred in relation to use of the FL-100 Headset should be reported to Flow Neuroscience (see section 18) and the FDA (see section 19).

9. The Treatment Program

- The treatment program consists of 15 sessions during the first 3 weeks, as shown in the table below (W1, W2, and W3).
- After this first treatment period, up to 3 sessions are recommended per week (W4, W5+).
- The number of sessions you can do per week is restricted.
- Talk with your medical provider if you want to make changes to your stimulation schedule.
- Each session lasts 30 minutes, plus a few minutes of preparation time.
- A maximum of 1 session can be completed per calendar day.

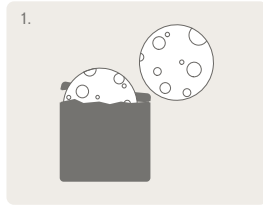
WEEK	W1	W2	W3	W4	W5+
No. of sessions	5	5	5	1-3	1-3

10. Downloading the App & Account Setup

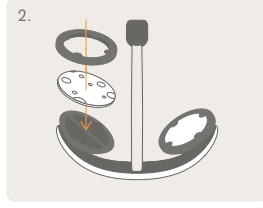
- Download the “Flow - Depression Treatment” app on your mobile device.
- Open the app and activate your account by entering the same email address you provided to your clinician and a secure password.
- Open the verification email sent to your email address, and click the confirmation link to complete your setup.

11. How to Perform a Treatment Session

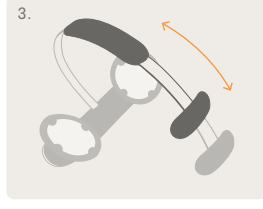
- Ensure your forehead is free from any makeup or hair products before you start. Not doing so can result in skin damage.
- If you have bangs, it is recommended that you use a hair tie to remove from your forehead.
- Take out the headset from the box.
- Press the Power Button on the headset and make sure the LED indicator starts blinking. 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 chose in Section 10 above.
- Follow the instructions in the app to start the stimulation.
- When told to, follow the instructions on how to prepare the headset, as below:



Take a new pair of Headset Pads from their sachet. Reuse of Headset Pads can lead to skin damage.

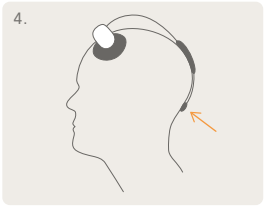


Attach them to the electrodes using the Pad Holder Rings.



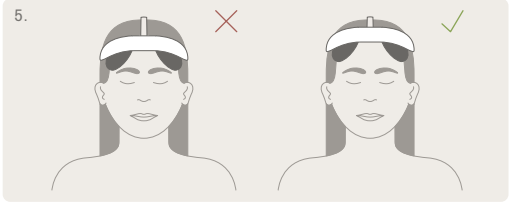
Adjust the length of the metal arch by sliding the back piece.

4.



The end of the arch should sit comfortably on the back of your head. Make sure the headset does not sit too low.

5.



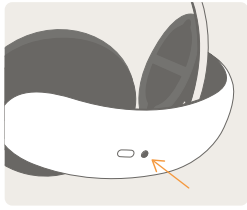
The app shows you how to correctly position the headset using the camera on your device.

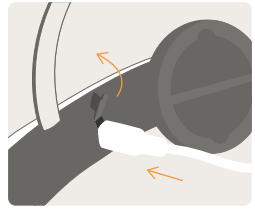
6. Before starting the stimulation, you can press and hold the “Tingle” button in the app to test how the stimulation feels. Hold the “Tingle” button for at least 10 seconds.

7. 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.
- If at any point you want to pause the stimulation, press the pause button in the app or the Power Button on the headset.
- Follow the instructions in the app during the rest of the session. The session will last for 30 minutes.
- Remain within Bluetooth® range during treatment.
- When the time is up, the headset will automatically start decreasing the current.
  - Do not remove the headset before the app indicates that the stimulation has stopped.
  - The headset gives a “beep” signal when the stimulation has finished.
  - After the session, dispose of the Headset Pads and put the Pad Holder Rings and headset back in the box.
- The headset will automatically turn itself off after a few minutes of inactivity. Start it again by pressing the Power Button on the headset.

12. Charging the Headset





- Charge the headset if the LED indicator on the front of the headset does not blink when pressing the Power Button.
- Remove the charger port cover and charge using the supplied Micro-USB charger and cable.
- 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 close the charger port cover again after charging.

13. Cleaning of the Headset

- It is recommended to clean the headset and especially the electrodes after each use.
- To clean the device, ensure that the Micro-USB cable is not connected to the headset and remove the Headset Pads.
- Use an IPA (isopropanol) wet wipe (45% is a good choice).
- Clean the electrodes using a gentle circular motion.
- Neither the device nor its accessories are supplied sterilized nor require sterilization prior to use.

14. Clinical Data

Pivotal study

The FL-100 Headset was studied in a fully remote, two-site (UK, US), double-blind,

placebo-controlled, randomized superiority trial of home-based treatment in patients diagnosed with major depressive disorder (MDD). Participants were adults 18 years or older who:

- were in a current depressive episode of at least moderate severity (based on a score ≥ 16 on the 17-item Hamilton Depression Rating Scale (HDRS-17);
- were not currently being treated for MDD, or had been receiving a stable dose of antidepressant medication or a stable schedule of psychotherapy for at least 6 weeks prior to study enrollment; and agreed to maintain the same treatment regimens throughout the trial.

The pivotal study included 2 parts (phases), each lasting 10 weeks:

1. Blinded phase: 50% of participants received active treatment with FL-100 and 50% received inactive (placebo) treatment; treatment schedule – 5 sessions per week for 3 weeks, then 3 sessions per week for 7 weeks.
2. Open-label phase: offered to participants who completed the Blinded phase; all participants received active treatment (FL-100); treatment schedule - initially in active arm: 3 sessions per week for 10 weeks - initially in sham arm: 5 sessions per week for 3 weeks, then 3 sessions per week for 7 weeks.

Active stimulation was 2 mA. The placebo (sham) stimulation, using the same FL-100 Headset, was an initial current ramp up to 1 mA over 30 seconds, then ramp down over 15 seconds, and repeated at session end to provide a tingling sensation which mimics active stimulation.

The primary outcome was the between-group difference in mean HDRS-17 change at Week 10 after the Blinded phase.

Results: 174 participants were randomized: active (n=87; mean age 37.1 ± 11.1 years) and sham (n=87; mean age 38.3± 10.9 years) treatment, with no differences in discontinuation rates between active (n=13) and sham (n=12). 63% were women.

Active treatment arm showed a statistically significant improvement in HDRS-17 from baseline to Week 10. Mean improvement was 9.4 points relative to 7.1 points for the sham treatment (delta: 2.3, 95% CI: 0.5 to 4.0, p = 0.012). Based on HDRS-17 ratings, active treatment arm showed a statistically significant greater clinical response rate of 54.4% relative to sham 26.9% (p = 0.001), Odds Ratio (OR): 3.25 (95% CI: 1.57 to 6.74), and the active treatment arm showed statistically significant greater remission rate of 44.9% relative to sham 21.8% (p = 0.004), OR: 2.93 (95% CI: 1.41 to 6.09).

Based on MADRS ratings, the active treatment arm showed a statistically significant improvement from baseline to Week 10. Mean improvement was 11.3 points relative to 7.7 points for the sham treatment (delta: 3.6, 95% CI: 1.1 to 6.1, p = 0.006). In clinical response, the active treatment arm showed a statistically significant greater response of 63.0% relative to sham 31.6% (p < 0.001), OR: 3.70 (95% CI: 1.82 to 7.52). In clinical remission, the active treatment arm showed a statistically significant greater remission rate 57.5% relative to sham 29.4% (p = 0.002), OR: 3.26 (95% CI: 1.53 to 6.94).

In the subgroup (N=52) who used the FL-100 as monotherapy (i.e., no adjunctive treatment): HDRS-17 response rate was 47.8% in the active group compared to 13.8% in the sham group (delta=34%, OR=5.76); the HDRS-17 remission rate was 34.8% in the active group compared to 13.8% in the sham group (delta=21.0%, OR=3.33).

In the subgroup who used FL-100 Headset adjunctively (i.e., together with antidepressant medication): HDRS-17 response rate was 63.2% in the active group compared to 35.4% in the sham group (delta=27.8%, OR=3.14); the HDRS-17 remission rate was 53.1% in the active group compared to 25.5% in (delta=27.6%, OR=3.33).

Safety: The most frequent adverse events (AEs) (active % vs. sham %) were skin redness (63.5% vs. 18.5%), itching (50.6% vs. 43.2%), burning sensation (43.5% vs. 38.3%), headache (42.4% vs. 35.8%), and scalp pain (21.2% vs. 12.3%). Headaches were generally mild in severity. No device-related serious adverse events, including hypomania, mania, or suicidality, were observed in the study.

Two cases of mild, superficial skin burns (first-degree burns) were reported. The burns healed without sequelae. In both cases, the participant used dried-out electrode Headset pads, a known cause of skin burns. Treatment was resumed after a few days.

15. Device Specifications

PERFORMANCE CHARACTERISTICS	
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

The Bluetooth® connection uses a non-secure mode where a device will not initiate security procedures and authentication and encryption are bypassed.

16. Markings

ICON	DEFINITION
	Consult the Instructions for Use
	Consult accompanying documentation
	Keep away from children
	Separate collection for electrical and electronic equipment per EC Directive 2012/19/EU. Waste Electrical and Electronic Equipment (WEEE).
	Type BF applied part
	Date of manufacture
	Keep dry
	Manufactured by Flow Neuroscience AB Södra Tullgatan 3, 211 40 Malmö, Sweden, Web: flowneuroscience.com
IP22	Water ingress protection: 22
	Bluetooth® Low Energy The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc . and any use of such marks by Flow Neuroscience AB is under license
	Prescription use only
CE 2797	EU statutory mark

ICON	DEFINITION
UK CA 0086	UK (GB) statutory mark
	Consult the Instruction for Use before operation
	Keep out of direct sunlight
	Medical device
	Name of the device: FL-100
	Unique Device Identifier
	Expiry date (Headset Pads only)
	Lot or Batch Number
	Serial number (FL-100 Headset only)
	Single- use only (Headset Pads only)
	To be used with FL-100 Headset
	Only use if still moist
	Contains integrated lithium-ion battery

17. Product Disposal

- Headset Pads are cellulose sponges and can safely be disposed of as household waste.
- The FL-100 Headset and charger should be disposed of as electronic waste according to the local legislation.

18. Contact Us

For any questions or troubleshooting help, visit our support center at https://www.flowneuroscience.com/support/

NOTE: Any serious incident that has occurred in relation to the device should be reported to Flow Neuroscience and the FDA (see section 19).

19. Reporting Adverse Events

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your healthcare provider, or your healthcare provider may choose not to complete the form. Your health care provider is not required to report the information. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from the FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting Adverse Event Reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

- Report Online at http://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home
- Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn. The form is available at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=consumer.reporting1
- Call FDA at 1-800-FDA-1088 to report by telephone.
- Reporting Form FDA 3500 is commonly used by health professionals. The form is available at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=professional.reporting1

20. EMC - Test Results

The device does not emit any radiation intended for medical purposes, neither hazardous nor potentially hazardous radiation.

EMISSION LIMITS & MEASUREMENT				
PHENOMENON	STANDARD	TEST METHOD	TEST LEVELS	RESILT
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 LIMITS & MEASUREMENT				
PHENOMENON	STANDARD	TEST METHOD	TEST LEVELS	RESILT
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
ELECTRICAL 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: 150 kHz 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