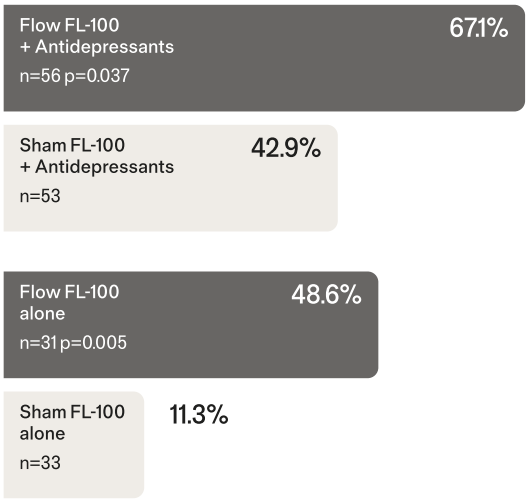
Clinician
Overview

Flow Neuroscience



Indication	The Flow Treatment is intended for the treatment of moderate to severe major depressive disorder either as monotherapy or as an adjunctive treatment, in patients 18 years and older who are not considered treatment refractory to medication.
Mechanism of action	The Flow Headset delivers a gentle 2mA electric current (transcranial Direct Current Stimulation, tDCS) to the left dorsolateral prefrontal cortex. This region is crucial for emotional regulation and is often hypoactive in individuals with depression. tDCS may enhance neuronal activity, counteracting hypoactivity, and reducing symptoms of depression.
Efficacy[1]	Results at 10 weeks from a multisite, double-blind, sham-controlled randomized superiority trial demonstrate that Flow FL-100 is effective*[1] when used both as a standalone treatment and as an adjunct to antidepressant therapy.†



* Remission is defined as a score of <10 on MADRS. MADRS remission rate was a secondary endpoint of the study. The primary endpoint of the study reviewed between-group mean difference in HDRS-17 scores and was −2.3 points in favour of the active group (p=0.012).

† Comparison of monotherapy and adjunctive use of Flow FL-100 was a sub-analysis evaluation included as table 10 and 11 in the EMPOWER Study.

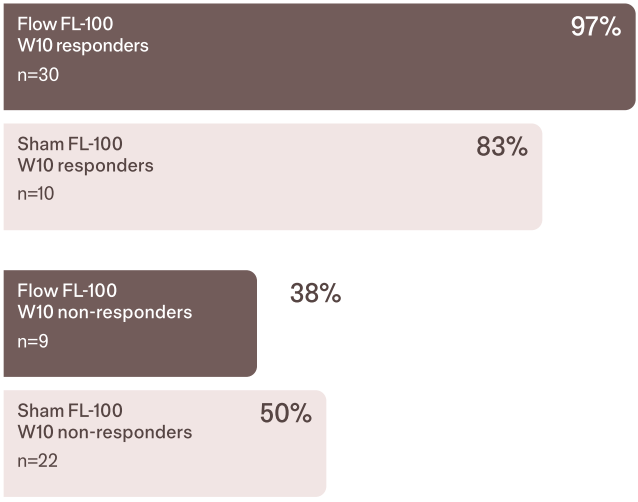


Response beyond 10 weeks[3]

Follow-up data indicates that many patients who responded early to Flow FL-100 maintained their clinical improvement at Week 20[3].

Importantly, a subset of patients who had not achieved response (depression score reduction of 50% or greater) by Week 10 experienced delayed improvements with continued treatment. These findings suggest that benefits may continue to emerge beyond the initial treatment period, highlighting the value of ongoing monitoring and structured treatment.

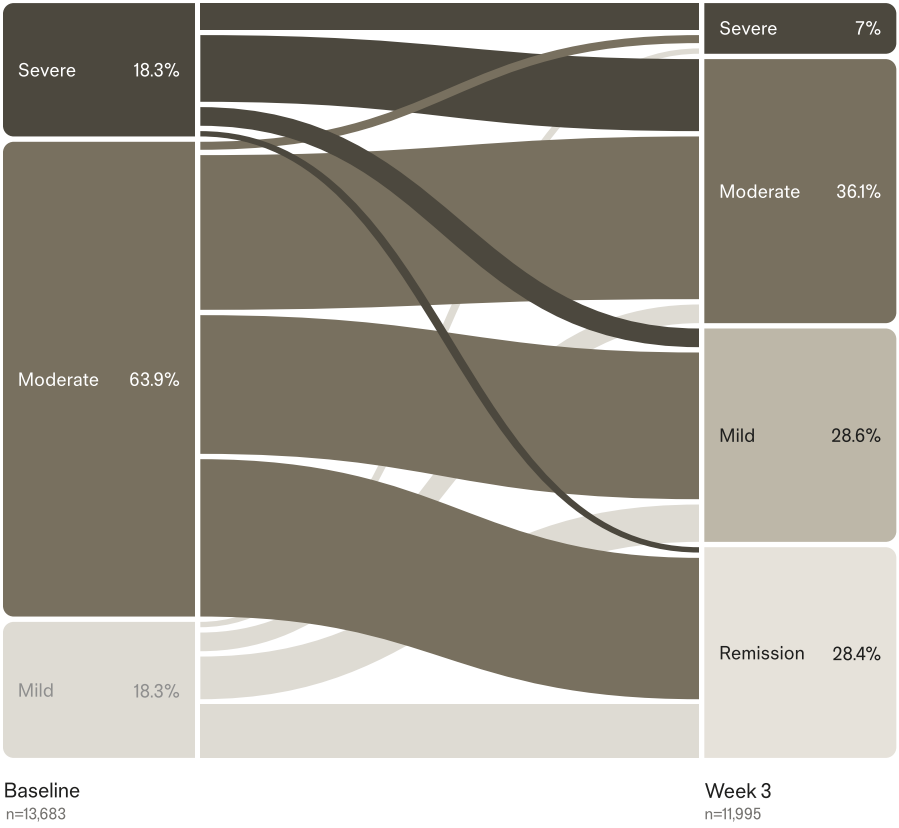
Week 20 open-label phase response rate[3]



Rapid response with sustained clinical outcomes[4]

Retrospective data from 13,683 non-US real-world users[4] indicates that adherent individuals achieved early clinical improvement, with a positive shift in severity levels observed by Week 3 across all baseline cohorts*. The durability of treatment effect was evidenced by high rates of sustained remission across multiple follow-ups and at one-year.

Depression severity changes of adherent users



* Following Week 3, the majority of users transitioned to a maintenance frequency of two sessions per week. While the recommended treatment duration is 10 weeks, clinical observation shows many users continue treatment beyond this window. This maintenance schedule represents a modification of the FDA-approved protocol (3 sessions/week) consistent with previous ex-US tDCS standards.

Treatment schedule

The standard Flow Treatment is split into 2 phases. Each session (termed stimulation) is 30 minutes long. Patients complete a PHQ-9 survey every 2 weeks to monitor progress.
These scores are synced to the clinician view enabling remote oversight and monitoring.



Activation Phase

Weeks 1-3

Includes 5 stimulations a week



Strengthening Phase

Week 4 onwards

Includes 1-3 stimulations a week

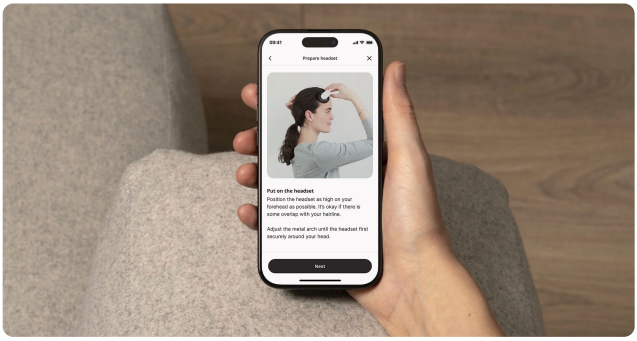
Personalized treatment schedules may be prescribed based on clinical need. More training on how and when this may be required can be supplied by the Flow Medical Education team.

The device and app

The Flow Treatment is a prescription only medical-device designed for at-home patient use to treat moderate to severe depression with clinician oversight.



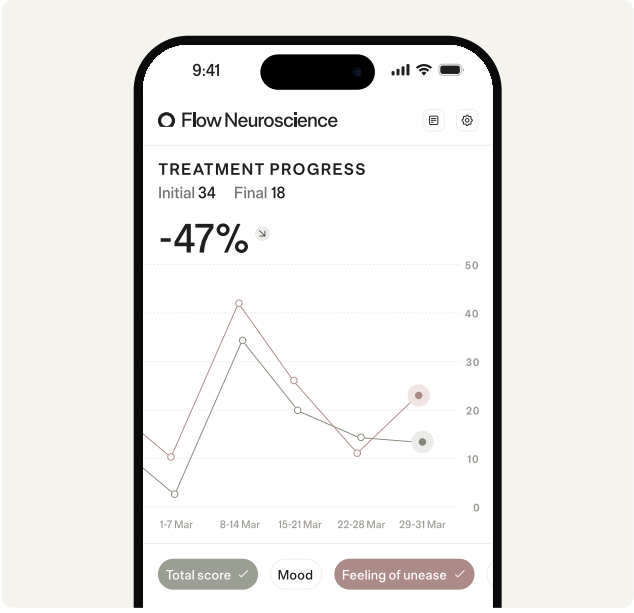
The Flow Headset is rechargeable via a charging port located at on the inner-side of the front band. It is recommended to charge the Headset for 1 hour every week. A popup will appear in the Flow Patient App if the battery is low and will prevent a stimulation until charged.



The Flow Patient App is required and connects to the headset via Bluetooth™ connection of a smartphone or tablet.
The app guides patients through proper use and helps ensure safety. An app account requires a patient email address and includes daily adherence reminders to support consistent use.

The weekly PHQ-9

Before a patient's first stimulation session, and once every 2 weeks following, they will be required to complete a PHQ-9 questionnaire. Completion of the baseline assessment is mandatory to unlock the first session and results of the PHQ-9 scores completed every 2 weeks must be completed to unlock the sessions for the following weeks.



Results of their PHQ-9 scores can be easily found in the Progress tab in the app. It is not intended as a diagnostic tool but to help track patient outcome snapshots and encourage continued use.

The setup

Once the baseline PHQ-9 assessment is completed, a session can begin. Each session requires pre-soaked Headset Pads to support conduction. There are three key steps for any session:

1. Turn on the headset
2. Apply the pads
3. Place headset on forehead

All steps are explained via the app in both text and video descriptions.

Contraindications	• Open wounds, broken skin, or damaged skin at the electrode site. • Metallic skull reconstruction at the electrode site
Warnings and Precautions	The Flow Headset should only be used by people at least 18 years old who are diagnosed with depression (Major Depressive Disorder or MDD) for which they are receiving treatment by a medical provider. *For reference, below is the label information patients receive:* 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 Headset should only be used by patients whose clinical course is supervised by a medical provider.

Special populations

Other chronic conditions:
Used by individuals with diabetes, heart disease, hypertension, asthma, co-occurring mental health conditions, neurodivergence, and brain injuries/disorders

Pregnancy:
Not licensed for use.

Breastfeeding:
No effect on breast milk production observed in existing studies.

Postpartum:
Successfully used in perinatal mental health services.

Children and Adolescents:
Not licensed for use; studies ongoing for ages 14+.

Side effects

The Flow Treatment has shown a favorable safety profile to date, with both clinical trial[1] and real-world user data[2] suggesting a low incidence of side effects. Based on real world evidence from >40,000 users, the self-reported incidence rate of side effects is 4.5%[2].

The side effects of the Flow Treatment reported in clinical studies were generally mild and transient. The main risks of the device are:

- Skin dryness.
- Skin irritation or redness after prolonged use.
- Transient headache.
- Stinging, burning, or itching sensations at the stimulation site.
- Skin burns (typically in cases of electrode pad reuse or use of dried-out electrode pads which is not recommended).

Side effects should be reported to the FDA MedWatch program. Reports can be submitted online at **www.fda.gov/medwatch**, by calling **1-800-FDA-1088**, or by submitting Form FDA 3500. Side effects should also be reported to Flow Neuroscience at **us-support@flowneuroscience.com**



Support and contact Information

For technical support and assistance, patients can contact us-support@flowneuroscience.com

Clinicians can enquire about setup, pricing, and training support by contacting us-clinical@flowneuroscience.com.

www.flowneuroscience.com

References:

1. Woodham, R.D., Selvaraj, S., Lajmi, N. et al. *Nat Med.* (2024).
2. Data on file. Flow Neuroscience. Real-world reports (2025).
3. Woodham RD, Selvaraj S, Lajmi N, et al. *J Psychiatr Res.* (2025);186:23-32.
4. Mu M., et al. *J Affect Disord Reports.* (2026);24:101044.

Flow Neuroscience

Flow Neuroscience Inc.
470 Ramona Street
Palo Alto, CA 94301
United States



Flow Neuroscience

www.flowneuroscience.com