Issued by (Name/Signature)
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01A	First issue for US market	Erik Rehn	2025-10-02

START OF THE CORE TEXT

USER MANUAL

Flow Clinic Patient Platform

Page: 03 English

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Instructions for Use – Clinic Patient platform

- Instructions on how to use the Flow Clinic Patient Platform.
- IFU Version and Issuing date: Ver 01 - yyyy-mm-dd
- Product model: Flow Clinic Patient Platform (FL-CPP).
- The latest version of this manual is available to download from the “About” page on the clinic patient platform.

1. Manufacturer

Flow Neuroscience AB
Södra Tullgatan 3, 211 40 Malmö, Sweden

2. Intended Use

- FL-100 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 adult patients (18 and older) who are not considered treatment refractory to medication.

- For prescription use only (Rx only).
- The clinic patient platform is a software accessory to the Flow FL-100 used by clinicians to monitor their patients device usage and set the administered stimulation protocol.
- The clinic patient platform does not require any special training before use.

3. Warnings

- Never rely on the information presented in the clinic patient platform for diagnostic or therapeutic decisions.
- Do not use the clinic patient platform as your main source of information about the patient's treatment progress.
- There is a risk that the device is ineffective for the individual patient. Maintain contact with the patient during the course of the treatment.
- Patient data is blinded by default. Only unblind these data in environments where you can maintain patient confidentiality.
- Never let a patient stimulate more than 30 minutes per day.
- Discuss changes to the stimulation schedule upfront with your patient.
- Ensure your password is not shared with anyone.
- Ensure that your password is different to the ones used for other services.
- Do not leave the patient platform logged in and unattended. The platform should not be used by unauthorized or unregistered users.
- Only connect via a trusted device authorised by your organisation.
- Only connect via a known and trusted network that is authorised by your organisation.
- It is strongly recommended that you enable 2-Factor-Authentication for your account (you can do so in the settings).
- In the event your clinician account is no longer needed, reach out to your patient platform admin to delete your account.
- In the event your clinic account is no longer needed, reach out to support@flowneuroscience.com so your clinic account can be deleted.
- If you suspect your account has been used by someone else, report this to support@flowneuroscience.com.

4. Prerequisites

- An internet connected computer, tablet, or smartphone with a web browser not older than three years.

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. First-Time Use: Clinician patient platform

- New clinics are created by the Flow Neuroscience staff. Clinicians with admin status can add their colleagues to their clinic.

- If you have been invited by Flow staff or colleagues, you will receive an email with a signup link to activate your account.
- You will be asked to confirm your details and set a password.
    - Your password must contain at least 8 characters.
    - Ensure that your password is not shared with anyone.

  - Ensure that your password is different to the ones used for other services.
  - For security reasons, commonly used passwords will not be permitted.
- Be aware that your name will be shown to patients when you add them to your clinic.
- After signup, you are asked to login with your details.
- If you are part of multiple clinics, you can switch clinics in the side panel after login.

- It is recommended that you activate Two-Factor-Authentication in the “Settings” area of the patient platform to ensure extra security. You will need an authenticator app that supports Two-factor authentication with QR code setup to your smartphone. We recommend Google Authenticator.
- Only connect via a trusted device authorised by your organisation.
- Always ensure that you connect via a known and trusted network that is authorised by your organisation.

7. Flow app: Demonstrating stimulations

- If you have a patient platform account, you can log into the Flow app with the same account. This will allow you to use clinician-specific features including the demo feature. If you use a different account for your app than the patient platform you will not have access to the clinic-specific features.
- In the menu of the app you have access to a section called “Your clinic”. This section contains a demo stimulation card, which allows you to give a demo stimulation to your patient.
- The demo stimulations are not connected to the stimulation schedule, meaning they are neither counted in the stimulation schedule nor are they restricted to one stimulation per day. This enables you to demo Flow with as many patients per day as you like.
- Stimulations started from other sections than the demo stimulation card are counted in the stimulation schedule and will be restricted according to the stimulation schedule.

Note: Never let a patient stimulate more than 30 minutes per day.

8. The patient overview

- In the patient platform, the patient overview shows all patients connected to your clinic. You can review your patient's activity and usage of Flow. Per default, all patient names are blinded. You can unblind them all in the header of the patients table, or individually on their specific profiles.
- If you search for a patient by their name, they will be part of your search results even if blinded.
- “Missed stimulations” shows you the number of stimulations missed since the last completed stimulation. Two or more stimulations missed are considered

non-adhering. If the patient stimulates once the count is set back to zero, even if the patient is missing multiple sessions according to the stimulation schedule.
- MADRS-s is a validated self-reported depression questionnaire. The first score is the score recorded by Flow when the user fills out the questionnaire for the first time. See below for more information about MADRS-s.
- Patient data can be exported blinded as a CSV.

9. Adding a patient

- If the patient already has a Flow app account, make sure to use the same email address that they used for their app account. Existing users will receive an email and a notification inviting them to connect to the clinic.
- New patients will receive an invitation email with instructions on how to get started with Flow.
- Both existing and new users need to accept the clinic invitation via the app before any data is shared to the patient platform.

10. The patient profile

- You can unblind a patient by clicking on the eye icon. Only then you can edit their contact information. Please note that you can adapt the patient's details with the exception of the email address. If the patient needs to change their email address, add them as a new patient via the "Add new patient" section in the navigation bar to the left. Be aware that this will create a new patient profile.
- The stimulation schedule shows whether the patient is adhering to the program. A standard schedule is 5 sessions for 3 weeks, followed by 3 sessions per week. Missed stimulations are added to future weeks. You can also view the stimulation schedule as a list view in order to see completed stimulation sessions.
- The MADRS-s section shows the patient's treatment progress over time. The start score is the first score recorded in the app. The dotted line marks 13 points. A score below 13 suggests that the patient has symptoms below the threshold of clinical depression.
  You can also switch to a listview in order to see the different results and the individual scoring for the nine answers.
- In the section "Currently in treatment" you can adjust whether you are actively treating the patient. If you want to pause the treatment but not remove the patient from the clinic, you can set the patient to inactive.
- If you remove the patient from your clinic, you will no longer have access to their treatment information.

11. The Stimulation Program

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

- The standard Flow stimulation program consists of 15 sessions during the first 3 weeks, as shown in the table below.
- After this first treatment period, up to 3 sessions per week are recommended.
- The number of sessions a patient can complete is restricted to 1 per day.
- Each session lasts 30 minutes, plus a few minutes of preparation time.
- In the patient profile, you can set a customized stimulation program with a maximum of 1 session per day or restart the program.

12. Resets and custom schedules

- You can reset or customize a patient's stimulation schedule from the patient profile page in the section "Treatment status" - "Stimulation schedule".
- You can reset the patient's stimulation schedule. If you reset the stimulation schedule, the patient will receive the initial stimulation schedule of 5 sessions for 3 weeks, followed by 2 sessions per week. You will still have access to all previously collected information about the patient's treatment.
- You can create a custom stimulation schedule for your patient. The stimulation schedule is divided into two phases: Activation and Strengthening.

  Note that if a patient stimulates less than the scheduled number of sessions during the first Activation phase, these sessions will be added to future weeks.

13. The MADRS-s Depression Score

- MADRS-s is a validated self-reported depression questionnaire with nine items covering: mood, feelings of unease, sleep, appetite, ability to concentrate, initiative, emotional involvement, pessimism, and zest for life.
- Flow users complete this questionnaire on a weekly basis. All changes are calculated based on the first MADRS-s questionnaire result. A negative change indicates an improvement in depression symptoms.
- MADRS-s scores can range from 0 to 54. A score below 13 suggests that the patient has symptoms below the threshold of clinical depression.
    - 0-12 – no / minimal symptoms
    - 13 to 19 – mild depression
    - 20 to 34 – moderate depression
    - >34 – severe depression

Note: Never rely on the information presented in the clinic patient platform for diagnostic or therapeutic decisions.

14. Settings

- You can change your contact details in the settings. If you need to change your email address, please contact support at https://flowneuroscience.com/support/
- If you have an admin account, you can add further clinicians to your clinic. They will receive an invitation to the specified email address. They can adjust their name or honorifics during signup.
- Clinicians with a member account cannot add or remove other clinicians.

15. Markings

MARKINGS	
ICON	**DEFINITION**
	Manufactured by Flow Neuroscience AB Södra Tullgatan 3, 211 40 Malmö, Sweden Web: flowneuroscience.com

16. Contact Us

If you have any questions regarding the Clinic Patient Platform or Flow, don’t hesitate to contact customer support at https://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 16.

17. 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 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 www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf
- 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 www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf

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