

starstim^{NE®}

Neuroelectrics User Manual
Home Study User Guide

CAUTION: INVESTIGATIONAL DEVICE
Limited by United States law to investigational use.



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Code: UM004A
Version: 2.4b



Model Name:
Starstim tCS Home

The manufacturer should be contacted:

- for assistance, if needed, in setting up, using or maintaining the Starstim 8 system;
- to report unexpected operation of events that result from the usage of the device.



Input: 5W, 4.8 - 5,5V

Change of Record

Issue	Date	Changes made
1.0	2082.12.28	First version

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I. Before You Start



Starstim tCS Home

I.1

What do I need to conduct a tCS Home Study

To conduct a tCS Home Study you will need:

- At least one Starstim tCS Home device, which you will provide to your subjects.
- NIC2.0.10 (software) or later which you will use in the lab to create 8-channel Starstim protocols.
- Tools to prepare customized subject headcaps.

All these needed components are included in the first Starstim tCS Home order.

For study management, you will be using Home Study Manager available from the Neuroelectrics portal (<https://portal.neuroelectrics.com/>). You will be provided access to the Neuroelectrics portal with your first order of Starstim tCS Home.

I.2

What is Starstim tCS Home

Starstim tCS Home is a wireless 8-channel transcranial current stimulator device with safety and usability aspects optimized for remote use from the patient's home. Read more about the device in the Starstim tCS Home Manual.

I.3

What is the Neuroelectrics portal

The Neuroelectrics portal is the secure entry point to cloud services offered to be used in conjunction your devices.

I.4

How do I access the Neuroelectrics portal

The Neuroelectrics portal is maintained for all modern desktop web browsers. It is validated to work with Apple Safari, Google Chrome, Microsoft Edge, and Mozilla Firefox.

To access Neuroelectrics portal, open one of these browsers and enter <https://portal.neuroelectrics.com/>

Make sure your institution already has access to the portal. The account is automatically created and shared with your institution's representative with the institution's first order of the Starstim tCS Home.

At any time, additional account logins for your institutions' employees can be requested by sending over a list of institutional emails to support@neuroelectrics.com. Once created, a welcome email containing credentials will be sent over shortly.

I.5

What is Home Study Manager

Home Study Manager is a service available from the Neuroelectrics portal. It provides your team with an interface to manage and monitor everything study-related from one place.

I.5

What is NIC 2

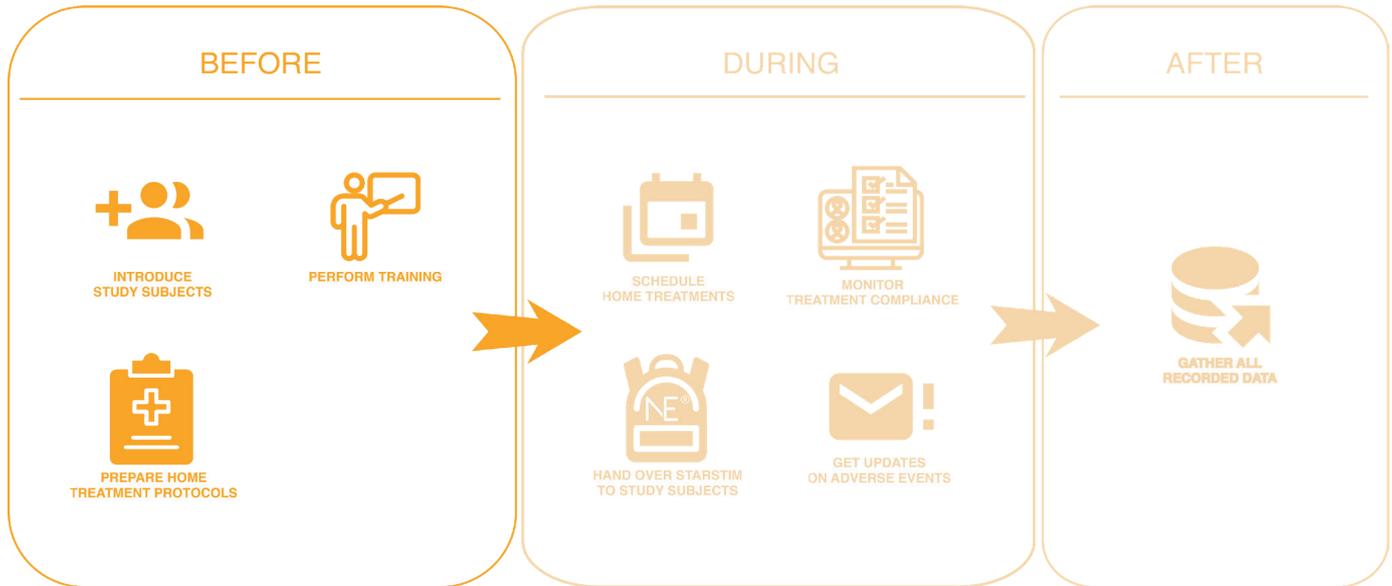
NIC (Neuroelectrics Instruments Controller) 2 is software which allows you to create 8-channel tCS protocols needed for the Home Study, from the lab PC or Mac. If you have a Starstim tCS or 8, it will allow you to run the protocols in the lab.

I.6

How do I receive support

In case of technical questions or issues other than explicitly mentioned in this User Guide, go to <https://www.neuroelectrics.com/support/> and fill out the support query form.

II. Prepare for the Study



II.1

Introduce Study Subjects

You can add study subjects one-by-one at any point in time before or during the study. The Neuroelectrics portal allows for the definition of the anonymous subject identifiers only, so make sure you have the study subject references stored elsewhere.

To prepare

- List of anonymous identifiers of study subjects.
- Preferred language for each subject (English / German / French).

Steps

1. Using a web browser on your computer, open the Neuroelectrics portal.
2. Use your institutional credentials to sign in.
3. In the left menu, click Home Study Manager.
4. In the top right of the Home Study screen, click New Subject. The New Subject modal window will appear.
5. Specify Subject code. Be cautious, as you will not be able to change it later.
6. Choose language from a drop-down list. This setting will later personalize Starstim tCS Home interface. You can update this setting later.
7. Click SAVE.

II.2

Prepare Home Treatment Protocols

For the Home Study, you can choose from the whole spectrum of 8-channel Starstim tCS protocols which NIC2 allows you to define. It may be tDCS, tACS, or tRNS with flexibility of ramp settings, and sham settings. Follow NIC2 User Manual Section III to learn more on how to design 8-channel Starstim tCS protocols and export them to file.

Note: You can choose to use optimized tCS montages during your study, which Neuroelectronics can provide you following your target specification and additionally MRI recordings. You can read more about the optimization services Stimweaver and Stimweaver-P on the Neuroelectronics website. Contact your sales representative for more information.

To prepare

- 8-channel Starstim tCS protocol files exported from NIC2.
- Electrode model – either NG Pistim or Sponstim. Read more about their characteristics in Electrodes User Manual .
- Procedure including number of treatment sessions and allowed period of the day during which study subjects will be able to execute the sessions.

Steps

You will use the prepared resources in procedures explained in Section II.4 and Section III.1.

II.3

Customize Headcaps accordingly with Treatment Montages

As a part of your Home Study License, you will receive the tools to customize the headcaps, so they can be used with ease at the study subject's homes. This section outlines how to proceed.

To prepare

- Headcaps you want to customize.
- Punch tool.
- Snap buttons and crimping tool.
- Color-coded electrode cable from one of the Starstim tCS Home kits.

Steps

1. In NIC2, open the Stimulation Design view of the protocol you want to customize the headcap for (follow NIC2 User Manual Section VI.1 for further details on how to access the view).
2. For each position included in the protocol:
 - a. Find position's signature on the headcap.

Note: Standard Neoprene Headcap does not have signatures for all positions available in NIC2.

- b. Make a hole for that position by pressing and rotating the Punch tool in a circle by the position's signature.



Step 2b

II.3

Customize Headcaps accordingly with Treatment Montages continued

Steps continued:

c. Pick a snap button of a color which corresponds to the channel's number.

Note: For colors mapping refer to color-coded electrode cables you have or the graphics on the next page.

d. Just by the position's signature, stick the snap button tip through the material of the headcap.

e. Pick a crimp tool and the snap button bottom part. On the interior side of the headcap, pair snap button bottom part with its tip. Then, press the snap button with the crimping tool.



Step 2c



Step 2d



Step 2e

II.3

Customize Headcaps Channel Numbers and Colors



II.4

Perform Training and In-lab Phase of the Study

Whether you want to train your staff, train your patients and their spouses/caregivers, or run first phase of your tCS home study in the lab, you can make use of your Starstim tCS Home devices right away.

Staff Training

For staff training, follow the steps described in Section II.1 to create a new “training subject”. Then, follow the steps in subsections of the Section III.

In-Lab Phase of the Home Study

If you want the entire information about your study subject’s treatment to be automatically recorded in one place, follow Section II.1 to introduce the subject already before the in-lab phase. Then follow Section III to conduct the study phase with Starstim tCS Home.

II.5

Define Rules for Automatic Email Updates

Any institutional email registered to access the Neuroelectrics portal can receive email updates on specific treatment events. The table below presents the available notification profiles.

Event	“Warning”	“Information”	“Detail”
Detailed Course of Session	No	No	Yes
Successfully Finished Session	No	Yes	Yes
Session Aborted by Patient	Yes	Yes	Yes
Session Auto-aborted by Starstim	Yes	Yes	Yes
Acute Event Reported	Yes	Yes	Yes

To prepare

- List of institutional emails registered for the Neuroelectrics portal use.
- Preferred notification profile for each of the emails.

Steps

1. Send an email to support@neuroelectrics.com including the prepared information on preferred settings.

II.6

Ensure that Home Interface is up-to-date

Neuroelectrics regularly releases software updates based on customers feedback to increase the flexibility of treatment design and improve accessibility as well as general patient experience. Check the website to learn about updates to the recent version of the home interface software before you begin a study.

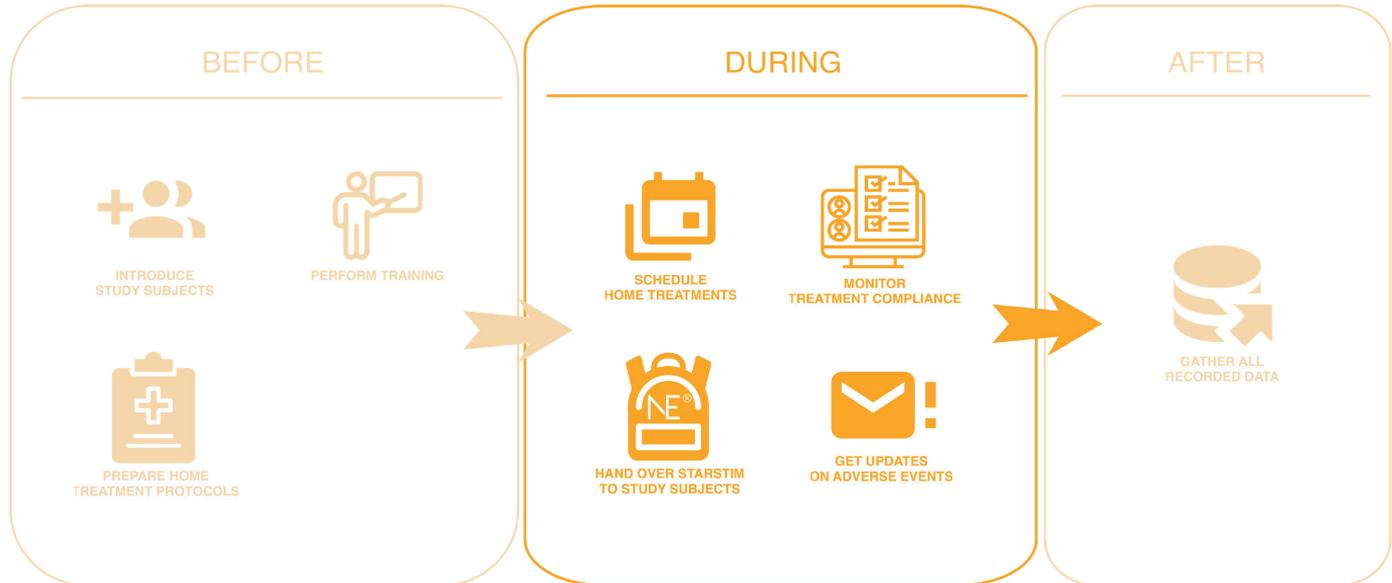
To prepare

- Prepare your home interface

Steps

1. Switch on home interface, the welcome screen will appear.
2. Swipe from the right edge of the screen, the Admin panel will appear.
3. Type and confirm a home interface admin password you have been provided in the welcome email. Protected admin options will appear.
4. In the available App Upgrades section, check if your application is up to date.
5. Click the RESTART & UPGRADE button and follow the instructions of the software update process. The software will be updated to the latest version.

III. During the Study



III.1

Schedule Home Study

You can schedule treatment sessions for each of your subjects, choosing a period of the day with precision down to one hour.

To prepare

- Dates and periods of the day when a subject is supposed to perform the sessions.
- Protocols for treatment sessions used for this study.

Steps

1. Using a web browser on your computer, open the Neuroelectrics portal .
2. Use your institutional credentials to sign in.
3. On the left menu, click Home Study Manager.
4. In the Study Summary table, click on the code of the subject who you want to schedule home treatment for. The subject profile will appear.
5. In the Treatment Schedule calendar, click on the day you want the subject to perform the session. Treatment Scheduler modal will appear.
6. In the Schedule card of the modal, choose the daytime period. Click NEXT. Protocol card will appear.
7. On the top left of the modal, choose the protocol you want the subject to apply. In the case it is missing on the list:
 - a. Open a folder on your drive where you have the exported NIC2 protocols stored (see: Section 2.2).
 - b. Drag-and-drop the required protocol on Upload area in the bottom left of Protocol card.
8. In the right column, verify that all the details of the protocol are as expected.
9. In the bottom of the right column, make sure the protocol's electrode is specified. In case it is not, choose the one you want to be used with the protocol.
10. Click SCHEDULE. If the information you provided is correct, the modal will close, and the session will automatically appear in the calendar.

III.2

Handover Starstim tCS Home Device to Subject

Right before or during your meeting with a subject, in the portal, you must mark the device as assigned to that subject. You can take a few additional steps to improve the experience of the study subject.

To prepare

- An available Starstim tCS Home backpack:
 - Make sure all the components (box, necbox, and home interface) have the same information on their labels.
 - Make sure all the components (necbox, and home interface) are fully charged. Connect the necbox to charge and wait for the light to turn green. You can ensure it for the home interface by switching it on and checking the battery status in the right corner of Windows task bar.

Steps

1. Using a web browser on your computer, open the Neuroelectrics portal.
2. Use your institutional credentials to sign-in.
3. In the left menu, click Home Study Manager.
4. In Study Summary table, click on the code of the subject who you want to hand over the device to.
5. In the top right of the Home Study screen, click Assign Device. The drop-down list will appear.
6. Click on the device of your choice on the list and follow the instructions in order to assign it. The button will change to Device Assigned.
7. On the next switch on, home interface will automatically synchronize the assigned subject's treatment.

III.3

Optional Actions

Personalize the home interface

1. Switch on the home interface, the welcome screen to appear.
2. Swipe from the right edge of the screen, the admin panel will appear.
3. Type and confirm the home interface admin password you have been provided in the welcome email. The protected admin options will appear.
4. In the Patient field, type and confirm a name of the study subject. On each start, home interface will welcome the study subject with their name.

Synchronize treatment information before the hand over

1. Switch on the home interface.
2. Connect to the wireless network through the Windows task bar.
3. Run the home app again. Click the Continue button.
4. Allow the application to synchronize. If you see the Upcoming Sessions screen right away, it means your scheduled treatment has already been synchronized.

III.4

Get Updates on Adverse Events and Progress

While your study subjects execute the treatment sessions at home, you will be receiving email updates accordingly with the rules explained in Section II.5.

In case you want to receive additional alerts, consult your email software documentation on how to specify rules for emails sent by dont-reply@neuroelectrics.com.

III.5

Monitor Compliance of Treatments

	Home interface internet connection continuously present	Home interface internet connection lost during the session
Session successfully finished	With maximum of a few seconds of delay	Whenever home interface is connected to the internet again (subject is unable to run the next treatment session unless reconnected)
Session aborted by subject		
Session auto-aborted on high impedances		
Session auto-aborted because of technical problems		
Session missed	The next day, starting at midnight. Note: This will be the case even if the session was scheduled for a limited daytime period.	

Steps

1. Using a web browser on your computer, open the Neuroelectrics portal.
2. Use your institutional credentials to sign-in.
3. In the left menu, click Home Study Manager.
4. In Study Summary table, take a look at the Treatment Compliance bar.



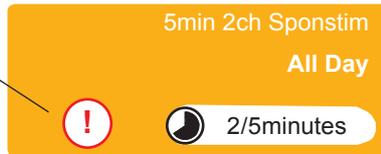
5. To see timing details of the compliance of a subject, hover the mouse over the Treatment Compliance bar of a that subject.

III.6

Analyze the course of subject's treatment sessions

1. In Study Summary table, click on the code of the chosen subject. The subject profile will appear.
2. In Treatment Schedule calendar, follow the key below the analyze the course of the subject's past sessions.

Incident requiring attention occurred

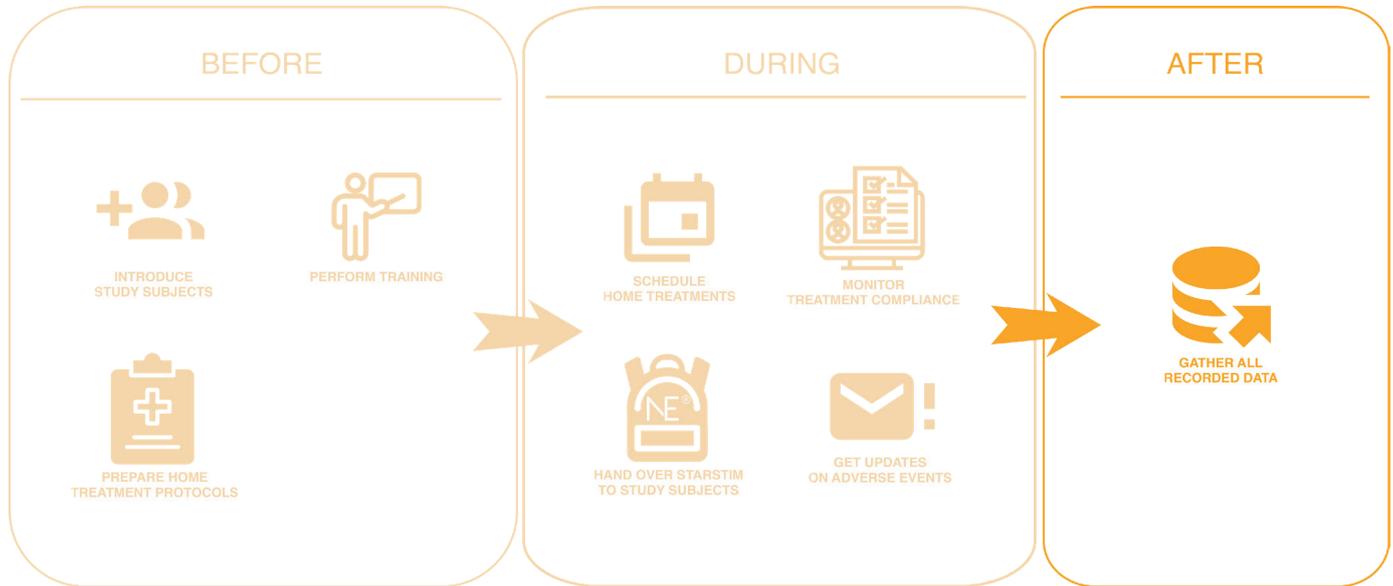


Color:

-  Fully executed or no more than 1 minute missed
-  Partially executed
-  Missed or less than 1 minute executed

3. To see more details about a chosen past session, click on it. The modal will appear.

IV. After the Study



IV.1

Gather all Recorded Data

We offer a report with all the recorded data during the home study in CSV format. The information includes the list of time-stamped events during each session, and recording of impedance values from the impedance check as well as from 20 second intervals during the session execution.

To prepare

- List of subjects or sessions which you would like to be included in the report.

Steps

1. Send an email to support@neuroelectronics.com requesting the recorded data report and attaching the prepared list.

