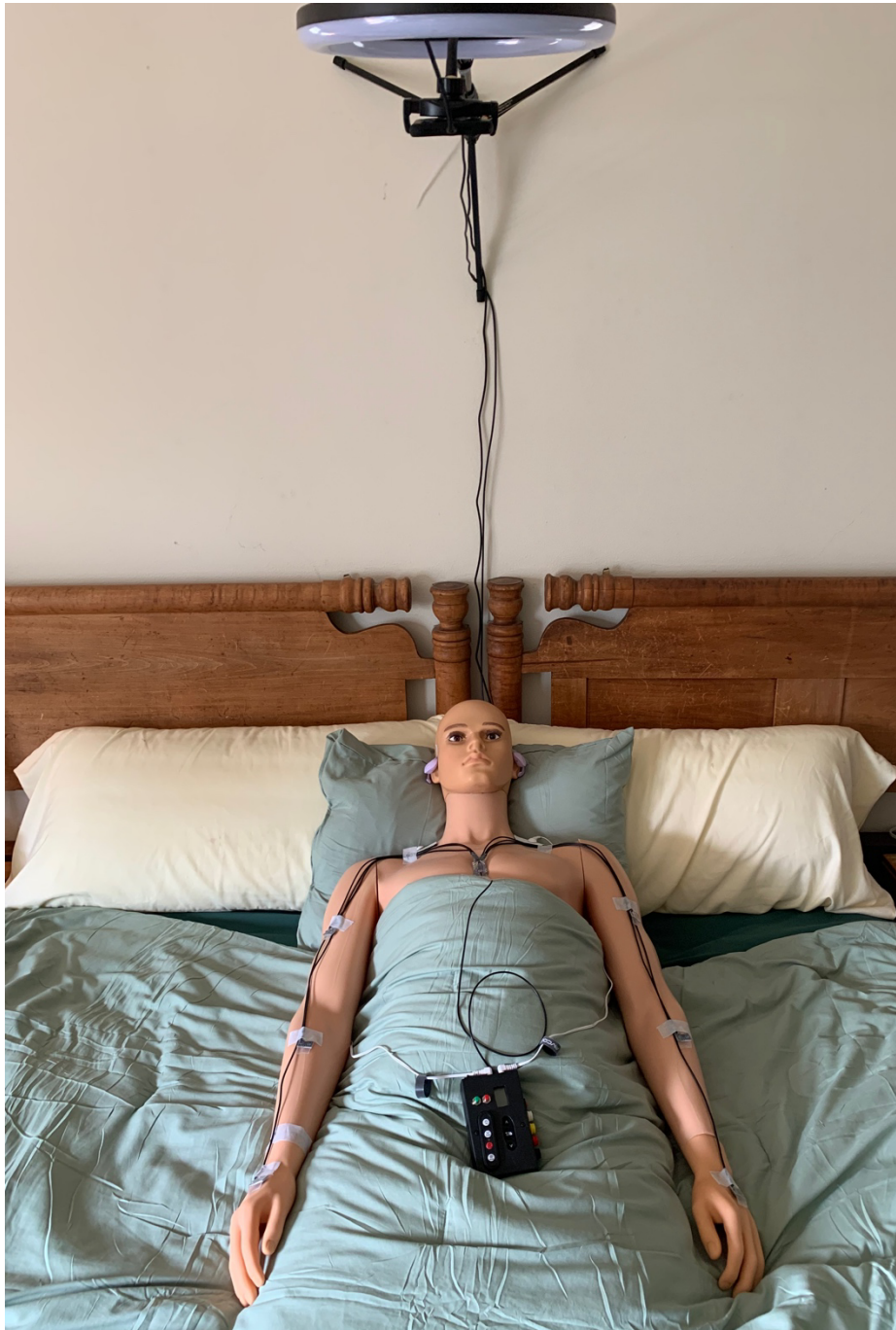


Automatic Glasgow Coma Score (AGCS) Quick Guide

AGCS system components

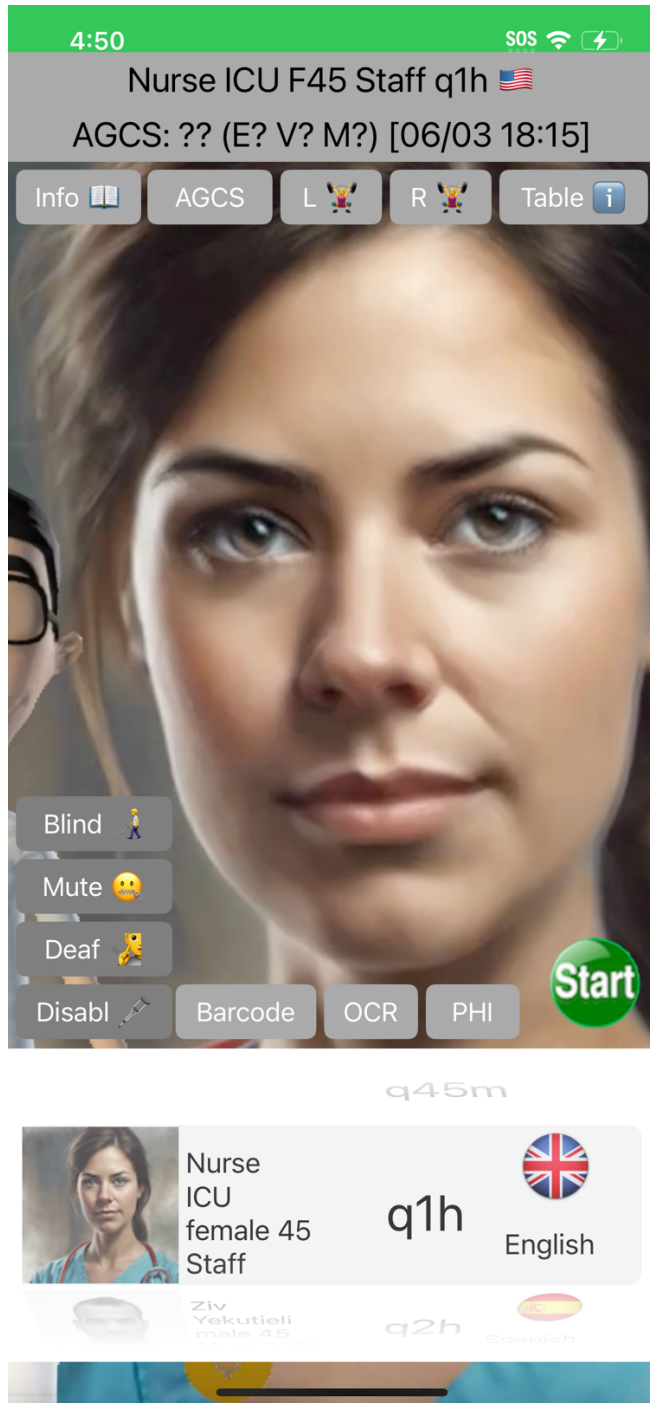


The AGCS system consists of:

1. AGCS hardware - a black plastic box with buttons, outlets, and a screen – the BOX. The box contains a TENS unit, an ESP32 microcontroller and interfacing components. In addition to the box there is an iPhone Xs Max which runs the NeurAsses (AGCS) app. A 12" LED ring with an iPhone mount is used to illuminate the patient when the AGCS test are performed at night.



2. AGCS software - the NeurAssess app, which runs on the iPhone XS Max. The app features a talking avatar who guides the patient through the test with verbal instructions in a language that the patient can understand. Supported languages currently include English and Spanish. The app controls the hardware including the TENS stimulator and the night LED light. It collects the patient responses in the form of iPhone screen capture video and audio as well as motion sensors data. The patient responses may include eye opening, verbal responses and motor responses (voluntary or reflexive posturing) in response to the noxious stimulation provided by the TENS unit.



AGCS system setup

The first step is installing the LED ring on a poll by the bed side. The ring has a built-in iPhone mount positioned over the patient's bed. For the proper operation of the system, it is imperative that the iPhone is mounted high enough over the bed so that the front iPhone camera can see the patient's head, arms and torso. This can be done and confirmed by a nurse, physician, or technician. For that purpose, they can use the app. A step stool or ladder might be necessary to reach and properly position the iPhone.

The second step is preparing the patient for continuous AGCS testing. This step can be done by a trained nurse or physician. It includes the following:

1. Attaching of the 6 motion sensors to the patient's arms as shown on the pictures. The sensors are connected to a multiplexed which must be connected to the color-matched outlet on the top of the black box.
2. Attaching of the 2 pairs of TENS stimulation electrodes to the left and right trapezius muscles of the patient - one in front and the other on the back of each trapezius. The locations of the electrodes should be the same as the locations where the nurse pinches the patient's trapezius during a standard routine GCS test.
3. Pairing of the Bluetooth ear buds with the iPhone (this is done automatically when the ear buds are removed from their charging case) and secure placement on the patient's ears. For this purpose, we recommend the use of medical tape to ensure that the ear buds do not fall off.

AGCS system calibration

The AGCS system calibration includes:





1. Motion sensors calibration. This is done automatically when the power switch on top of the black box is turned on. The calibration takes a few seconds during which a red LED on top of the black box is turned on. After the calibration is done the red LED turns off and a blue LED is turned on for the duration of the testing until the black box power switch is turned off. It indicates that the ESP32 microcontroller in the black box is paired and communicating with the NeurAssess app via Bluetooth and bi-directional flow of data and commands between the app and the microcontroller is established.
2. The AGCS system provides an option for assigning of the motor scores (M2-M5) to patient postures. This is done by an experienced GCS person. The four (white, yellow, red and blue) side buttons plus a 4-way black switch with red cap are used for this purpose. The calibration process is simple. The calibrator is asked to press one of the 4 buttons when the patient strikes one of the 4 poses (M2-M5). The app automatically records that and uses this in future assessments of the patient's posturing. The 4-way switch is used for calibrating the left and right side of the responses to left and right-side noxious stimulation. The app guides the calibrator with verbal indications.



LEFT trapezius TENS stimulation

Noxious stimulus intensity

0.60

M5 Localize	M4 Withdraw	M3 Decorticate	M2 Decerebrate
 9.03	 36.70	 17.22	 10.94

M5
 M4
 M3
 M2

When the patient strikes one of these 4 poses click the corresponding button on the black box.

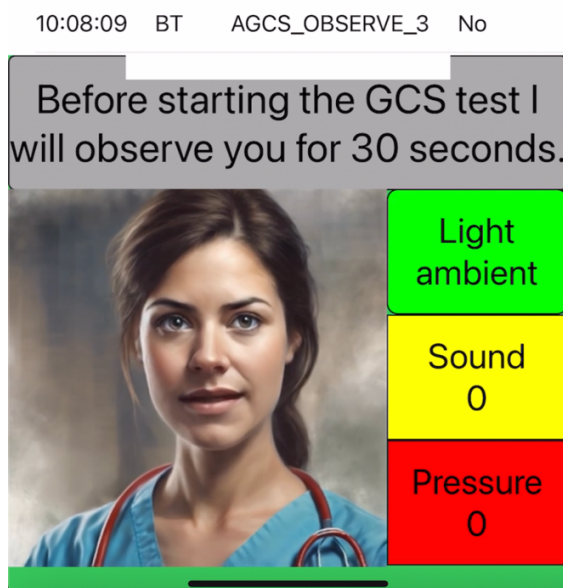
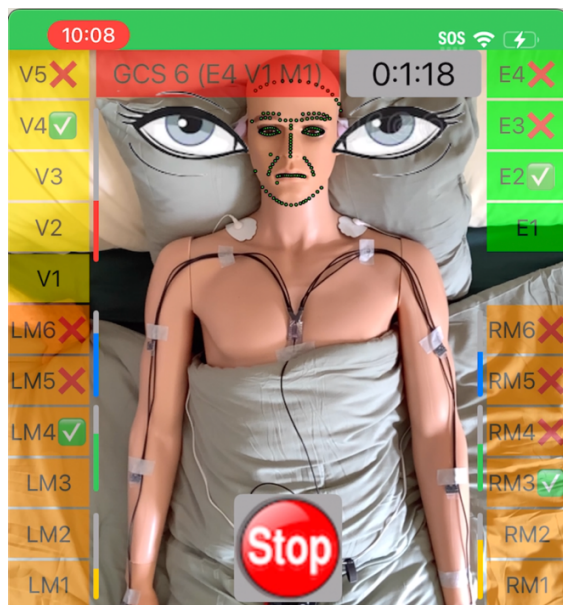
AGCS test performance

The AGCS test can be run automatically at preset times (e.g., q1h). It can also be run manually. To start the test, click the green button on the box. You can stop the test at any time by pressing the red button on the front of the black box.

Before running the first test for a new patient his/her information needs to be entered in the app. If the patient has been already entered in the app the examiner needs to select it and choose the frequency at which the AGCS test will be performed and the patient's preferred communication language. In addition, if the patient has any known conditions the corresponding buttons on the app

need to be tapped. These include: 1) Patient has his eyes covered due to head trauma or other reason. In this case tap the [BLIND] button. 2) The patient is intubated and/or ventilated and as a result cannot speak. In this case tap the [MUTE] button. 3) The patient is hearing impaired and as a result cannot hear and understand verbal commands. If this is the case tap the [DEAF] button. 4) If the patient is sedated or has some disabilities such as one or two arms in a cast – tap the [DISABL] button. Correct setting of these conditions when the patient is initially set up and prompt changes if the conditions change during the time when the patient is hooked to the AGCS system is imperative. These settings directly affect the functioning of the system and the automatically generated Glasgow Coma scores.

If the patient info has not been entered in the app the examiner has to enter it using one of three available options; 1) Manually by tapping the [PHI] button and completing the basic demographics form; 2) Scanning the barcode on the patient's wrist - tap the [BARCODE] button, or 3) Scanning the text info of the patient's hospital wristband - tap the [OCR] button.



AGCS data management

During each AGCS test the following data sets are collected:

1. Video and audio - by iPhone screen capture
2. Patient responses in a time-stamped table
3. Raw motion sensors data as time-series array in CSV format
4. AGCS test results in a color-coded spreadsheet

The collected data will be off-loaded from the iPhone by the study investigator upon completion of the tests and patient discharge from the AGCS system.

AGCS system maintenance

The system maintenance includes:

1. Batteries charging. The hardware components of the AGCS system have separate power supplies. This is by design with the purpose to isolate them electrically. The iPhone should be plugged and charged continuously since it is running the NeurAssess app continuously while the patient is hooked to the system. A charging cable is included in the package and is treaded along with the LED ring cable. The LED ring should be also plugged to a color-coded USB-C charger on the bottom of the black box. The power supply of the TENS unit is a USB-C connector which is also located on the bottom of the black box – on the TENS unit itself. The TENS unit has a built-in LiPo battery and has a very limited duty cycle. It is used for up to 20 seconds every hour on average. So, it does not require frequent charging. In fact, it should NOT be charged during the AGCS testing since by design the TENS unit won't work during charging. The ESP32 microcontroller has a 1100mAh LiPo battery built-in the black box. It does not need to be charged continuously but being plugged in the provided USB-mini charging cable gives the operator a piece of mind.
2. Replacement of dried or damaged TENS electrodes
3. Re-attachment of detached or displaced motion sensors.
4. Data off-loading from the iPhone