



# ETNA™-MS Instructions for Use (Clinicians)

**ETNA™-MS App Version 1.0**  
**ETNA™-Cloud Version 1.8**



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# 1. Introduction

## 1.1. About this Document

This document is intended for clinicians who prescribe and may help administer an Eye-Tracking Neurological Assessment for Multiple Sclerosis using the **ETNA™-MS** software system. The document provides an overview of the principle of operation and validation of **ETNA™-MS** and contains directions for use of its two components: the **ETNA™-MS App**, the patient-facing software component of the test, and the **ETNA™-Cloud**, the offline analysis, data management, and reporting component. This document is intended to be used together with the instructions provided by the software itself.

Directions for use of the **ETNA™-MS App** are separately available for patients and caregivers in the document: *ETNA™-MS Instructions for Use (Patients)*.

## 1.2. Intended Use of the Device

The Eye-Tracking Neurological Assessment for Multiple Sclerosis (ETNA™-MS) is a software as a medical device (SaMD) intended to administer a non-invasive test and provide an Expanded Disability Status Scale (EDSS) score in the range between 1.0 and 4.5 for use in tracking the disease progression in MS patients.

**Note:** The intended patient population includes all individuals having already received a diagnosis of MS, irrespective of MS subtype (relapsing-remitting (RRMS), secondary-progressive (SPMS), primary-progressive (PPMS), and progressive-relapsing (PRMS)), and being able to walk without aid or rest for a distance of 300 meters (approximately the length of 3 football fields)\*.

\***ETNA™-MS** should not be used by individuals with non-MS related walking impairments (e.g., gait disorders, leg/foot injuries) as this will impact the time needed to complete the Timed 25-foot Walk (T25-FW) test. Given that the T25-FW value is an input for **ETNA™-MS** to estimate the EDSS score, the device may provide an erroneous estimate (score).

## 1.3. ETNA™-MS Device Overview

**ETNA™-MS** is a Software as a Medical Device (SaMD) comprising two components that operate as a software system in a client-server architecture:

- **ETNA™-MS App** is a visual stimulation, video recording and data collection App running on an off-the-shelf electronic tablet (iPad Pro). The App guides an MS patient to perform a test comprising distinct oculomotor (visual) tasks that require the patient to either follow, track, or respond to visual targets on the screen. Using the tablet's embedded front camera, the App captures facial images of the patient performing those tasks and analyzes the images to extract several gaze and eye-movement metrics. The test data and basic patient information are then uploaded for offline analysis to **ETNA™-Cloud**.

- **ETNA™-Cloud** is a software application running offline on a company-controlled server that is ISO/IEC 27001, PIPEDA and HIPAA compliant. It is intended for use by healthcare providers only. The software uses a clinically validated and locked AI Machine Learning Model (Classifier) to analyze the gaze and eye-movement metrics and patient information uploaded by the **ETNA™-MS App** at the end of a test session; it identifies relevant features that can best determine MS disease status and outputs an Expanded Disability Status Scale (EDSS) score for clinicians to consult.

#### 1.4. ETNA™-MS App Overview

The **ETNA™-MS App** may be downloaded by healthcare providers or patients from the Apple Store and it is installed on an iPad Pro tablet. The healthcare provider assigns each MS patient a unique username and password needed by the App to log into the cloud-based server and connect with the **ETNA™-Cloud** software.

The App may be used to administer the prescribed test at a clinic/physician's office or at the patient's home. The first time the App is run, it installs on the tablet the video data and instructions associated with the oculomotor (visual) tasks of the test.

To perform the test, the patient must be positioned in front of the iPad, so that the screen is visible; the screen must be stable, straight, centered at eye level and positioned 45 cm from the patient's face. The App provides on-screen instructions to help ensure the patient is properly positioned and the patient's face and eyes are clearly seen by the camera.

Throughout the test session, the App guides the patient to perform 6 distinct oculomotor (visual) tasks and uses patent-pending machine learning technology to extract several gaze and eye-movement metrics. The following tasks are defined:

- I. The calibration task is designed to fine-tune the gaze tracking algorithms and to specifically tailor them to the patient and current environmental lighting conditions.
- II. The fixation task is designed to measure the presence of fixation instability and of saccade instructions, both in terms of their extent and frequency.
- III. The pro-saccades task is designed to assess reactive saccades to rapidly appearing visual stimuli. Parameters of interest include reaction time, saccadic velocity and saccadic precision.
- IV. The anti-saccades task is designed to assess the inhibitory control of the reflexive saccade. The task is divided into three sub-tests where the difficulty level is parametrically increased at each sub-test. Parameters of interest include reaction time and directional success rate.
- V. The optokinetic nystagmus task is designed to assess the integrity of the optokinetic response – a reflexive sawtooth motion (drift followed by a return saccade) of the eye that occurs in response to drifting visual stimuli. Parameters of interest include amplitude of the drift and velocity of the return saccade.
- VI. The smooth pursuit task is designed to assess the ability to track moving visual targets at various velocities. Parameters of interest include pursuit velocity and the quantification of catch-up saccades.

At the end of the test session, the App uploads the extracted metrics and basic patient information (Patient Identifier, Patient Age, and Timed 25-Foot Walk measure) to a secure cloud-based server

for offline analysis by **ETNA™-Cloud**. The App does not provide any diagnostic information for patients or end users.

## 1.5. ETNA™-Cloud Overview

The medical device function of **ETNA™-Cloud** consists of a data analysis pipeline that uses an AI Machine Learning Model (Classifier) to parse the eye-tracking test data that are uploaded by **ETNA™-MS App** at the end of a test session and identify the relevant features that can best determine MS disease status. The software uses this information to provide the treating clinician with an EDSS score.

The Classifier was developed following the guiding principles for Good Machine Learning Practice (GLMP) intended to promote the development of safe, effective, and high-quality medical devices that use artificial intelligence and machine learning (AI/ML)<sup>1</sup>. It was trained and tuned on a dataset collected both in clinic and home settings using equivalent investigational devices and methods from a MS patient population in Canada with the following demographic and clinical inclusion criteria: men and women aged 18 years or older, able to read in French or English, able to provide informed consent, with sufficient visual acuity to read on-screen instructions, with confirmed diagnosis of MS as per the McDonald criteria<sup>2</sup>, irrespective of MS subtype (relapsing-remitting (RRMS), secondary-progressive (SPMS), primary-progressive (PPMS), and progressive-relapsing (PRMS)), who presented with oculomotor symptoms or signs, while still having a high degree of ambulatory ability, and a neurologist-determined EDSS score between 1.0 and 4.5.

The Classifier was locked in this version of the software and the performance of the **ETNA™-MS** device was clinically validated on a different cohort of 43 adult MS patients in Canada and the US meeting the same demographic and clinical inclusion criteria.

The dataset collection for the development of the Classifier and the clinical validation excluded patients with (a) evidence or medical history of psychiatric issues, which are known to also affect movements and oculomotor control; (b) presence of comorbid neurological conditions (strabismus, cranial nerve palsy, stroke-causing hemianopsia); (c) diagnosis of macular edema or other pre-existing ocular conditions; and (d) patients having started a new prescription medication or having changed the dose of a medication known to influence ocular motor visual function (e.g. benzodiazepines, antipsychotics and anticonvulsants) within the past three months.

The clinical validation determined that 88.9% (95%CI: 79.2-96.4) of the estimates were within +/- 0.5 EDSS points of the ground truth clinical data (neurologist-determined EDSS score). This level of agreement between device estimates and ground truth scores was shown to be statistically non-inferior to the average percent agreement (within +/- 0.5 EDSS points) between two human neurologist EDSS raters, which was determined by means of a meta-analysis of several EDSS inter-rater reliability studies (limited to patients with EDSS scores between 1.0 and 4.5) found in the scientific literature (average percent agreement: 77% (95%CI: 63.6-90.9); see section 1.8.)

**ETNA™-Cloud** is also used to perform several non-device functions:

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<sup>1</sup> [Good Machine Learning Practice for Medical Device Development: Guiding Principles](#) (Health Canada)







<sup>2</sup> Carroll WM. 2017 McDonald MS diagnostic criteria: Evidence-based revisions. *Multiple Sclerosis Journal*. 2018;24(2):92-95. doi:[10.1177/1352458517751861](https://doi.org/10.1177/1352458517751861)

- User management: clinic set-up, user creation, user’s privileges, permissions, roles (patients, doctors, admins, etc.), and consolidation of doctors and patients within a clinic
- User authentication
- Handling of test prescriptions and clinic payments (fee for service)
- Storage and transmission of user instructions needed by **ETNA™-MS App**
- Organization and secure storage of test data
- Access to administrative reports and historical clinical data

## 1.6. Terms Glossary

Term	Definition / Description
2FA	2-Factor Authentication
ETNA™	Eye-Tracking Neurological Assessment
ETNA™-MS	Eye-Tracking Neurological Assessment for Multiple Sclerosis
ETNA™-Cloud	Eye-Tracking Neurological Assessment Cloud (Server Application)
EDSS	Expanded Disability Status Scale (Clinical Measure)
HIPAA	Health Insurance Portability and Accountability Act (United States)
MS	Multiple Sclerosis
PIPEDA	Personal Information Protection and Electronic Documents Act (Canada)
SaMD	Software as a Medical Device
T25-FW	Timed 25-Foot Walk (Clinical Measure)

## 1.7. Symbols Glossary

Symbol	Title: Meaning	Standard (Reference)
RxOnly	Caution: US Federal law restricts this device to sale by or on the order of a physician.	21 CFR 801 (801.109)
	Consult instructions for use	ISO 15223-1 (5.4.3)
	Manufacturer	ISO 15223-1 (5.1.1)
	Date of Manufacture	ISO 15223-1 (5.1.3)
	Catalogue Number	ISO 15223-1 (5.1.6)
	Patient information website	ISO 15223-1 (5.7.4)
	Medical device	ISO 15223-1 (5.7.4)

ISO 15223-1:2021. Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

21 CFR 801. Code of Federal Regulations Title 21 – Chapter 1, Food and Drug Administration, Department of Health and Human Services – Subchapter H, Medical Devices – Part 801, Labeling

## 1.8. References

1. Amato M.P., Fratiglioni L., Groppi C., Siracusa G., Amaducci L. Interrater Reliability in Assessing Functional Systems and Disability on the Kurtzke Scale in Multiple Sclerosis. *Arch. Neurol.* 1988; 45:746–748. [DOI:10.1001/archneur.1988.00520310052017](https://doi.org/10.1001/archneur.1988.00520310052017).
2. Verdier-Taillefer, M.H., Zuber, M., Lyon-Caen, O., Clanet, M., Gout, O., Louis, C., & Alpérovitch, A. Observer disagreement in rating neurologic impairment in multiple sclerosis: facts and consequences. *European neurology.* 1991 31 2, 117-9. [DOI:10.1159/000116658](https://doi.org/10.1159/000116658)
3. Francis DA, Bain P, Swan AV, Hughes RA. An assessment of disability rating scales used in multiple sclerosis. *Arch Neurol.* 1991 Mar; 48(3): 299-301. PMID: 2001188. [DOI: 10.1001/archneur.1991.00530150067020](https://doi.org/10.1001/archneur.1991.00530150067020).
4. Hohol MJ, Orav EJ, Weiner HL. Disease steps in multiple sclerosis: a simple approach to evaluate disease progression. *Neurology.* 1995 Feb; 45(2):251-5. PMID: 7854521. [DOI: 10.1212/wnl.45.2.251](https://doi.org/10.1212/wnl.45.2.251).
5. Noseworthy JH, Vandervoort MK, Wong CJ, Ebers GC. Interrater variability with the Expanded Disability Status Scale (EDSS) and Functional Systems (FS) in a multiple sclerosis clinical trial. The Canadian Cooperation MS Study Group. *Neurology.* 1990 Jun; 40(6):971-5. PMID: 2189084. [DOI: 10.1212/wnl.40.6.971](https://doi.org/10.1212/wnl.40.6.971).

## 2. Directions for Use

### 2.1. Requirements to Access ETNA™-Cloud

ETNA™-Cloud is an Amazon Web Services (AWS)-hosted cloud server application running on a company-controlled server, accessible via a web browser (e.g., Microsoft Edge, Apple Safari, Google Chrome) .

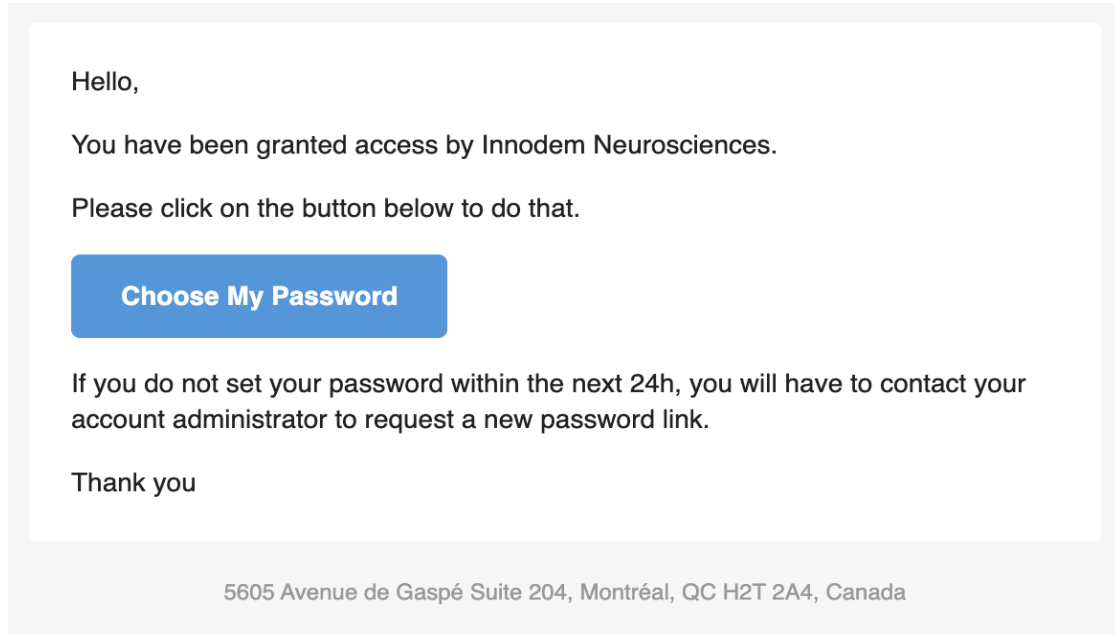
Access to the server is first granted by Innodem Neurosciences via email to a Clinic Administrator, who will subsequently manage clinician and patient accounts. All ETNA™-MS and ETNA™-Cloud users must have a valid email address. The following user roles and privileges are defined by the system:

Role	Privileges
Clinician	<p><b>ETNA™-Cloud:</b></p> <ul style="list-style-type: none"><li>● Edit own user account (profile) settings</li><li>● Create patient profiles and identifiers</li><li>● Edit patient profiles</li><li>● Enter test prescriptions</li><li>● Authorize patient password change</li><li>● View detailed test results of all patients in the clinic</li></ul> <p><b>ETNA™-MS App:</b></p> <ul style="list-style-type: none"><li>● Create patient profiles and identifiers</li><li>● Perform test</li></ul>
Clinic Administrator	<p><b>ETNA™-Cloud:</b></p> <ul style="list-style-type: none"><li>● Edit own clinic and user account (profile) settings</li><li>● Manage clinicians' and patients' accounts within a clinic</li><li>● reload test bank/credits</li><li>● Authorize patient password change</li><li>● View limited test results of all patients in the clinic</li></ul> <p><b>ETNA™-MS App:</b></p> <ul style="list-style-type: none"><li>● No access</li></ul>
Patients	<p><b>ETNA™-Cloud:</b></p> <ul style="list-style-type: none"><li>● No access</li></ul> <p><b>ETNA™-MS App:</b></p> <ul style="list-style-type: none"><li>● Perform Tests</li></ul>

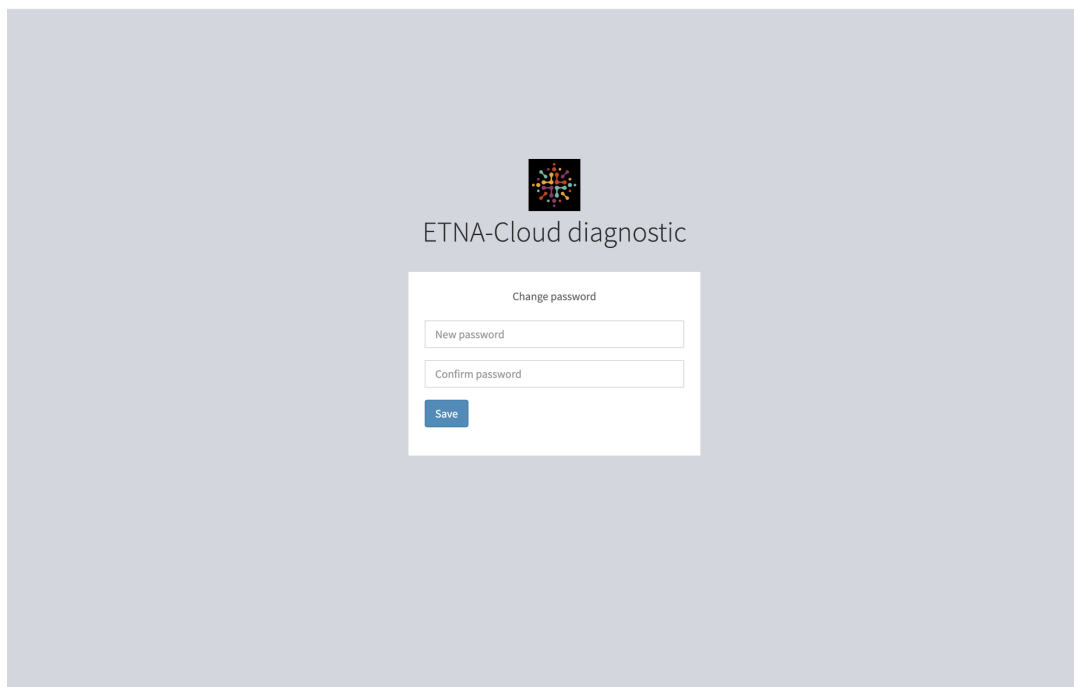


## 2.2. User Account Confirmation and Password Creation

As an **ETNA™-MS** and **ETNA™-Cloud** user, you will receive an email from the system, triggered by the clinic administrator, prompting you to choose your password (see example email content below):



By clicking on the “Choose My Password” button, you will be directed to the following web page to create a unique password:



Upon entering and confirming your new password, click on “Save” to complete the process.

For data security purposes, 2-Factor Authentication via email or a third-party Authenticator App is used to confirm user identity. Email is used as the default setting but this can be changed (as described in Section 3). Note that users are required to periodically change passwords; the system will send an email message with instructions to all users at set time points.

Patients will also receive a similar email to set a password (see below) once their account is created by the clinician (more details in Section 2.5).

Greeting Rosenberg Ramos,

Doctor Étienne de Villers-Sidani has prepared the way for your MS tests with ETNA-MS.

You have been asked to perform your test every **month**.

To use the ETNA-MS application, you will have to first install it from the [Apple App Store](#).

You will need to choose a password first.

[Choose My Password](#)

Once that is done, here are the credentials you need to do your tests:

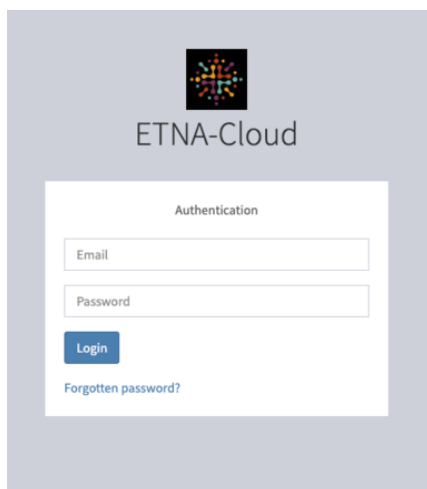
User: **rosebergramos@hotmail.com**

Password: **The one you just created**

### 2.3. ETNA™-Cloud Login

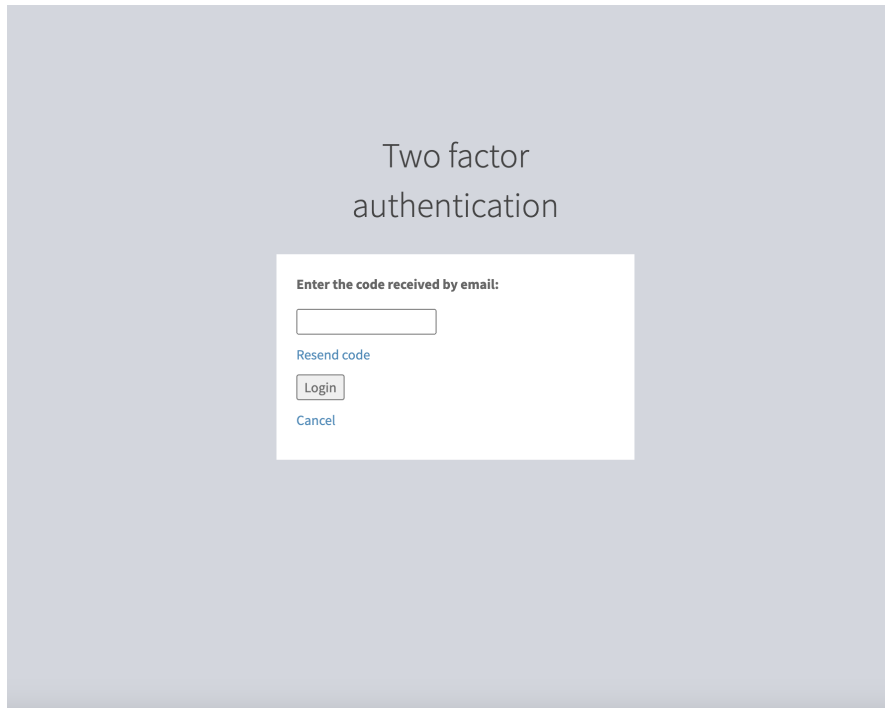
You will be able to login to the ETNA™-Cloud Server using a web browser (e.g., Microsoft Edge, Apple Safari, Google Chrome) via the URL provided in the email sent by the clinic administrator.

To have access to the database's functionalities, enter the email address and password associated with your account:

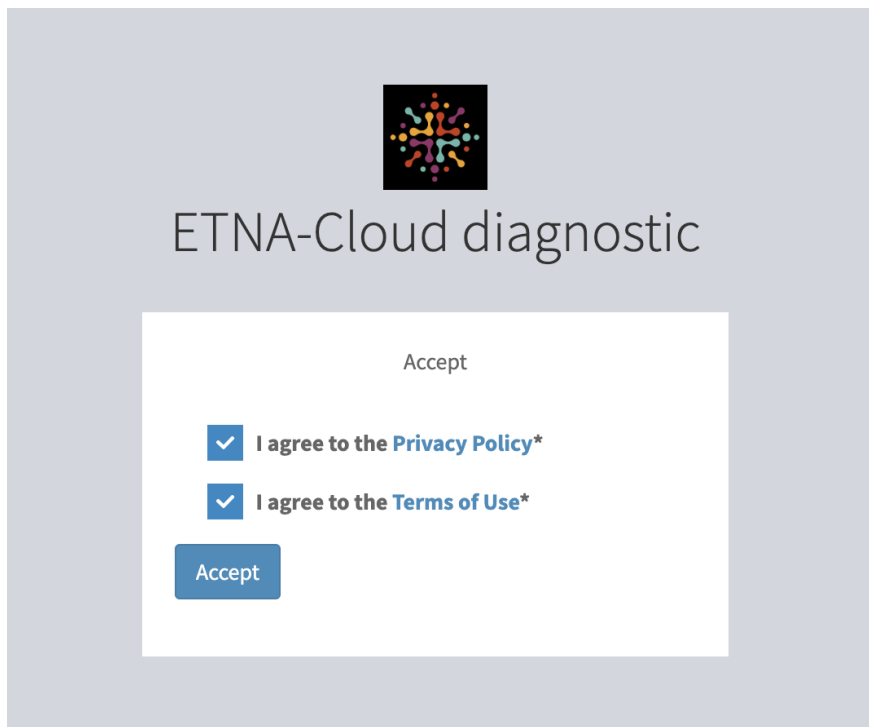


The image shows a screenshot of the ETNA-Cloud login interface. At the top center is a logo consisting of a grid of colorful dots. Below the logo, the text 'ETNA-Cloud' is displayed. Underneath, there is a white box titled 'Authentication'. Inside this box, there are two input fields: 'Email' and 'Password'. Below the 'Password' field is a blue 'Login' button. At the bottom left of the 'Authentication' box, there is a blue link that says 'Forgotten password?'.

After clicking “Login”, you will be asked to enter a 2FA code that will be sent to your email (default settings):



If this is your first time logging in, you will be asked to read and accept the “Privacy Policy” and “Terms of Use”:



## 2.4. Manage Your Own User Profile Settings

Once logged in, you can change your user profile settings by clicking on the dropdown arrow located next to your email address:

The screenshot shows the ETNA-Cloud diagnostic application interface. The top navigation bar includes the logo, a home icon, and the path 'Clinic List / Neuro CRU'. The user's email 'roseberg.ramos+doc@innodemneurosciences.com' is displayed in the top right. A left sidebar contains navigation options: 'Clinic', 'Test Results', 'Patients', and 'Patient Identifiers'. The main content area displays the 'Show "Neuro CRU"' page. It features a 'Documentation' section with a note: 'Bank credit must be 10 or more to be considered available or "has unlimited credit".' Below this is a 'Clinic' information table with the following data:

Name	Neuro CRU
Active	yes
Address	3801 Rue University
Suite	
Country Code	CA
State Code	CA-QC
City	Montreal
Postal Code	H3A 2B4
Credit Bank	60
Has Unlimited Credit	yes
Weekly Credit Requirement	25

Buttons for 'Profile' and 'Logout' are visible in the top right of the main content area. The URL at the bottom is 'https://api-beta.innodem-neurosciences.com/diagnostic/admin/app/patient/list'.

In the profile information window, click on "Edit" to modify "User" information and/or "Security" settings:

The screenshot shows the ETNA-Cloud diagnostic application interface for the user profile. The top navigation bar includes the logo, a home icon, and the path 'Doctor List / roseberg.ramos+doc@innodemneurosciences.com'. The user's email 'roseberg.ramos+doc@innodemneurosciences.com' is displayed in the top right. A left sidebar contains navigation options: 'Clinic' and '<'. The main content area displays the 'Show "roseberg.ramos+doc@innodemneurosciences.com"' page. It features two columns of profile information:

User	Security
Email: roseberg.ramos+doc@innodemneurosciences.com	Password Updated At: 2023-09-12 14:06:06
Last Name: Ramos	Password Expires At: 2024-09-12 14:06:06
First Name: Roseberg	Is Password Expired: no
Created At: 2023-09-11 13:16:02	Last Connection: 2023-10-10 14:31:30
Updated At: 2023-10-10 14:31:30	Active 2FA Provider: Email

An 'Edit' button is located at the bottom left of the profile information area.

You can modify your first and last name, password and 2FA provider.

The screenshot shows the 'Edit User' form for the user 'roseberg,ramos+doc@innodemneurosciences.com'. The form is divided into two main sections: 'User' and 'Security'.  
The 'User' section includes:

- Email\***: roseberg,ramos+doc@innodemneurosciences.com
- Last Name**: Ramos
- First Name**: Rosenberg
- Patient Default Information Visibility\***: private

The 'Security' section includes:

- New Password**: A text input field with a note: 'Leave empty if you do not need to change it.'
- Active 2FA Provider\***: A section with two radio buttons: 'Email' (checked) and 'App' (unchecked). Below the radio buttons is the text 'Select just one'.

At the bottom of the form, there are two buttons: 'Update' and 'Update and close'.

**\*OPTIONAL\*** To change 2FA provider from Email to an Authenticator App, un-check the Email box and check the App box, then click “Update”.

The screenshot shows the 'Edit User' form for the user 'jimmy.lai+neurodoc@innodemneurosciences.com'. The form is divided into two main sections: 'User' and 'Security'.  
The 'User' section includes:

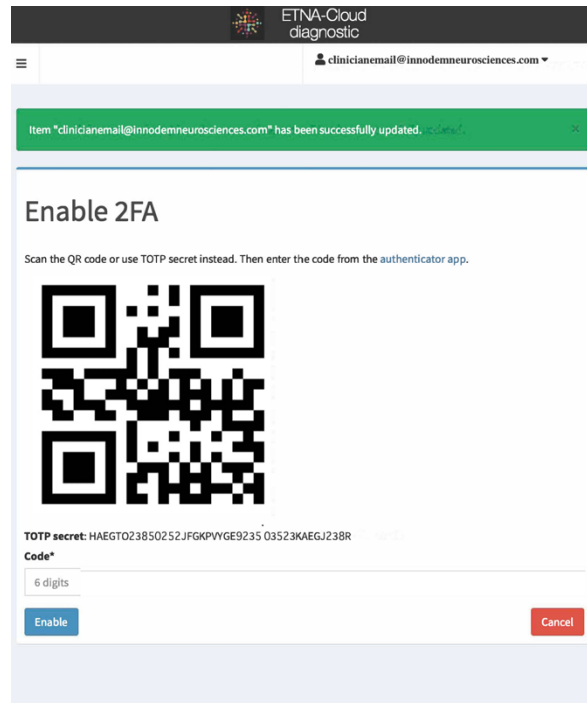
- Email\***: jimmy.lai+neurodoc@innodemneurosciences.com
- Preferred Locale\***: en
- Last Name**: (empty)
- First Name**: (empty)
- Patient Test Result Availability\***: MANUAL

The 'Security' section includes:

- New Password**: A text input field with a note: 'Leave empty if you do not need to change it.'
- Two Factor Authentication Enabled Providers\***: A section with two radio buttons: 'Email' (unchecked) and 'App' (checked). The 'App' radio button is circled in red. Below the radio buttons is the text 'Select just one'.

At the bottom of the form, there are two buttons: 'Update' and 'Update and close'.

After clicking “Update”, the following screen will appear (see below) to enable the 2FA provider of your choice. Simply scan the QR code with your 2FA Authenticator App and complete the set up (enter the code generated by the App and click “Enable”).



Upon making all necessary changes, it will bring you back to your profile page. Click “Update and close” to return to the “Doctor” tab.

## 2.5. Creating Patients

There are two steps in creating a patient in the **ETNA™-MS and ETNA™-Cloud** system:

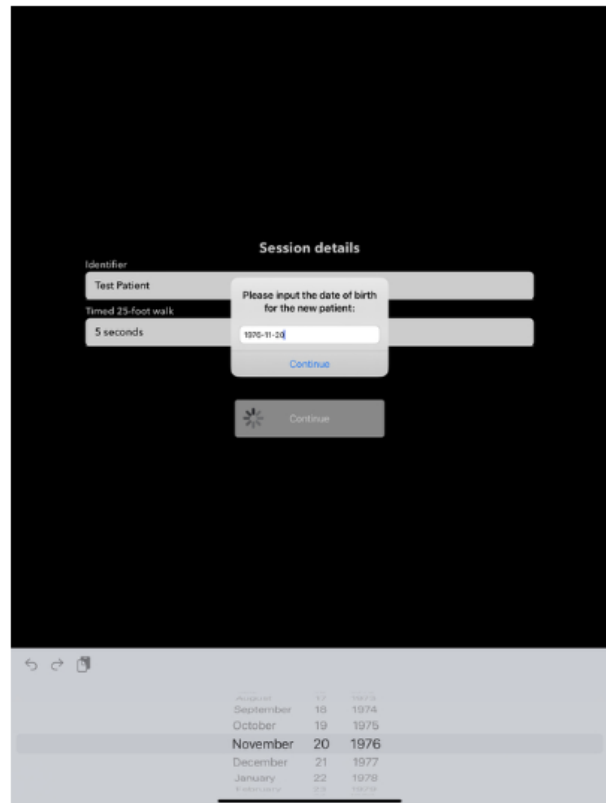
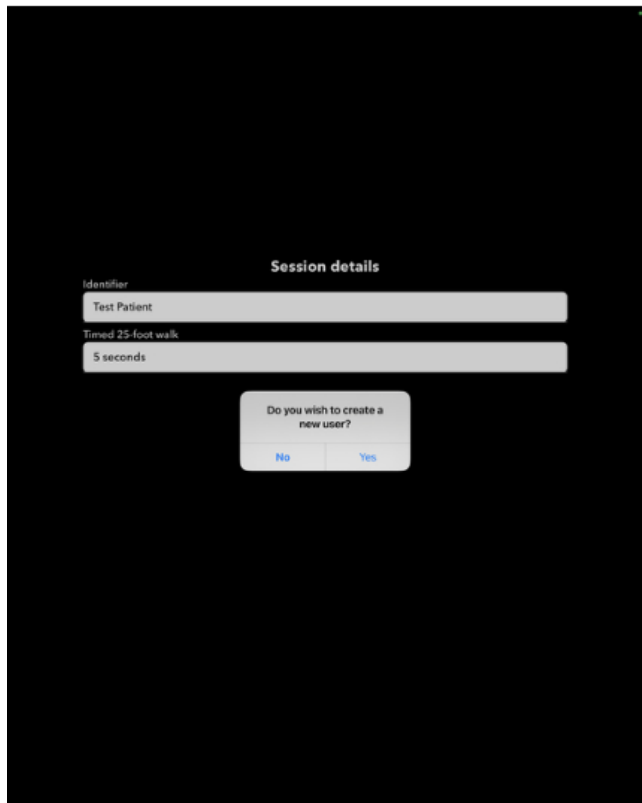
1. The Clinician creates a unique patient identifier using the **ETNA™-MS App** the first time the patient performs the test in the clinic (see section 2.5.1 below).
2. The Clinician (or Clinical Administrator) will then create a patient profile, fill out the patient information on the **ETNA™-Cloud** Server database and link the ETNA™-MS Test/Identifier to the profile to complete the process. They can also enter a prescription for the patient to perform tests at-home at the same time (see section 2.5.2 below).

### 2.5.1. Create a Patient Identifier on the ETNA™-MS App

Log into the App with your Clinician credentials (the same login credentials at the ETNA™-Cloud server. A “Session details” screen will be shown (as seen below).

Enter the patient's unique identifier. This is an autocomplete field (the App remembers previous entries); the identifier can be any unique number you are using in the clinic to identify the patient (such as the patient’s Medical Record Number) but it should not contain identifying features such as the patient's name, Medicare number or social insurance/security number. You will also need to input the average of the two Timed 25-foot walk trials.

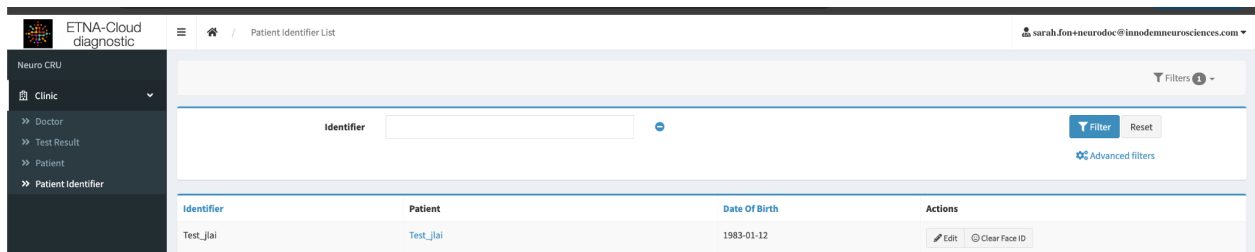
If a patient identifier is being input for the first time, a message will appear saying “Do you wish to create a new user?”. After clicking “Yes”, you will be prompted to input the date of birth of the newly created patient.



Proceed with performing the test as described in section 2.10 below. Upon completion of the test, the patient identifier will be automatically viewable under the “Patient Identifiers” tab on the **ETNA™-Cloud** Server. All subsequent tests with the same patient will use the same identifier.

### 2.5.2. Creating a Patient Profile on the ETNA™-Cloud Server and Linking the ETNA™-MS test

Once the iPad test is complete and uploaded, the newly created patient identifier will appear in the “Patient Identifier” tab



To create a new patient and to link it to the identifier, you must click on the “Patients” menu/tab and click “Add new” in the top right corner

Filters 1 **Add new**

Patient Identifier

Doctor

Email

In the 'Create' window, you will fill out the required user fields (email, patient identifier, associated clinician, test frequency, test information visibility). Please make sure to link the new identifier by clicking "List" and selecting the right identifier. At the bottom have the option to "Create" and remain on the same page, "Create and return to list", or "Create and add another":

Neuro CRU

Clinic

- >> Doctor
- >> Test Result
- >> Patient
- >> Patient Identifier

Privacy Policy  
Terms of Use

Create

User

Email\*

Preferred Locale\*

Last Name

First Name

Phone Number\*

Patient Identifier

Doctor\*

Test Frequency

Test Result Availability\*

Security

No fields available.

## 2.6. Prescribing Tests

A Clinician can prescribe the **ETNA™-MS** for the patient to self-test at home.

This can be done in two ways:

1. In the "Test Results" page in the **ETNA™-Cloud**, select the patient to whom you would like to subscribe a test, and then click on "Prescribe":



ETNA-Cloud diagnostic / Test Result List

Filters: Filter, Reset, Advanced filters

Id	Patient Identifier	Patient	Doctor	Result	Created At	Actions
905bad57-f0e7-4c2f-a534-7b7806241e8e	Test_jlai	Test_jlai	jimmy.lai+neurodoc@innodemneurosciences.com	[edss => 1.0]	2024-01-12 20:57:29	Show
f6771375-4d46-4876-9372-8f804621ef8b	Test_jlai	Test_jlai	jimmy.lai+neurodoc@innodemneurosciences.com	[edss => 1.0]	2024-01-12 20:13:59	Show
00dd3dd8-7c34-4070-b536-1b6470876e5e	MS-MCG-893126		jimmy.lai+neurodoc@innodemneurosciences.com	[edss => 1.0]	2023-12-19 20:18:40	Prescribe Show
2369d388-5f6b-42b4-8949-1fec2115c3a5	TestJLAI		jimmy.lai+neurodoc@innodemneurosciences.com	[edss => 1.0]	2023-11-24 15:48:32	Prescribe Show

1 / 1 - 4 results - Per page 25

After clicking on “Prescribe”, enter the required patient and test prescription information; mandatory fields are marked with an asterisk (\*). Please make sure to also link the patient identifier to the profile:

ETNA-Cloud diagnostic / Patient List / Test\_jlai

Edit "Test\_jlai"

User

Email\*

Preferred Locale\*

Last Name

First Name

Phone Number\*

Date Of Birth\*

Patient Identifier

Doctor\*

Test Frequency

Test Result Availability\*

After entering the information in the prescription window above, click on “Create” to complete the creation of a patient in the **ETNA™-Cloud** Server database. This will now allow the identifier to be used for future tests performed at home by the patient. Patients will receive an email to create a login for the ETNA™-MS App once tests are prescribed. All patients can be viewed in the “Patients” tab (see section 2.7).

- Alternatively, to prescribe tests to a patient who already has a Patient Profile, go to the “Patient” tab and click on “Edit” next to the desired patient.

The screenshot shows the 'Patient List' interface. On the left is a dark sidebar with 'Neuro CRU' and a 'Clinic' dropdown menu. The main content area has a search filter section with the following fields:

- Patient Identifier:
- Doctor: sarah.fon+neurodoc@innodemne... (dropdown)
- Email:
- Last Name:
- First Name:

Buttons for 'Filter', 'Reset', and 'Advanced filters' are present. Below the filter is a table with the following data:

email	Last Name	First Name	Doctor	First Test Created At	Last Test Created At	Test Frequency	Next expected test	# of test	Action
sarah.fon+02018@innodemneurosciences.com		02-018	sarah.fon+neurodoc@innodemneurosciences.com	2024-01-02 19:35:59	2024-01-02 20:05:02	every_1_month	2024-02-01 20:05:02	2	Show, Edit
sarah.fon+01011@innodemneurosciences.com		01-011	sarah.fon+neurodoc@innodemneurosciences.com	2024-01-04 20:59:47	2024-01-04 20:59:47	every_1_month	2024-02-03 20:59:47	1	Show, Edit
sarah.fon+01013@innodemneurosciences.com		01-013	sarah.fon+neurodoc@innodemneurosciences.com	2024-01-08 21:00:39	2024-01-08 21:00:39	every_1_month	2024-02-07 21:00:39	1	Show, Edit

You can then edit the Patient Profile and add the desired “Test Frequency”. Click “Update” to finish prescribing the test. The patient will receive an email to create a login for the ETNA™-MS App once tests are prescribed.

The 'Edit Sarah' form contains the following fields and values:

- User:
- Email\*: sarah.fon+pt@innodemneurosciences.com
- Preferred Locale\*: en
- Last Name:
- First Name:
- Phone Number\*: (514) 664-5998
- Date Of Birth\*: 1998-06-11
- Patient Identifier: Sarah
- Doctor\*: sarah.fon+neurodoc@innodemneurosciences.com
- Test Frequency: every\_1\_month
- Test Result Availability\*: MANUAL

Buttons at the bottom: Update, Update and close.

## 2.7. Reset Patient Password

If a patient forgets their password or their password expires, a Clinician (or Clinic Administrator) can send a request to the patient’s email to change it. Click on “Edit” next to the desired patient in the “Patients” tab to open the patient’s (“user’s”) information window.

Patient Identifier	Email	Last Name	First Name	Doctor	First Test Created At	Last Test Created At	Test Frequency	Next expected test	# of test	Action
Test_jlai	jimmy.lai+1@innodemneurosciences.com			jimmy.lai+neurodoc@innodemneurosciences.com	2024-01-12 20:13:59	2024-01-12 20:57:29	every_1_month	2024-02-11 20:57:29	2	<a href="#">Show</a> <a href="#">Edit</a>

Click on “Actions” at the top right and select “Request password change” in the dropdown menu:

The screenshot shows the 'Edit "Test\_jlai"' form. The 'Security' section is active, displaying 'No fields available.' A dropdown menu is open from the 'Actions' button, listing options: 'Add new', 'Show', 'Return to list', 'Print', 'Request test', and 'Request password change'. The 'Request password change' option is circled in red.

## 2.8. Patient Filtering and Modifications



A list of patient identifiers can be found in the “Patient identifiers” tab. Patient identifiers are created from the **ETNA™-MS App** (see section 2.5.1 above) when their first test is performed. At the completion of the test, a Face ID will be associated with the respective patient identifier.

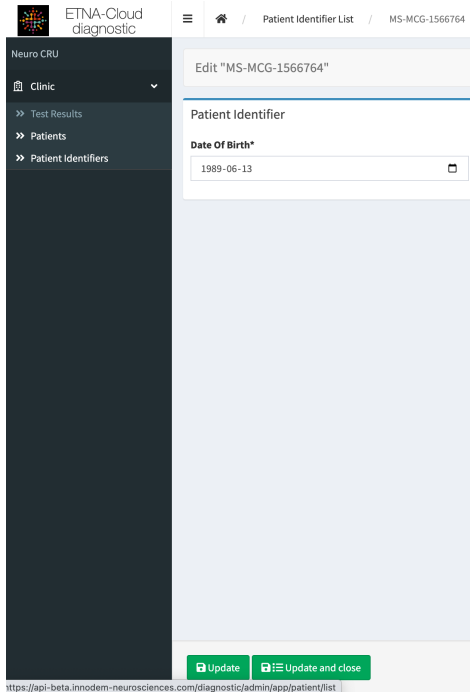
In the “Patient Identifiers” tab, you can filter the list by “Identifier” to find a specific patient or sort by “Identifier” and “Date of Birth” by clicking on their respective column labels.

The screenshot shows the 'Patient Identifier List' page. A search bar for 'Identifier' is at the top. Below is a table with the following data:

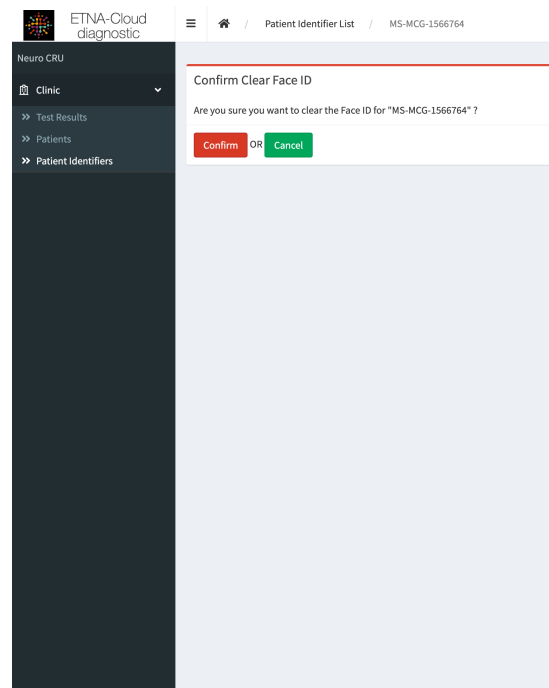
Identifier	Patient	Date of Birth	Actions
MS-MCG-1566764		1989-06-13	<a href="#">Edit</a> <a href="#">Clear Face ID</a>
MS-MCG-5187018		1977-10-01	<a href="#">Edit</a> <a href="#">Clear Face ID</a>
MS-MCG-5790151		1958-02-25	<a href="#">Edit</a> <a href="#">Clear Face ID</a>
MS-MCG-1566760		1975-10-14	<a href="#">Edit</a> <a href="#">Clear Face ID</a>
MS-MCG-5190384		1977-06-15	<a href="#">Edit</a> <a href="#">Clear Face ID</a>
MS-MCG-5366207		1973-02-28	<a href="#">Edit</a> <a href="#">Clear Face ID</a>
MS-MCG-5441286		1961-09-28	<a href="#">Edit</a> <a href="#">Clear Face ID</a>
MS-MCG-1572133		1983-09-15	<a href="#">Edit</a> <a href="#">Clear Face ID</a>
MS-MCG-0578329		1959-05-14	<a href="#">Edit</a> <a href="#">Clear Face ID</a>
MS-MCG-5085122		1986-06-22	<a href="#">Edit</a> <a href="#">Clear Face ID</a>
MS-MCG-5427453		1991-04-22	<a href="#">Edit</a> <a href="#">Clear Face ID</a>
MS-MCG-5792713		1985-03-15	<a href="#">Edit</a> <a href="#">Clear Face ID</a>
Youngtienne		1999-01-06	<a href="#">Edit</a> <a href="#">Clear Face ID</a>
MS-MCG-1149212		1969-10-17	<a href="#">Edit</a> <a href="#">Clear Face ID</a>

You can edit a patient’s date of birth by clicking on “Edit” and/or clear a patient's face ID by clicking on “Clear Face ID”.

Identifier	Patient	Date Of Birth	Actions
Test_jlai	Test_jlai	1983-01-12	 Edit  Clear Face ID

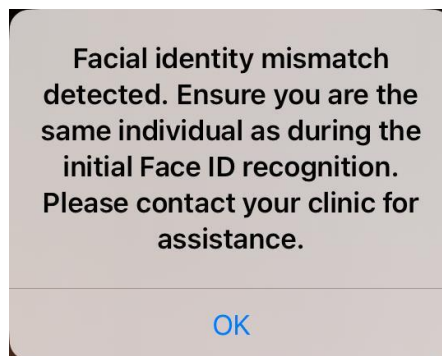


**Edit Date Of Birth**



**Clear Face ID**

The “Clear Face ID” function only works if there is a previously existing patient identifier on the **ETNA™-Cloud**. Using the “Clear Face ID” function is sometimes required to delete the face identity associated with a patient. This is applicable when the **ETNA™-MS App** reports a facial identity mismatch error (see image below). A new face identity will be saved upon completion of a new test.



## 2.9. View Test Results

### 2.9.1. Viewing Individual Test Results (Limited View)

A summary listing of test results for all patients individual iPad test results in the clinic are available through the **“Test Results”** tab of the **ETNA™-Cloud** database.

By default, the software displays a list with the EDSS score for every test session of all patients created by the currently logged-in clinician.

In order to view the test results for a specific patient only, enter three digits or more of the patient identifier in the **“Patient Identifier”** field and click the **“Filter”** button. The software will display only test results for those patients with a matching identifier.

Id	Patient Identifier	Patient	Doctor	Result	Created At	Actions
5f7ca504-c3eb-43cb-8694-c8e16d95d203	Sarah		sarah.fon+neurodoc@innodemneurosciences.com	[edss == 1.0]	2024-01-12 20:12:01	<input type="checkbox"/> Prescribe <input type="button" value="Show"/>
d44fcad0-2584-47f7-8841-8a0c33096dc5	Sarah		sarah.fon+neurodoc@innodemneurosciences.com	[edss == 1.0]	2024-01-12 19:55:31	<input type="checkbox"/> Prescribe <input type="button" value="Show"/>
d6cd8a68-7bb8-46d0-bcce-eaf00767408	Sarah		sarah.fon+neurodoc@innodemneurosciences.com	[edss == 1.0]	2023-12-11 14:55:13	<input type="checkbox"/> Prescribe <input type="button" value="Show"/>
2d24f930-8885-45e3-a570-42d867414d27	Sarah		sarah.fon+neurodoc@innodemneurosciences.com	[edss == 1.0]	2023-11-28 18:55:12	<input type="checkbox"/> Prescribe <input type="button" value="Show"/>

The column **“Result”** displays the list of EDSS scores from all tests performed by a specific patient with the date when the test was completed under the column **“Created At”**.

By clicking on the **“Show”** button of a specific test, you will be able to see a summary of the test’s information and the inputs used by the Classifier.

Navigating Back on the browser, or simply clicking on the **“Test Results”** tab on the left menu will bring you back to the previous page. Click on the **“Reset”** button to clear the filter and display the default list.

To view test results of patients created by another clinician in your clinic, click on the **“Advanced filters”** link, select **“is equal to”** under the **“Doctor”** field, select the clinician’s account in the drop down list next to it and click the **“Filter”** button.

Alternatively, you can select **“is not equal to”** under the **“Doctor”** field to display patients of every other clinician except the one selected. There are multiple permutations possible in the **“Advanced filters”** function to help you filter the displayed list of test results. Please note that the **“Filter”** button needs to be clicked every time for new filter parameters to be applied.

Patient Identifier:

Doctor: is equal to

Created At:

From:

To:

[Advanced filters](#)

To view all test results at once, make sure to all filters cleared and to remove the doctor by clicking on the “x”

### 2.9.2. Viewing All Tests Results per Patient (Detailed View)

A listing of all tests performed by each patient are also available through the “**Patients**” tab of the **ETNA™-Cloud** database.

By default, the software displays a list of every patient created by the currently logged-in clinician with a summary of testing (e.g., number of tests performed to date, prescribed frequency, etc.).

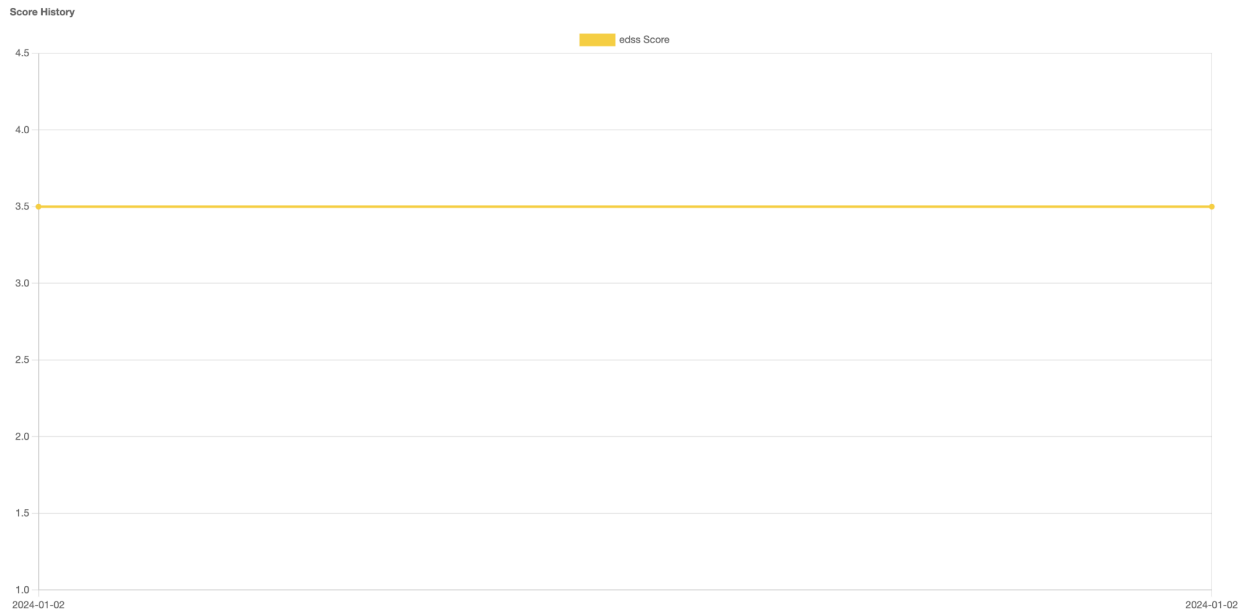
You can use the “Filter” function to search for a specific “patient or patients for a specific clinician. Click on the “Reset” button” to clear the filter and display the default list. You can view all patients by clicking on the “x” next to the clinician email in the “Doctor” field.

The screenshot shows the Neuro CRU interface. On the left is a dark sidebar with navigation options: Clinic, Test Results, Patients, and Patient Identifiers. The main area has a filter form with fields for Patient Identifier, Doctor (selected as sarah.fon+doc@innodemneurosc...), Email, Last Name, and First Name. There are Filter and Reset buttons, and an Advanced filters link. Below the form is a table with the following data:

Identifier	Email	Last Name	First Name	Doctor	First Test Created At	Last Test Created At	Test Frequency	Next expected test	# of test	Action
	sarah.fon+pt@innodemneurosciences.com			sarah.fon+doc@innodemneurosciences.com	2023-09-06 18:19:50	2023-10-12 15:13:49	every_1_month	2023-11-11 15:13:49	8	Show, Edit

At the bottom right of the table, it says "1 / 1 - 1 result - Per page 25".

To view the history of a desired patient, click Show. The following page will display two graphs and a table, as seen below. The first graph, shown below, is a history of EDSS scores for all tests done by the patient. The X-axis shows the dates of each test, and the Y-axis shows the EDSS score equivalent for each test.

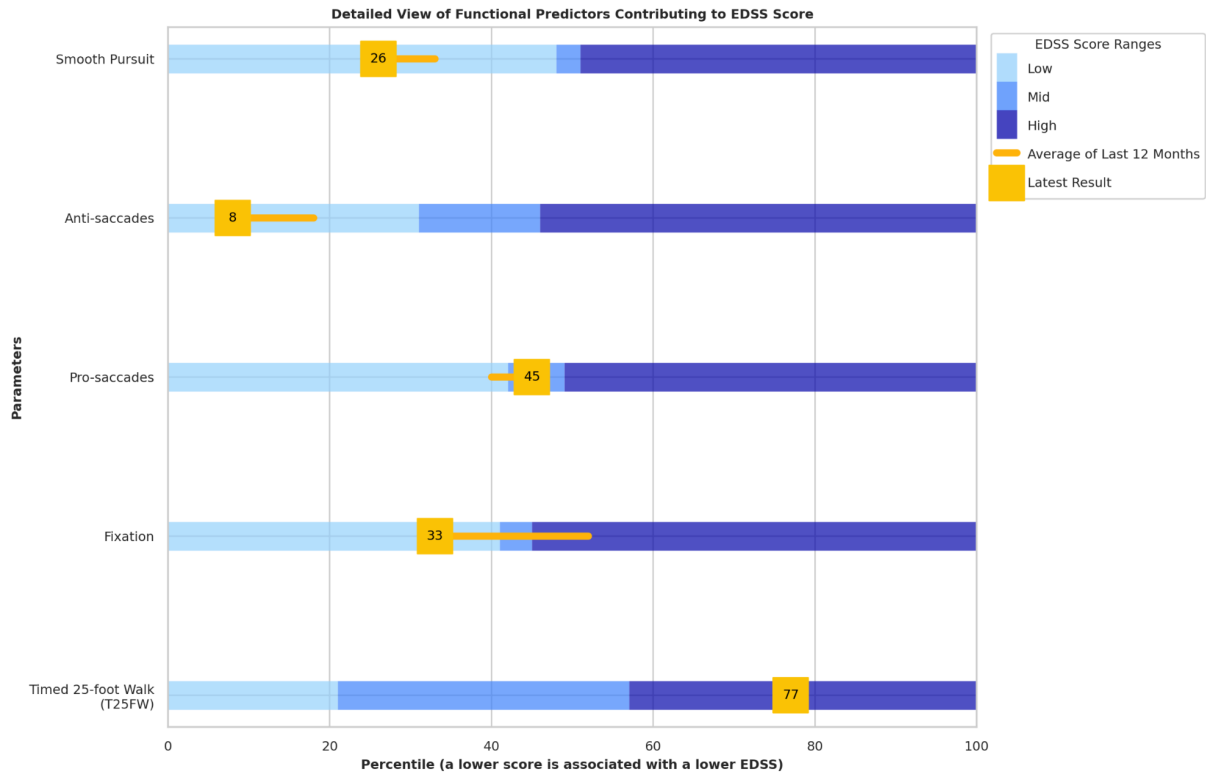


The second graph shows a breakdown of how each eye-tracking category (Smooth Pursuit, Anti-saccade, Pro-saccade, Fixation) as well as the Timed 25-foot walk, contributes to the EDSS score prediction. For each metric, a patient’s test result is ranked relative to an EDSS score that is low (1.0, 1.5, 2.0), mid (2.5, 3.0), or high (4.0, 4.5). The number represents a percentile amount, comparing the current patient’s test to all of the test population results in the training data. The line emanating from the score box shows either an increase or decrease from the patient’s average test results over the last 12 months.

For a practical example, the following conclusions can be drawn from this graph:

- The patient’s latest smooth pursuit category result ranks in the 26th percentile of the low EDSS test population section. This score is lower than the patient’s 12-month average showing a small improvement.
- The patient’s latest pro-saccade category result ranks in the 45th percentile of the mid . EDSS test population section. This score is higher than the patient’s 12-month average showing a small worsening.
- The patient’s Timed 25-foot walk ranks in the 77th percentile of the high EDSS test population section. This score has not changed from the patient’s 12-month average showing stability.

The synthesis of all of the extracted eye movement parameters, after being weighed and analyzed by Innodem’s ETNA™-MS validated algorithms, outputs an EDSS score equivalent of 3.5 for this patient’s most recent test result (as seen in the above figure.)



## 2.10. Administering a Test with the ETNA™-MS App

As a clinician, you must use the **ETNA™-MS App** to administer the first test with each of your patients. Patients should subsequently use their own credentials to login into the App and perform the test on their own (or with the help of a caregiver).

Follow *ETNA™-MS Instructions for Use (Patients)* to install and login into the **ETNA™-MS App** and prepare the iPad and patient for a test session.

## 3. Tech Support and Troubleshooting

### 3.1. Tech Support Contact Information

For technical support, please contact: [support@innodemneurosciences.com](mailto:support@innodemneurosciences.com)

### 3.2. Troubleshooting Guide

The following error messages might appear before/during/after a test:

Error Message	Recommended Action
"Failed to download multimedia"	Contact Technical Support



<i>“Sorry, your test session could not be saved, please run the test again at your earliest convenience”</i>	Please restart the test
<i>“Battery level must be 30% or more to run test”</i>	Please make sure the iPad is charged before running a test
<i>“No Face ID. Please contact your clinic to correct this”</i>	Contact Technical Support
<i>“Not enough credit available to start the test. Please contact your clinic to correct this”</i>	Contact Technical Support
<i>“There are results saved on the device which cannot be processed until they are uploaded. Are you sure you want to log out?”</i>	Contact Technical Support
<i>“Test interrupted because unexpected error”</i>	This is most likely caused by the iPad overheating. Please wait a few minutes for the iPad to cool down before restarting the task. If the error persists, contact Technical Support.
<i>“Lost too much data. Please start again”</i>	This error is most likely caused by the iPad overheating. Please wait a few minutes to allow it to cool before restarting the task. If the error persists, contact Technical Support.
<i>“Ambient light changed too much”</i>	This is caused when the lighting in the room has changed during a task (i.e., lights got dimmer, lighting through a window was brighter/darker). Please make sure to be in a well lit and stable environment before beginning the test.
<i>“Your eyes must stay opened at least 80% of the time during the test”</i>	Restart the task keeping your eyes open/wide as much as possible.
<i>“Detected too many invalid segments. Please redo the test”</i>	This can be the result of two things: <ol style="list-style-type: none"> <li>1. The patient blinked too much throughout the task. Repeat the test with as little as possible blinking.</li> <li>2. The patient’s gaze is not detected near the target, meaning the visual task is not performed correctly. Please make sure you understand the visual task by reading the instructions before the beginning of the task.</li> </ol>

<i>“Device is too hot. Please wait a few minutes for the thermal state to return to nominal to resume the test”</i>	Please wait a few minutes to allow the iPad to cool before restarting the task.
<i>“Failed to connect to the server”</i>	Contact Technical Support