ETNA™-MS
Instructions for Use
(Clinic Administrators)

ETNA™-MS Cloud Version 1.8

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1. Introduction

1.1. About this Document

This document is targeted for clinic administrators and will describe how they will be setting-up the clinic, account settings, managing clinicians and patients accounts within a clinic, reloading test bank, and other administrative procedures required to set up the **ETNA™-MS** testing environment.

1.2. Terms Glossary

Term	Definition
ETNA™	Eye-Tracking Neurological Assessment
MS	Multiple Sclerosis
ETNA™-MS	Eye-Tracking Neurological Assessment for Multiple Sclerosis
ETNA™-Cloud	Eye-Tracking Neurological Assessment Cloud server
EDSS	Expanded Disability Status Scale
HIPAA	Health Insurance Portability and Accountability Act
PIPEDA	Personal Information Protection and Electronic Documents Act
2FA	2-Factor Authentication
T25-FW	Timed 25-Foot Walk

1.3. Symbol 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)
REF	Catalogue Number	ISO 15223-1 (5.1.6)
	Patient information website	ISO 15223-1 (5.7.4)
MD	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

2. 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 to you by Innodem Neurosciences via email, so you can subsequently manage clinician and patient accounts. All **ETNA™-MS** users must have a valid email address. The following user roles and privileges are defined by the system:

To operate in the ecosystem the following roles are defined:

| Role	Privileges
Clinician	**ETNA™-Cloud**: ● Edit own user account (profile) settings ● Create patient profiles and identifiers ● Edit patient profiles ● Enter test prescriptions ● Authorize patient password change ● View detailed test results of all patients in the clinic **ETNA™-MS App**: ● Create patient profiles and identifiers ● Perform test
Clinic Administrator	**ETNA™-Cloud**: ● Edit own clinic and user account (profile) settings ● Manage clinicians' and patients' and Clinic Admin accounts within a clinic ● Reload test bank/credits ● Authorize patient password change ● View limited test results of all patients in the clinic ● Enter test prescriptions ● Create test results report **ETNA™-MS App**: ● No access
Patients	**ETNA™-Cloud**: ● No access **ETNA™-MS App**: ● Perform Tests

3. The Clinic Administrator Role

You have the responsibility to complete the following ETNA™-MS specific clinic tasks:

a. Getting and configuring their access to ETNA™-Cloud
b. Creating/managing Clinicians
c. Reset passwords for Clinicians and Patients
d. Manage credits in test bank

e. View/edit test results
f. Prescribe tests
g. Test Results Report

3.1. User Account Confirmation and Password Creation

Once Innodem Neurosciences has validated and approved a clinic, you will receive a one-time email to create your password in order to access the database.
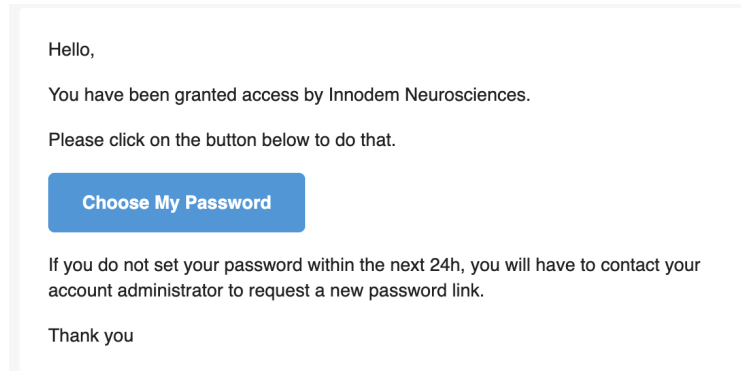
By clicking on "Choose My Password", you will be redirected to the following web page to create a unique password:
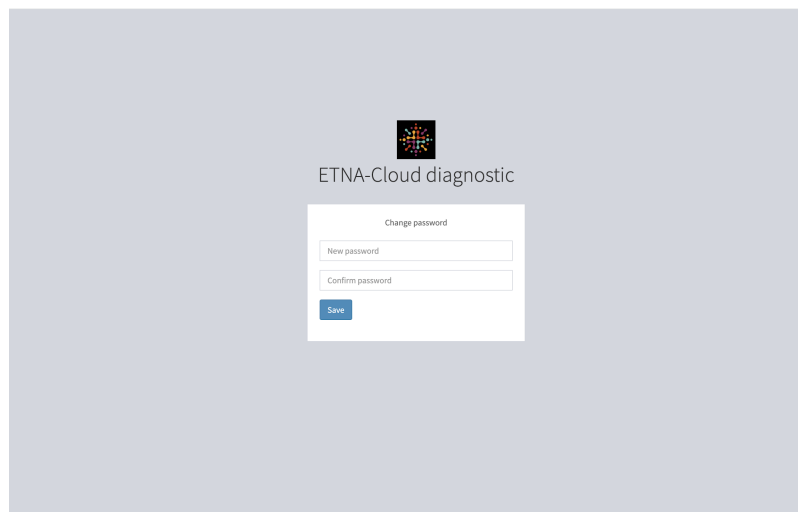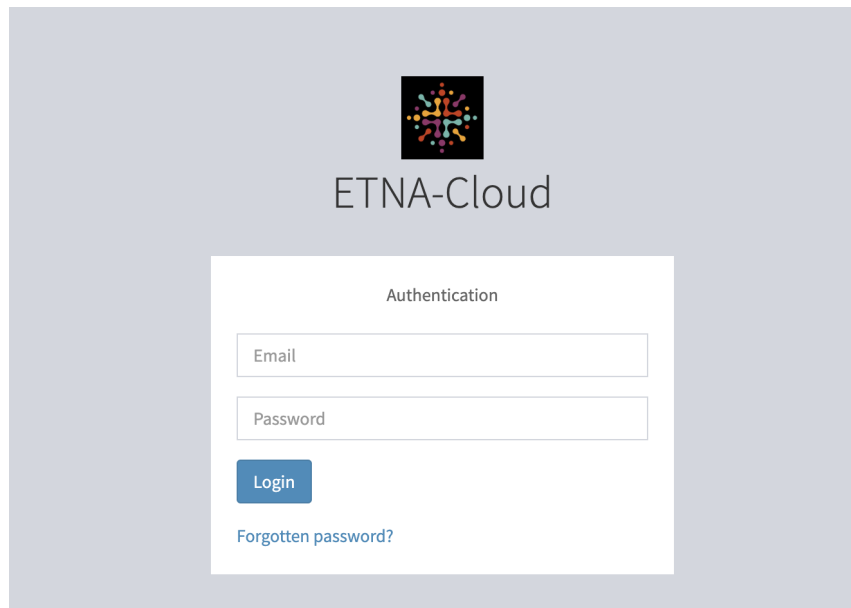

Upon entering and confirming your password, click on "Save" to complete the process.

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 3.2). 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.

3.2. Accessing the database (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 by Innodem Neurosciences.

To have access to the database's functionalities, you must enter your email address and password:

After clicking "Login", you will be prompted to enter the 2FA code that was sent to you by email (default settings):

Two factor
authentication

Enter the code received by email:

Resend code

Login
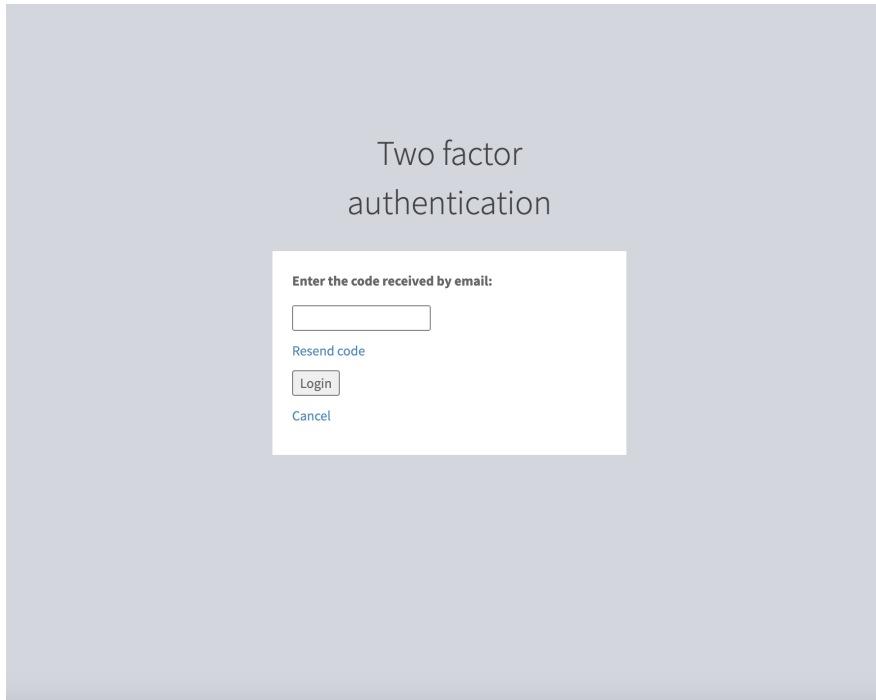
Cancel

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

ETNA-Cloud diagnostic

Accept

✓ I agree to the **Privacy Policy***

✓ I agree to the **Terms of Use***

Accept
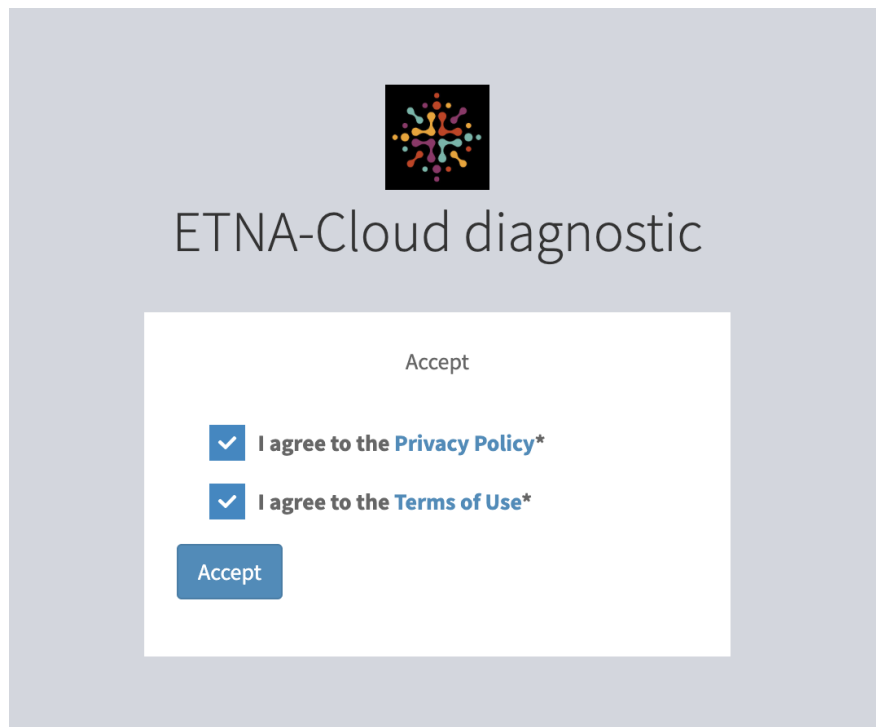
Once logged in, you can change your user profile settings by clicking on the dropdown arrow located next to your email address, followed by "Profile":
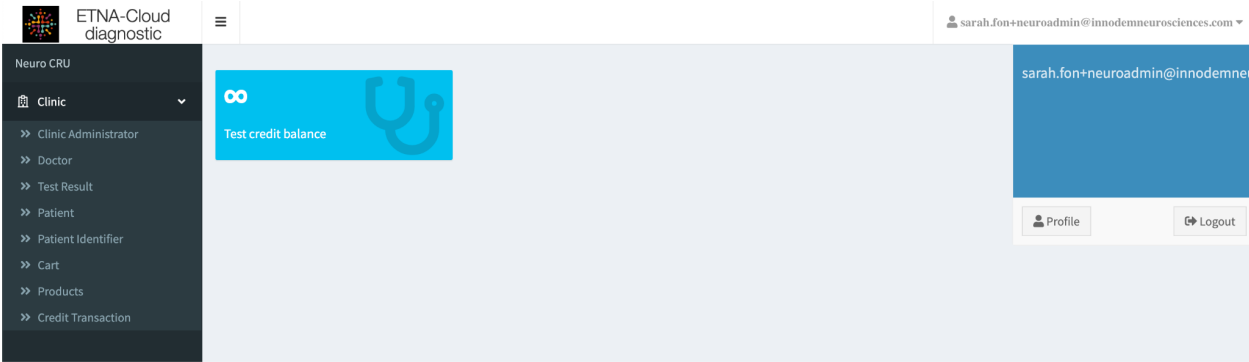
In the profile information window, click on "Edit" to modify "User" information and/or "Security" settings:
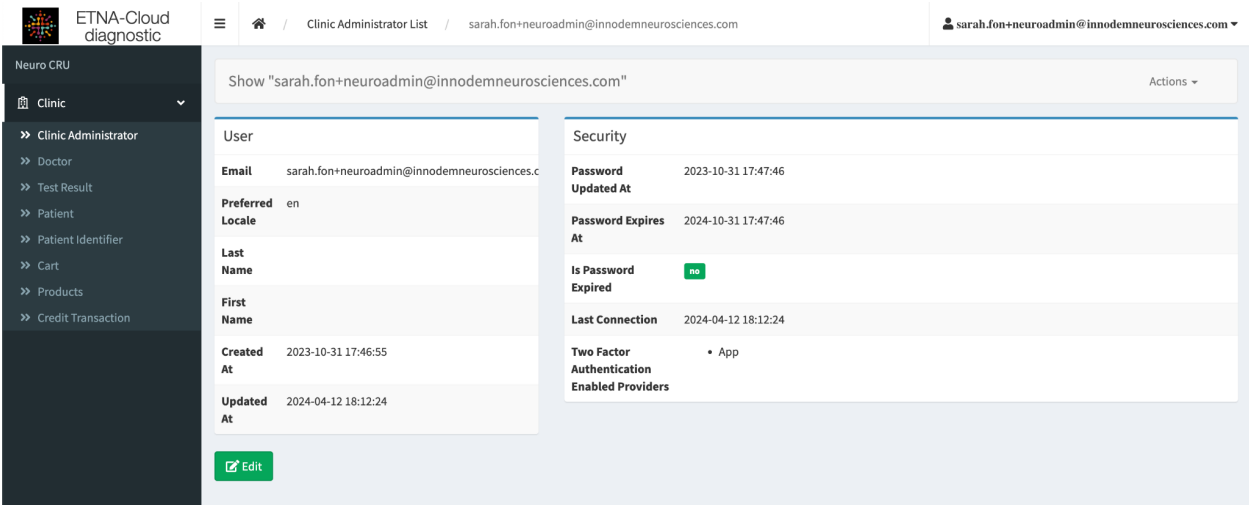
You can modify your first and last name, password and 2FA provider.

Optional: To change 2FA provider from Email to an Authenticator App, un-check the Email box and check the App box, then click "Update".
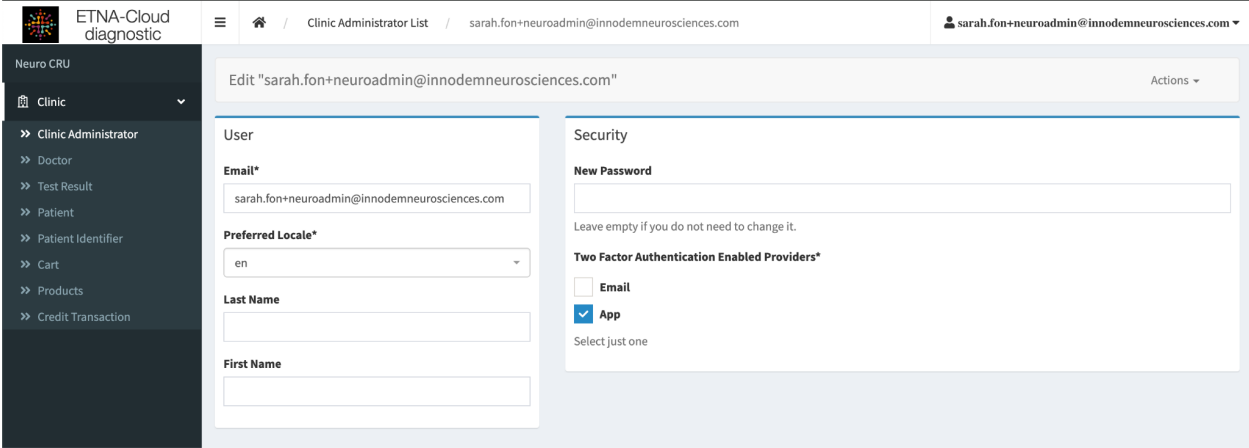
After clicking "Update", the following screen will appear (see below) to enable the 2FA provider of your choice. Simply scan the QR code with your 2FA Authenticator App and complete the set up (enter the code generated by the App and click "Enable").
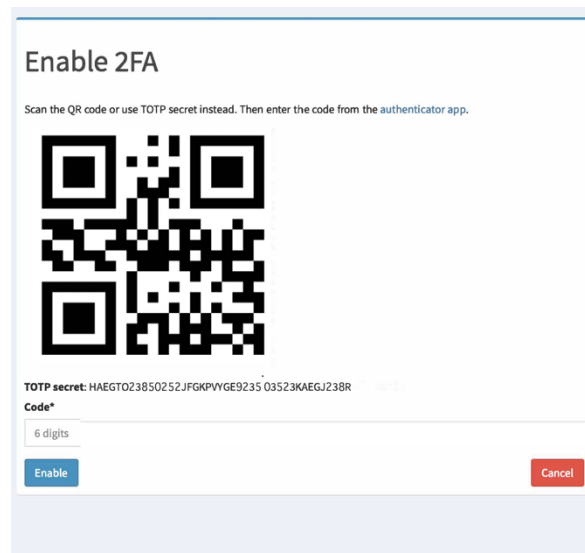
Upon making all necessary changes, it will bring you back to your profile page. Click "Update and close" to return to the "Clinic Administrator" tab.

3.3.   Create/Assign clinicians to the clinic

In order to create/assign clinicians to the specific clinic, you need to click on the "Clinic" dropdown arrow → "Doctor" → "Add new":

In the 'Create' window, you will then fill out the required fields and at the bottom have the option of "Create" and remain on the same page, "Create and return to list", or "Create and add another":
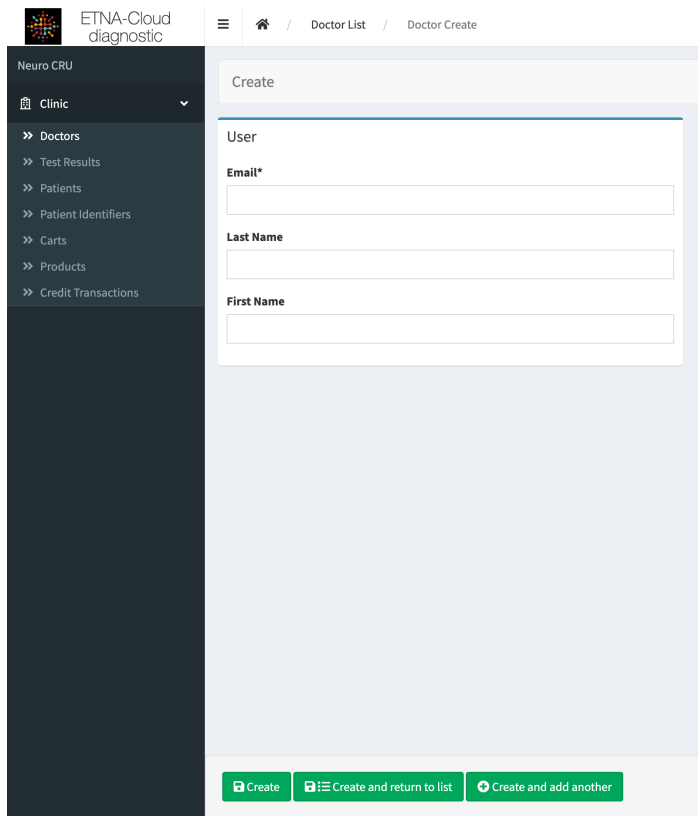
3.4.   Edit clinician Settings

You have the ability to have a full view of each clinician's user and security settings by clicking on the "Show" button under the "Action" column:
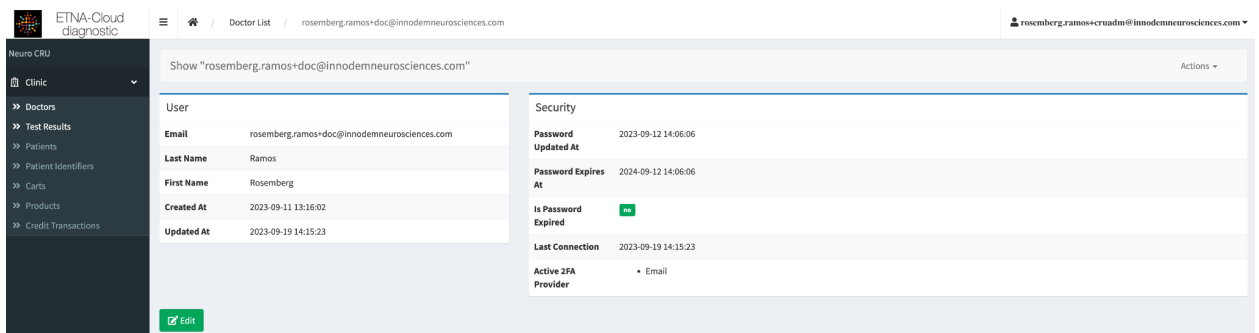
In addition, you also have the ability to edit a clinician's user information by clicking on the "Edit" button under the "Action" column:
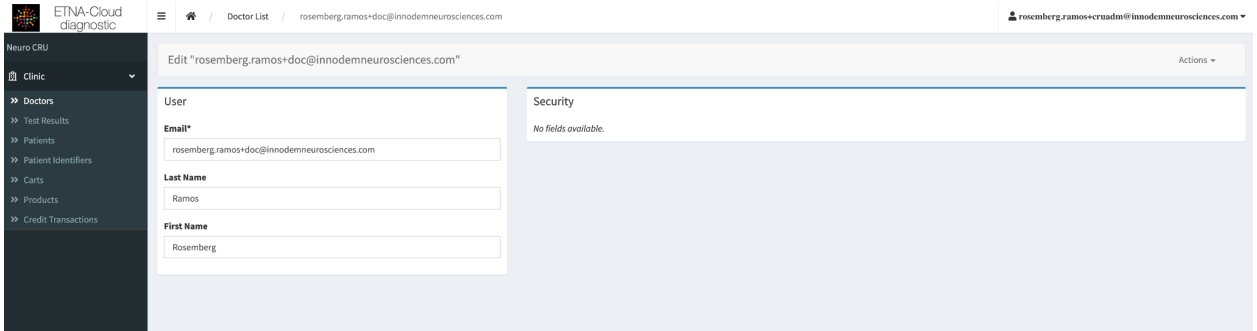
3.5. Clinician Password Reset

You are able to trigger a password reset upon receiving a clinician's request to do so. To do this, you must select the clinician from the clinician's list by applying the checkbox to the relevant email and select "Request Password Change" from the dropdown box at the bottom of the screen and then click the "OK" button:
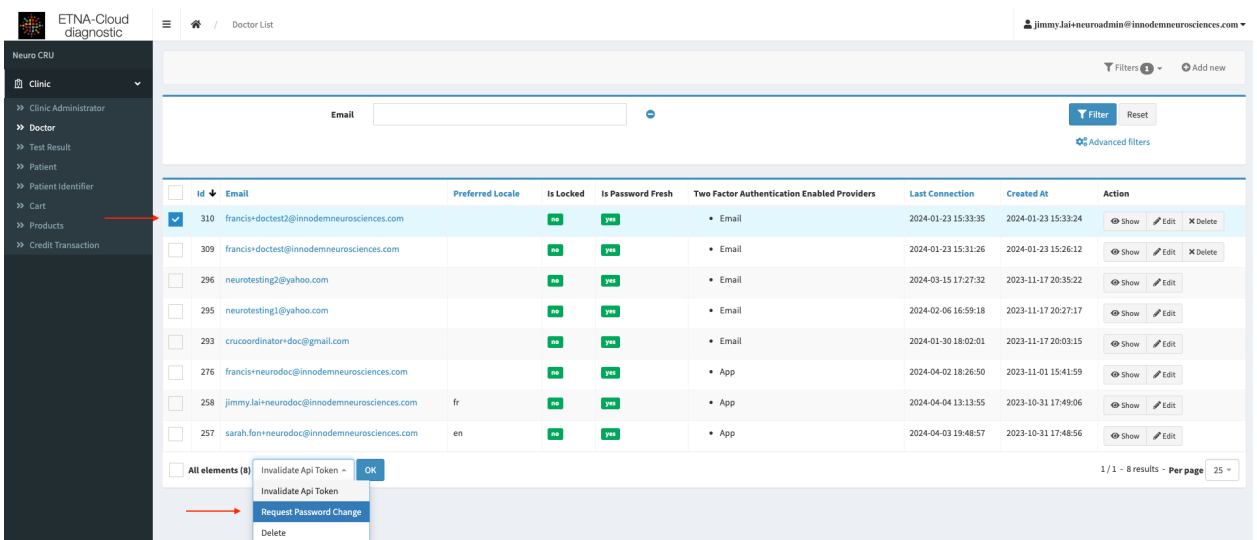
In the next window, there will be a confirmation step to validate the execution of the password change request. You simply have to click "Yes, execute" to complete the process.
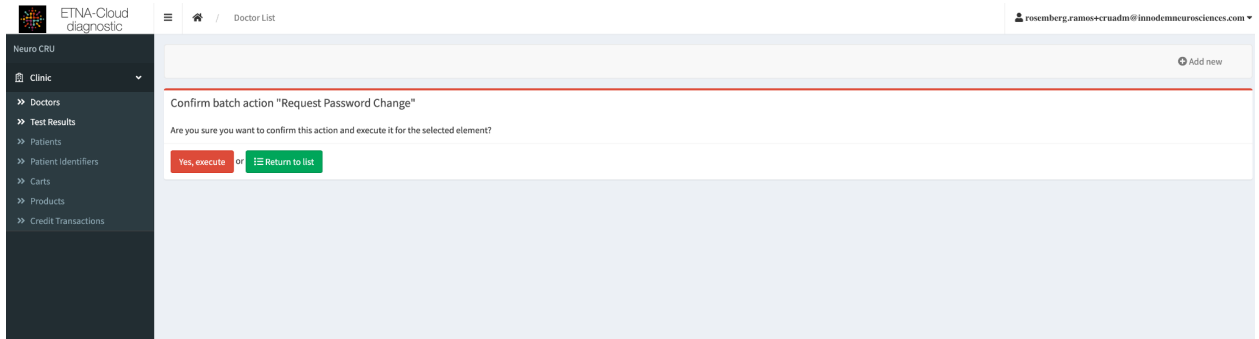
3.6. Create Patients

To create a new patient and to associate it to a specific clinician, you must click on the "Patients" menu/tab and click "Add new" in the top right corner
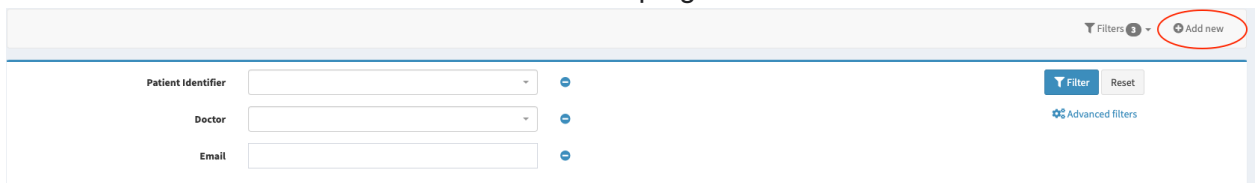
In the 'Create" window, you will fill out the required user fields (email, patient identifier, associated clinician, test frequency, test information visibility), and at the bottom have the option to "Create" and remain on the same page, "Create and return to list", or "Create and add another":

The list of all patients under the clinic can be seen in the "Patient Identifier" menu/window:

You can sort by "Identifier", "Date of Birth", and/or can also filter for a specific Identifier:

You can also "✏Edit" a specific patient's Date of Birth:
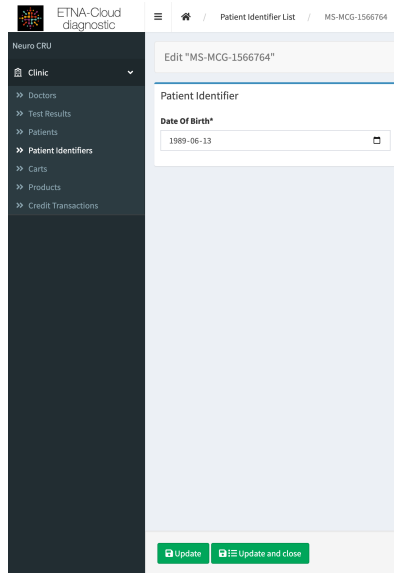
And/or, if necessary, clear/reset the patient's Face ID ("Clear Face ID"). This function is only to be used if a significant change to the patient's face has occurred and the app does not recognize him/her. This will usually be required when a patient calls the clinic about a frequent ID problem with the ETNA™-MS app. A physical meeting with the consulting clinician will be required to first verify the patient ID, then either the clinic admin or the clinician will reset the Face ID and the patient will run a new test that will record and save the new ID.
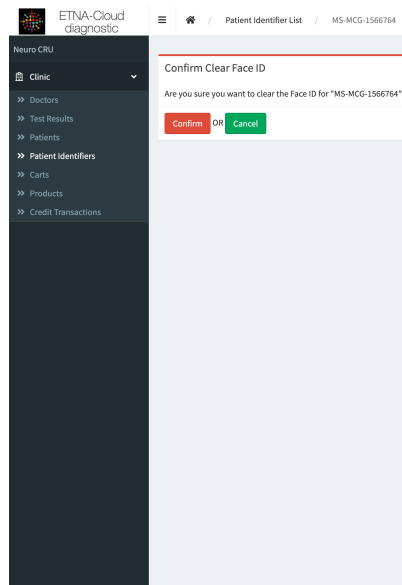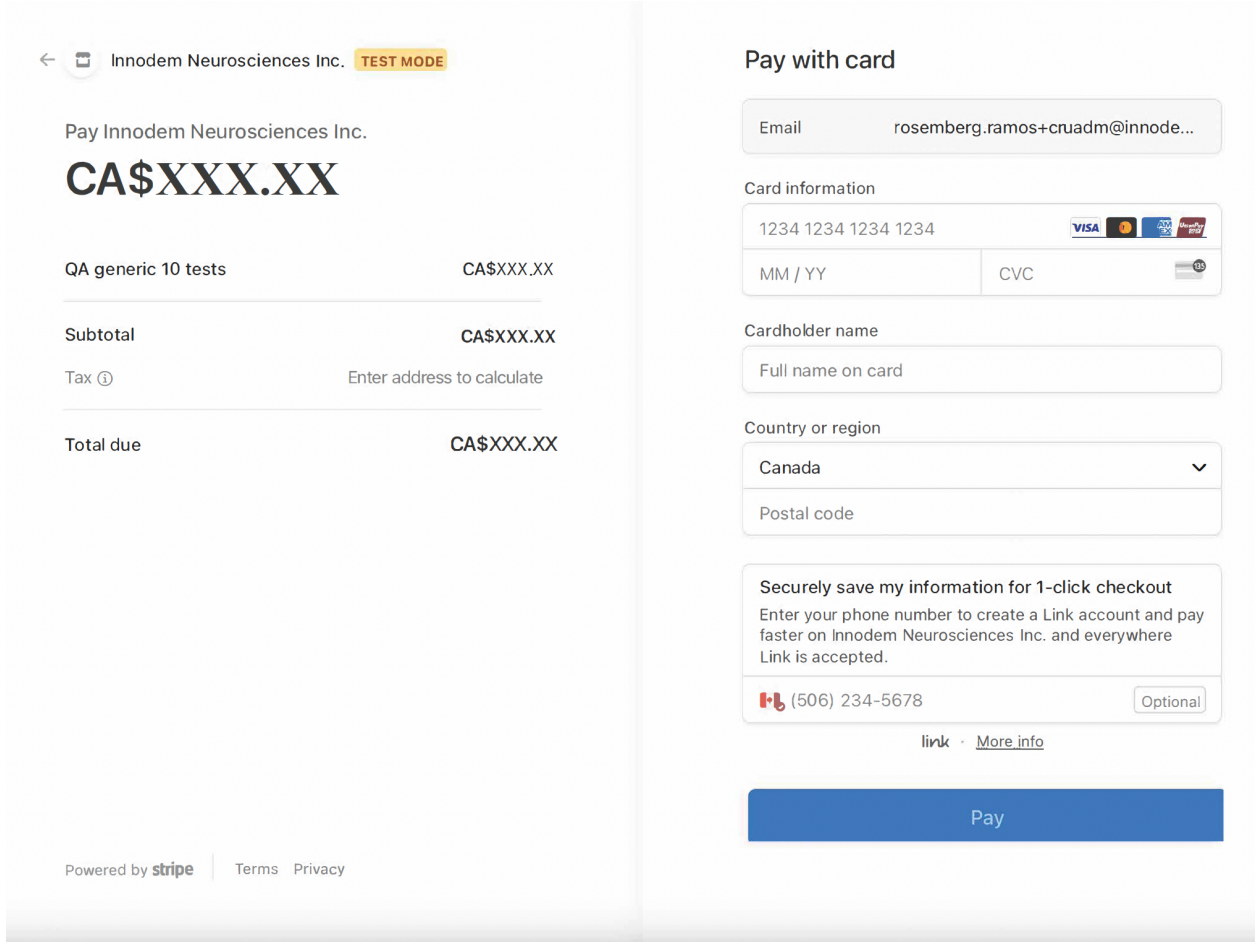
3.7. Loading/Reloading Test Bank

To load/add test credits to the clinic's account, you can do this by clicking on the "Products" tab. There, the necessary bundle(s) of tests can be purchased.
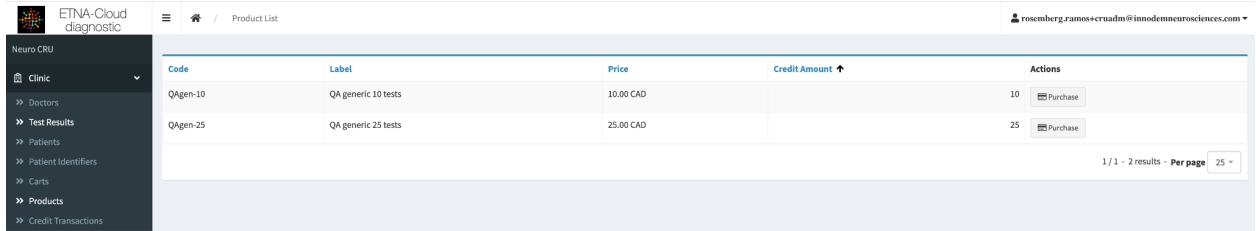
Upon selection to purchase the required bundle of tests, you will be directed to a secure stripe payment platform to complete the purchase/transaction:

Upon completion of the purchase, you will be redirected to the database "Carts" page where you will find the details of the executed transaction. In addition, you will receive a purchase confirmation email:

3.8.   View/Edit Test Results

You have access to limited test results and can only view the EDSS score result for each test. To view these results, you can click on "Test Results" in the left tab.

Once in the Test Results section, you have access to edit the average T25FW value of the patients if it was incorrectly entered into the ETNA™-MS App. To do this, you can click on "Edit" next to the corresponding patient.

You can then enter the average T25FW (average of the 2 trials) value of the patient in the field "Timed 25-foot walk". To save the newly entered value, click "Update". Once the average value is updated, the EDSS score will recalculate.

3.9.   Create Test Results Report

You can create a summary of tests consumed per period, and optionally for a doctor. To do this, click on the "Tests Results" tab, followed by "Test Results Report"

You can filter by day, month or a specific time frame for all tests performed at that clinic. You can also filter the tests by doctor during different time frames.

Filter

Doctor

| No selection | ≔ List | ⊖ Delete |

Created at

From

| yyyy-mm-dd | 🗓 |

To

| yyyy-mm-dd | 🗓 |

Group by*

| Month | ▾ |

Submit

Report from 2024-02 to 2024-02

Date	Total
2023-10	2
2023-11	18
2023-12	86
2024-01	38

3.10.   Set Test Prescriptions

You can prescribe at-home testing to patients following the instructions provided by (on behalf of) the clinician (Doctor). To do this, go to the "Test Results" tab and click on "Prescribe".

You will need to fill out all of the mandatory fields and choose the "Test Frequency." Once all fields are filled out, you can click on "Create" to confirm the creation of the patient and their test prescription.

Create

Email*

[   ]

No fields available.

Preferred Locale*

[en   ▾]

Last Name

[   ]

First Name

[   ]

Phone Number*

[(999) 999-9999]

Patient Identifier

[MS-MCG-1580448]   [☰ List]

Doctor*

[No selection]   [☰ List]

Test Frequency

[▾]

Test Information Visibility*

[private   ▾]

[🖫 Create] [🖫☰ Create and return to list] [⊕ Create and add another]

If a patient profile has already been created and you need to prescribe a test or change the test prescription on behalf of the Clinician, you must click on the "Patient" tab, followed by "Edit" next to the corresponding patient.
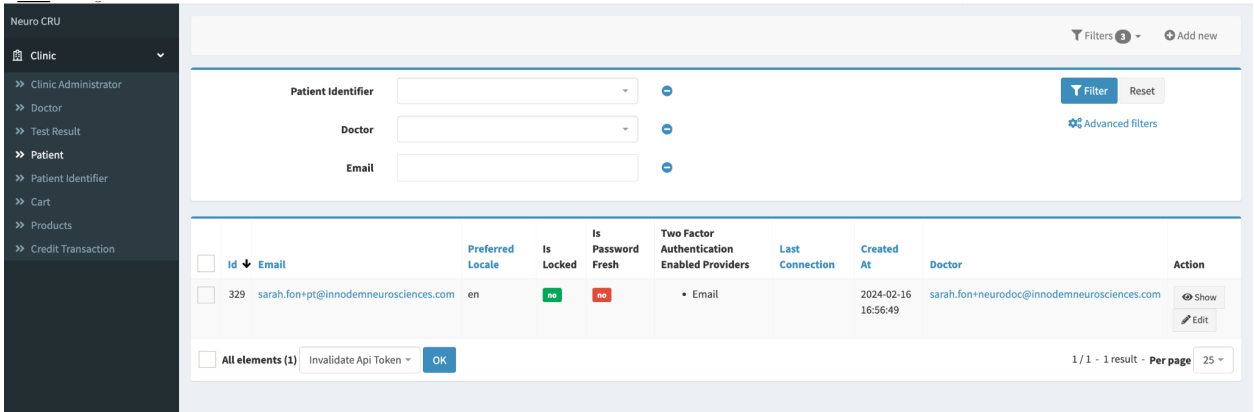
You will then be able to remove or edit the test prescription by clicking on "Test Frequency". To save the changes, click "Update".
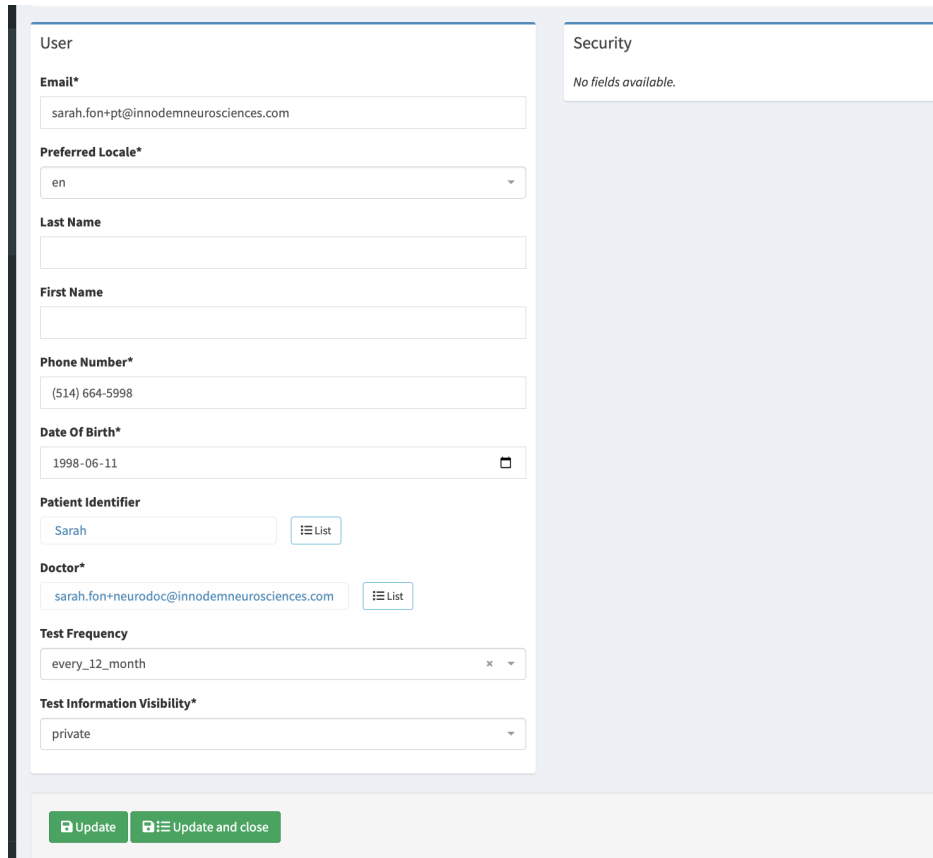
4.   Tech Support and Troubleshooting

4.1. Tech Support Contact Information

For technical support, please contact: support@innodemneurosciences.com