



Telephone: (216) 361-5410 or toll-free 1-855-GLNeuro (1-855-456-3876)

9:00 a.m. - 5:00 p.m. EST, Monday - Friday

Fax: (216) 361-5420

Customer Support: support@GLNeuroTech.com

Sales: sales@GLNeuroTech.com

Great Lakes NeuroTechnologies (glneurotech.com)

Mailing Address:



Great Lakes NeuroTechnologies Inc. 6100 Rockside Woods Blvd. Suite 415

Cleveland, Ohio 44131 United States of America

Phone: 216-361-5410, Fax: 216-361-5420



AF Pharma Service Europe SL Muntaner 281 08021, Barcelona Espana





UK Responsible Person AF Pharma Service UK LTD - 2022040500254753 Suite 140 Temple Chambers 3-7, Temple Avenue, London, CE4Y 0DA, England, United Kingdom

Phone: +447862223321

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Great Lakes NeuroTechnologies Inc.'s KinesiaU motor assessment system and its use is covered by one or more patents listed at: https://www.glneurotech.com/patents/

Use of the KinesiaU motor assessment system is governed by the terms and conditions and end user license agreement (EULA) at http://www.glneurotech.com/eula and privacy policy at https://www.glneurotech.com/support/privacy-policy/

KinesiaU™ is a trademark of Great Lakes NeuroTechnologies Inc.

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Chapter 1. About The KinesiaU[™] Motor Assessment System

The KinesiaU motor assessment system is a medical system designed to capture and evaluate motor symptoms using a smartwatch and smartphone app. Patients can view reports that show symptom severities over time.

Intended Use

Kinesia motor assessment systems are intended to monitor physical motion and muscle activity to quantify kinematics of movement disorder symptoms such as tremor and assess activity in any instance where quantifiable analysis of motion and muscle activity is desired.

In Canada, Kinesia systems may only be used for therapeutic (not diagnostic) purposes of nonserious situations or conditions.

In the EU, KinesiaU[™] motor assessment system may only be used to monitor physical motion and activity that are not physiological processes and may not be used for diagnostic or therapeutic purposes.

NOTE: Kinesia family of motor assessment systems are approved in many regions around the world, but due to individual country regulations, such as language translations, data restrictions, and other regulatory requirements, specific Kinesia products lines may not be approved or available and therefore should not be used in those locations.

Warnings

The product is to be used only under the direction of a qualified clinician and all changes to therapy regimens are to be based solely on the clinical judgment of the clinician.

Smartphone and Smartwatch Compatibility

The KinesiaU motor assessment system is designed for use with Android and iPhone smartphones and smartwatches but is NOT compatible with all models and is only validated for use with certain models.

For more information, please refer to:

https://www.glneurotech.com/products/kinesiau/frequently-asked-questions/

and for a list of validated models:

https://www.glneurotech.com/products/validated-devices/

Furthermore, some features may only be available in one version or the other, and some screens will be displayed differently from the images shown in this guide depending on the platform, software version, and device settings.

All data in this manual was created for example purposes. No actual patient, provider, or institution is included. Images used in this manual and pages in the portal may vary slightly.

Chapter 2: Accessing the KinesiaU Provider Portal

Purpose

The KinesiaU Provider Portal can be accessed at https://KinesiaU.glneurotech.com. The purpose of the KinesiaU Provider Portal is to give providers access to view their patient's KinesiaU data.

Getting Access to the Portal

Providers should contact Great Lakes NeuroTechnologies (GLNT) to get access to the portal. GLNT contact information can be found at https://www.glneurotech.com/about/contact/. The provider should provide the email address that they wish to associate with their account when contacting GLNT.

Once the account has been created, the provided email address will receive an email from KinesiaU with an activation link. Selecting this link will direct the Provider to the Provider Portal for account activation (Figure 1).

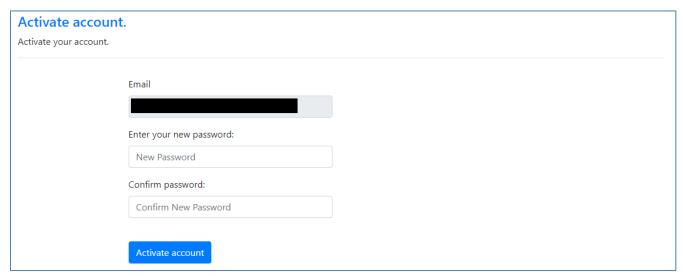


Figure 1. Activation Page

This activation link will expire after 24 hours. If a new link is required, please contact GLNT and an email with a new link will be sent to the email assigned to the account.

The account password must contain the following:

- A minimum of 8 characters
- A minimum of one lowercase letter
- A minimum of one uppercase letter
- A minimum of one number

Once a password has been accepted, the provider will be able to log into the portal and access its features.

Chapter 3: Navigating the Provider Portal

Login Page

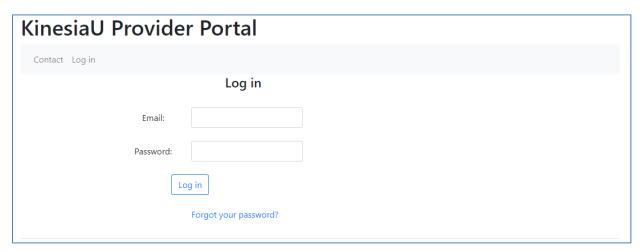


Figure 2. Portal Login Page

Log into the portal by entering the account email and password (Figure 2). If the password has been forgotten, the provider can select the "Forgot your password?" option. Enter in the account's email address and select "Reset my Password" (Figure 3). An email will be sent to the email address with a link. Select the link in the email and follow the steps to reset the password. The link sent in the email will not work if the user account has not been activated. The same password requirements listed previously apply to resetting the password (Figure 4).

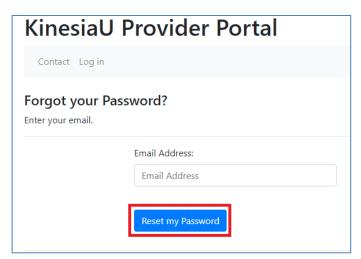


Figure 3. Forgot Password Page

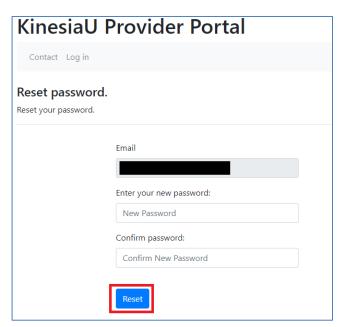


Figure 4. Reset Password

KinesiaU Provider Portal – Home Page

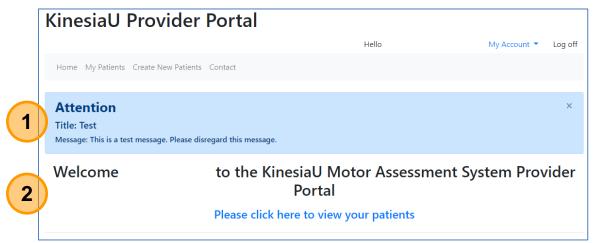


Figure 5. Home Page

The home page (Figure 5) gives the provider access to an overview of the following:

- 1. Any system messages from GLNT for all providers
- 2. Welcome message and a link to view list of available patients.

The navigation bar under the page header is available on all pages in the portal. This bar includes the following links: Home, My Patients, and Contact.

- **Home** When selected while on any other page, this will navigate back to the home page as shown in Figure 5.
- My Patients When selected, will take the provider to a list of all patients with active KinesiaU accounts, including any patients who have not yet collected any motion data (see Chapter 5: Patients and Adding New Patients).
- Contact When selected, will take the provider to a page with all contact information for GLNT.
- Create New Patients (Only available if the provider account has been set up to allow creation of new patients) When selected, will take the provider to a page where a new patient account may be generated (Figure 6 illustrates the navigation bar with and without this option).



Figure 6. Home Page with and without "Create New Patients" Option

See Chapter 6: Patient Reports and Notes and Chapter 7: Downloading Patient Reports and Data for further information on viewing and downloading reports.

Chapter 4: Editing Provider Account

My Account

Providers can make changes to their account under the "My Account" dropdown (Figure 7).

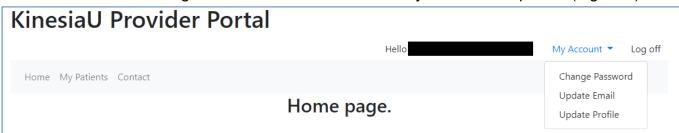


Figure 7. My Account Options

Options under the "My Account" dropdown include:

- **Change Password** Allows providers to update their password. Providers must know their current password to make this change. Password requirements still apply (Figure 8).
- **Update Email** Allows providers to change the email address associated with their account. This change will affect the email used to login. Providers must also know their password to make this change (Figure 9).
- **Update Profile** Providers can make changes to the information in their profile. This includes information like name, address, and phone number (Figure 10).

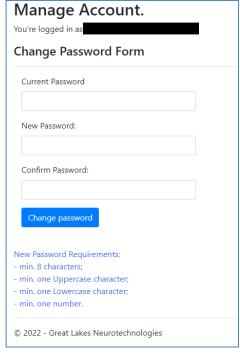


Figure 8. Change Password

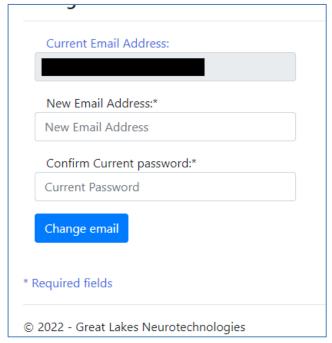


Figure 9. Update Email

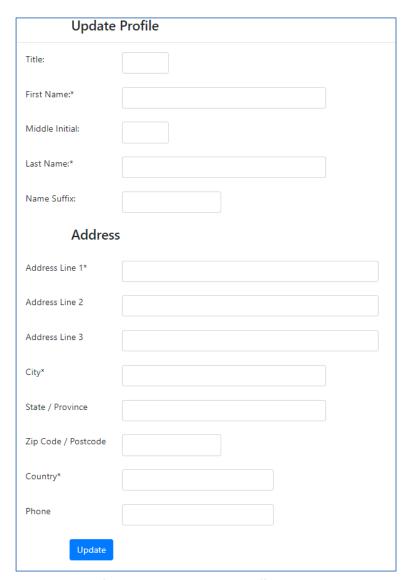


Figure 10. Update Profile Page

Required fields in the provider profile include First Name, Last Name, and Address for the institution to which provider is affiliated (Street, City, and Country).

Chapter 5: Patients and Adding New Patients

Patient List

Selecting the "My Patients" option in the navigation bar will take the provider to a list of the patients affiliated with their account (Figure 11). There are options to filter this list based on patient names and institutions. Selecting the link in the "Last Name", "Internal Id", or "Last Uploaded" fields will open that patient's details and results.

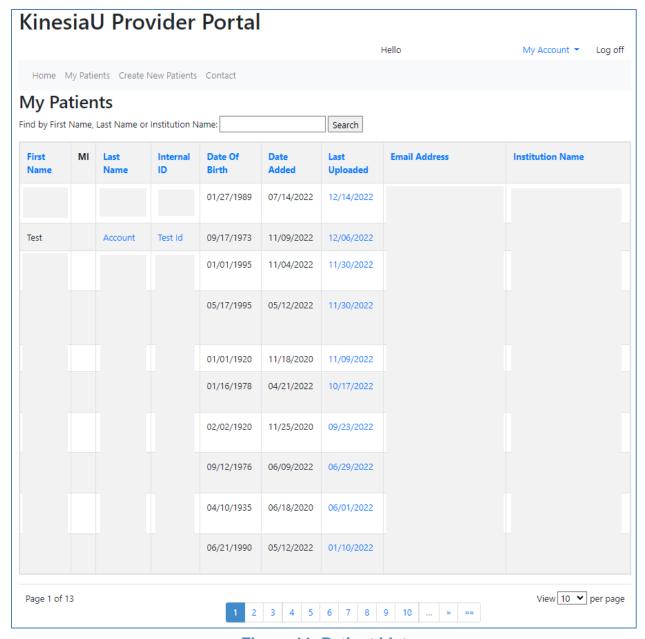


Figure 11. Patient List

Adding New Patients

Patient use of the KinesiaU system requires a prescription. The provider can mail or fax the prescription to GLNT or add the patient electronically in the KinesiaU provider portal. Please note, only verified providers may add patients electronically in the KinesiaU Provider Portal. Please contact GLNT to obtain permission to enter patients electronically, which will allow the provider to set up patients in real-time, including when the patient is on site with the provider.

For providers with permission to add patients, select the option in the navigation bar, towards the top of the website (Figure 12).



Figure 12. Create Patient Option

Fill in the required fields in the Patient Creation form (Figure 13). These fields include:

- a. First Name
- b. Last Name
- c. Date of Birth (year, month, and day)
- d. Patient email address.
 - This email address must be the email address that they will use to sign into the KinesiaU app and must be the email associated with their Apple Id on iOS devices or Google Play account on Android devices.

Create New Patient

Personal Details

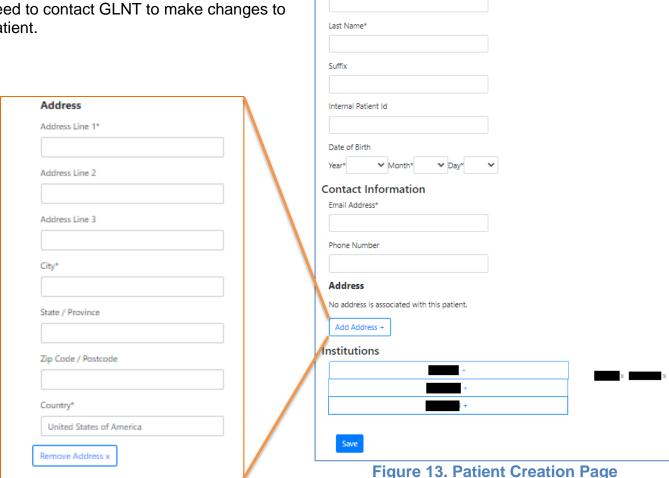
Title

First Name*

Middle Initial

- e. There is an optional section to add an address to the patient's profile. This section also has its own required fields.
- f. The provider may also add their institution(s) to this patient. Multiple institutions may be assigned to a single patient. Any provider within the selected institutions will be able to view this patient's assessment data.

Select 'Save' once the fields are filled correctly. Providers are not able to edit these fields. You will need to contact GLNT to make changes to the patient.



Chapter 6: Patient Reports and Notes

Patient Dashboard

When you select the link on the patient's Last Name, Internal ID, or the Last Uploaded date, that patient's Patient Dashboard is displayed (Figure 14). This dashboard will list all the patient's completed assessments ordered by the date the assessments were completed. Continuous assessments and Discrete assessments (Quick Tasks) appear as separate options.

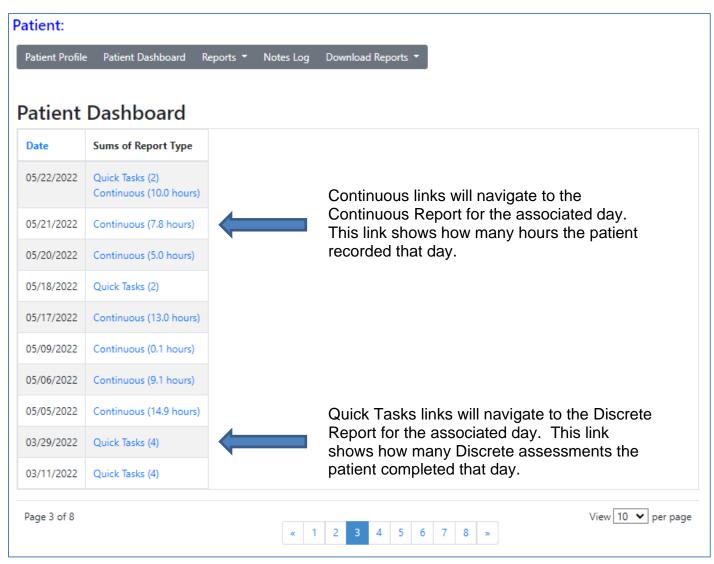


Figure 14. Patient Dashboard

Navigating the Patient Details

The bar on the top (outlined in red in Figure 15) can be used to navigate to different sections of the patient's details. The Reports dropdown (Figure 16) allows the provider to select the report to be viewed, and once selected will automatically refresh the screen. The Download Reports dropdown (Figure 16) menu lists the same report options, but when selected will take the provider directly to a screen showing the required criteria for the downloadable report. All reports can be downloaded as PDFs. Raw data can be downloaded as a text file (Tab Separated Values) or Excel (.xlsx) formatted spreadsheet, depending on the report type.

See Chapter 7: Downloading Patient Reports and Data for more information on downloading reports.

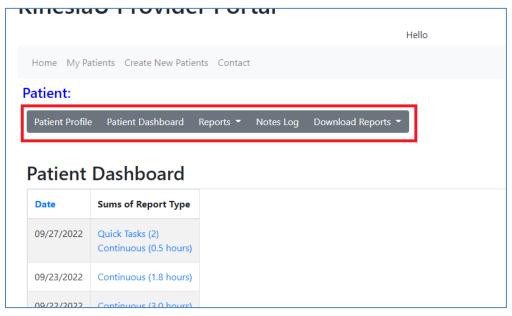


Figure 15. Patient Navigation Bar



Figure 16. Report and Download Report Options

Patient Profile

Patient Profile (Figure 17) displays information regarding the patient. Some information cannot be changed, except by contacting GLNT. The "Internal Patient ID" is an editable patient label that providers may utilize as an additional identifier for patients. When populated, this field will show in the "Internal ID" column on the My Patients screen.

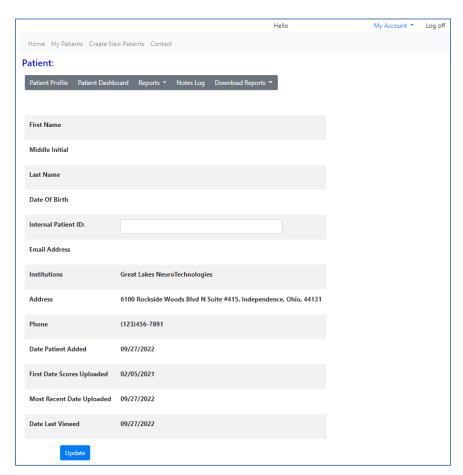


Figure 17. Patient Profile

Patient Reports

KinesiaU patients can complete Continuous or Discrete (task-based) assessments. Based on this, there are multiple reports available to the provider to view patient assessment data. These reports include:

- Discrete Reports Results from Quick Task assessments, where the patient runs the Arms Resting and Wrist Rotation tasks. This is similar to what patients can view in the app.
- **Continuous Report** Results from the Continuous assessments where the symptom severities are shown every two minutes.
- **Continuous Hourly Reports** Results from the Continuous assessments where the data is displayed in hourly bins. This is similar to what patients can view in the app.

All reports display medication and exercise entries made by the patient.

Discrete Reports

Results in these reports display discrete (quick task) data (Figure 18). The provider can select "Symptom Types" (red box) to change what symptom values are being displayed. These symptoms include Tremor, Dyskinesia, Slowness, and an average of the three.

The options for "Report Type" (orange box) change the range for the report. Options include:

- Monthly Displays data averaged for the month. Shows 12 months at a time, organized by year.
- **Weekly** Displays data averaged for the week, from Sunday to Saturday. The bars are labelled based on the Sunday of that week. Shows about 8 weeks (~2 months) at a time.
- **Daily** Displays data averaged for each day, displaying one week at a time.
- **Hourly** Displays data averaged for each hour of a day.
- By Assessment Displays the results of each assessment, displayed one day at a time.

Figure 19 show different examples of Report Types and Symptoms.

The "Go to Date..." (green box) option allows the provider to change the date range used in the report chart. The "Go to Date..." option also allows the provider to enter a specific date and the chart range will update to include that date in the display. Selecting the "Go to Earliest Date" option displays the earliest assessment available for the patient. "Previous" and "Next" (purple boxes) move the chart to the previous or next date range.

The number below the date represents the number of results averaged at that timepoint. The symbols and indicate medication and exercise events, respectively.

Hovering over the

medication icon will detail the medication taken. This is only available in the By Assessment and Hourly views of this report. If the patient did not specify the medication taken, the event will appear as "Not Specified".

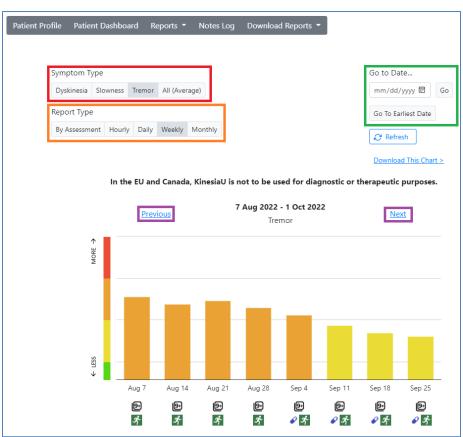


Figure 18. Discrete Report Example



Figure 19. Examples of the different symptom results are shown in the Discrete Report by assessment (top left), hourly (top right), daily (bottom left), and monthly (bottom right).

Continuous Report

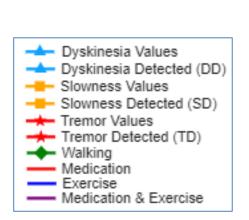
The Continuous Reports (Figures 20-22) display data from the patient's continuous assessments in 2-minute intervals. Providers can display or hide symptoms in the chart by selecting the options towards the top of the report.

- **Symptom Detect** (top of graph area) Symbols on the TD (Tremor Detect), SD (Slowness Detect), and DD (Dyskinesia Detect) lines represent instances where the corresponding symptom was detected.
- **Symptom Values** (main graph area) This chart displays the calculated values for each symptom on a 0 to 4 scale, with 0 being normal and 4 being the most severe. The provider can hover the cursor over the symbols on the chart to see more details about that entry such as values, timestamps, and number of steps (Figure 22).
- **Walking** (bottom of graph area) This line represents if the patient was walking (as measured by the iPhone) during the two-minute bin. Hovering over the symbol will display the number of steps.
- Diary Events Medication and exercise events appear on the chart as color-coded vertical lines.
 You can hover over the dot at the top of the line to view more details on the events, including the specific medication the patient selected.

The options outlined in purple in Figure 20 allow the provider to select the displayed date, refresh the page and download the current chart. The "Go to Date…" option allows the provider to manually enter a date or select a date from a calendar. Only the dates with data will be selectable options in the calendar. Dates with no viewable data will be grayed out.

The option labelled "Go to Earliest Date" will display the earliest assessment for the patient. Likewise, the "Go to Latest Date" option goes to the most recent patient assessment.

The "Download This Chart >" option will navigate the provider to a page to download a PDF report. The presets of this report will include the currently displayed chart in its options.



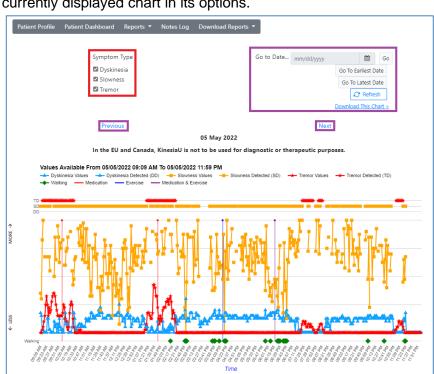


Figure 20. Continuous Interval Report Legend and Example



Figure 21. Report with only dyskinesia and tremor selected



Figure 22. Hovering over a symptom to show its value

Continuous Hourly Reports

Continuous Hourly Reports (Figure 23) display continuous assessment data in the same manner that the KinesiaU app displays on the patient's device. Results are shown in the hourly format and only one day at a time. You can hover your cursor over a bar to display the numerical value.

The options outlined in red in Figure 23 and labelled "Symptom Type" allow the provider to select which symptom results are being displayed.

The options outlined in purple in Figure 23 allow the provider to change what day is being displayed.

Hovering over the medication icon will display the medications taken within that hour and the time the individual medications were taken. If the patient did not enter in a medication with the event, the medication information will display as "Not Specified".

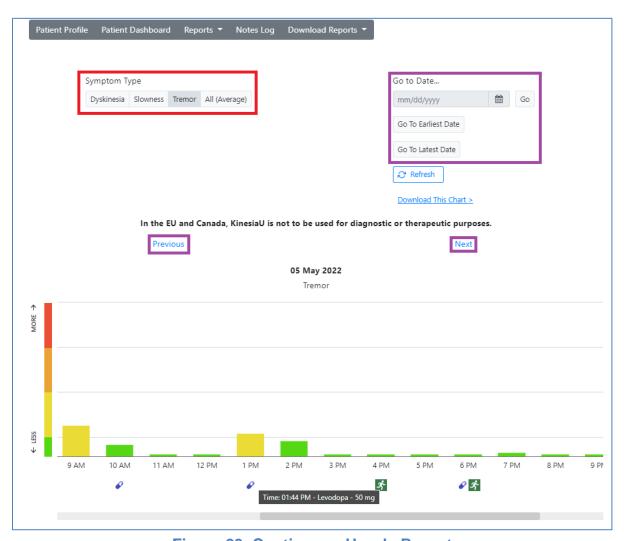


Figure 23. Continuous Hourly Report

Chapter 7: Downloading Patient Reports and Data

The KinesiaU Provider Portal has a variety of features that allow the provider to download custom PDFs of patient reports. There are also options to download tab separated value (tsv) and Excel Workbook (xlsx) files.

Downloading Discrete Reports

Reports can be customized by start and end dates. Only assessment data collected on and within the selected date range will appear in the report. (Figure 24)

Only one Report Type can be selected but multiple symptoms can be included. The PDF file will have separate sets of charts for each selected symptom.

Patient notes are optional and can be included in the report. The provider can select to include all patient notes, only the notes generated between the report start and end dates or set a separate date range of generated notes. These notes will appear on the last page of the PDF file.

Once these settings are entered, the provider can select the "Download PDF Report" button to have a PDF generated and saved. Selecting "Download Raw Data Report" will download a text file (tab separated values) with the numerical values based on the report settings (Figure 25).

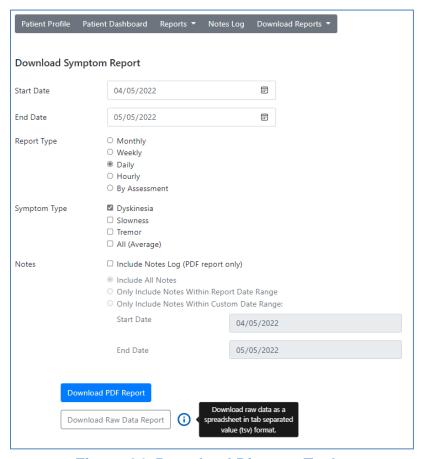


Figure 24. Download Discrete Tasks

```
KinesiaU Raw Value Report
Patient:
5 May 2022 - 12 May 2022
Dyskinesia
The data shown on this report are quantified symptom values. For more information, please visit www.KinesiaU.co
Date Dyskinesia Value Slowness Value
                                          Tremor Value
                                                            Medication Exercise
                                                                                    Value Count
2022-05-05T00:00:00
                                          False False 0
2022-05-05T01:00:00
                                          False False 0
2022-05-05T02:00:00
                                          False False 0
2022-05-05T03:00:00
                                          False False 0
2022-05-05T04:00:00
                                          False False 0
2022-05-05T05:00:00
                                          False False 0
                                          False False 0
2022-05-05T06:00:00
                                          False False 0
2022-05-05T07:00:00
                        0.0 1.3 1.8
2022-05-05T08:00:00
                                          False False 1
2022-05-05T09:00:00
                                          False False 0
2022-05-05T10:00:00
                                          Time: 10:00 AM - Not Specified
                                                                              False 0
2022-05-05T11:00:00
                                          False False 0
2022-05-05T12:00:00
                                          False False 0
2022-05-05T13:00:00
                        0.0 2.0
                                   1.6
                                          Time: 01:44 PM - Levodopa - 50 mg
                                                                              False 1
2022-05-05T14:00:00
                                          False False 0
2022-05-05T15:00:00
                                          False False 0
2022-05-05T16:00:00
                                          False True 0
2022-05-05T17:00:00
                                          False False 0
2022-05-05T18:00:00
                        0.4 0.8
                                   0.0
                                          Time: 06:17 PM - Rasagiline
                                                                        True 1
2022-05-05T19:00:00
                                          False False 0
                                          False False 0
2022-05-05T20:00:00
2022-05-05T21:00:00
                                          False False 0
                                          False False 0
2022-05-05T22:00:00
                                          False False 1
2022-05-05T23:00:00
                                   0.0
                                          False False 0
2022-05-06T00:00:00
                                          False False 0
2022-05-06T01:00:00
                                          False False 0
2022-05-06T02:00:00
2022-05-06T03:00:00
                                          False False 0
                                          False False 0
2022-05-06T04:00:00
                                          False False 0
2022-05-06T05:00:00
                                          False False 0
2022-05-06T06:00:00
2022-05-06T07:00:00
                                          False False 0
```

Figure 25. Discrete Result Text File Example

Downloading Continuous Reports

The customization menu for "Download Continuous Reports" includes options to set a start date and end date, and which symptoms appear in the charts (Figure 26).

Once these are set, selecting "Download PDF Report" will download a PDF. The contents of the file will include charts similar to the charts in the patient's continuous interval reports. Only charts on and within the range of the start and end dates will be displayed and only the selected symptoms will appear in the charts.

Selecting "Download Raw Data Report" will download an Excel Workbook file that contains two worksheets. One for the values for each 2-minute interval during the continuous assessment and a second for the diary events (Figure 27). Columns in this Excel file include:

- Date
- Time
- Dyskinesia Value
- Dyskinesia Detect
- Slowness Value
- Slowness Detect

- Tremor Value
- Tremor Detect
- Steps
- Pauses
- Diary Entries

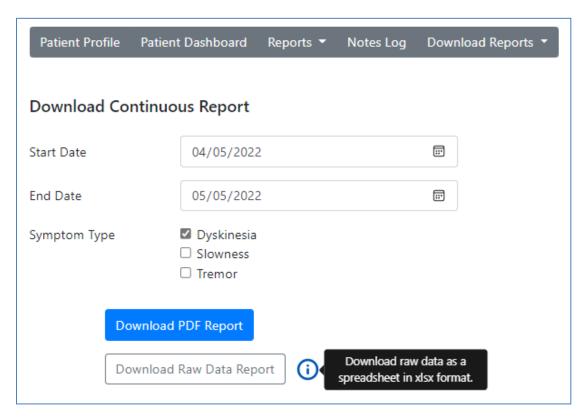


Figure 26. Download Continuous Report

KinesiaU Ra	w Value Re	eport							
Patient:									
5 May 2022 -	- 12 May 20	122							
Continuous	2 Minutes	Symptom Values							
Tremor, Dys	kinesia, Sl	owness							
The data sho	own on thi	s report are quanti	fied symptom valu	es. For more info	rmation, please vi	sit www.Kinesi	aU.com. This re	ort should	d be trea
Date	Time	Dyskinesia Value	Dyskinesia Detect	Slowness Value	Slowness Detect	Tremor Value	Tremor Detect	Steps	Pause
05/05/2022	09:09 AM	0.7	0	1.4	1	0	0	0	False
05/05/2022	09:11 AM	0.6	0	1.2	1	0	0	0	False
05/05/2022	09:13 AM	0.1	0	3.3	1	0.1	1	0	False
05/05/2022	09:15 AM	0.1	0	4	1	0.2	1	0	False
05/05/2022	09:17 AM	0	0		0	0.4	1	0	False
05/05/2022	09:19 AM	0	0	2.7	1	0.6	1	0	False
05/05/2022	09:21 AM	0	0		0	1	1	0	False
05/05/2022	09:23 AM	0	0		0	1.3	1	0	False
05/05/2022	09:25 AM	0.5	0	2.7	1	1	1	0	False
05/05/2022	09:27 AM	0.5	0	2.7	1	0.6	1	0	False
05/05/2022	09:29 AM	0.1	0	2.7	1	0.9	1	0	False
05/05/2022	09:31 AM	0.1	0	2.2	1	0.7	1	0	False
05/05/2022	09:33 AM	0	0		0	0.8	1	0	False
05/05/2022	09:35 AM	0	0		0	1.1	1	0	False
05/05/2022	09:37 AM	0	0		0	1.3	1	0	False
05/05/2022	09:39 AM	0	0		0	1.4	1	0	False
05/05/2022	09:41 AM	0.4	0	2	1	1.4	1	0	False
05/05/2022	09:43 AM	0.2	0	3.4	1	1.3	1	0	False
05/05/2022	09:45 AM	0.3	0	2.6	1	1	1	0	False
05/05/2022	09:47 AM	0	0		0	0.8	1	0	False
05/05/2022	09:49 AM	0.3	0	3.8	1	0.6	1	0	False
05/05/2022	09:51 AM	0	0	3.4	1	0.6	1	0	False
05/05/2022	09:53 AM	0.5	0	2.5	1	0.6	1	0	False
05/05/2022	09:55 AM	0.2	0	3.2	1	0.6	1	0	False
05/05/2022	09:57 AM	0.1	0	3	1	0.6	1	0	False
05/05/2022	09:59 AM	0	0		0	0.6	1	0	False
05/05/2022	10:01 AM	0.1	0	3.3	1	0.7	1	0	False
15/05/2022	10.03 AM	n	n		n	1	1	0	Falca

KinesiaU Rav	v Value Rep	ort				
Patient:						
5 May 2022 - 12 May 2022						
Diary Entires	;					
Medication A	And Exercise					
The data shown on this report are quantified symptom value						
Date	Time	Entry	Medication Name			
05/05/2022	10:00 AM	Medication	Not Specified			
05/05/2022	01:44 PM	Medication	Levodopa - 50 mg			
05/05/2022	04:16 PM	Exercise				
05/05/2022	06:17 PM	Exercise				
05/05/2022	06:17 PM	Medication	Rasagiline			

Figure 27. Continuous Recording Excel File Example

Downloading Continuous Hourly Reports

Providers also have the option to download patient continuous hourly data reports (Figure 28).

The provider may set a start date and an end date, choose what symptoms are included in the report, and whether to include patient notes.

Charts will be generated for dates on and within the range of the start and end dates where the patient has completed a continuous assessment.

Continuous assessments need to contain over 31 minutes of active recording within the hour to generate a value for that hour.

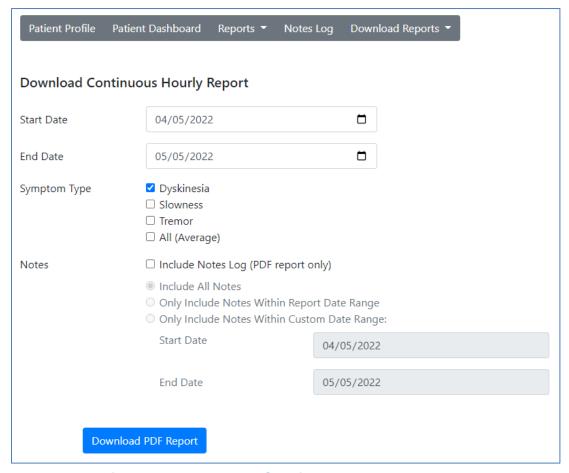


Figure 28. Download Continuous Hourly Reports

Chapter 8: Support

Additional information and FAQ and GLNT contact information can be found at https://www.KinesiaU.com.

For information regarding KinesiaU Research Mode and clinical studies, please contact Great Lakes NeuroTechnologies.

Telephone: (216) 361-5410 or toll-free 1-855-GLNeuro (1-855-456-3876)

9:00 a.m. - 5:00 p.m. EST, Monday - Friday

Fax: (216) 361-5420

Customer Support: support@GLNeuroTech.com

Sales: sales@GLNeuroTech.com

Great Lakes NeuroTechnologies (glneurotech.com)