



User Manual

Cognivue Clarity® User Manual

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2 About This Guide

This User Manual contains information that describes the operation of Cognivue Clarity®. Additional information can be found at www.cognivue.com. Cognivue Support personnel can be reached via at 1-585-433-2992 from 9-5 pm ET or by emailing support@cognivue.com.

UM-410-U Cognivue Clarity® User Manual 3/22/2023



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3 About Cognivue Clarity®

Cognivue Clarity® is a computerized cognitive assessment aid to evaluate cognitive function objectively, quantitatively, and reliably. Cognivue Clarity® relies on a series of 10 subtests. Using the results from these subtests, Cognivue Clarity® creates short, easy-to-interpret reports. These cognitive scores and classifications provide a baseline for future comparison and enable discussion between the clinician and the test-taker about cognitive health.

3.1 Intended Purpose

Cognivue Clarity® is indicated for use as an adjunctive tool for evaluation cognitive function in ages 18 and over.

3.2 Indications for Use

Cognivue Clarity® is indicated for use as an adjunctive tool for evaluating cognitive function in ages 18 and over. It is not a stand-alone diagnostic tool. The device results are to be assessed and interpreted by a licensed clinician.

Warnings

- 1) Cognivue Clarity® does not identify the presence or absence of clinical diagnoses.
- 2) Cognivue Clarity® cannot be used as a stand-alone diagnostic.
- 3) Cognivue Clarity® is intended to be used in clinical professional offices or similar settings.

3.3 Clinical Reference Information

Cognivue® scores ≤ 50 are consistent with impairment (moderate to severe), scores ≥ 75 are consistent with no impairment (normal) and scores between 51 and 74 are consistent with intermediate impairment (low). In the Cognivue® clinical validation study, 401 participants completed ≥ 1 testing session, and 358 completed 2 sessions 1-2 weeks apart. The study showed that SLUMS cut-off scores of < 21 (impairment) and > 26 (no impairment) corresponded to Cognivue® scores of 54.5 (NPA = 0.92; PPA = 0.64) and 78.5 (NPA = 0.5; PPA = 0.79), respectively. Cognivue® classification scores demonstrated good agreement with SLUMS scores (weighted κ 0.57; 95%CI: 0.50-0.63). Reliability analyses showed similar scores across repeated testing for Cognivue® ($R^2 = 0.81$; $r = 0.90$) and SLUMS ($R^2 = 0.67$; $r = 0.82$).

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Cognivue Clarity® has been validated with Cognivue Advanced® in a clinical trial with 31 subjects. The correlation between Advanced and Clarity was very high positive (0.943), and Clarity's test reliability analysis was similar to Advanced ($R^2 = 0.859$; $r = 0.927$)

Additional information is available in the following references:

- Cognivue Advanced De Novo Clearance, DEN130033
- Diego Cahn-Hidalgo, Paul W Estes, Reina Benabou, "Validity, reliability, and psychometric properties of a computerized cognitive assessment test (Cognivue®)," World Journal of Psychiatry 2020 January 19; 10(1): 1-11.
- Cognivue Clinical Analysis Report CAR-401-A.

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4 Device Description

The **Cognivue Clarity®** is a portable, battery-powered, laptop-like device that includes a wireless keyboard with a touchpad, a rotary CogniWheel®, and a CogniCover®. The CogniWheel® is the sole patient input device. The CogniCover® is designed for privacy and to reduce distraction and light reflections on the computer screen. The CogniCover® and CogniWheel® are designed to fold for portability.

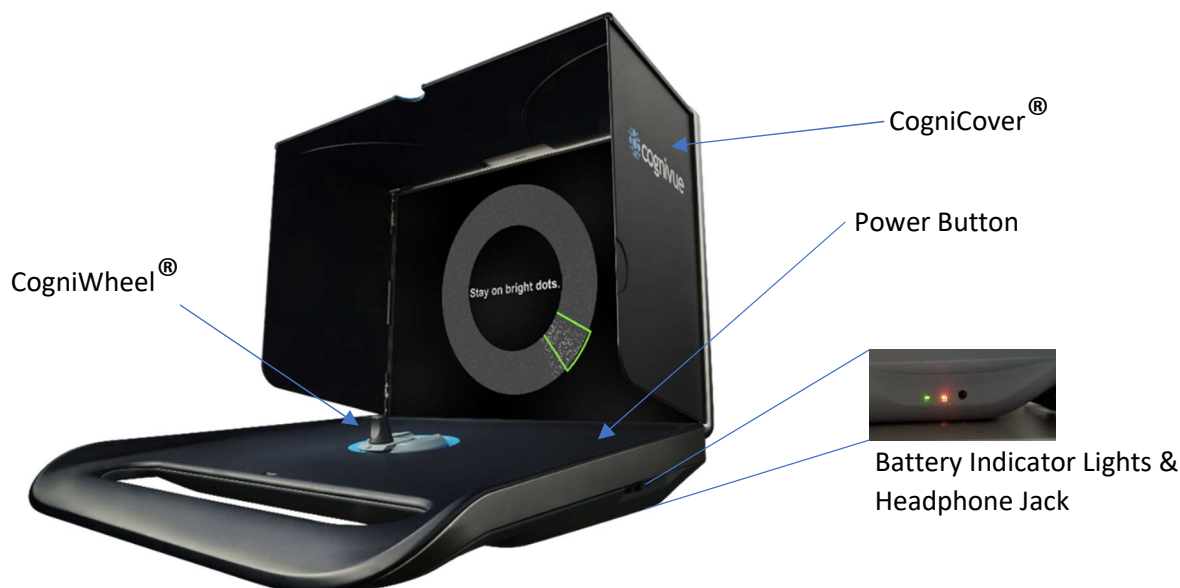


Figure 1 Cognivue Device (Front)



Figure 2 Cognivue Device (Rear)

USB (for Keyboard)

Ethernet

Battery Charger

5 Power Management

The Cognivue Clarity®, much like a laptop, is designed to be battery-powered during regular use but can also be used when the provided charging adapter is plugged in.

The battery sustains 4 hours of intensive, off charger usage but can last for over 8 hours typical usage. The battery recharges in approximately 4 hours if depleted completely.

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5.1 Indicator Lights

There are two indicator lights on the right side of the device.

| | <i>Left Light</i> | <i>Right Light</i> |
|-------------------------------------|-------------------|--------------------|
| <i>Device is unpowered</i> | Off | Off |
| <i>Device is discharging</i> | Orange | Off |
| <i>Device is charging</i> | Green/Off | Orange |
| <i>Plugged in and fully charged</i> | Green/Off | Green |

Table 1 Charging Lights

5.2 Screen Sleep

When the Cognivue device is not in use for 10 minutes, the screen will go into sleep mode. When the screen is asleep, it can be awakened by clicking or pressing a key on the keyboard.

5.3 Power Alert

When the device is low on battery charge and not plugged in, if an attempt is made to start a testing session, e.g., upon clicking the **Run a Test** button on the main screen, it will display an alert and not allow the testing session to begin. Plugging in the device will allow tests to be administered. In order to avoid running out of power during a test, please charge the device for at least one hour before again administering tests on battery power.

6 Recommendations for Use

6.1 General Testing Location

When possible, choose a test location that reduces distractions (e.g. an exam room, office, or conference room rather than a busy hallway).

Put the device on a flat, stable surface that is ergonomically comfortable for the patient. The patient should be able to comfortably reach and manipulate the CogniWheel® and view the computer screen. Avoid placing the Cognivue Clarity® in a location where there may be distractions behind the device which are visible to the patient.



Avoid Distractions in the Patient Viewing Area Behind the Device

Figure 3 Example Setup

DO NOT place the device on the patient's lap for the test. This does not provide a stable surface during the administration of the test. This interferes with a patient's ability to take the test.

6.2 Cleaning and Disinfecting Cognivue Clarity®

Cognivue recommends sanitizing the Cognivue Clarity® before and after administering a test using one of the following procedures:

- **Preferred:** Use sanitizing or disinfectant wipes to thoroughly wipe the CogniWheel® and the base of the device where the patient palm rests. **DO NOT** wipe the screen!
- Please turn the power off on the Cognivue Keyboard using the appropriate slider switch prior to cleaning/transport; this prevents unintentional keypress combinations on the device.
- In the event wipes are not available, spray a sanitizer onto a paper towel, being careful not to oversaturate the paper towel, and thoroughly wipe the CogniWheel® and the base of the device where the patient palm rests. **DO NOT** wipe the screen, and do NOT spray sanitizer or disinfectant directly onto the device!

6.3 Use of Personal Protective Equipment


In addition to sanitizing the device, Cognivue recommends that operators and patients wear a disposable mask while interacting with the device. If it is not possible to sanitize the device between patients, Cognivue recommends operators and patients use disposable gloves.

7 Network Connectivity


Cognivue Clarity® requires connection to a qualified network for initial setup and configuration but thereafter can be used to administer assessments offline. However certain features like Portal Sync, Printing, and Drive Mapping will be unavailable until the device is reconnected to a qualified network. In addition to these features, continued connection to qualified networks allows Cognivue to deploy both general purpose and security patches to the devices.

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7.1 Basic Wired Connection

1. Connect one end of a standard network cable to an active network jack at your location
2. Connect the other end to the network port on the back of the Cognivue Clarity® device
3. If not automatically connected, follow the instructions above, selecting **Wired Connection 1**.
4. Success is indicated when the icon in the top left corner is the  Network icon.

7.2 Basic Wi-Fi Configuration

1. Click on the  Network icon in the status bar at the upper left corner of the screen
2. From the drop-down menu, select the available Wi-Fi network to which you wish to connect
 - a. If there are a large number of networks available, you may see a **More networks** option which you can check if you do not see your network listed.

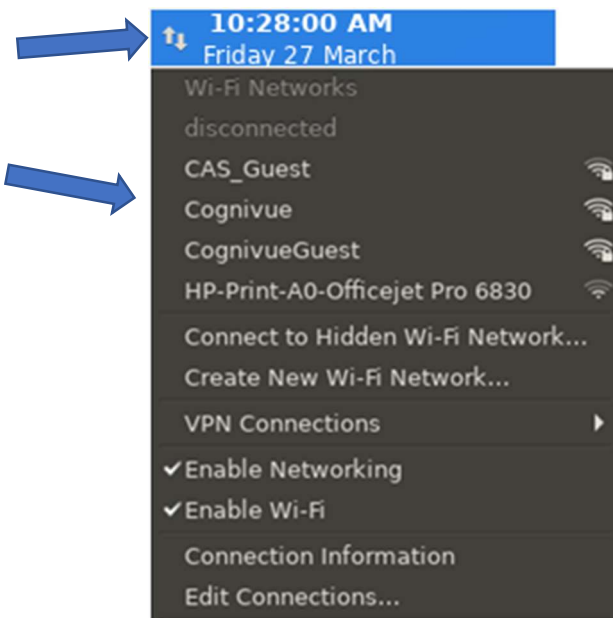



Figure 4 Network Menu

3. Enter the Wi-Fi password for the selected network
4. Click **Connect**



Figure 5 Authentication Prompt

5. Connection can take a few seconds. A successful connection is indicated by when the network icon in the top left changes to the  Wi-Fi connection strength icon indicating network connectivity.

In the future, the device will remember the network and automatically connect when possible.



Figure 6 Network Selection Menu

7.3 Connection Details

When logged on to a Cognivue Clarity® device, administrators can view and test the current network configuration information on the Network Configuration window

To open the **Network Configuration** window

1. Log in
2. Select **Device Administration >> Settings**
3. Click the **Network** tab

The **Network Configuration** window contains network configuration properties and their values

- The **Refresh** button refreshes the displayed connection values
- The **Test Connection** button confirms that the device has network connectivity
- The **Advanced Configuration** button opens settings for more advanced networking options

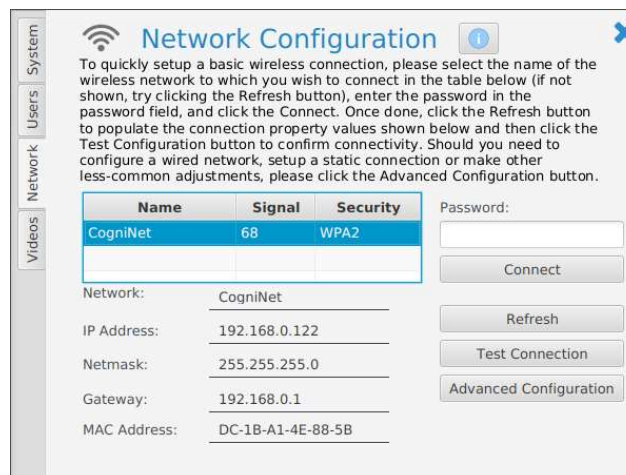


Figure 7 Network Configuration Screen

Advanced Configuration is intended for use by network administrators and/or Cognivue Support Staff.

The most common usage of this functionality is outlined in the guide for Static IP Configuration

8 Security

8.1 Login

The user **Login** window is how you log in to a device.

It is how you log in to the device. Logging in with an individual account ensures an audit trail for viewing patient reports and running assessments.

The image shows a login screen with a light gray background. It contains two input fields: 'Username:' and 'Password:'. Below the 'Username:' field is a blue 'Login' button. Below the 'Password:' field is a gray 'Shutdown' button.

Figure 8 Login Screen

The **Shutdown** button appears on the **Login** window can be used by anyone to power down the device. Clicking the **Shutdown** button will prompt confirmation before shutting down the device.

Note: This is the preferred way to shut down the device. The physical power button should be used only if necessary.

8.2 User Management

Each Cognivue Clarity® user should have their own user account to ensure audit trail and safety of patient data.

User accounts can be assigned as an Administrator or an Operator on the **User Management Screen**.

| | Administrator | Operator |
|--|---------------|----------|
| Setting up new accounts | X | |
| Delete accounts | X | |
| Changing accounts | X | |
| Configure network connection | X | X |
| Entering patient data & running a test | X | X |
| Running a test with an intro video | X | X |
| Viewing past test reports | X | |

Table 2

Cognivue Clarity® User Manual

To open the **User Management Screen**

1. Log in
2. Select **Device Administration >> Settings**
3. Click the **Users** tab

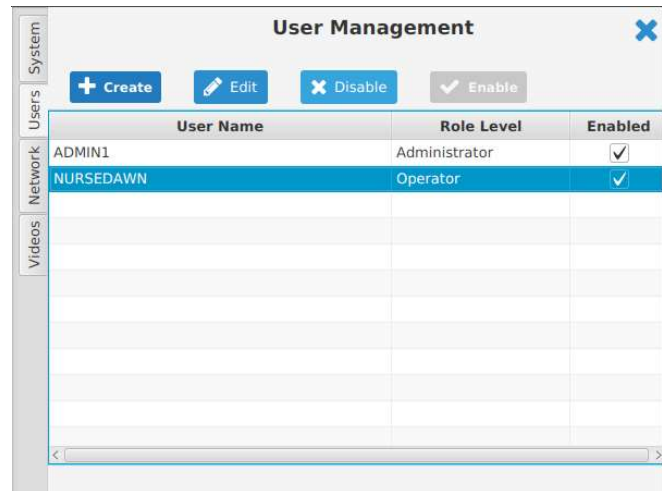


Figure 9 User Management Screen

8.3 User Creation

From the **User Management Screen**

1. Click **Create**
2. Fill out form
3. Click **Save**
4. Click **Yes** to confirm when prompted

The screenshot shows the 'User Creation' window. It contains the following fields and controls:

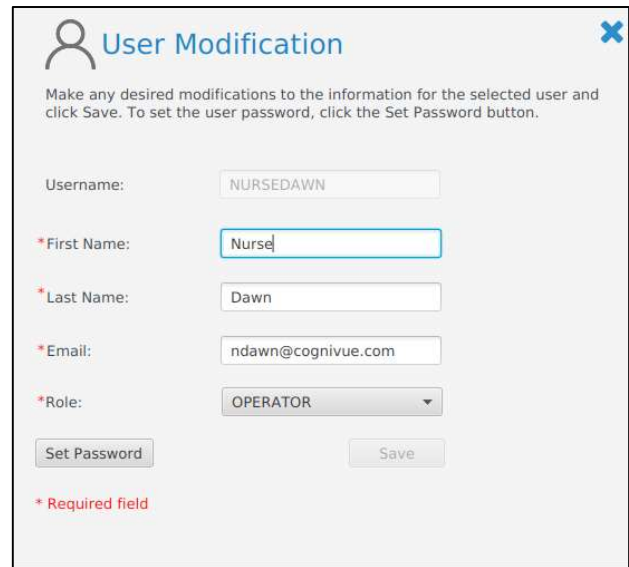
- *Username:** Text input field.
- *Password:** Text input field with placeholder 'password'.
- *Confirm Password:** Text input field with placeholder 'confirm password'.
- *First Name:** Text input field with placeholder 'first name'.
- *Last Name:** Text input field with placeholder 'last name'.
- *Email:** Text input field with placeholder 'email'.
- *Confirm Email:** Text input field with placeholder 'confirm email'.
- *Role:** Dropdown menu with 'OPERATOR' selected.
- * Required field** label in red text.
- Save** button.

Figure 10 User Creation Screen

8.4 User Modification

From the **User Management Screen**

1. Select a user from the list
2. Click **Edit**
3. Make the desired changes
4. Click **Save**
5. Click **Yes** to confirm when prompted



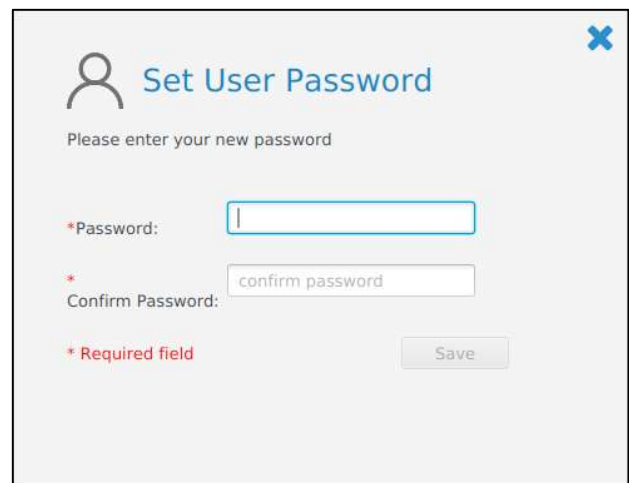
The 'User Modification' screen features a title bar with a user icon and a close button. Below the title, a subtitle reads: 'Make any desired modifications to the information for the selected user and click Save. To set the user password, click the Set Password button.' The form contains several fields: 'Username' (text box with 'NURSEDAWN'), '*First Name' (text box with 'Nurse'), '*Last Name' (text box with 'Dawn'), '*Email' (text box with 'ndawn@cognivue.com'), and '*Role' (dropdown menu with 'OPERATOR' selected). At the bottom left is a 'Set Password' button, and at the bottom right is a 'Save' button. A red asterisk legend indicates that fields marked with an asterisk are required.

Figure 11 User Modification Screen

8.5 Password Reset

From the **User Management Screen**

1. Select a user from the list
2. Click **Set Password**
3. Fill out the Set Password form
4. Click **Save**
5. Click **Yes** to confirm when prompted



The 'Set User Password' screen features a title bar with a user icon and a close button. Below the title, a subtitle reads: 'Please enter your new password'. The form contains two fields: '*Password' (text box) and '*Confirm Password' (text box with placeholder text 'confirm password'). At the bottom right is a 'Save' button. A red asterisk legend indicates that fields marked with an asterisk are required.

Figure 12 Password Reset

8.6 Auto-Logout

The device will be logged out after 30 minutes of inactivity to prevent unauthorized access.

8.7 Password Expiration

Password expiration forces users to change their account passwords after a set number of days. Password expiration applies to all user accounts but is disabled by default.

Users are warned about password expiration for three days before it expires. Once expired, the user will be forced to change their passwords before they can log in.

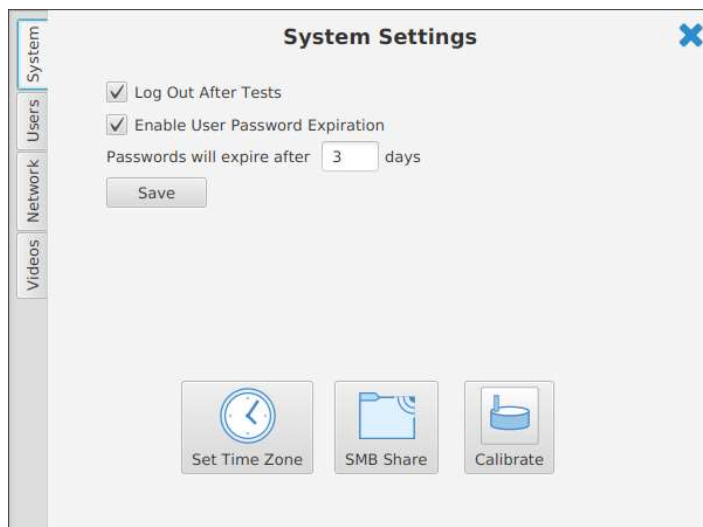


Figure 14 Password Expiration Section



Figure 13 Password Expiration Prompt

To enable/disable password expiration:

1. Navigate to **Device Administration >> Settings**
2. Click the **Enable Password Expiration** checkbox
3. When this feature is enabled, a password lifetime must be specified
4. Enter the number of days in the text field labeled **Password Expires after**

8.8 Disabling Accounts

To maintain an audit trail, User Accounts cannot be fully removed from the system. Disabling prevents the user from logging in. Disabled accounts can be reactivated in the future.

From the **User Management Screen**

1. Click on a user in the list
2. Click the **Disable User** button
3. Click **Yes** to confirm when prompted

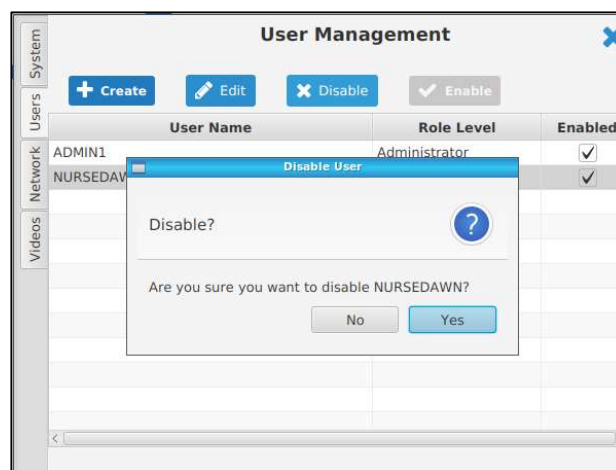


Figure 15 Disable User Prompt

9 System Settings

The Cognivue Clarity® device includes several configurable options. The ability to make these configuration changes is available only to Administrator users on the **System Settings** screen

The System Settings Screen is on the System tab of the Device Administration page

To open the **System Settings** Screen

1. Log in
2. Select **Device Administration**
 >> **Settings**
3. Click the **System** tab

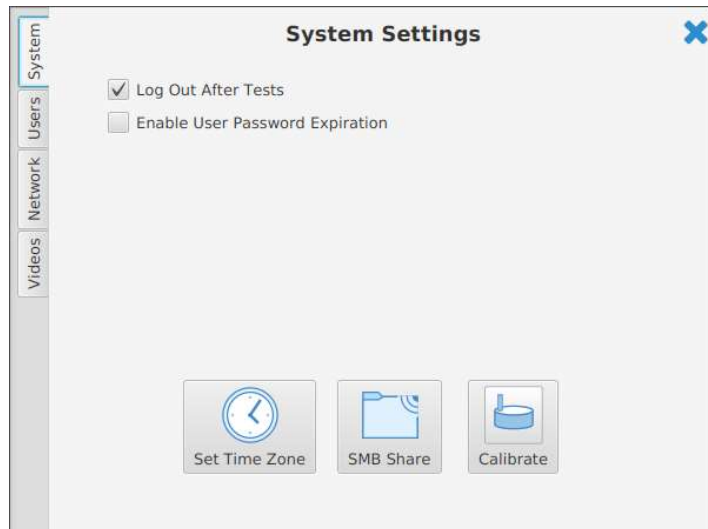


Figure 16 System Settings Screen

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9.1 Video Settings

This screen allows Administrators to ensure the intro video will always be shown to patients. If the option is unchecked here, the choice is left to the Operator who sets up the test for the patient.

- Always Play Intro Video → Play the introduction video before every test
- Always Play Instructional Videos → Plays short instructional videos during the test
- Always Play Post Test Video → Plays a congratulatory video when the test completes

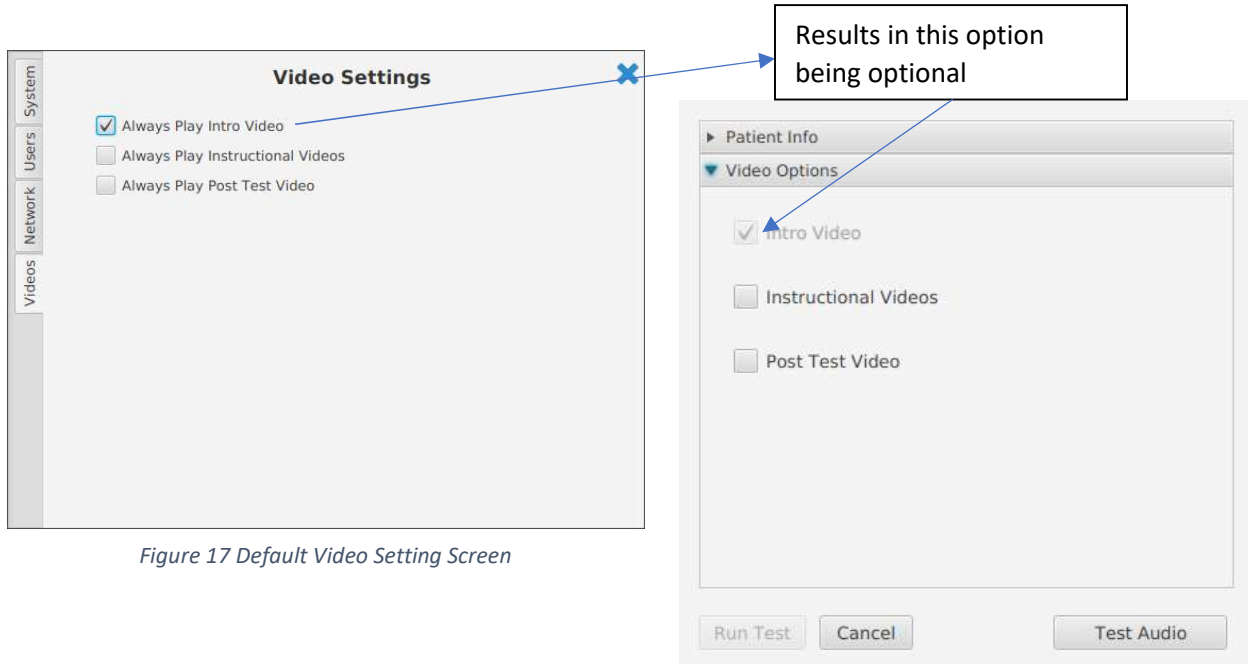


Figure 17 Default Video Setting Screen

Figure 18 Assessment Setup Screen (Videos)

10 Report Settings

The Clarity reports are configurable to meet the needs of the practice using the device. These configuration changes are available only to Administrator user accounts on the **Report Configuration** screen.

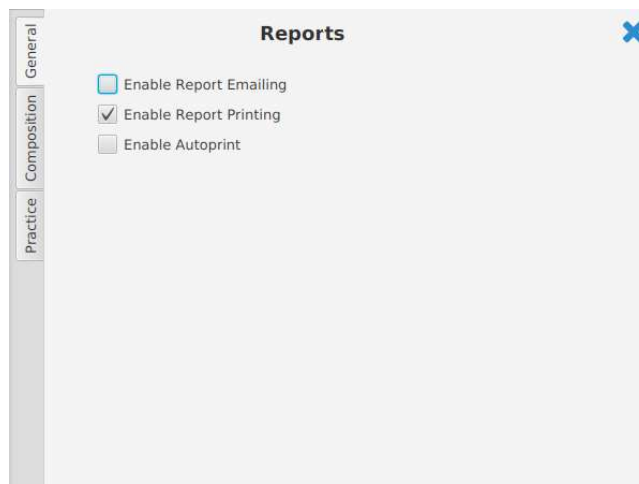


Figure 19 Default Report Settings Screen

10.1 Report Emailing

Cognivue Clarity® provides the ability to send the test report via an encrypted email to a patient following completion of a test. This feature is enabled by default. An Administrator can disable this functionality by unchecking the **Enable Report Emailing** checkbox.

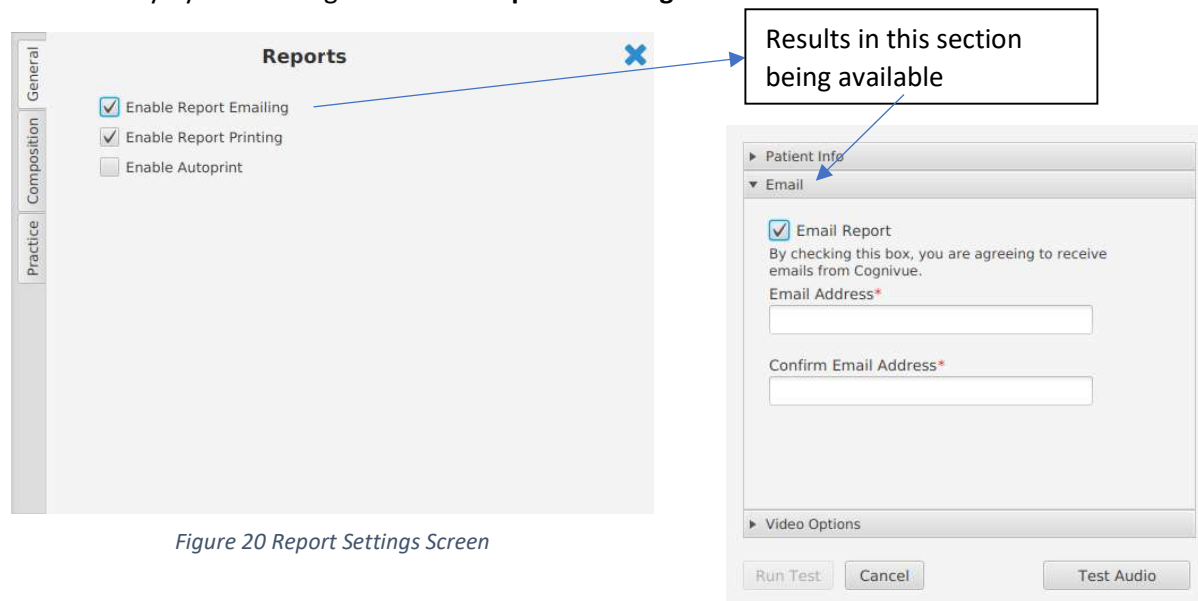


Figure 20 Report Settings Screen

Figure 21 Assessment Setup Screen (Email)

When enabled, the option for the patient to receive a copy of the test report via encrypted email will be provided on the **Assessment Setup** Screen.

10.2 Report Printing

Cognivue Clarity® provides the ability to print the test report to a configured, connected printer. Printing test reports from Cognivue Clarity® is enabled by default. An Administrator can disable this functionality by unchecking the **Enable Report Printing** checkbox.

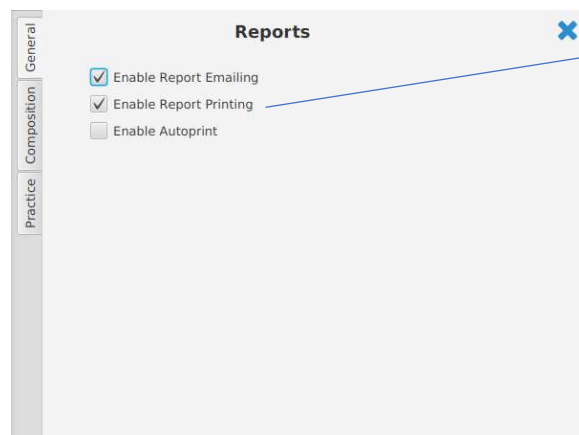


Figure 23 Report Settings Screen

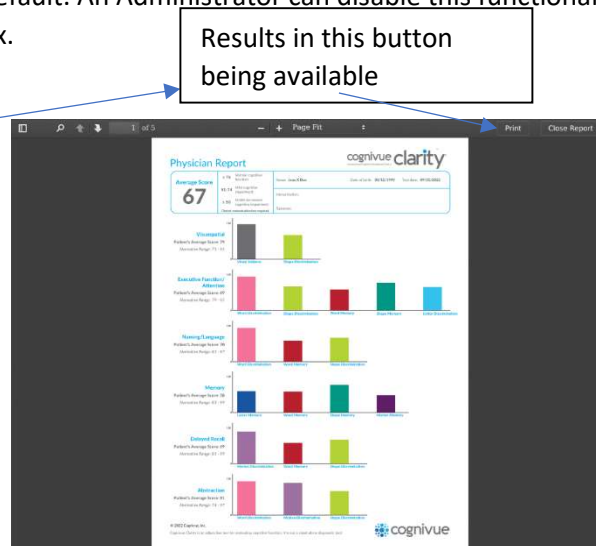


Figure 22 Report Viewer Screen

When enabled, a **Print** button will be displayed on the top navigation bar of the **Report Viewer** screen.

10.3 Automatic Printing

Cognivue Clarity® provides the ability to automatically print the associated report upon completion of a test. Automatic printing of test reports is disabled by default. An Administrator can enable this functionality by checking the **Auto Print** checkbox

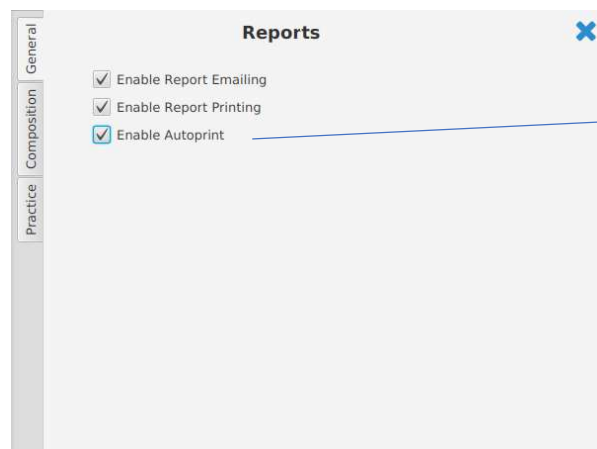


Figure 25 Reports Settings Screen

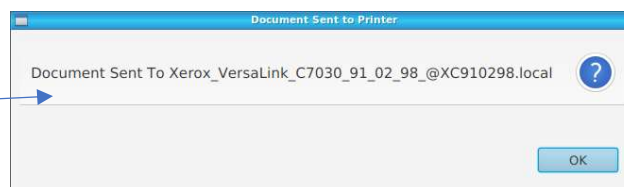


Figure 24 Automatic Print Post Assessment Prompt

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10.4 Report Composition

To open the **Report Settings Screen**

1. Log in
2. Select **Device Administration >> Report Settings**
3. Click the **Composition** tab

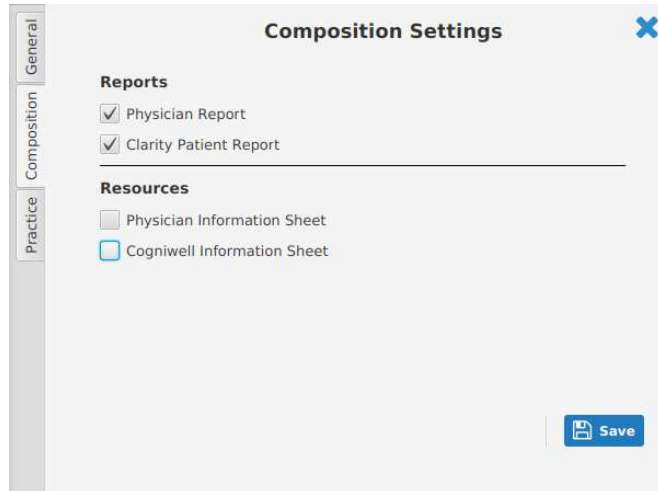


Figure 26 Report Composition Screen

Report Composition allows the inclusion of the Cogniwell Information Sheet and picking one or both reports.

WARNING Only the report generated will be available.

10.5 Practice Information

To open the **Practice Information Screen**

1. Log in
2. Select **Device Administration >> Report Settings**
3. Click the **Practice** tab

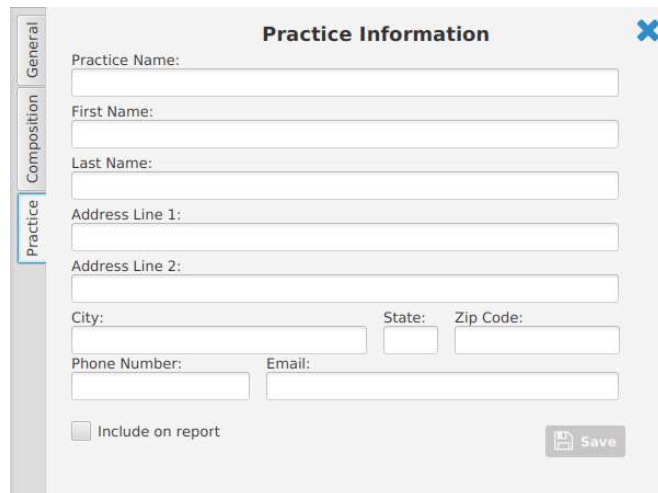


Figure 27 Practice Info Screen

11 Portal Menu

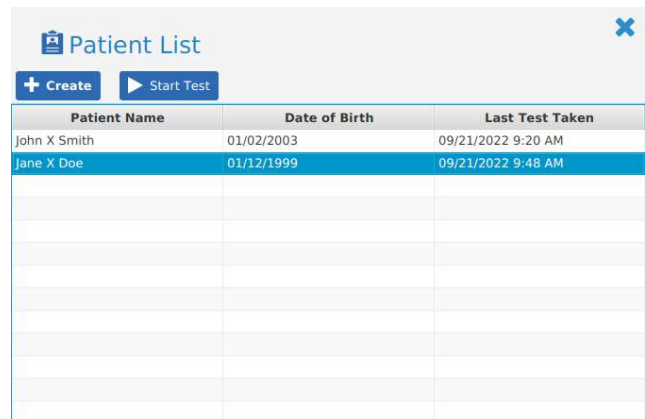
For details about how to setup and utilize the Portal see the **Portal User Manual**

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12 Patient Management

To open the **Patient List** Screen

1. Log in
2. Click the **Patient** button



The screenshot shows the 'Patient List' screen with a title bar, a close button, and two buttons: '+ Create' and '▶ Start Test'. Below these is a table with three columns: 'Patient Name', 'Date of Birth', and 'Last Test Taken'. The table contains two rows of patient data.

| Patient Name | Date of Birth | Last Test Taken |
|--------------|---------------|--------------------|
| John X Smith | 01/02/2003 | 09/21/2022 9:20 AM |
| Jane X Doe | 01/12/1999 | 09/21/2022 9:48 AM |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

Figure 28 Patient List Screen

12.1 Pre Entering Patients

Patient demographic information can be pre-filled to speed up the test setup process

1. Click on the **Create** button to display the **Patient Creation** Screen
2. Fill out form
3. Click **Save**
4. Click **OK** to confirm when prompted



The screenshot shows the 'Patient Creation' screen with a title bar, a close button, and a user icon. Below the title bar is a form with fields for 'First Name*', 'MI*', 'Last Name*', 'Date of Birth*', 'Sex*', and 'Email Address'. The 'First Name' field contains 'John', 'MI' contains 'X', and 'Last Name' contains 'Smith'. The 'Date of Birth' field is split into three parts: '01', '02', and '2001'. The 'Sex' field is a dropdown menu with 'Male' selected. The 'Email Address' field is empty. At the bottom right is a 'Save' button. A red asterisk indicates required fields.

Complete the form with the information for the new patient and click Save.

First Name* MI* Last Name*

John X Smith

Date of Birth*

01 / 02 / 2001

Sex* Male

Email Address

* Required field

Save

Figure 29 Patient Creation Screen

13 Assessments

Test administration is the core feature of Cognivue Clarity®. There are two paths to starting an assessment: From the **Main** Screen and from the **Patient List** Screen.

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13.1 Run Test (Main Screen)

1. From the **Main Screen** Click the **Run a Test** button

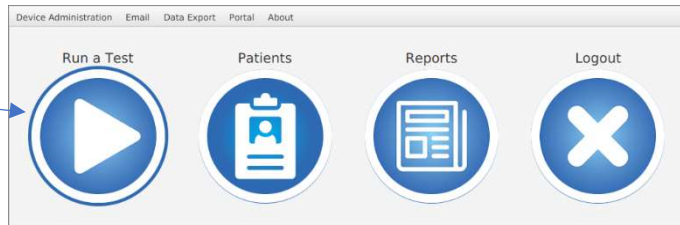


Figure 30 Main Screen (Administrator)

2. Fill out patient data (Name, *sex, date of birth)
3. Select the patient's preferred language for the test (English or Spanish)
4. Enter any additional information as desired
5. Select appropriate video options or use the defaults
6. Click **Run Test**

The image shows the 'Patient Info' form in the application. It contains fields for 'First Name*' (John), 'MI*' (X), 'Last Name*' (Smith), 'Date of Birth*' (01 / 01 / 2001), 'Sex*' (Male), and 'Test Language' (English). There are also expandable sections for 'Email' and 'Video Options'. At the bottom, there are three buttons: 'Run Test', 'Cancel', and 'Test Audio'. Blue arrows point from the list items to the corresponding fields: item 2 points to the name fields, item 3 points to the language dropdown, item 4 points to the email section, item 5 points to the video options section, and item 6 points to the 'Run Test' button.

Figure 31 Assessment Setup Screen

7. The patient should turn the CogniWheel when ready to begin

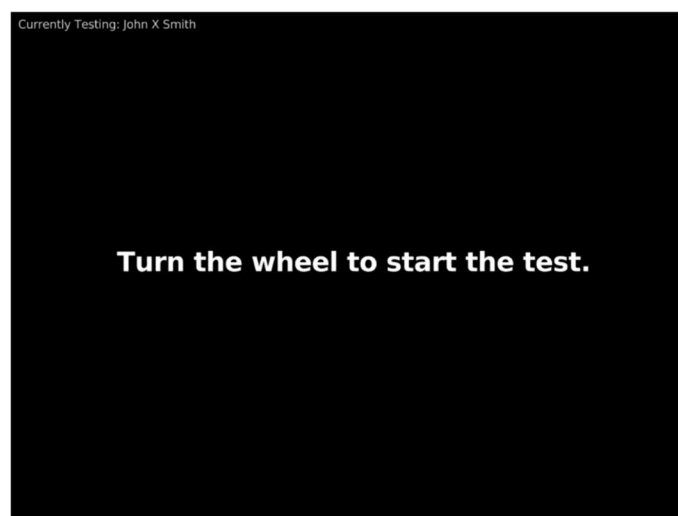
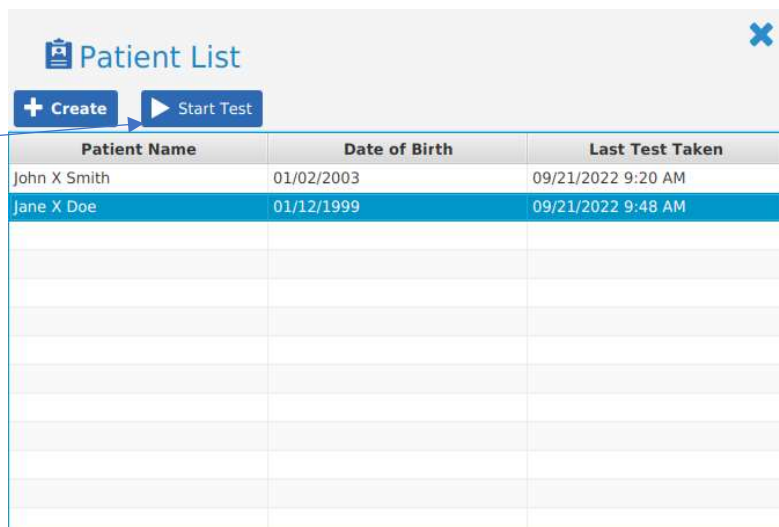


Figure 32 Start of the Cognivue Assessment

13.2 Run Test (Patient List Screen)

From the **Patient List** Screen

1. Select a patient
2. Click the **Start Test** button

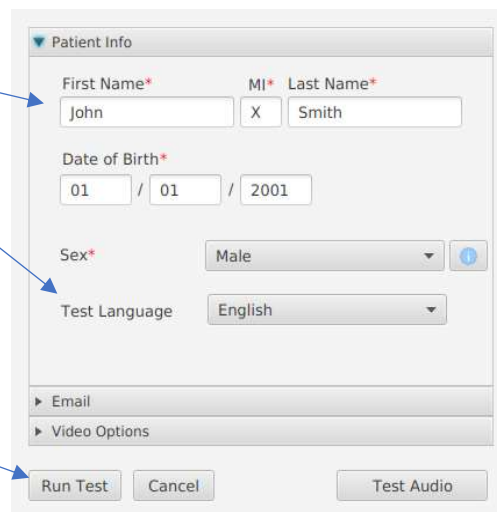


The Patient List screen features a title bar with a 'Patient List' header and a close button. Below the header are two buttons: '+ Create' and '▶ Start Test'. The main area is a table with three columns: 'Patient Name', 'Date of Birth', and 'Last Test Taken'. The table contains two rows of data, with the second row highlighted in blue. Below the table are several empty rows for additional entries.

| Patient Name | Date of Birth | Last Test Taken |
|--------------|---------------|--------------------|
| John X Smith | 01/02/2003 | 09/21/2022 9:20 AM |
| Jane X Doe | 01/12/1999 | 09/21/2022 9:48 AM |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

Figure 35 Patient List Screen

3. Fill out patient data (Name, *sex, date of birth)
4. Select the patient's preferred language for the test (English or Spanish)
5. Select appropriate video options or use the defaults
6. Enter any additional information as desired
7. Click **Run Test**



The Assessment Setup screen is a form titled 'Patient Info'. It contains fields for 'First Name*' (John), 'MI*' (X), and 'Last Name*' (Smith). Below these is a 'Date of Birth*' field with a date picker set to 01/01/2001. The 'Sex*' field is a dropdown menu set to 'Male'. The 'Test Language' field is a dropdown menu set to 'English'. At the bottom, there are three buttons: 'Run Test', 'Cancel', and 'Test Audio'. There are also expandable sections for 'Email' and 'Video Options'.

Figure 34 Assessment Setup Screen

8. The patient should turn the CogniWheel when ready to begin

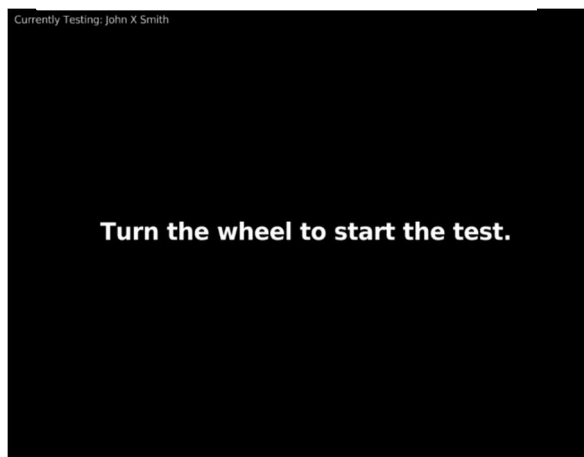
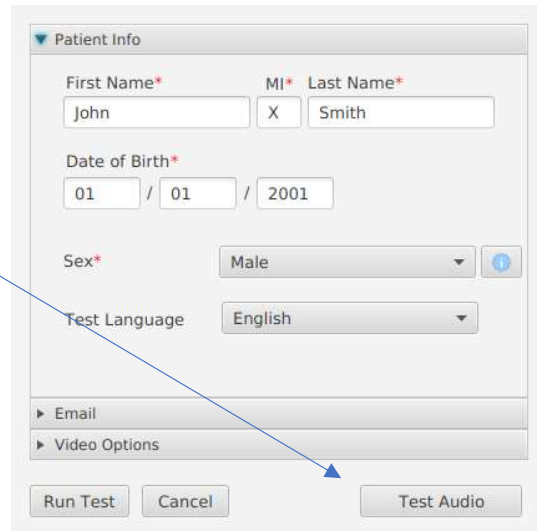


Figure 33 Start Assessment Screen

13.3 Video Volume Control

Before starting Cognitive Assessments test the audio using the **Test Audio** button on the **Assessment Setup Screen**



The screenshot shows a 'Patient Info' form with the following fields: First Name* (John), MI* (X), Last Name* (Smith), Date of Birth* (01 / 01 / 2001), Sex* (Male), and Test Language (English). Below these fields are expandable sections for 'Email' and 'Video Options'. At the bottom are three buttons: 'Run Test', 'Cancel', and 'Test Audio'. A blue arrow originates from the text 'Test Audio button' in the preceding paragraph and points directly to the 'Test Audio' button.

Figure 36 Assessment Setup Screen

In order to control the volume of video playback, the volume control keys on the keyboard can be used.



Figure 37 Volume Keys

Note: The **Mute** button sets the volume to its lowest setting. To unmute, it is necessary to use the volume-up key to increase the volume to the desired level.

14 Assessment Reports

14.1 Physician Report

This two-page report is intended for the physician. It displays the average test score and the scores in various areas of cognitive function and the reaction times and speed processing scores. Clinical contextualization is required.

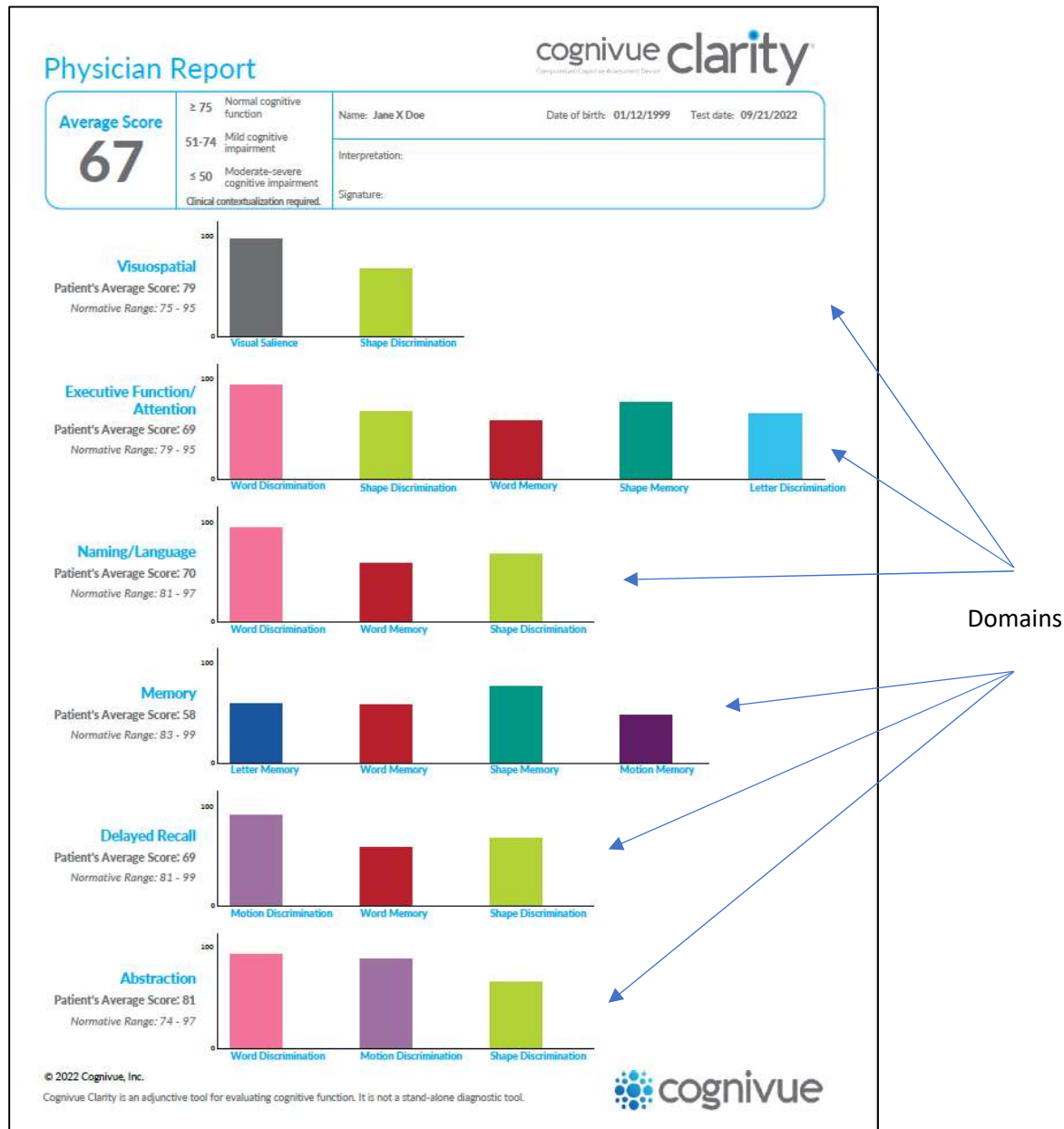


Figure 38 Practitioner Report (Page 1)

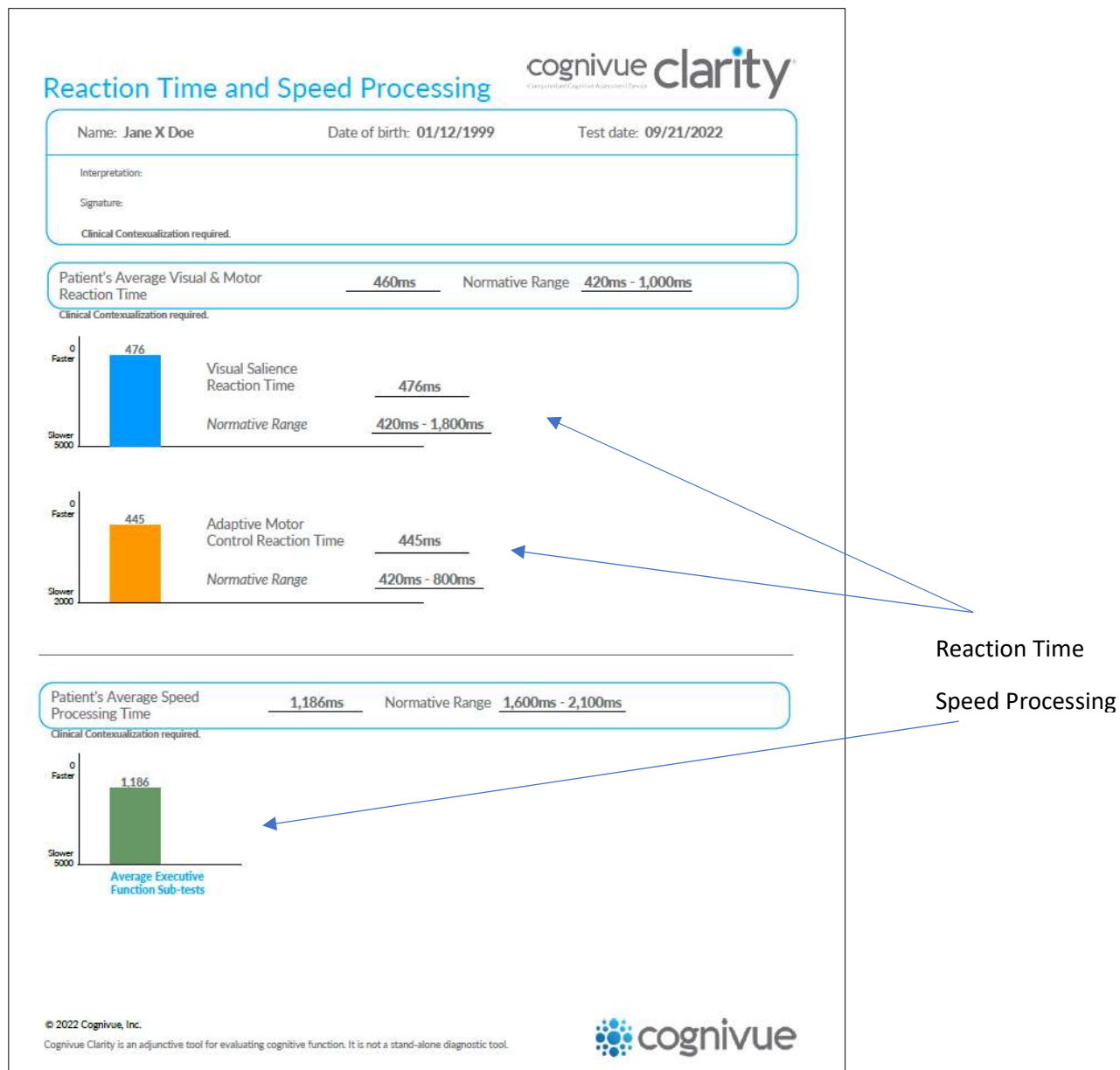


Figure 39 Physician Report (Page 2)


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14.3 Physician Information Sheet

This sheet provides general information about the normalized ranges for the overall score. These ranges were created as part of Clinical contextualization is required.

Physician Information

Clinical contextualization required



Computerized Cognitive Assessment Device

≥ 75

Normal Cognitive Function

Encourage patient to maintain healthy lifestyle

- Re-test next year

51-74

Mild Cognitive Impairment

Start dialogue with the patient

Not limited to, but some common causes/underlying conditions to check for:

- Unhealthy lifestyle
Poor diet, sedentarism, substance abuse (alcohol & others), stress & unbalanced work-life style
- Cardiovascular & metabolic conditions
Diabetes, vitamin deficiencies, dyslipidemia hepatic/renal issues
- Sleep disorders
Sleep apnea, RLS
- Neurological focal & chronic issues
Chronic pain, depression, epilepsy, TBI, post-stroke
- Hormonal changes
Thyroid, menopause
- Post-surgery, post-chemo

Consider referring to a specialist/counselor for further evaluation and management

≤ 50

Moderate-Severe Cognitive Impairment

Optimal management matters

- Available treatment/clinical trials
- Other therapies
- Planning

Consider referring to a specialist/counselor for further evaluation and management

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Cognivue Clarity is an adjunctive tool for evaluating cognitive function. It is not a stand-alone diagnostic tool.




Figure 41 Physician Information

Cognivue Clarity® User Manual

14.4 Cogniwell Letter

This Letter provides information about Cognivue's Cogniwell program



Take control of your memory and brain health

You have the power to optimize your cognition by adopting a combination of key healthy lifestyle habits and being aware of your overall wellness. Studies show that taking proactive steps may help reduce your risk of memory loss and other forms of cognitive decline. Here are evidence-based recommendations to proactively manage lifestyle-related risk factors and certain medical conditions that may affect cognition. For more information, please contact one of our Cogniwell Coaches at wellness@cognivue.com or (844) 654-1009

| | |
|--|---|
|  Stay Mentally Fit | Exercising your mind can help your brain perform at its best Participating in cognitively stimulating activities may help sharpen certain thinking skills that tend to diminish with age. Have fun engaging your brain by reading books, playing games, and doing puzzles. |
|  Maintain Connections | Being socially active is brain friendly Studies have shown that increased social activity is linked to a lower rate of cognitive decline. To stay social, connect with friends and family, or consider volunteering for a local organization. |
|  Exercise Regularly | Exercising your body can help keep your brain in shape Research supports a strong link between physical activity and brain health. It is recommended to get at least 150 minutes of moderate aerobic activity a week. Any activity that gets your heart pumping counts as aerobic activity, such as walking, dancing, and biking. |
|  Eat Healthy | Eating right feeds a healthy body and mind Food that is good for your overall health is good for your brain. Talk to your physician about whether you are consuming a balanced diet that takes into consideration appropriate numbers of calories and nutrients. |
|  Sleep & Relax | Getting a good night's sleep rests your body and mind Insufficient sleep can not only make a person irritable, it can affect memory and decision making. Healthy adults need between 7 and 9 hours of sleep per night. |
|  Healthy Hearing | Hearing health is important to your cognitive health Hearing impairment has been recognized as a modifiable contributor to cognitive decline when identified in mid-life. See your hearing healthcare professional to help maintain your hearing health. |
|  Optimal Vision | Manage or prevent vision impairment Research has found the relationship between cognitive decline and vision impairment may be a modifiable risk factor. To manage or prevent vision impairment, schedule regular visits with your vision healthcare provider. |
|  Medication Management | Medication management is important to your overall health Taking your medicine as prescribed is important for overall health. Reviewing your medications with your healthcare provider or pharmacist is an integral part of medication management. |

For a free Consultation, contact our Wellness Coach at (844) 654-1009

 **cognivue**
cognivue.com

Disclaimer: Cognivue Clarity/Thrive® is indicated for use as an adjunctive tool for evaluating cognitive function. It is not a stand-alone diagnostic tool and does not identify the presence or absence of clinical diagnoses. The device results are to be assessed and interpreted by a licensed clinician. Cognivue, Cognivue Thrive and Cognivue Clarity are trademarks or registered trademarks of Cognivue in the US and/or other countries. © Cognivue. All rights reserved. CG-1003 (07/2022)

Figure 42 Cogniwell Letter

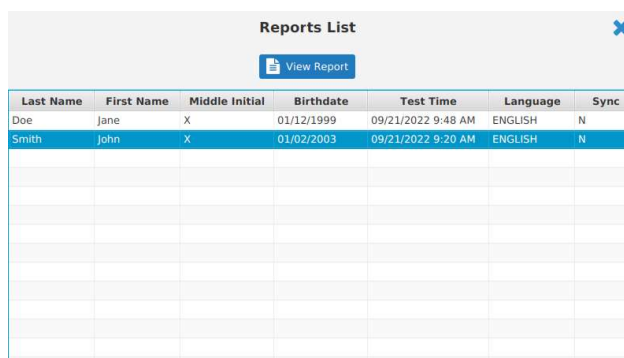
15 Accessing Reports

15.1 Viewing Reports

After a Cognitive Assessment is completed When the test has been completed the report can be reviewed by going to the **Report List** Screen.

15.2 Reviewing Reports

Administrators can review the test report by Selecting the **Reports** button from the Main Menu Screen. A list of available reports will be presented. After selecting the desired report from the list, click the **View Report** button to display the report.



The screenshot shows a window titled "Reports List" with a close button (X) in the top right corner. Below the title bar is a "View Report" button. A table contains the following data:

| Last Name | First Name | Middle Initial | Birthdate | Test Time | Language | Sync |
|-----------|------------|----------------|------------|--------------------|----------|------|
| Doe | Jane | X | 01/12/1999 | 09/21/2022 9:48 AM | ENGLISH | N |
| Smith | John | X | 01/02/2003 | 09/21/2022 9:20 AM | ENGLISH | N |
| | | | | | | |
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Figure 43 Report List Screen

15.3 Printing

Test reports may be printed from the Clarity device whenever a report is opened in the report viewer. The print feature prints to the device's default printer.

The Default printer can be set from any screen

1. Click the printer icon using the menu bar in the upper left corner of the screen
2. Right click on the preferred Printer
3. Click **Set As Default**

A green checkbox indicates that the printer has been set as default

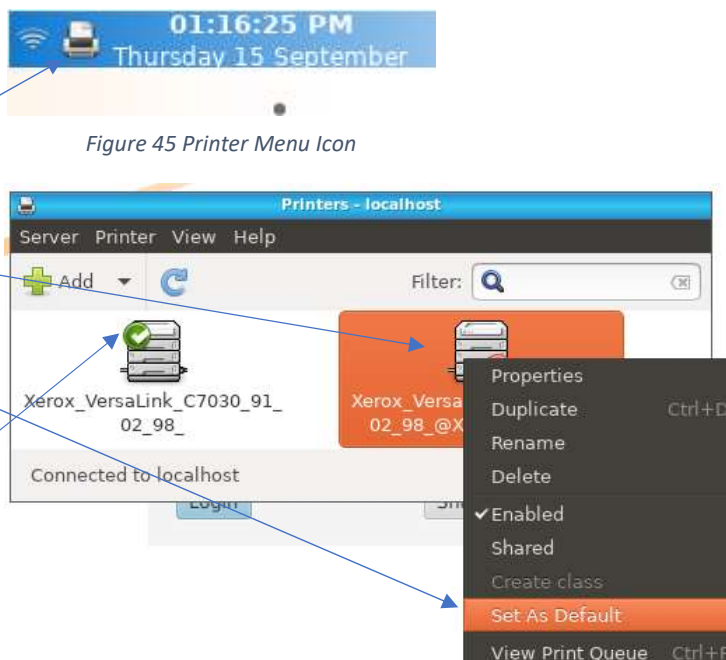
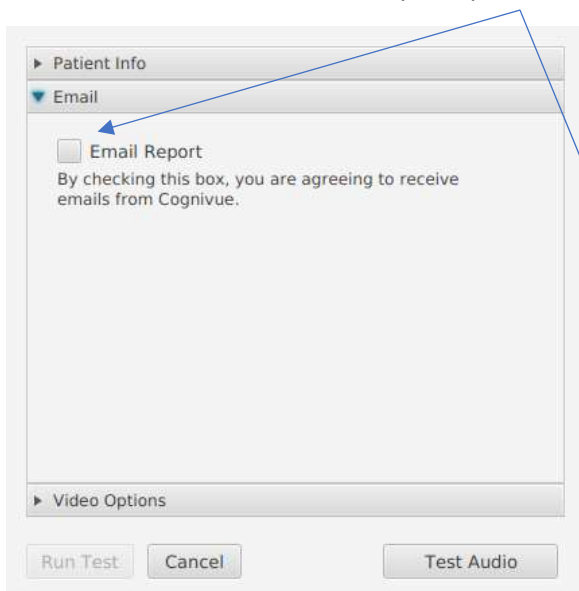


Figure 44 Printer Management Screen

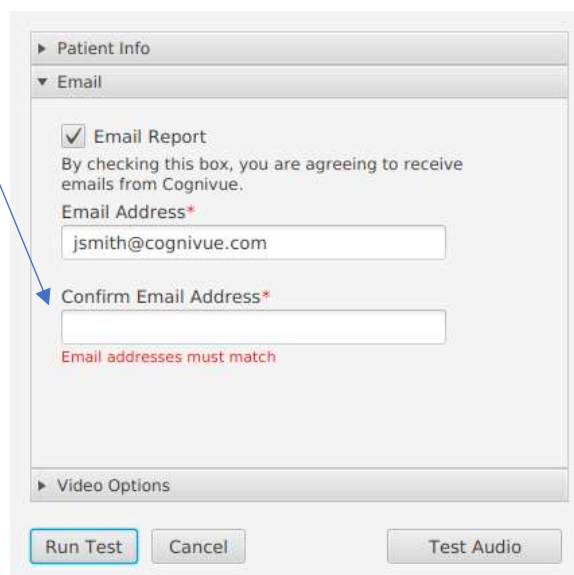
15.4 Emailing

Emailing reports from the device requires consent on a per assessment basis. The checkbox on the start assessment screen or the re-entry of a pre-existing patient's email serves as this consent.



The screenshot shows a software interface with a 'Patient Info' header and an 'Email' section. In the 'Email' section, there is a checkbox labeled 'Email Report'. Below the checkbox, a message states: 'By checking this box, you are agreeing to receive emails from Cognivue.' At the bottom of the interface, there are three buttons: 'Run Test', 'Cancel', and 'Test Audio'. A blue arrow points from the 'Email Report' checkbox to the 'Email Report Confirmation' screen shown in Figure 46.

Figure 47 Email Report Checkbox



The screenshot shows a software interface with a 'Patient Info' header and an 'Email' section. The 'Email Report' checkbox is checked. Below it, the same message is present: 'By checking this box, you are agreeing to receive emails from Cognivue.' Below the message, there are two text input fields. The first is labeled 'Email Address*' and contains the text 'jsmith@cognivue.com'. The second is labeled 'Confirm Email Address*' and is empty. Below the second field, a red error message reads: 'Email addresses must match'. At the bottom, there are three buttons: 'Run Test', 'Cancel', and 'Test Audio'. A blue arrow points from the 'Email Report' checkbox in Figure 47 to this screen.

Figure 46 Email Report Confirmation

If the email cannot be sent after the assessment due to network interruption the email can be resent once the network is restored via the **Email Menu** on the **Main** Screen for an administrator user.

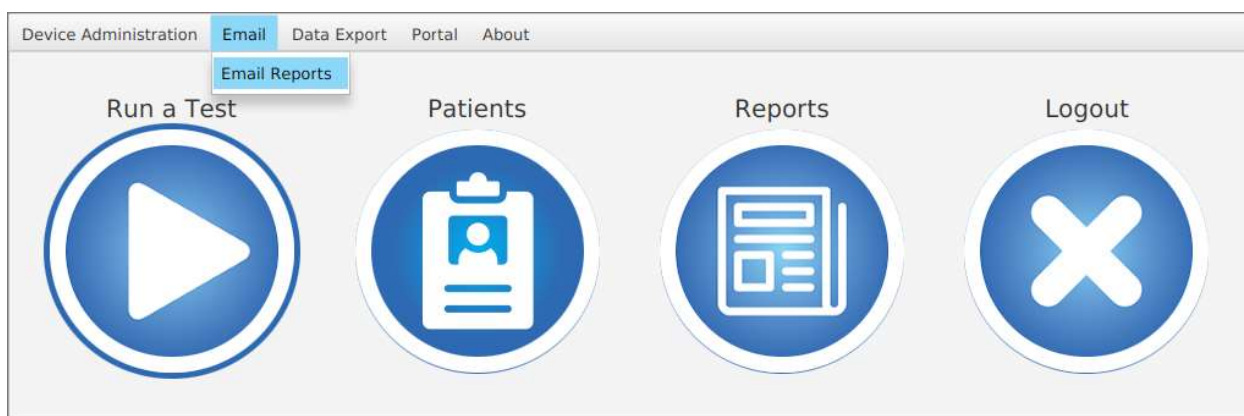


Figure 48 Email Report Menu

15.5 Drive Mapping

15.5.1 Setting the SMB Share Password

The SMB password can be set and reset on device by an administrator user.

From the **System Settings** Screen

1. Click the **SMB Share** Button

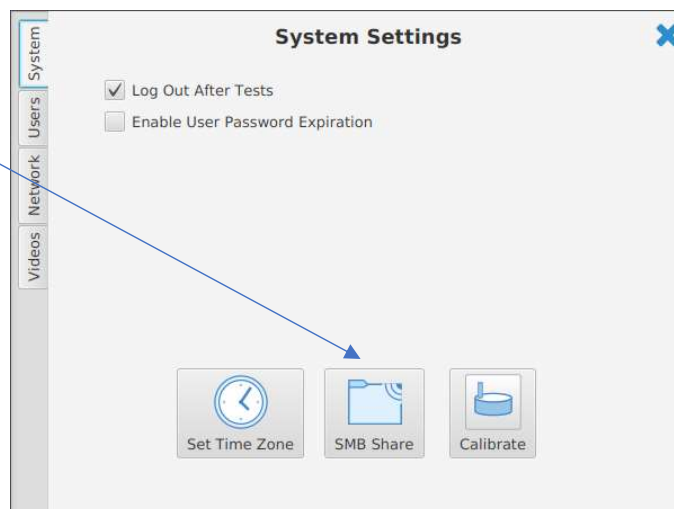


Figure 51 System Settings Screen

2. Enter a password that meets all the requirements

Figure 50 Change SMB Password

3. Click **Change Password** Button

4. Click to confirm the change

Figure 49 SMB Change Confirmation

15.5.2 Reports Mapping

This mapping provides access to the report pdfs sorted into folders based on the name and date of birth of the patient.

To map this drive, follow the appropriate Drive Mapping Instructions available at www.cognivue.com/support.

The information you will need for this share is

- Ip Address: Retrieved from the Network tab
- Mapping folder: Reports (e.g., \\192.168.0.48\Reports)
- Username: cogaccess
- Password: Set by device administrator

15.5.3 CSV Mapping

The CSV store provides access to csv files with the condensed data from all patient reports. These exports are generated by clicking the **Data Export** menu and selecting the **CSV Export** menu item.

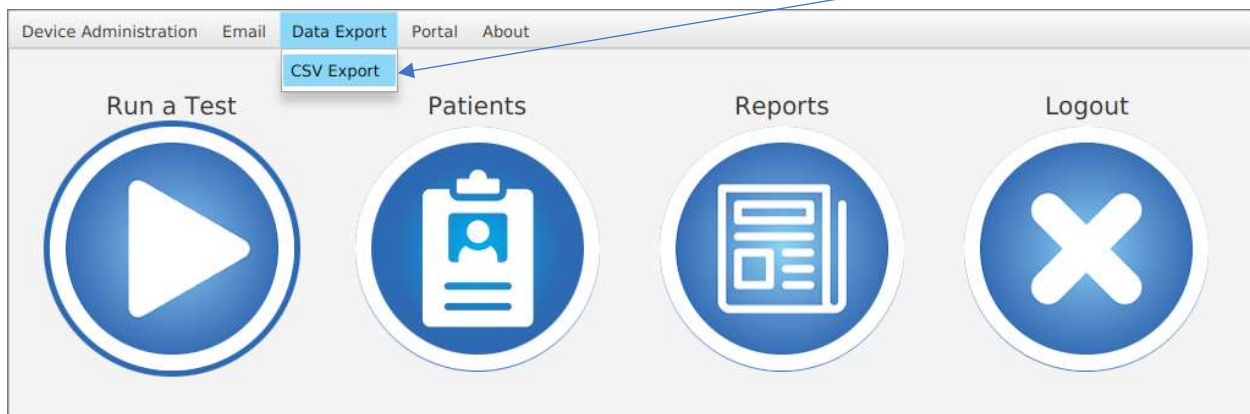


Figure 52 Main Screen (CSV Export)

The data included is:

- Last Name
- First Name
- Middle Initial
- Patient ID
- Sex
- Date of Birth
- Test Start Date-Time
- Serial Number
- Language
- Intro Video
- Visual Saliency Subtest
- Letter Discrimination Subtest
- Word Discrimination Subtest
- Shape Discrimination Subtest

- Motion Discrimination Subtest
- Letter Memory Subtest
- Word Memory Subtest
- Shape Memory Subtest
- Motion Memory Subtest
- Average Score
- Visuospatial
- Executive Function/Attention
- Naming/Language
- Memory
- Delayed Recall
- Abstraction
- Adaptive Motor Control Reaction Time (ms)
- Visual Saliency Reaction Time (ms)
- Average Visual & Motor Reaction Time (ms)
- Average Speed Processing Time (ms)

To map this drive, follow the appropriate Drive Mapping Instructions available at www.cognivue.com/support.

The information you will need for this share is

- Ip Address: Retrieved from the Network tab
- Mapping folder: Csv (e.g., \\192.168.0.48\Csv)
- Username: cogaccess
- Password: Set by device administrator

16 Technical Specifications

| | |
|--|---|
| Operating Environment | 10 to 30 °C (50 to 86 °F) 10% to 85% Relative humidity, non-condensing 70 to 106 kPa Atmospheric Pressure |
| Transport and Storage Environment | -20 to 50 °C (-4 to 122 °F) 10 to 85% Relative humidity, non-condensing 50 to 106 kPa Atmospheric Pressure |
| Power Input | 19V DC, 3.5 A Nominal |
| Weight | 4.2 kg (9lbs 2oz) |
| Wireless Communications | Intel Dual Band Wireless-AC 3168 20 dBm max output power for 2.4 GHz 802.11b/g/n 23 dBm max output power for 5.0 GHz 802.11a/n/ac |

17 Safety Precautions

Observe the following precautions to ensure safety and prevent damage to Cognivue Clarity®:

- Do not place on uneven or unstable surfaces.
- Do not make any modifications or alterations to the device.
- Do not connect unauthorized peripherals to the device.
- Do not open the device cover or modify the device. There are no customer serviceable parts.
- Do not apply weight onto the device.
- Do not connect a multiple socket outlet or extension cords to Cognivue Clarity®.
- Do not install the unit such that the power cord is a tripping hazard.
- Do not expose to liquids, rain, or moisture except in routine cleaning of surfaces.
- This product contains rechargeable batteries. At end of use, return the device to Cognivue or dispose according to local guidelines.
- Only use the provided AC Power Adapter with this device.
- Removal of the power cord from the inlet is the mains disconnect.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Cognivue Clarity® User Manual

WARNING: Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of Cognivue Clarity®. Otherwise, degradation of the performance of this equipment could result.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

18 Product Safety Standards

This device meets the following product safety standards:

USA ANSI/AAMI ES60601-1:2005+A2 (R2012) +A1 - Medical Electrical Equipment—Part 1: General requirements for safety and essential performance








Canada CAN/CSA C22.2 No. 60601-1:2014 - Medical Electrical Equipment—Part 1: General requirements for safety and essential performance (includes Amendment 1)

EMC IEC 60601-1-2:2014 includes EMC requirements and tests. Medical Electrical Equipment including CISPR 11:2009 + A1:2010, Group 1, Class A as shown in the table below:

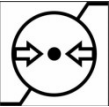




| EMC | Parameter | Standard | Test Level/Note |
|----------|------------------------------|---------------------------------------|--|
| Emission | Conducted Emissions | 5011:2009, CISPR 11:2009 + A1:2010 | Class A |
| | Radiated Emissions | N 55011:2009, CISPR 11:2009 + A1:2010 | Class A |
| | Harmonic Current | EN/IEC 61000-3-2 | Class A |
| | Voltage Flicker | EN/IEC 61000-3 | - |
| | | | |
| Immunity | Electrostatic Discharge | IEC/EN 61000-4-2 | 15 kV air, 8kV contact |
| | Radiated Immunity | IEC/EN 61000-4-3 | 3V/m (80Mhz-2.7GHz) |
| | Electrical Fast Transients | IEC/EN 61000-4-4 | 2kV |
| | Surge Line to Line | IEC/EN 61000-4-5 | 1kV Line to Line 2kV Line to Ground |
| | Conducted Immunity | IEC/EN 61000-4-6 | 3Vrms and 6Vrms |
| | Magnetic Immunity | IEC/EN 61000-4-8 | 30 A/m |
| | Voltage Dips & Interruptions | IEC/EN 61000-4-11 | |

19 Product Safety Symbols

The following symbols may be used for marking on this equipment:

| | |
|--|---------------------------------------|
|  | Follow the operating instructions |
|  | Type B applied part |
|  | Serial Number |
|  | DC input |
|  | Manufacturer Date |
|  | Manufacturer's name and address |
|  | NRTL Mark (Safety Certification Mark) |

The following symbols may be used for Environmental Conditions for Transport

| | |
|---|---------------------------------|
|  | Atmospheric Pressure Limitation |
|  | Temperature Limitation |
|  | Relative Humidity Limitation |
|  | Keep away from rain |
|  | Handle with Care |

Cognivue Clarity® User Manual

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