cognivue clarity®
Computerized Cognitive Assessment Device

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-510-C Cognivue Clarity® User Manual 5/7/2024

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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

At the conclusion of each cognitive assessment, Cognivue Clarity® generates a report containing a patient's cognitive scores based on their performance during the cognitive assessment's various subtests.

Score values range from 0 to 100, and are associated with three different categories or levels of cognitive impairment: Impaired Performance, Borderline Impaired Performance, and Normal Performance.

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® (R2 = 0.81; r = 0.90) and SLUMS (R2 =0.67; r = 0.82).

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 (R2 = 0.859; r = 0.927).

The reports generated by Cognivue Clarity® include upper and lower bounds for the normative range of Cognivue® scores. Normative ranges were calculated based on the compiled results of the Cognivue®

There were 1,575 subjects, from 14 U.S. sites enrolled in the FOCUS study. Of these subjects, 599 completed a Clarity testing session capturing normative ranges by age. These data captures resulted in refined normative ages by age, within decades:

- 18 to 29 years of age
- 30 to 39 years of age
- 40 to 49 years of age
- 50 to 59 years of age
- 60 to 69 years of age
- 70+ years of age

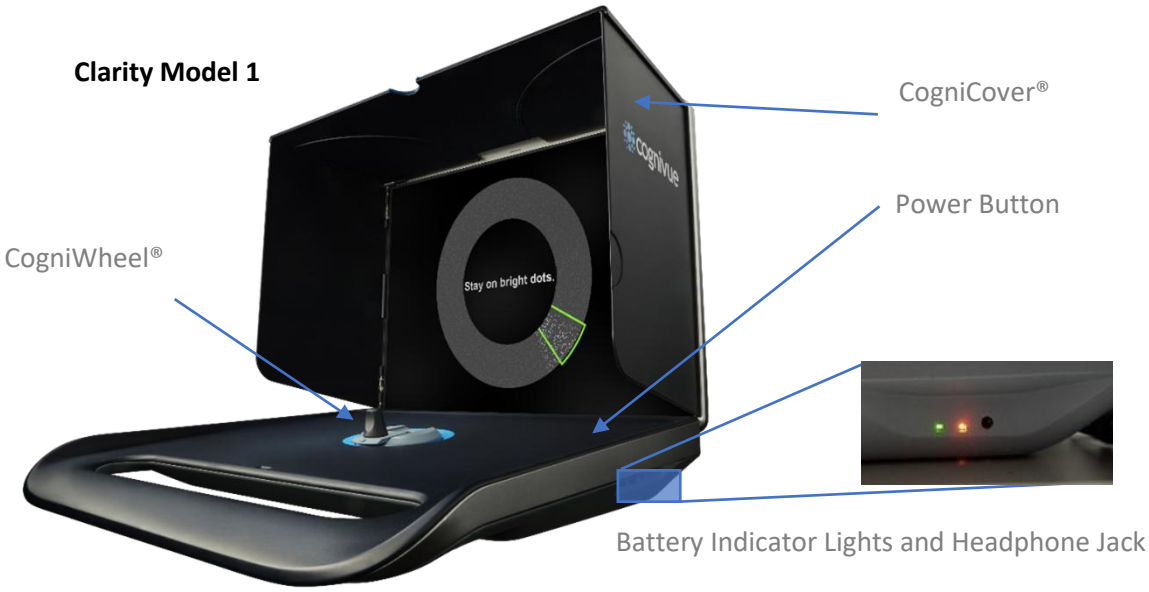
For additional clinical information, please consult the following references:

- 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.

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.

Clarity Model 1



Clarity Model 2

Clarity Model 1

USB Ports
(for Keyboard)

Ethernet Port

Battery Charging Port

Clarity Model 2

5 Power Management

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

When not connected to the charging adapter, a fully charged Cognivue Clarity® battery will power the device for 4 hours of intensive usage but can last for 8+ hours of typical usage.

Once it has been reconnected to the charging adapter, a completely drained Cognivue Clarity® battery will fully recharge in approximately 4 hours.

5.1 Battery Indicator Lights

Both models of Cognivue Clarity® have LED lights to indicate the status of the device's battery, as well as whether the device is currently charging or not. Please refer to the tables below:

Battery and Charging Status of Cognivue® Clarity Model 1	*Color of Left LED Indicator*	*Color of Right LED Indicator*
Device is Plugged In, Battery is Fully Charged	Green / Off	Green
Device is Plugged In, Battery is Charging	Green / Off	Orange
Device is Unplugged, Battery is Discharging	Orange	Off
Device is Unplugged, Battery is Completely Drained ***OR*** *Device is Off*	Off	Off

Table 5-1 Battery Indicator Light Statuses for Cognivue Clarity® Model 1

Battery and Charging Status of Cognivue® Clarity Model 2	*Color of LED Indicator*
Device is Plugged In, Battery is Fully Charged	Green
Device is off and Plugged In, Battery is Charging	Red -> Orange -> Green
Device is on and Plugged In, Battery is Charging	Blue
Device is Unplugged, Battery is Discharging	White -> Orange -> Blinking Red
Device is Unplugged, Battery is Completely Drained ***OR*** *Device is Off*	Off

Table 5-2 Battery Indicator Light Statuses for Cognivue Clarity® Model 2

5.2 Screen Sleep

When the Cognivue Clarity® 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 Cognivue Clarity® 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. 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

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

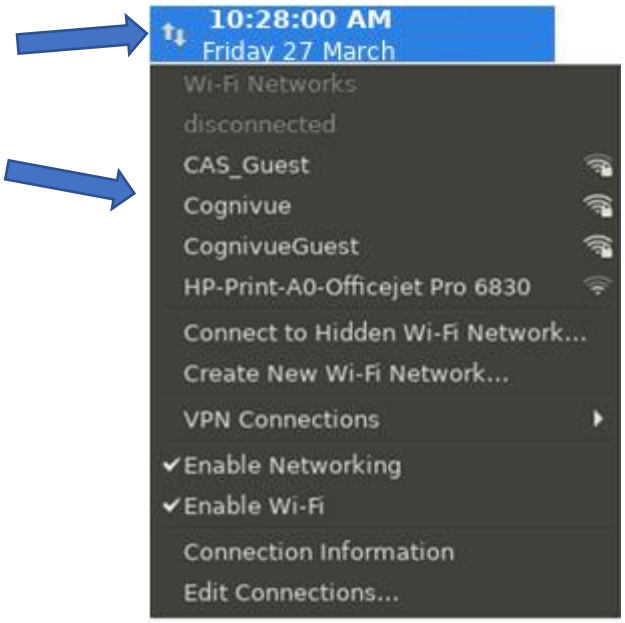
Cognivue Clarity® requires connection to a qualified network for initial setup and configuration but thereafter can be used to administer assessments offline. However certain features like Portal Sync, Printing, and Drive Mapping will be unavailable until the device is reconnected to a qualified network.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

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.



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

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.

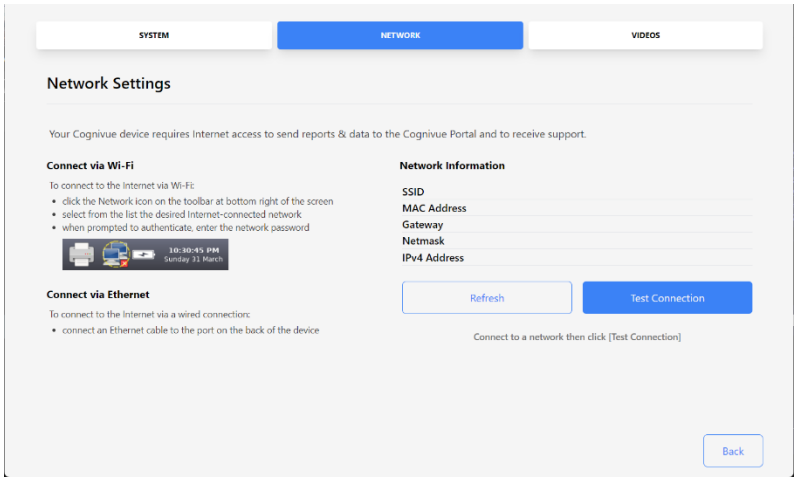
7.3 Connection Details

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

To open the **Network Configuration** window

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

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



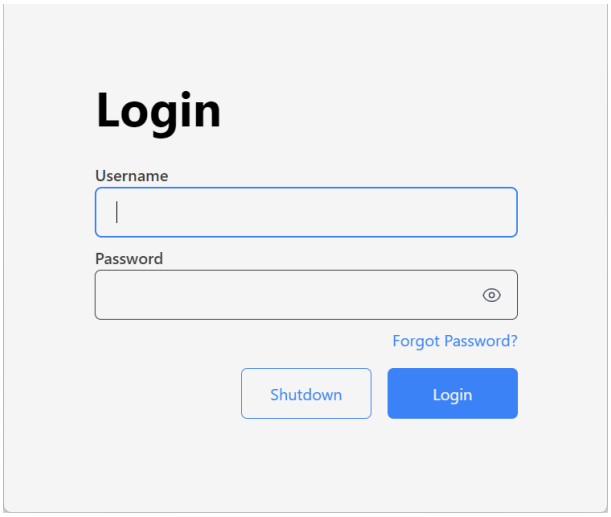
The **Refresh** button refreshes the displayed connection values

The **Test Connection** button confirms that the device has network connectivity

8 Security

8.1 Login

The user **Login** window is how you log in to a device. Logging in with an individual account ensures an audit trail for viewing patient reports and running assessments.



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.

8.2 User Management

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

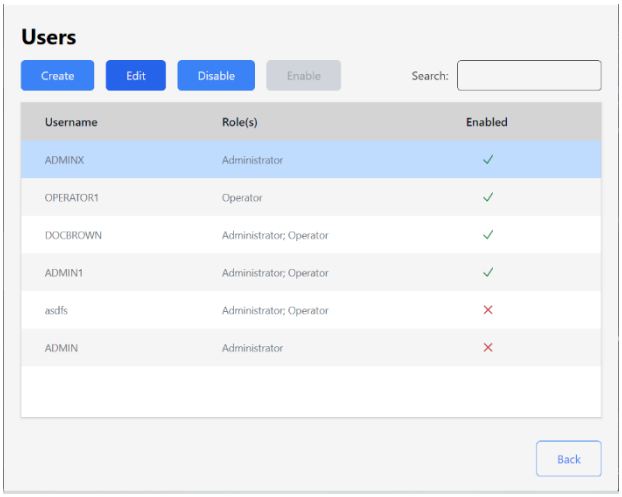
User accounts can be assigned as an Administrator or an Operator on the **User Management Screen**.

	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 8-1 User Account Roles and Permissions

To open the **User Management Screen**

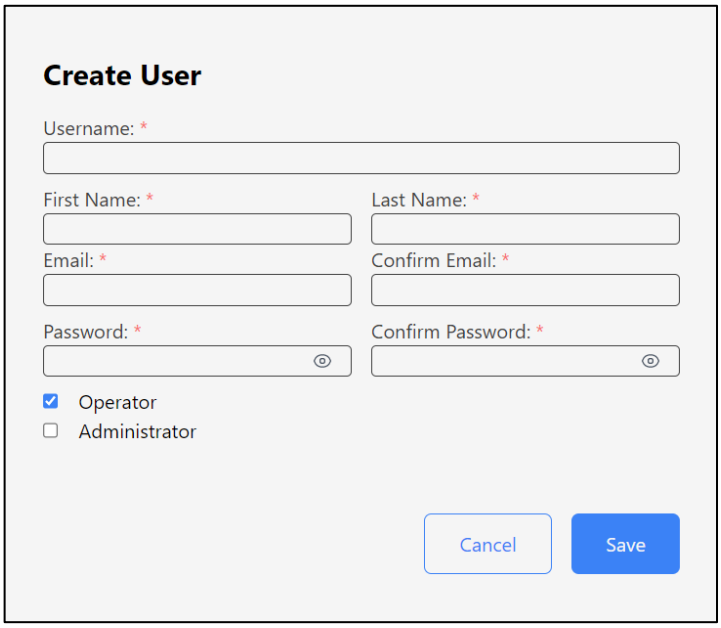
1. Log in
2. Select **Administration** >> **Device Settings**
3. Click the **Users** tab



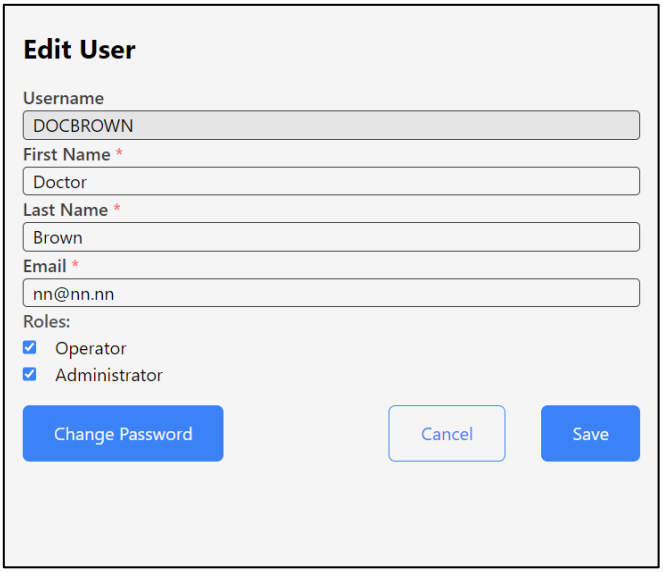
8.3 User Creation

From the **User Management** Screen

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



8.4 User Modification



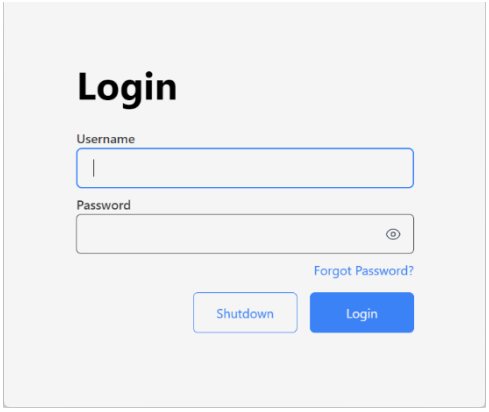
From the **User Management** Screen

1. Select a user from the list
2. Click **Edit**
3. Make the desired changes
4. Click **Save**

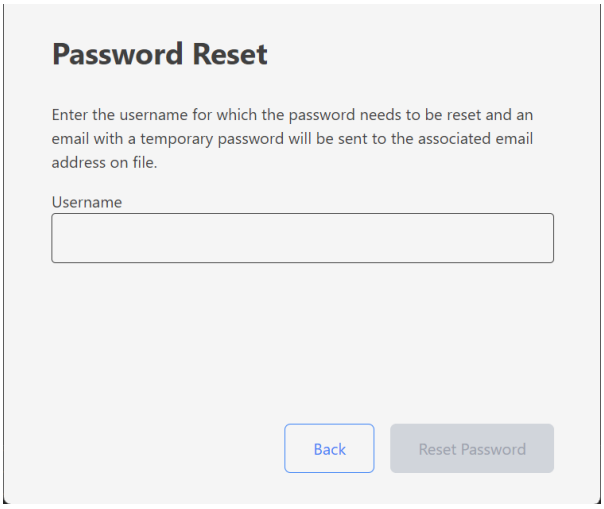
Click **Yes** to confirm when prompted

8.5 Password Reset

If a Cognivue Clarity® user is unable to remember their password, the process to reset their password can be initiated from the device's Login Screen:



1. Click **Reset Password**
2. Enter the username to reset
3. Click **OK** to confirm when prompted
4. Check user's associated email account for an email from donotreply@cognivue.com with a temporary password
5. Once the email from donotreply@cognivue.com has been sent, that user has 24 hours to login to their Cognivue Clarity® device and enter the temporary password they received



After logging in successfully, the user will be prompted to create a new password – this is the password they will use to login to the Cognivue Clarity® device going forward

8.6 Auto-Logout

To prevent unauthorized access, the Cognivue Clarity® device will automatically log out the active user after 30 minutes of inactivity.

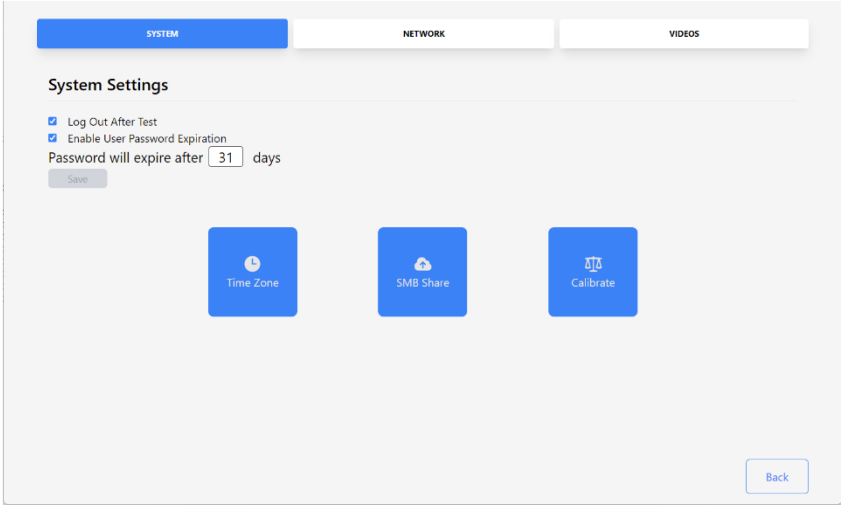
8.7 Password Expiration

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.

To enable/disable password expiration:

1. Navigate to **Administration** >> **Device 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**

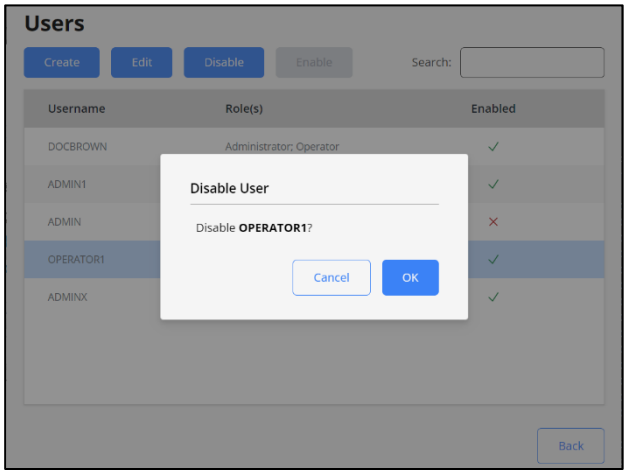


8.8 Disabling Accounts

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



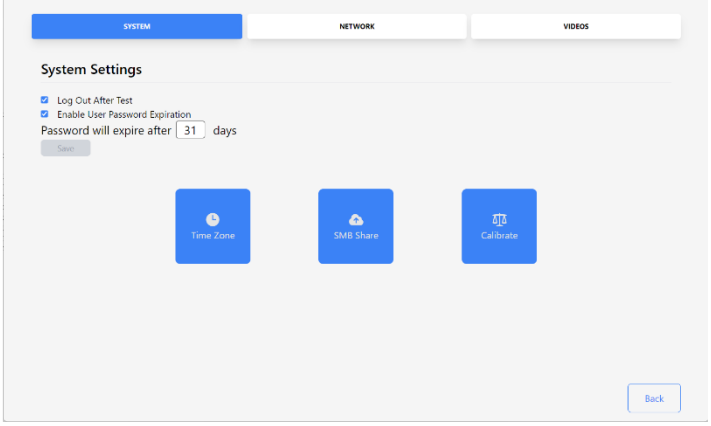
9 System Settings

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

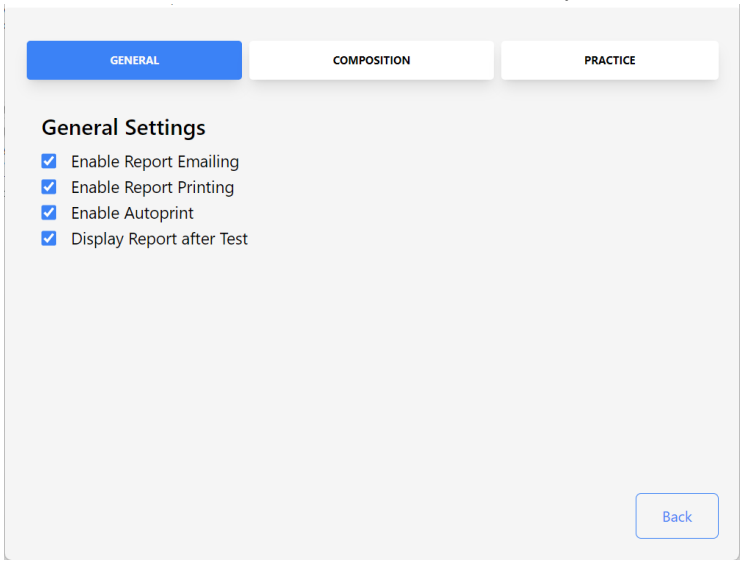
To open the **System Settings Screen**

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



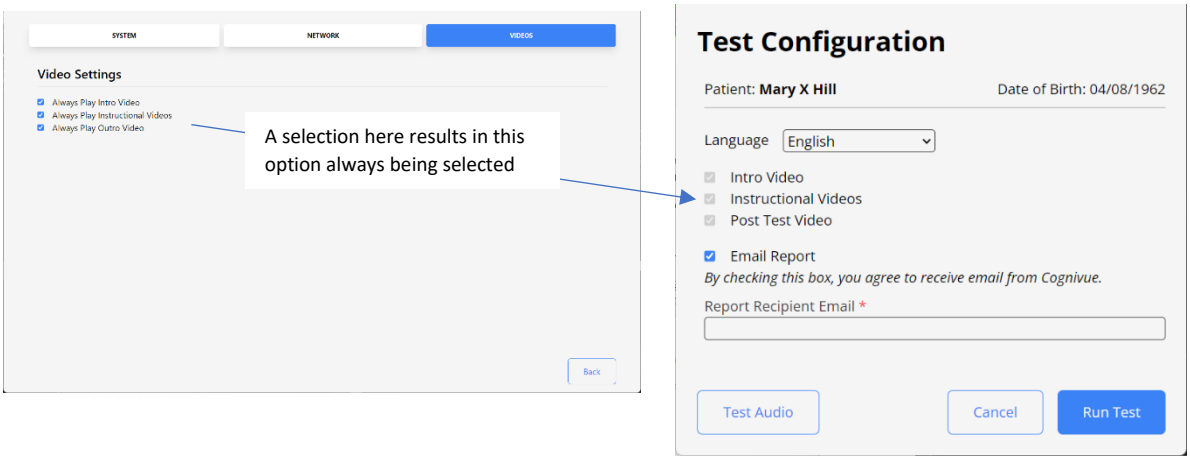
9.1 Video Settings

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



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.

To open the **Report Settings Screen:**

1. Login to the device as a user with administrator privileges
2. Select **Administration** >> **Report Settings**

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.

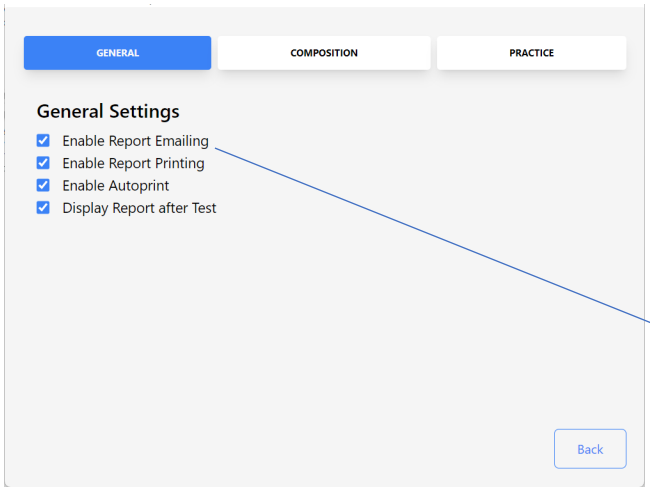


Figure 10-2 Reports Settings Screen

Checking the box for "Enable Report Emailing" results in this section being available on the Assessment Setup Screen

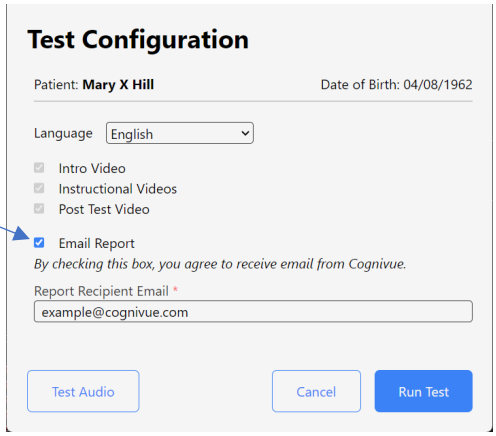
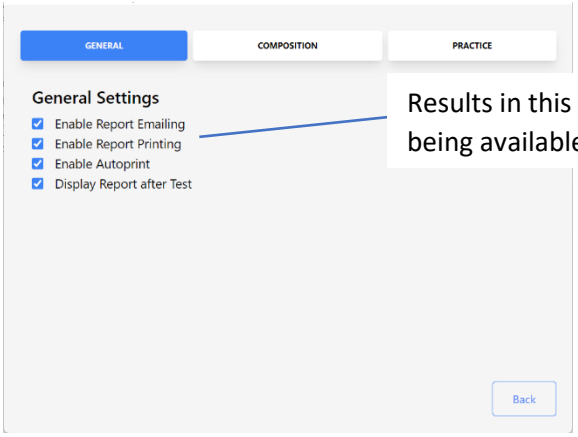


Figure 10-3 Email (Assessment Setup Screen)

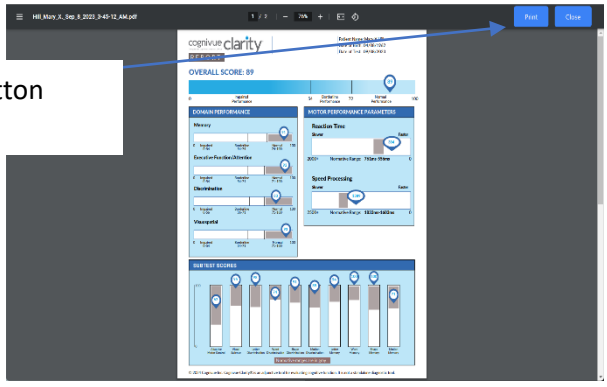
When enabled, the option for the patient to receive a copy of the test report via encrypted email will be provided on the **Assessment Setup** Screen.

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.



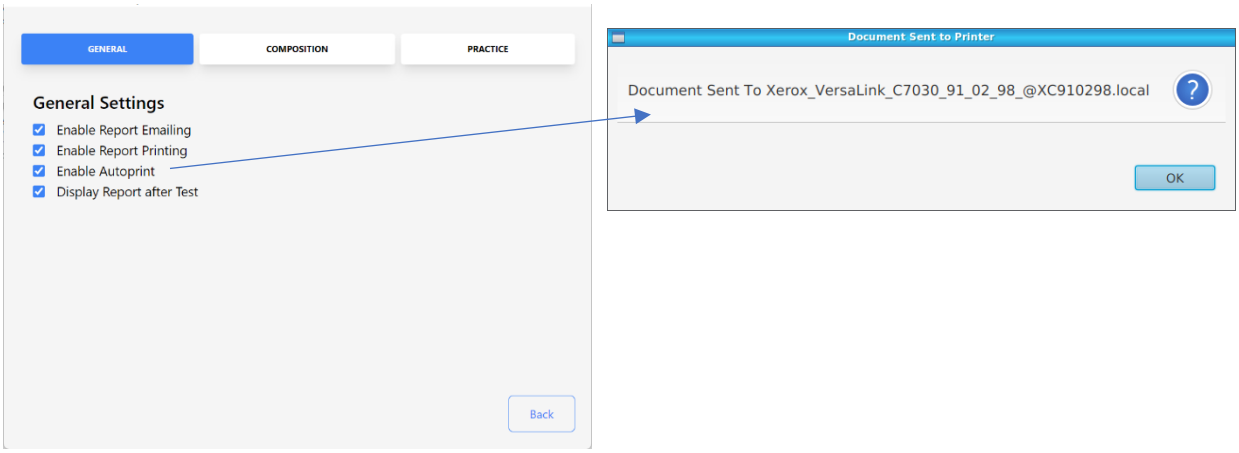
Results in this button being available



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

10.3 Automatic Printing

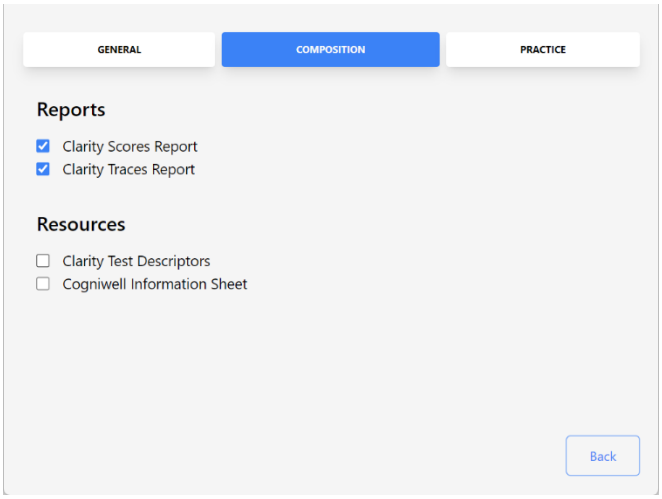
Cognivue Clarity® provides the ability to automatically print the associated report upon completion of a test. Automatic printing of test reports is disabled by default. An Administrator can enable this functionality by checking the **Auto Print** checkbox



10.4 Report Composition

To open the **Report Settings Screen**

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

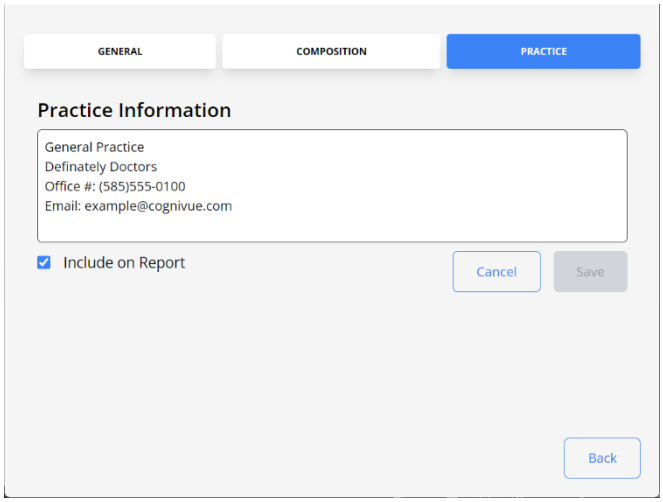


WARNING: At the conclusion of the assessment, only the selected reports will be generated. Reports that do not have check marks next to them will not be generated. Reports cannot be generated after an assessment has been completed either, so unchecked reports will be permanently unavailable.

10.5 Practice Information

To open the **Practice Information Screen**

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



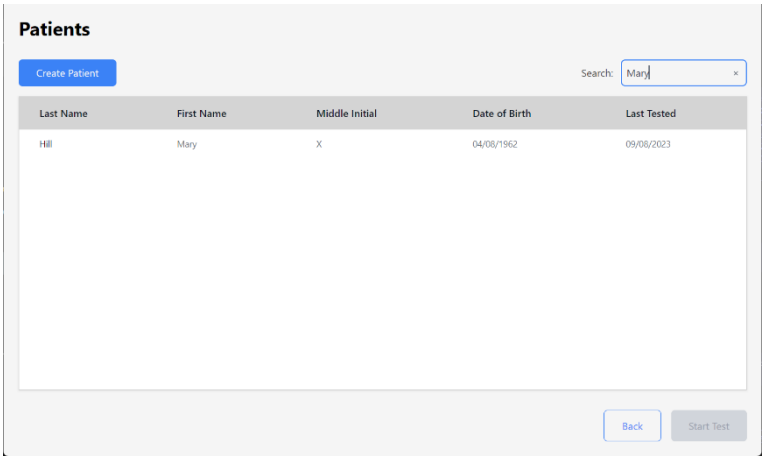
11 Portal Menu

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

12 Patient Management

To open the **Patient List** Screen

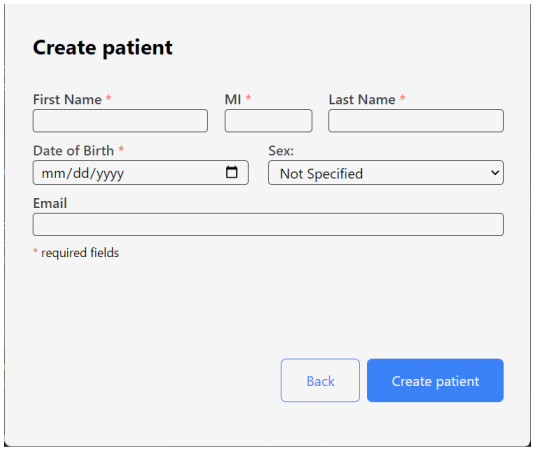
1. Log in
2. Click the **Patient** button



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



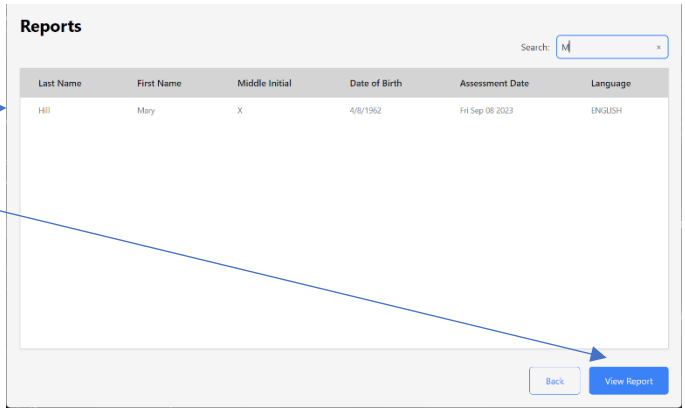
13 Assessments

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.

13.1 Run Test (Patient Screen)

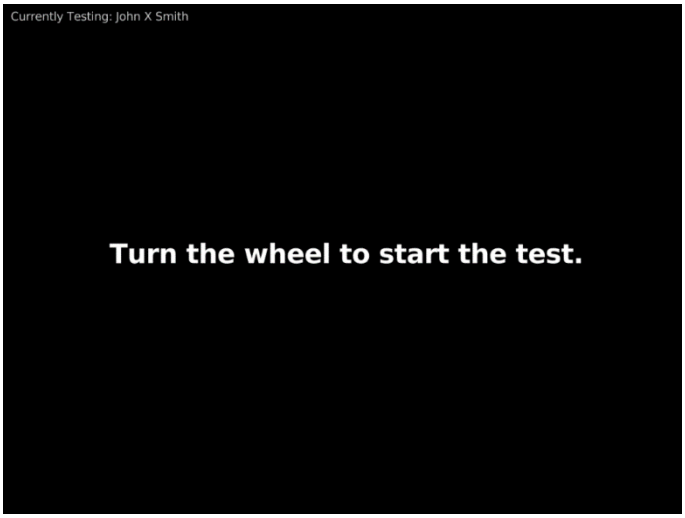
From the **Patient List** Screen

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



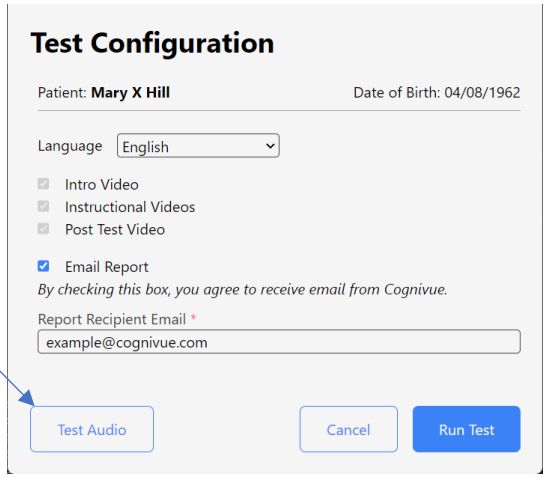
3. Patient data (Name and date of birth)
4. Select the patient's preferred language for the test (English or Spanish)
5. Select appropriate video options or use the defaults
6. Enter any additional information as desired
7. Click **Run Test**

8. The patient should turn the CogniWheel® to start the test



13.2 Video Volume Control

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



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

Thrive Model 1

Thrive Model 2

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

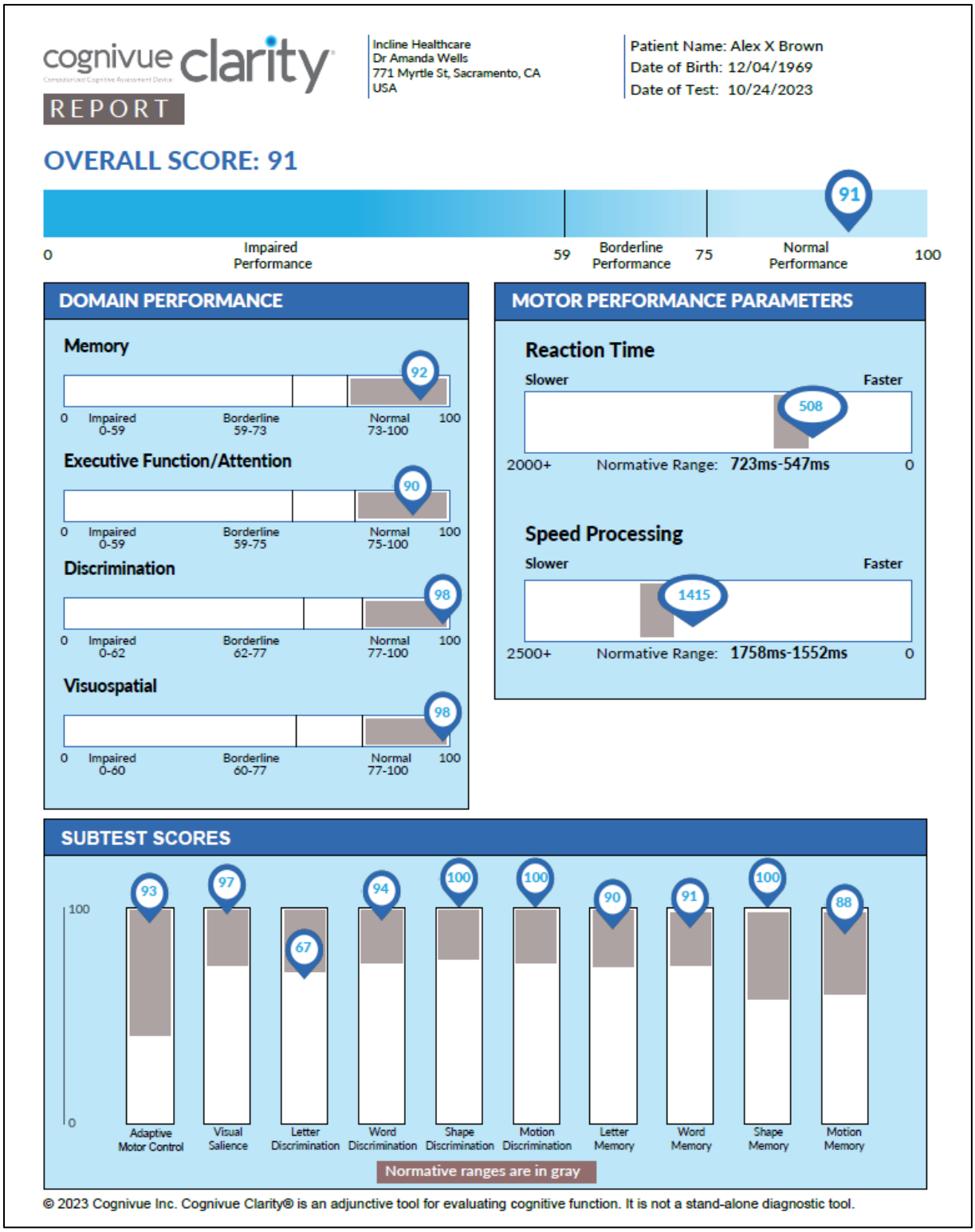
There are four different reports and resources that can be generated at the conclusion of a cognitive assessment:

- Clarity Scores Report
- Clarity Traces Report
- Cogniwell Information Sheet
- Clarity Test Descriptors

Device administrators can configure which reports are generated from the Composition Settings tab of the Report Setting screen (see the **Report Setting** section of this manual).

14.1 Clarity Scores Report

This report contains a more detailed breakdown of the patient's scores and indicates the normative range of scores for the patient's age group.



14.2 Clarity Traces Report

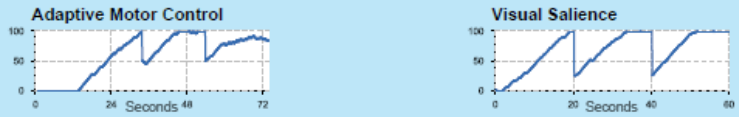
This report contains response traces for each of the ten subtests executed as part of the Cognivue Clarity® assessment.

cognivue clarity
Computerized Cognitive Assessment Device
REPORT

Incline Healthcare
Dr Amanda Wells
771 Myrtle St, Sacramento, CA
USA

Patient Name: Alex X Brown
Date of Birth: 12/04/1969
Date of Test: 10/24/2023

CALIBRATION RESPONSE TRACES

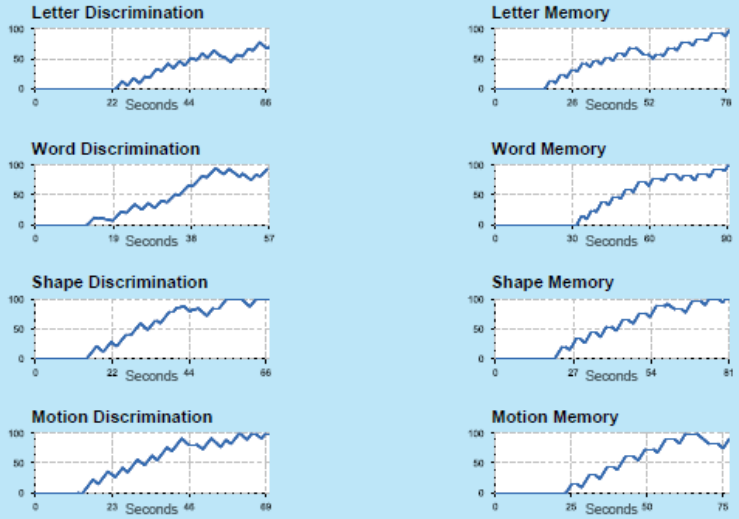


CALIBRATION INTERPRETATION:

The Adaptive Motor Control Test evaluates the individual's ability to control their rotary movement response of the CogniWheel® in response to a rotating visual cue. The individual's performance for this subtest is **valid**.

In the Visual Salience Test, the individual being tested must locate a wedge of bright dots on the screen and follow it as the dots begin to fade. The individual's performance for this subtest is **valid**.

SUBTEST RESPONSE TRACES



SUBTEST RESPONSE TRACES INTERPRETATION:

Response Traces are a function of subtest and response dynamics. For each domain, the x-axis represents time (seconds) and y-axis represents subtest difficulty (percent of maximum).

- Fast and accurate responses throughout a subtest generate a steadily rising response with a consistent slope from the beginning of the subtest to maximum score. This supports optimal performance.
- Delayed responses may reflect difficulty in comprehension, or a lapse in performance. This supports suboptimal performance and scores should be interpreted in this context.
- Irregular responses, with inclines and declines in sensitivity may indicate fluctuating attention, difficulty maintaining response rate, or a potential indication of declining abilities. This supports suboptimal performance and scores should be interpreted in this context.

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14.3 Cogniwell Letter

The CogniWell Lifestyle Letter provides information about modifiable lifestyle factors that can have an impact on cognitive performance.

cogniwell LIFESTYLE

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.

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.

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 (06_2023)

14.4 Clarity Test Descriptors

This document contains descriptions of each of the ten subtests executed as part of the Cognivue Clarity® assessment.

cognivue clarity

TEST DESCRIPTORS

CALIBRATION

The calibration sub-battery consists of two subtests of basic motor and visual abilities. These subtests verify that the individual can move the CogniWheel® and see the visual stimuli. The rate and manner of stimulus presentation in the remaining tasks is then modulated by the scores on these subtests.

- **Adaptive Motor Control:** The Adaptive Motor Control Test evaluates the individual's ability to control rotary movement of the hand while using the CogniWheel in response to a rotating visual cue. This subtest is used to assess visual-motor coordination using speed and accuracy measures in a composite score.

- **Visual Salience:** In the Visual Salience Test, the individual being tested must locate a wedge of bright dots on the screen and follow it as the dots begin to fade. The Visual Salience subtest includes several phases with changes in the spatial frequency of the dot stimulus pattern. The subtest begins with the dots at a broad range of sizes, and then go through periods of being smaller or larger.

COGNITIVE TESTING TECHNOLOGY

Cognivue technology continually changes the strength of the distinguishable perceptual signal and continually monitors speed and accuracy to indicate the distinguishable target location on the computer screen. The continual monitoring of the individuals indication of the perceived stimulus assesses information processing capacity for each stimulus domain.

- **Letter Discrimination:** The Letter Discrimination Test presents a measure of the individual's ability to identify a letter as discriminated from a variety of non-letter, letter-like shapes. This assesses how effectively the individual can process the highly over-learned set of specialized shapes that compose written language.

- **Word Discrimination:** The Word Discrimination Test quantifies the individual's ability to identify three-letter words as discriminated from a variety of non-words composed of three-letter sets. This is a test of how effectively the individual can process three letter words that are commonly encountered.

- **Shape Discrimination:** The Shape Discrimination Test quantifies the individual's ability to discriminate one regular shape from others in an annular array. This is a test of how effectively the individual can process simple shapes that are similar to those commonly encountered in nature.

- **Motion Discrimination:** The Motion Discrimination Test quantifies the individual's ability to identify a circle of dots moving in a different pattern from that in other dot circles. This is a test of how effectively the individual can process visual motion that is commonly encountered in nature and synthetic displays.

- **Letter Memory:** The Letter Memory Test assesses the individual's ability to recall which letter of the alphabet was presented as a pre-cue and then select that letter from an annular array of alternative letters. This is a test of how well the individual can remember which letter first preceded the choice array.

- **Word Memory:** In the Word Memory Test, individuals must recall a three-letter word presented as a pre-cue and then select that word from an annular array of alternative words. The robustness of the memory for the target word is measured by the individual's ability to continue successfully in the subtest despite the addition of increasing amounts of visual clutter to the target and masking words in the display.

- **Shape Memory:** The Shape Memory Test measures the individual's ability to recall which common shape was presented as a pre-cue and then select that shape from an annular array of alternative shapes. This assesses how effectively the individual remembers which shape immediately preceded the choice array.

- **Motion Memory:** The Motion Memory Test evaluates the individual's ability to recall which pattern of motion was presented as a pre-cue and then select that direction of motion from a small annular array of alternative motion directions. This is a test of how effectively the individual can remember which pattern of motion first preceded the choice array.

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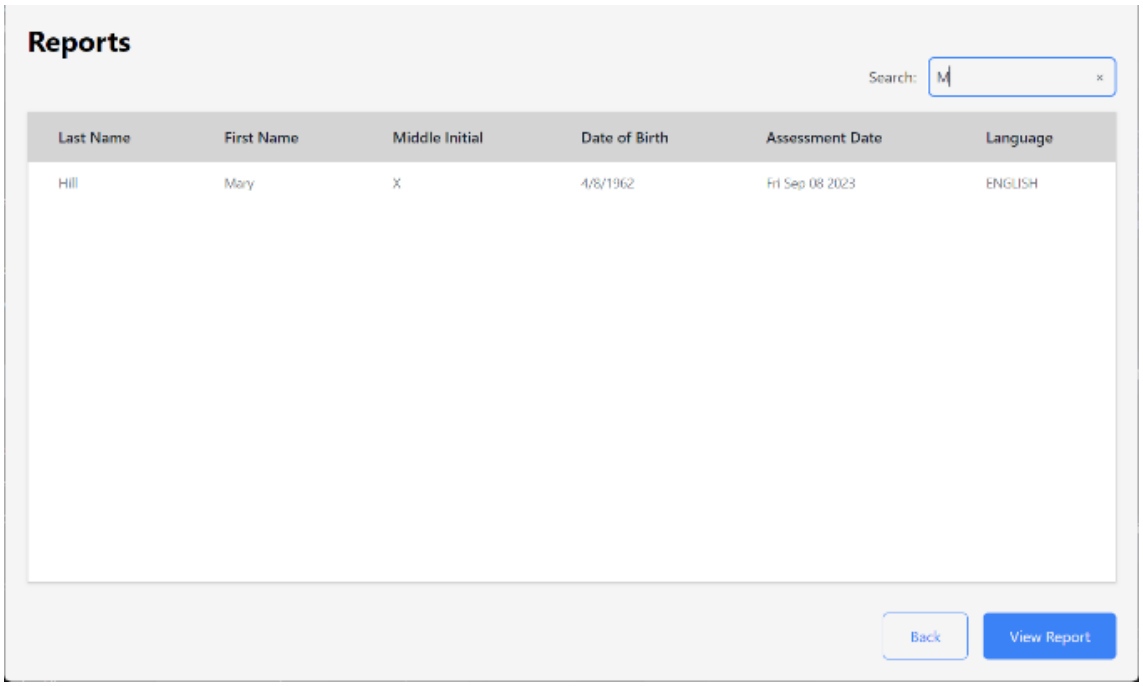
15 Accessing Reports

15.1 Viewing Reports

After a Cognitive Assessment 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.



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**

Figure 15-2 Printer Menu Icon

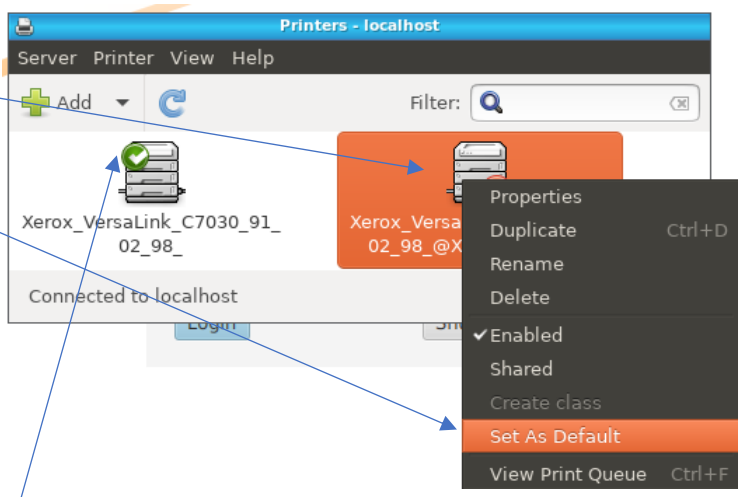


Figure 15-1 Printer Management Screen

4. A pop-up Set Default Printer will appear. Selecting Set as the system-wide default printer, press OK to continue

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

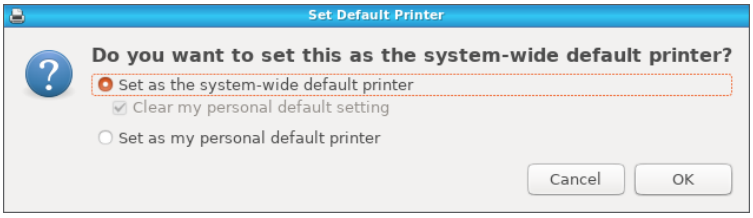
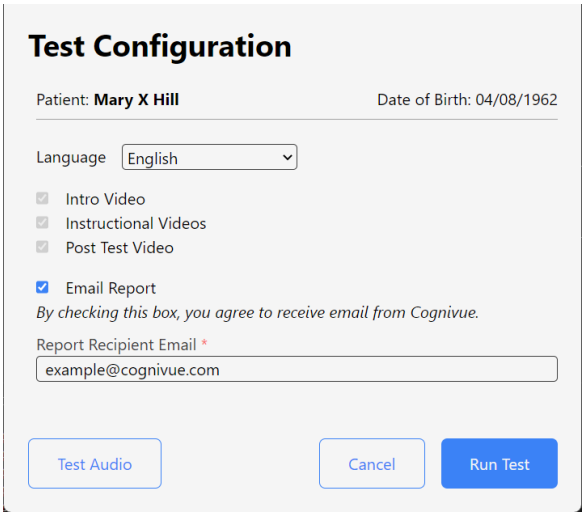


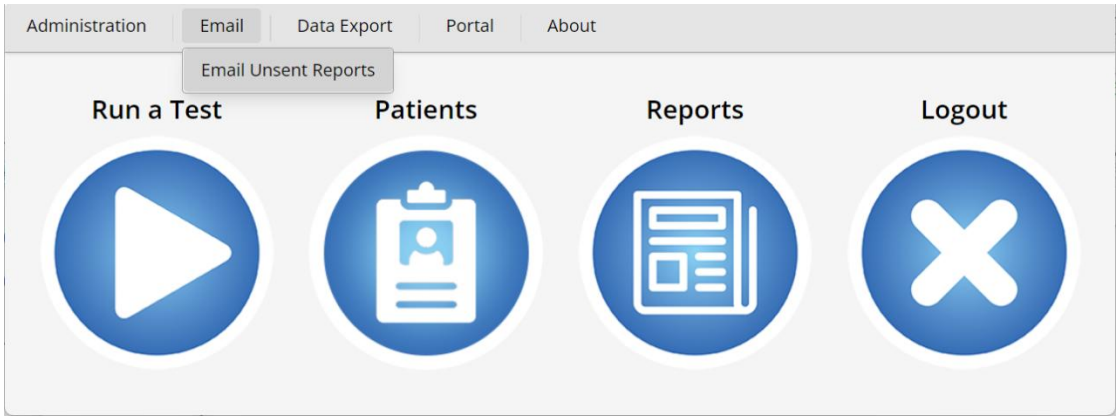
Figure 15-4 Set Default Printer Prompt

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.

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.





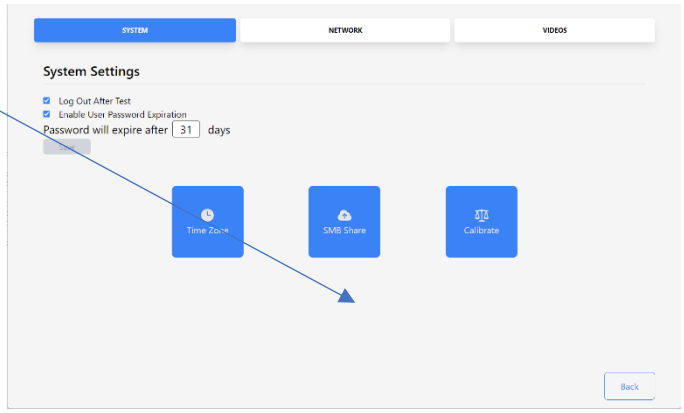
15.5 Drive Mapping

15.5.1 Setting the SMB Share Password

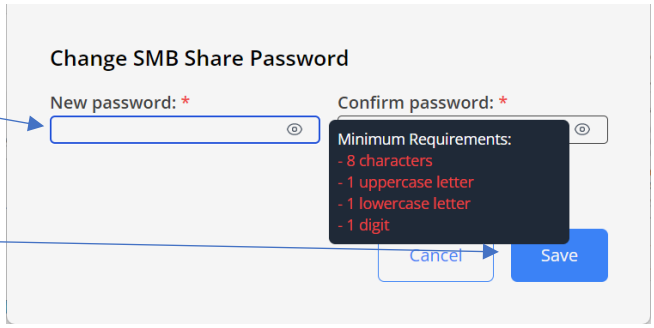
The SMB password can be set and reset on device by an administrator user.

From the **System Settings** Screen

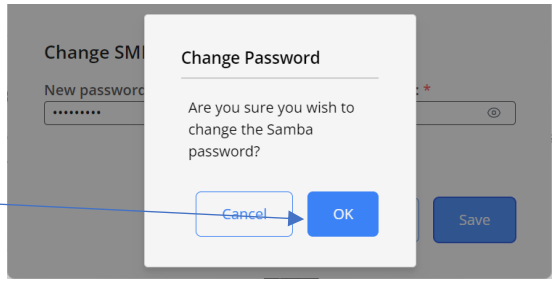
1. Click the **SMB Share** Button



2. Enter a password that meets all the requirements
3. Click **Save** Button



4. Click to confirm the change



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.

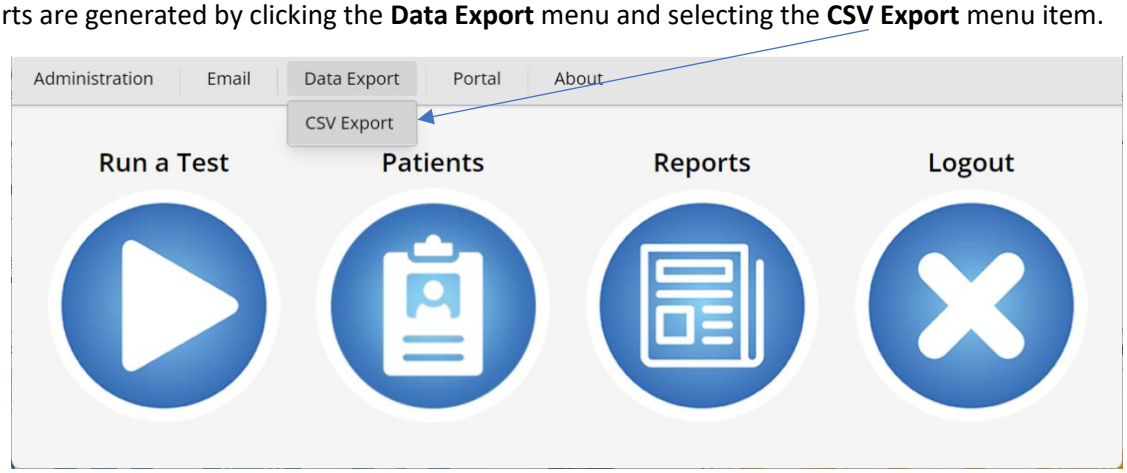
To map this drive, follow the appropriate Drive Mapping Instructions available at https://cognivue.com/customer-resource-center/.

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.



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 Salience 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 Salience 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 https://cognivue.com/customer-resource-center/.

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

Parameter	Clarity Model 1	Clarity Model 2
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	19V DC, 2.5 A Nominal
Weight	4.2 kg (9lbs 2oz)	3.3 kg (7lbs 3oz)
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	Infineon CYW43455 • 20.5 dBm max output power for 2.4 GHz 802.11b/g/n • 21.5 dBm max output power for 5.0 GHz 802.11a/n/ac

17 Safety Precautions

Observe the following precautions to ensure safety and to 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.

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:

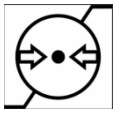
EMC Emission	Parameter	Standard	Test Level/Note
	Conducted Emissions	5011:2009, CISPR 11:2009 + A1:2010	Class A
	Radiated Emissions	N 55011:2009, CISPR 11:2009 + A1:2010	Class A
	Harmonic Current	EN/IEC 61000-3-2	Class A
	Voltage Flicker	EN/IEC 61000-3	-
EMC Immunity	Electrostatic Discharge	IEC/EN 61000-4-2	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

Manufactured by:
Cognivue, Inc.
7911 Rae Blvd
Victor, NY 14564
USA

United Kingdom Responsible Person
Donawa Lifescience Limited
Aviation Business Park
Christchurch
BH23 6NX
UK