

User Manual

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2 About This Guide

This User Manual contains information that describes the operation of Cognivue Thrive[®]. 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-420-U Cognivue Thrive® User Manual 3/22/2023



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3 About Cognivue Thrive®

Cognivue Thrive® is a computerized cognitive assessment device to evaluate cognitive function objectively, quantitatively, and reliably. Cognivue Thrive® relies on a series of 6 subtests. Using the results from these subtests, Cognivue Thrive® creates a short, easy-to-interpret report. The report shows three cognitive domain scores: Memory, Visuospatial, and Executive Function. Below these are two metrics on Reaction Time and Speed Processing. Normative ranges appear below the visual of each cognitive domain score and metric. These segment into classifications of good, moderate, or poor ability. 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 Thrive® is indicated for use as an adjunctive tool for evaluation cognitive function in ages 18 and over.

3.2 Indications for Use

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

3.3 Clinical Reference Information

Cognivue Thrive® is based on the same technology as Cognivue® Advanced and Cognivue® Clarity. Cognivue Thrive uses a subset of the Cognivue Advanced® algorithms to provide a similar breakdown of cognitive scores in a shorter duration test.

Cognivue Thrive® algorithms have been compared vs. Cognivue Advanced® in a clinical trial with 100 subjects. The correlation between Advanced and Thrive was in the same category of Advanced vs.

Advanced, which was statistically significant (moderate positive 0.57), and Thrive's test reliability was high positive (0.74).

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.

4 Device Description

The *Cognivue Thrive*® 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.

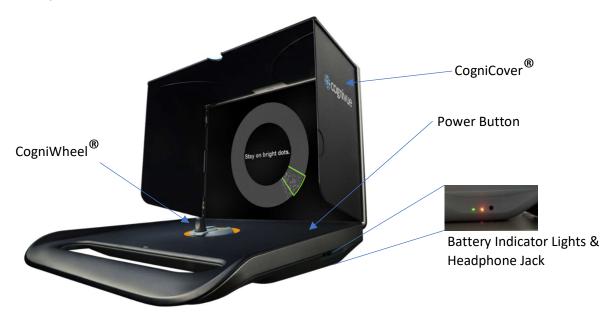


Figure 1 Cognivue Device (Front)

5 Power Management

The Cognivue Thrive®, 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.

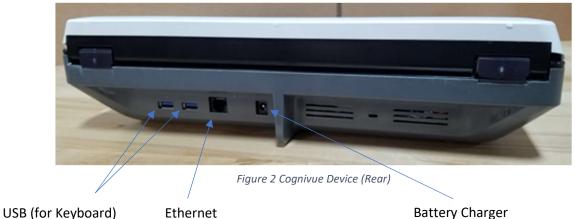
The battery sustains 4 hours of intensive, off charger usage but can last for over 8 hours typical usage. The battery recharges in approximately 4 hours if depleted completely.

5.1 Indicator Lights

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

	Left Light	Right Light
Device is unpowered	Off	Off
Device is discharging	Orange	Off
Device is charging	Green/Off	Orange
Plugged in and fully	Green/Off	Green
charged		

Table 1 Charging Lights



5.2 Screen Sleep

When the Cognivue Thrive 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 Thrive® 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

<u>DO NOT</u> 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 Thrive®

Cognivue recommends sanitizing the Cognivue Thrive® 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. <u>DO NOT</u> 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 Thrive® 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 Thrive® 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 Ω 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
- 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

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

automatically connect when possible.



Figure 5 Authentication Prompt



Figure 6 Network Selection Menu

7.3 Connection Details

When logged on to a Cognivue Thrive® 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

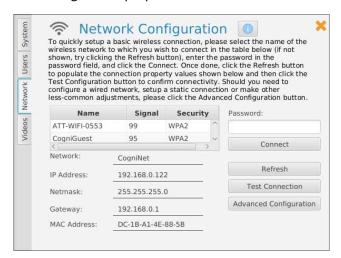


Figure 7 Network Configuration Screen

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.



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 Thrive® 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	Х	Х
Entering patient data & running a test	Х	Х
Running a test with an intro video	Х	Х
Viewing past test reports	Х	

Table 8-1

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

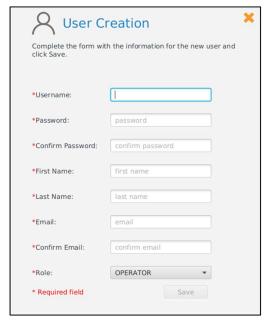


Figure 10 User Creation Screen

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



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



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 Prompt

Figure 14 Password Expiration Section

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 Thrive® 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
- Select Device Administration >> Settings
- 3. Click the System tab



Figure 16 System Settings Screen

9.1 Client Code

The Cognivue Thrive® device provides the option to include a custom code on all tests for purposes of categorization. Any sequence of up to 100 characters can be entered for each patient test session.

A user account with the Administrator role can enable it by checking the **Enable Client Code** checkbox on the **System Settings** screen. Making this selection will add the Client Code text box to the **Assessment Setup** screen before each assessment, where operators can enter the client code.

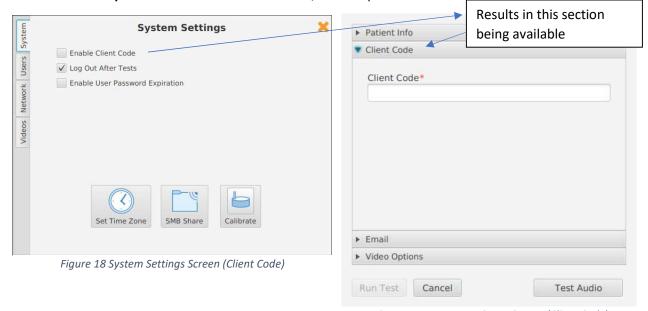


Figure 17 Assessment Setup Screen (Client Code)

9.2 Video Settings

This screen allows Administrators to ensure certain videos 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

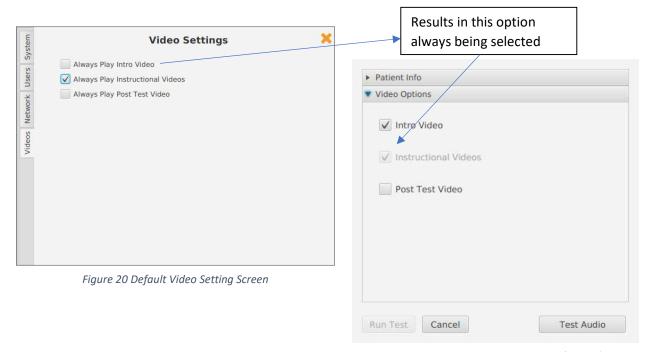


Figure 20 Assessment Setup Screen (Videos)

10 Report Settings

The Thrive 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.

10.1 Report Emailing

Cognivue Thrive® 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.

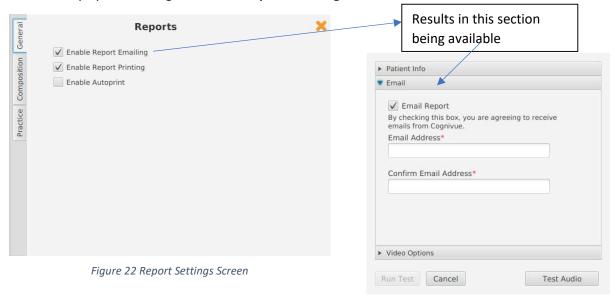


Figure 23 Assessment Setup Screen (Email)

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.



Figure 21 Default Report Settings Screen

10.2 Report Printing

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

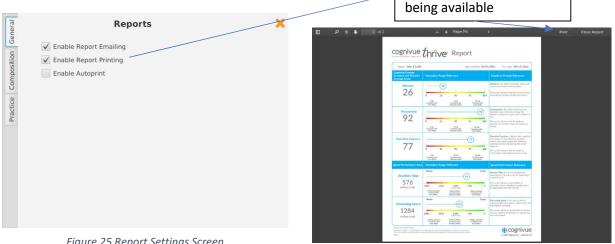


Figure 25 Report Settings Screen

Figure 24 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 Thrive® 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

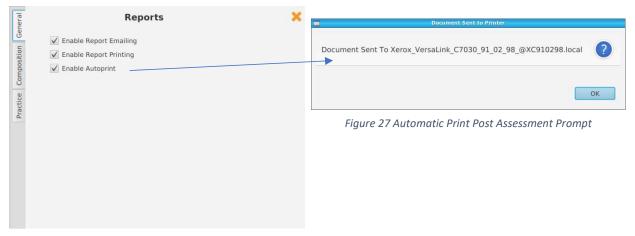


Figure 27 Reports Settings Screen

10.4 Report Composition

To open the Report Settings Screen

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



Figure 28 Report Composition Screen

Report Composition allows the inclusion of the Coginwell 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
- Select Device AdministrationReport Settings
- 3. Click the Practice tab

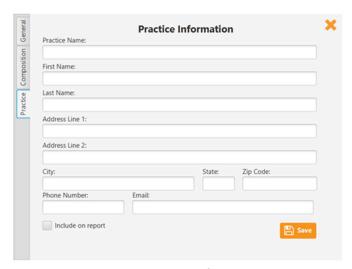


Figure 29 Practice Info Screen

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

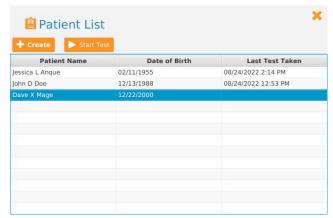


Figure 30 Patient List Screen

12.1 Pre Entering Patients

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

- 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



Figure 31 Patient Creation Screen

13 Assessments

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

13.1 Run Test (Main Screen)



Figure 13-1 Main Screen (Administrator)

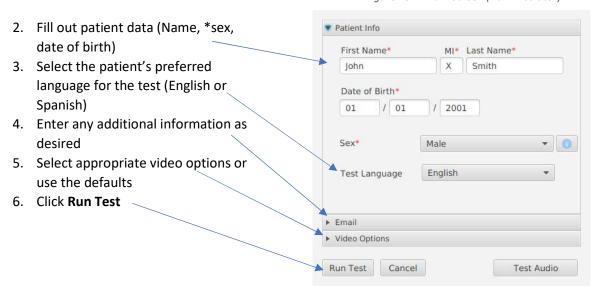


Figure 13-2 Assessment Setup Screen

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

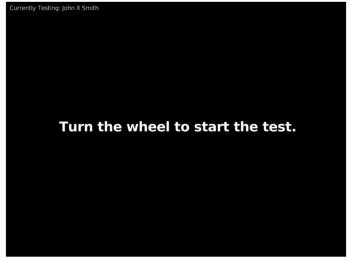
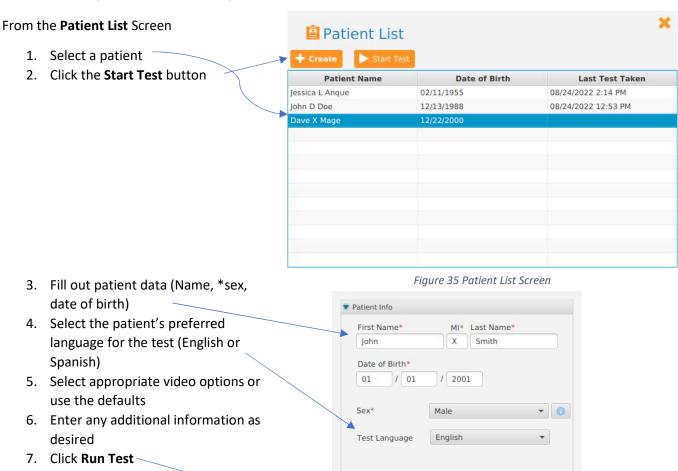


Figure 32 Start of the Cognivue Assessment

13.2 Run Test (Patient List Screen)



▶ Email▶ Video Options

Run Test Cancel

Figure 35 Assessment Setup Screen

Test Audio

The patient should turn the CogniWheel when ready to begin



Figure 35 Start Assessment Screen

13.3 Video Volume Control

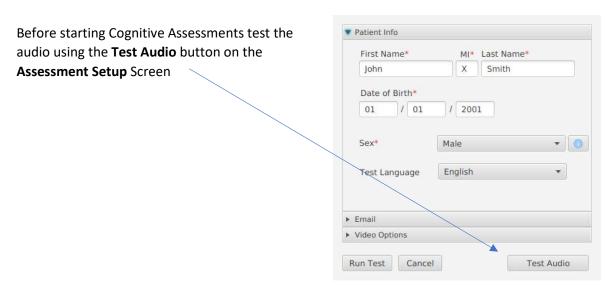


Figure 36 Assessment Setup Screen

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



Table 13-1 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 Practitioner Report

This document is intended for the practitioner. It contains the test scores and normalized ranges. Additional information is provided to the practitioner to help with explaining scores to the patient.

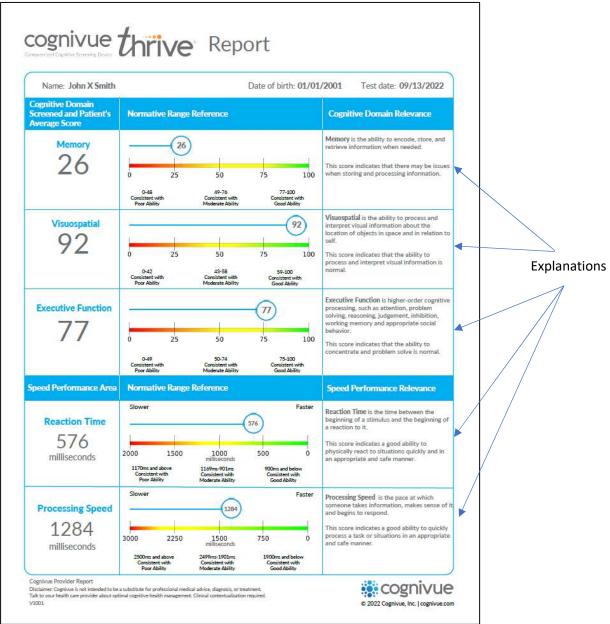


Figure 37 Practitioner Report

14.2 Patient Report

This document is intended for the patient. It contains the test scores and normalized ranges. Additional information is provided to define the domains in patient-friendly language.

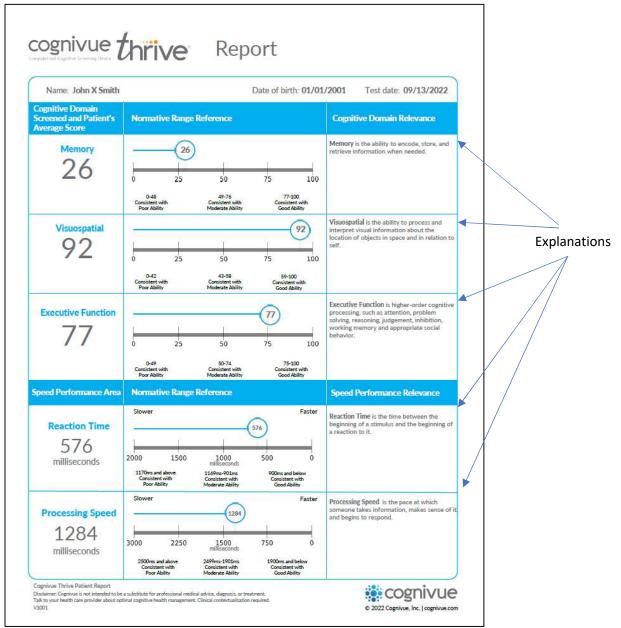


Figure 14-2 Patient Report

14.3 Cogniwell Letter

It provides information about Cognivue's Cogniwell program



Figure 14-3 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.



Figure 38 Report List Screen

15.3 Printing

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

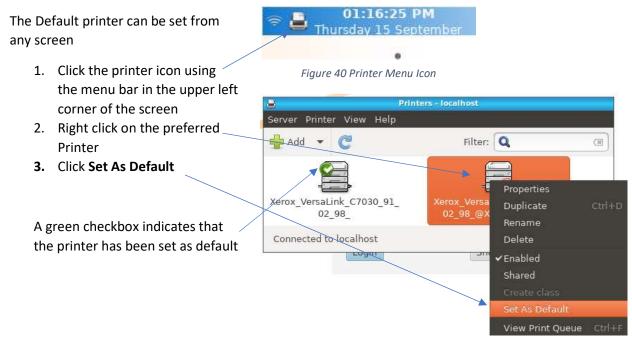


Figure 40 Printer Management Screen

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.

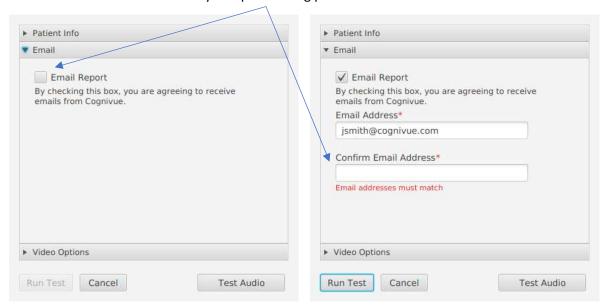


Figure 42 Email Report Checkbox

Figure 42 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 43 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.

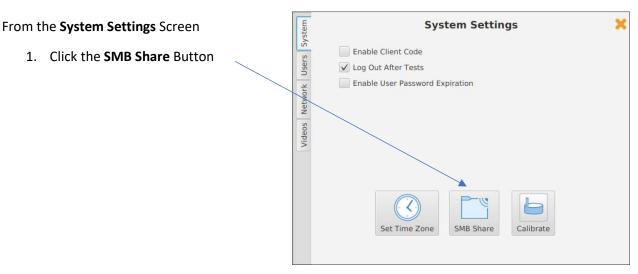


Figure 46 System Settings Screen

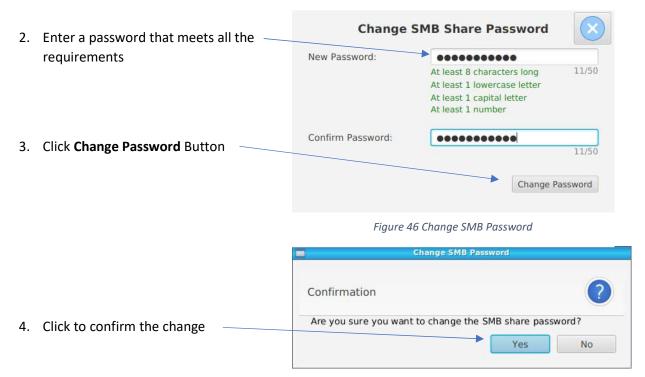


Figure 46 SMB Change Confirmation

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.

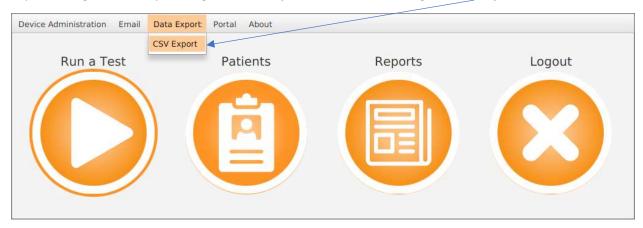


Table 15-1 Main Screen (CSV Export)

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
- Instructional Videos
- Post Test Video
- Visuospatial
- Executive Function
- Memory
- Reaction Time (ms)
- Processing Speed (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

	10 to 30 °C (50 to 86 °F)
Operating Environment	10% to 85% Relative humidity, non-condensing
	70 to 106 kPa Atmospheric Pressure
Transport and Storage	-20 to 50 °C (-4 to 122 °F)
Environment	10 to 85% Relative humidity, non-condensing
Environment	50 to 106 kPa Atmospheric Pressure
Power Input	19V DC, 3.5 A Nominal
Weight	4.2 kg (9lbs 2oz)
	Intel Dual Band Wireless-AC 3168
Wireless Communications	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 Thrive®:

- 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 Thrive[®].
- 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 Thrive[®]. 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 reorienting 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

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	Class A
		11:2009 + A1:2010	
	Radiated Emissions	N 55011:2009, CISPR	Class A
		11:2009 + A1:2010	
	Harmonic Current	EN/IEC 61000-3-2	Class A
	Voltage Flicker	EN/IEC 61000-3	-
EMC	Electrostatic Discharge	IEC/EN 61000-4-2	15 kV air, 8kV contact
Immunity	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:

[]i	Follow the operating instructions		
 	Type B applied part		
SN	Serial Number		
=	DC input		
M	Manufacturer Date		
***	Manufacturer's name and address		
TÜVReeland c us	NRTL Mark (Safety Certification Mark)		

The following symbols may be used for Environmental Conditions for Transport

\$••	Atmospheric Pressure Limitation
*	Temperature Limitation
<u></u>	Relative Humidity Limitation
Ť	Keep away from rain
Ţ	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