

# User Manual

Τ		ontents	
2	Ak	bout This Guide	4
3	Ak	bout Cognivue Thrive®	5
	3.1	Intended Purpose	5
	3.2	Indications for Use	5
	3.3	Clinical Reference Information	5
4	De	evice Description	6
5	Po	ower Management	8
	5.1	Battery Indicator Lights	8
	5.2	Screen Sleep	8
	5.3	Power Alert	8
6	Re	ecommendations for Use	9
	6.1	General Testing Location	9
	6.2	Cleaning and Disinfecting Cognivue Thrive ®	9
	6.3	Use of Personal Protective Equipment	9
7	Ne	etwork Connectivity	10
	7.1	Basic Wired Connection	10
	7.2	Basic Wi-Fi Configuration	10
	7.3	Connection Details	11
8	Se	ecurity	12
	8.1	Login	12
	8.2	User Management	12
	8.3	User Creation	13
	8.4	User Modification	14
	8.5	Password Reset	15
	8.6	Auto-Logout	
	8.7	Password Expiration	16
	8.8	Disabling Accounts	16
9	Sy	ystem Settings	
	9.1	Video Settings	
10	)	Report Settings	18
	10.1	Report Emailing	18
	10.2	Report Printing	19

1	10.3	Α	Automatic Printing	19
1	0.4	R	Report Composition	20
1	10.5	Р	Practice Information	20
11		Por	tal Menu	20
12		Pati	ient Management	21
1	2.1	Р	Pre Entering Patients	21
13		Ass	essments	21
		R	Run Test ( <b>Main</b> Screen)	22
1	13.1			22
1	13.2	٧	/ideo Volume Control	22
14		Ass	essment Reports	23
1	4.1	Р	Provider Report	24
1	4.2	Т	hrive Patient Report	25
1	L4.3	C	Cogniwell Letter	26
15		Acc	essing Reports	27
1	15.1	٧	/iewing Reports	27
1	15.2	R	Reviewing Reports	27
1	15.3	Р	Printing	28
1	L5.4	Ε	mailing	29
1	15.5	D	Prive Mapping	30
	15	5.5.1	Setting the SMB Share Password	30
	15	5.5.2	Reports Mapping	31
	15	5.5.3	S CSV Mapping	31
16		Tec	hnical Specifications	.33
17		Safe	ety Precautions	34
18		Pro	duct Safety Standards	35
19		Pro	duct Safety Symbols	. 36

#### 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 <a href="mailto:support@cognivue.com">support@cognivue.com</a>.

UM-520-B Cognivue Thrive® User Manual 5/7/2024



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#### 3 About Cognivue Thrive®

Cognivue Thrive® is a computerized cognitive assessment aid 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 short, easy-to-interpret reports. 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 performance scores 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.

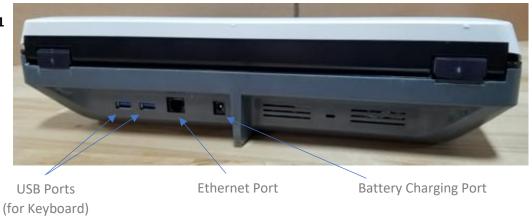
#### 4 Device Description

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.





#### **Thrive Model 1**





**Battery Indicator** 

#### 5 Power Management

Much like a laptop, the Cognivue Thrive® 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 Thrive® 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 Thrive® battery will fully recharge in approximately 4 hours.

#### 5.1 Battery Indicator Lights

Both models of Cognivue Thrive® 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® Thrive Model 1	Color of Left LED	Color of Right
, , , , , , , , , , , , , , , , , , , ,	Indicator	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	Off	Off
<b>OR</b> Device is Off		

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

Battery and Charging Status of Cognivue® Thrive 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 Pluaged In. Battery is Chargina	Blue

Device is on and Plugged In, Battery is Charging
Device is Unplugged, Battery is Discharging
Device is Unplugged, Battery is Completely Drained

OR Device is Off

White -> Orange -> Blinking Red

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

#### 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 Cognivue Thrive® 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 patient 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 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

<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  $^{\hat{U}\hat{U}}$  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.



- 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.



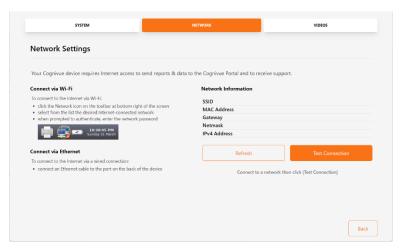
#### 7.3 Connection Details

When logged on to a Cognivue Thrive® 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 Settings window contains network configuration properties and their values



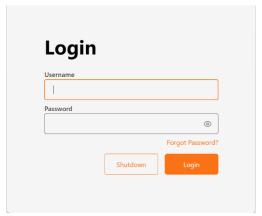
The **Refresh** button refreshes the displayed connection values

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

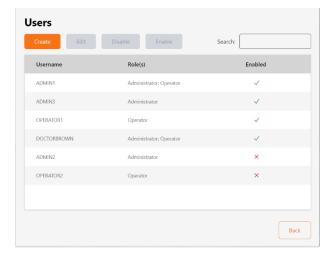
Each Cognivue Thrive® user should have their own user account to ensure audit trail and safety of patient data.

User accounts can be assigned with Administrator and Operator roles on the User Management Screen.

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

#### To open the User Management Screen

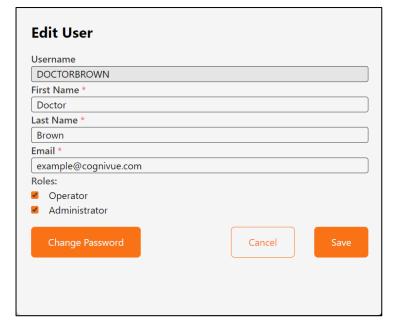
- 1. Log in
- 2. Select Administration >> Device Settings
- 3. Click the Users tab



#### 8.3 User Creation

#### From the User Management Screen

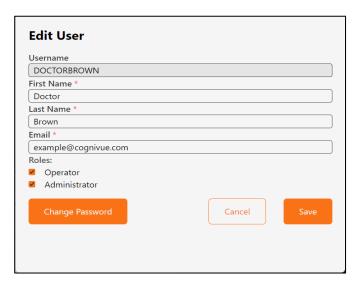
- 1. Click Create
- 2. Fill out form
- 3. Click Save
- 4. Click **Yes** to confirm when prompted



#### 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
- 5. Click Yes to confirm when prompted

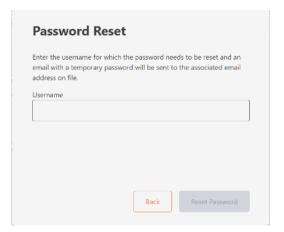


#### 8.5 Password Reset

If a Cognivue Thrive® 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
- Check user's associated email account for an email from donotreply@cognivue.com with a temporary password
- Once the email from <u>donotreply@cognivue.com</u> has been sent, that user has 24 hours to login to their Cognivue Thrive® device and enter the temporary password they received
- 6. 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 Thrive® device going forward





#### 8.6 Auto-Logout

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

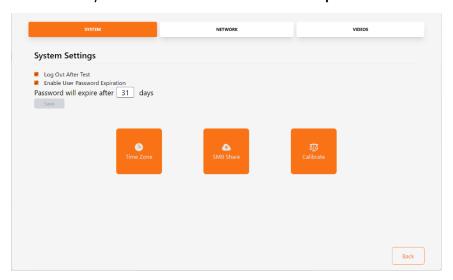
#### 8.7 Password Expiration

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

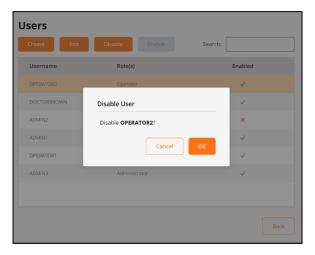


#### 8.8 Disabling Accounts

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



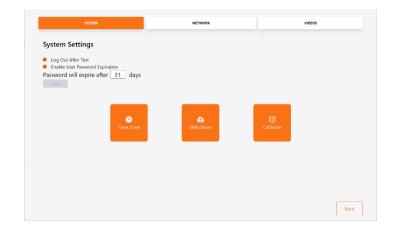
#### 9 System Settings

The Cognivue 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**

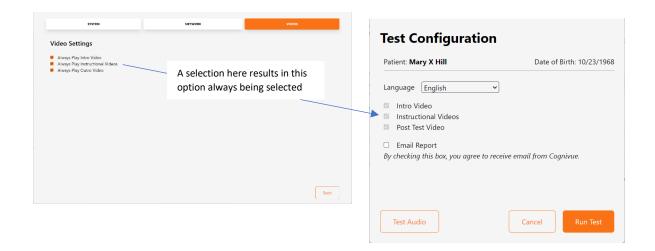
- 1. Log in
- Select Administration >> Device Settings
- 3. Click the **System** tab



#### 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

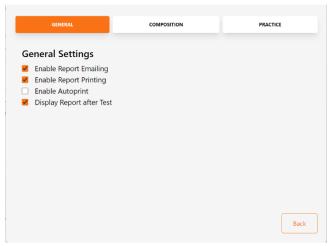


#### 10 Report Settings

The Cognivue 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.

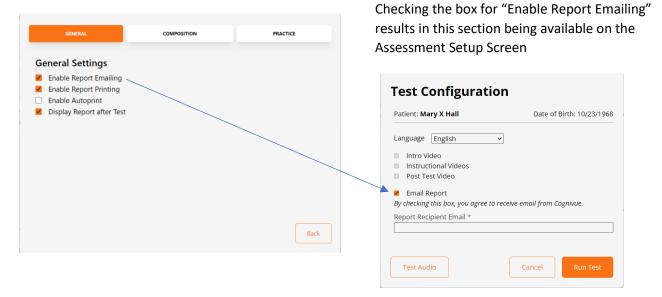
#### To open the **Report Settings Screen:**

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



#### 10.1 Report Emailing

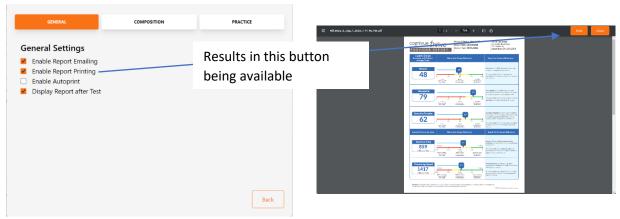
Cognivue Thrive® provides the ability to send the test report via an encrypted email to a patient following completion of a test. This feature is enabled by default. An Administrator can disable this functionality by unchecking the **Enable Report Emailing** checkbox.



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

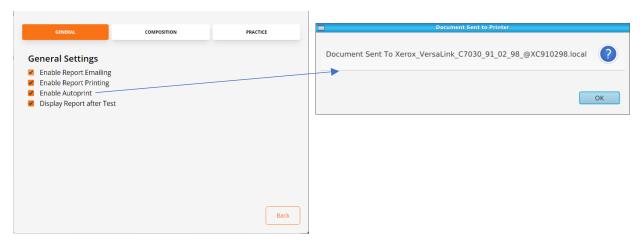
Cognivue Thrive® provides the ability to print the test report to a configured, connected printer. Printing test reports from Cognivue Thrive® is enabled by default. An Administrator can disable this functionality by unchecking the **Enable Report Printing** checkbox.



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

#### 10.3 Automatic Printing

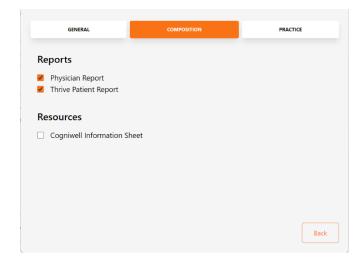
Cognivue Thrive® provides the ability to automatically print the associated report upon completion of a test. Automatic printing of test reports is disabled by default. An Administrator can enable this functionality by checking the **Auto Print** checkbox



#### 10.4 Report Composition

To open the Report Settings Screen

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

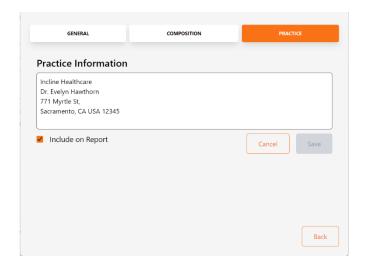


**WARNING:** At the conclusion of the assessment, only the selected reports will be generated. Reports that do not have check marks next to them will not be generated. Reports cannot be generated after an assessment has been completed either, so unchecked reports will be permanently unavailable.

#### 10.5 Practice Information

To open the **Practice Information Screen** 

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



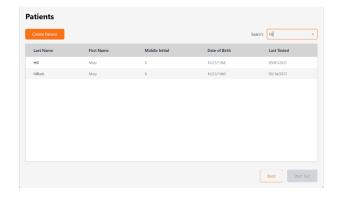
#### 11 Portal Menu

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

- 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

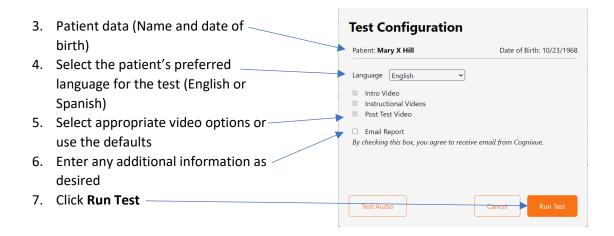


#### 13 Assessments

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

#### 13.1 Run Test (Patient Screen)

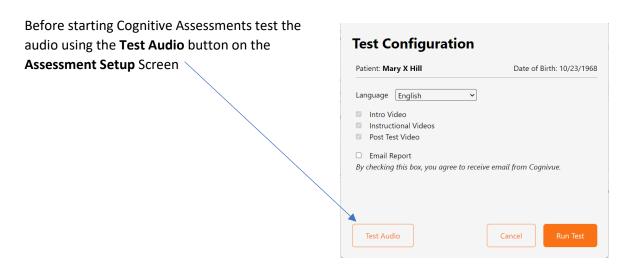




8. The patient should turn the CogniWheel® to start the test



#### 13.2 Video Volume Control



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

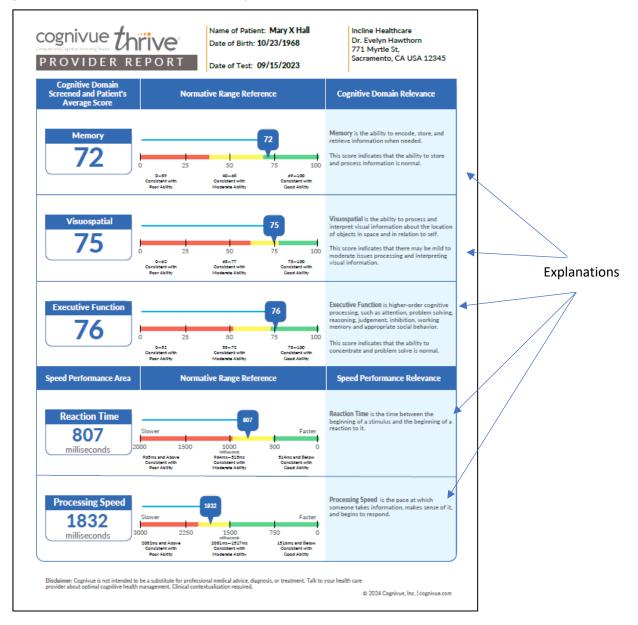
There are three different reports and resources that can be generated at the conclusion of a cognitive assessment:

- Practitioner Report
- Thrive Patient Report
- Cogniwell Information Sheet

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).

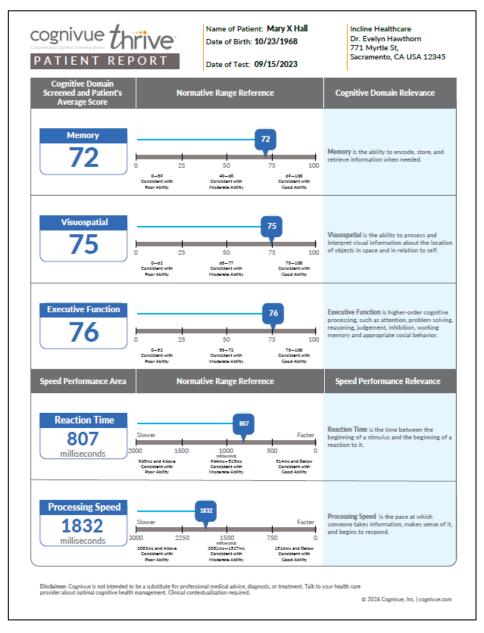
#### 14.1 Provider Report

This report is intended for the practitioner or physician. It displays the test scores and normalized ranges. Additional information is provided to the practitioner to help them explain the scores to the patient. Clinical contextualization is required.



#### 14.2 Thrive Patient Report

This report 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. Clinical contextualization is required.



#### 14.3 Cogniwell Letter

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



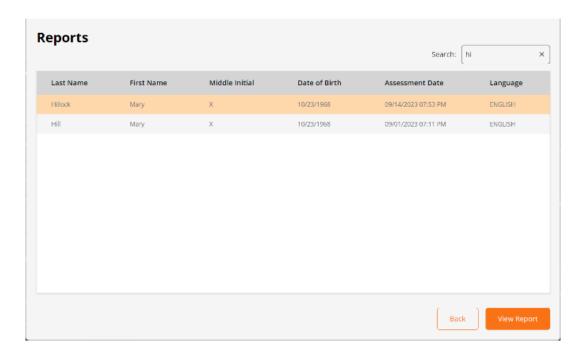
#### 15 Accessing Reports

#### 15.1 Viewing Reports

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

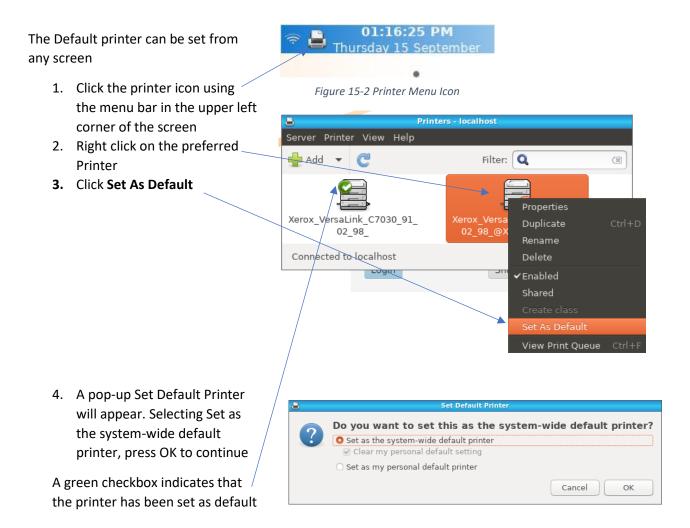
#### 15.2 Reviewing Reports

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 Cognivue Thrive® device whenever a report is opened in the report viewer. The print feature prints to the device's default printer.



#### 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

System Settings

Log Out After Test

Resword Pall-expire after 31 days

Time Zone

SYSTEM NETWORK VIOLOGE

System Settings

Log Out After Test

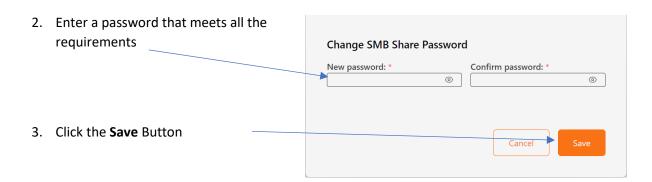
SAMB Share

SAMB Share

Log Out After Test

SAMB Share

SAMB Share





#### 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 <a href="https://cognivue.com/customer-resource-center/">https://cognivue.com/customer-resource-center/</a>.

The information you will need for this share is

• Ip Address: Retrieved from the Network tab

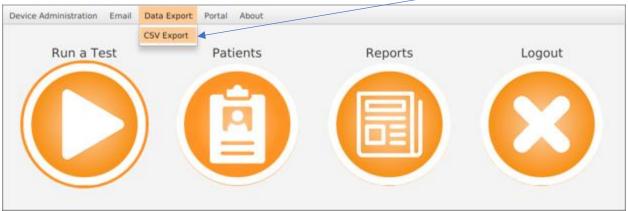
Mapping folder: Reports (e.g., \\192.168.0.48\Reports)

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
- 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 <a href="https://cognivue.com/customer-resource-center/">https://cognivue.com/customer-resource-center/</a>.

The information you will need for this share is

Ip Address: Retrieved from the Network tabMapping folder: Csv (e.g., \\192.168.0.48\Csv)

• Username: cogaccess

• Password: Set by device administrator

# 16 Technical Specifications

Parameter	Thrive Model 1	Thrive Model 2	
Operating	10 to 30 °C (50 to 86 °F)		
Environment	10% to 85% Relative hur	,,	
	70 to 106 kPa Atmospheric Pressure		
Transport and	-20 to 50 °C (-4 to 122 °F)		
Storage	10 to 85% Relative humidity, non-condensing		
Environment	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)	
	Intel Dual Band Wireless-AC 3168	Infineon CYW43455	
Wireless	<ul> <li>20 dBm max output power for</li> </ul>	• 20.5 dBm max output power	
	2.4 GHz 802.11b/g/n	for 2.4 GHz 802.11b/g/n	
Communications	• 23 dBm max output power for	• 21.5 dBm max output power	
	5.0 GHz 802.11a/n/ac for 5.0 GHz 802.11a/n/ac		

#### 17 Safety Precautions

Observe the following precautions to ensure safety and to 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<sup>®</sup>. 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

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	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
<b>†</b>	Type B applied part
SN	Serial Number
	DC input
M	Manufacturer Date
	Manufacturer's name and address
TÜVRevitand c us	NRTL Mark (Safety Certification Mark)

The following symbols may be used for Environmental Conditions for Transport

<b>\$•</b> \$	Atmospheric Pressure Limitation
*	Temperature Limitation
<u></u>	Relative Humidity Limitation
<del>**</del>	Keep away from rain
Ţ	Handle with Care



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