User Manual

NEXT-Cue
Version v1.0.0.x

NEXT-Cue User Manual, English
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Thank you for using NeuroXT's Product.

This user manual is intended for NEXT-Cue users' reference. It contains information about the components, instructions for use, and safety precautions for NEXT-Cue. Please read the manual before using NEXT-Cue. We suggest keeping the manual stored safely for future reference.

*A printed copy of this User Manual is available upon request from the manufacturer or its authorized representative.

Homepage

For more information about NeuroXT Inc. and our product, please visit us at www.neuroxt.co.kr.

The NEXT-Cue service can only be accessed via the official URL provided by NeuroXT Inc.. Access through any unauthorized or alternative URL is not supported.

General Information

- **NEXT-Cue** is a registered trademark of NeuroXT Inc.
- The contents of this User Manual are protected by copyright. If any part of this User Manual is modified or distributed without the written consent of NeuroXT Inc., you will be held legally responsible.
- NeuroXT Inc. may change or update the product specifications and the manual's contents without prior notice.

Certified Use

- The use of NEXT-Cue is subject to local laws and regulatory conditions.
- HAS/HSS (FDA): NEXT-Cue has received FDA 510(K) clearance as a medical device, K261805. Rx Only.

1. Introduction

1.1. Product Overview

NEXT-Cue is a cloud-based brain imaging analysis software designed to support clinical assessment of patterns associated with progression from mild cognitive impairment (MCI) to clinical Alzheimer's disease (AD) dementia within five years. By automatically generating quantitative analysis results from clinical and MRI data, the software supports healthcare professionals in making faster and more accurate assessments of cognitive decline risk.

Key features are as follows:

- **Prognitor Score:** Provides a scaled similarity score reflecting the degree of similarity between the patient profile and the converter and non-converter reference populations, based on structural MRI data and clinical variables. The Prognitor Score is not an individual probability of progression and must be interpreted together with other relevant clinical information.
- **Key Predictive Factors:** Highlights the contribution of major predictors such as MMSE, CDR-SOB, hippocampal and entorhinal volumes and brainstem measurements.
- **AI-Driven Automated Analysis:** Automatically processes imaging data without manual intervention once scans are uploaded.
- **Seamless PACS/EHR Integration:** Connects with hospital systems to ensure smooth and efficient clinical workflow.

1.2. Indications for use

1.2.1. Intended Use and Indications for Use

NEXT-Cue is a software application indicated as a prognostic tool to aid in the clinical assessment of patients aged 55 through 88 years who are diagnosed with mild cognitive impairment (MCI) and are being evaluated for progression to clinical Alzheimer's disease (AD) dementia within five years of assessment.

NEXT-Cue analyzes inputs of brain magnetic resonance imaging (MRI), patient demographic information, and cognitive assessment scores to produce a similarity score between 0 and 100 reflecting the degree of similarity between the patient and two reference populations of MCI patients who either did not progress to clinical AD-dementia within 5 years (non-converters) or progressed to clinical AD-dementia within 5 years (converters).

NEXT-Cue is intended to be used in clinical environments by trained healthcare professionals as a supplementary tool, and its outputs are meant to support not replace comprehensive clinical evaluation and must be interpreted alongside clinical history, physician examination, and

other diagnostic tests. NEXT-Cue is not intended to be used as a diagnostic tool for MCI or Alzheimer's disease.

1.2.2. Intended Patient Population

The intended patient population for NEXT-Cue includes individuals aged 55 through 88 years who have been clinically diagnosed with mild cognitive impairment (MCI) and are undergoing evaluation for progression to clinical Alzheimer's disease (AD) dementia within 5 years.
The software is intended for use in adult and elderly populations consistent with its prognostic purpose.

*__Note__: Clinical performance was evaluated in an ADNI-derived external-validation cohort of patients aged 55 years and older with mild cognitive impairment (MCI) who were assessed for progression to clinical Alzheimer's disease dementia within approximately five years. The cohort was predominantly White and was collected in a controlled academic research setting. Clinical performance has not been independently estimated in every clinical environment, scanner configuration, MRI protocol, demographic subgroup, or workflow condition.

The available premarket data were insufficient to reliably estimate performance in Black/African American, Hispanic/Latino, Asian, and other underrepresented racial and ethnic populations. Performance in these populations has not been established. Clinical interpretation should account for this limitation. Clinicians should consider these limitations when interpreting the NEXT-Cue output. Observed perfect estimates in the Asian subgroup were based on five subjects and are statistically uninterpretable; they do not demonstrate equivalent performance in Asian patients.

Performance has not been established for patients younger than 55 years or older than 88 years, patients without a clinical diagnosis of MCI, or use outside the supported operating conditions represented in premarket validation.

1.2.3. Intended Users

- Healthcare Professionals:
  - Appropriately trained licensed healthcare professionals involved in the clinical assessment of patients with cognitive impairment.
  - Training and Qualifications:

- Applicable professional licensure and appropriate clinical training.
- Experience in assessing patients with cognitive disorders.
- Familiarity with clinical cognitive assessments and with interpreting or using brain MRI findings in clinical decision-making.
- Ability to read and understand the English-language user interface, labeling, User Manual, and warnings.

1.2.4. Intended Use Environment

Use in clinical settings, including hospitals, community hospitals, memory clinics, neurology practices, and other settings in which qualified healthcare professionals evaluate adults with mild cognitive impairment, on supported desktop or laptop computers. The software is not intended for use on mobile devices such as smartphones or tablets.

1.2.5. Medical Indication Summary

NEXT-Cue is indicated for use in patients aged 55 through 88 years with a clinical diagnosis of mild cognitive impairment (MCI) who are being evaluated for progression to clinical Alzheimer's disease (AD) dementia within five years.

1.3. Safety Information

1.3.1. Contraindications

No known specific contraindications.

1.3.2. Precautions



- **Warning**
  - The analysis results are intended to support clinical decision-making and **must not be used as a standalone diagnostic or prognostic tool**.
  - If no AI result is generated because of image quality, missing required patient data, preprocessing failure, or system-related failure, clinical management should proceed according to standard clinical practice and independent clinician judgment. The absence of an AI result must not be interpreted as a low-risk finding.
  - A reduced-input result generated without MMSE input is not equivalent to a result generated with complete input data. The simulated MMSE-masking analysis does not establish prospective performance in patients with actually unavailable MMSE data. When MMSE is not entered, interpret the result together with other available clinical information and consider obtaining a valid cognitive assessment when clinically appropriate. A reduced-input result must not be used as the sole basis for diagnosis, treatment selection, referral, or patient-management decisions.
  - Only authorized users with assigned accounts are permitted to access the software.
  - Do not terminate the software during data processing, as this may result in data corruption or incomplete results.

- The software has been validated for patients aged 55 through 88 years with mild cognitive impairment undergoing assessment for progression to clinical Alzheimer's disease dementia. Premarket performance has not been adequately established in Black/African American, Hispanic/Latino, Asian, and other underrepresented racial and ethnic populations. Performance outside the validated age range, intended patient population, and supported operating conditions has not been established.



- **General Caution**
  - The software must be used only for its approved purpose and in accordance with authorized guidelines. The user is responsible for any issues resulting from unauthorized use.
  - Do not delete or move image data while it is being processed.
  - The installation, maintenance, and repair of NEXT-Cue must be performed only by engineers qualified by NeuroXT Inc.
  - MRI data used for analysis must follow the recommended acquisition protocol (e.g., resolution, coil type, and scan parameters). Images with distortion, noise, or artifacts may reduce the reliability of the analysis results.
  - NEXT-Cue is intended for analysis of supported T1-weighted structural brain MRI acquired according to the recommended acquisition protocol. If required MRI conditions or essential DICOM information are not met, the analysis may fail and no result may be generated.
  - Errors in demographic information or cognitive assessment scores can directly affect the prediction outcome; therefore, all input data must be carefully verified before submission.
  - An MMSE value that is entered but outside the valid range is treated as invalid input and does not support analysis.

- **Caution for Use**
  - Be sure to log out after using the program for security.
  - User accounts must not be shared between individuals. Each healthcare professional should use a personal account with appropriate access rights to ensure traceability and data security.
  - In shared clinical environments, users should ensure that screens and reports displaying patient information are not left unattended and are closed or locked when not in use.
  - The primary responsibility for patient and examination identification remains with the source systems and clinical users, including EHR, EMR, PACS, and local clinical workflow. Before interpreting the AI

output, users should confirm consistency between the report, the original clinical information, and the corresponding imaging study.
- When no MMSE value is entered, the MMSE field displays “Not available.” A completed result with MMSE displayed as “Not available” was generated without MMSE input. Verify the displayed input status before interpreting the result.
- Do not turn off the PC or its programs while in use.
- Change your password every 90 days to enhance security.
- If a cybersecurity incident is suspected, users must immediately report the event to the manufacturer.
- The NEXT-Cue service can only be accessed via the official URL provided by NeuroXT Inc.. Access through any unauthorized or alternative URL is not supported.
- The report is designed to display the Patient ID and Patient Name in an identifiable location. The intended clinical workflow provides access to the corresponding patient identity and relevant clinical information through the hospital EHR, EMR, and PACS systems, and the User Manual instructs users to verify consistency before interpreting the AI output.
- If ImageQC rejects an MRI study or no AI result is generated, do not interpret the unavailable result as a low-risk finding. Verify the MRI study and required input data; if clinically appropriate, submit an appropriate study or repeat MRI according to local workflow. Continue standard clinical evaluation without delay.

1.4. System Information

1.4.1. Functionalities

NEXT-Cue provides the following key functionalities:

- Worklist view
  - Review the status of input data received from PACS and EHR.
  - Monitor analysis progress and completion status.
- Data Analysis
  - Generates a numerical 0–100 scaled similarity score reflecting similarity to converter and non-converter reference populations in the validated MCI cohort.
  - Provides quantitative contributions of key predictive features (e.g., brain regional volumes, demographic variables, cognitive scores).
  - Produces visualizations of regional structural abnormalities using Z-score maps compared to healthy controls.
  - Automatically generates a PDF report that can be downloaded or transferred to PACS.

1.4.2. Minimum System Requirements for the Software

Users can access NEXT-Cue software through a web browser via a specific URL. The system specifications detail the minimum and recommended requirements for operating the Client application.

Minimum Specification	Client (for user interface)
OS	Microsoft window 11 64-bit
Hardware	- CPU: 6 physical core or higher - RAM: 16GB or higher - Storage: 80GB or higher - Network: 100Mbps or higher
Web-Browser	Google Chrome 140 or higher
Network	100Mbps Ethernet-based Intranet/Internet connection

1.4.3. Labeling

Symbol	Definition
	'User Manual' reference symbol. This product is provided with the electronic instructions for use (eIFU), which can be accessed and downloaded directly within the software.

1.4.4. Symbols Glossary

Symbols used in this user manual are as follows. Please take a moment to understand the symbols in the table below.
Warnings, cautions, and notes are for the correct and safe use of the product. Please be aware of the following for safety. NeuroXT Inc. is not responsible for failures resulting from negligence regarding safety warnings and cautions.

Symbols	Meaning
Note	Indicates useful information about features of the software.
Caution 	Indicates potentially hazardous situations for the patient or user that could result in lost time, reduced image quality and/or re-examination of the patient.
Warning 	Indicates potentially hazardous situations that could result in direct or indirect patient injury, mainly in the form of misinterpretation or misdiagnosis.
	Manufacturer. The symbol is accompanied by the name and address of the manufacturer.

	e-IFU (electronic-Instructions for Use) The link that directs users to this user manual is alongside the symbol.
	Catalog number
	Lot number. Version number of the software.
	Medical Device. Indicates that this software is a medical device as defined by applicable regulations.
	Unique Device Identification. Indicates the Unique Device Identifier assigned to this software for product identification and traceability.
	Indicates that U.S. federal law restricts this device to sale by or on the order of a licensed healthcare professional.

1.4.5. Abbreviations

The following are the definitions of the abbreviations used in this User Manual.

Abbreviation	Definition
MRI	Magnetic Resonance Imaging – A non-invasive imaging technique used to visualize internal structures of the body, especially the brain.
MMSE	Mini-Mental State Examination – A brief questionnaire used to screen for cognitive impairment.
CDR-SOB	Clinical Dementia Rating Sum of Boxes – An assessment scale that rates six domains (memory, orientation, judgment and problem solving, community affairs, home and hobbies, personal care) and sums the scores to evaluate the severity and progression of cognitive impairment.
T1 Image	T1-weighted Image – A type of MRI image with specific contrast useful for anatomical detail.
PACS	Picture Archiving and Communication System – A medical imaging system used for storing and accessing images.
EHR	Electronic Medical Record / Electronic Health Record – Digital versions of patient medical history maintained by healthcare institutions.
HL7	Health Level 7 – A set of international standards for the exchange of health data between systems.
FHIR	Fast Healthcare Interoperability Resources – A standard for electronic exchange of healthcare information.
AUC	Area Under the Curve – A metric used to evaluate the performance of a predictive model (e.g., diagnostic accuracy).
Z-score	A statistical measurement that describes a value's relationship to the mean of a group of values. In NEXT-Cue, it represents the deviation from normal tau accumulation levels.

SOC 2 Type II	Service Organization Control 2, Type II – A certification standard for data security and operational effectiveness of cloud systems.
HIPAA	Health Insurance Portability and Accountability Act – U.S. legislation providing data privacy and security provisions for safeguarding medical information.
GDPR	General Data Protection Regulation – EU regulation on data protection and privacy for individuals.
RBAC	Role-Based Access Control – A system for restricting access to authorized users based on their role within an organization.
MFA	Multi-Factor Authentication – A security system that requires more than one method of authentication to verify user identity.
Control Group	A reference group composed of individuals without the target condition, used to establish baseline values. In NEXT-Cue, regional tau accumulation levels are compared against this group for normalization (Z-score).
High Value (Z-score)	In the context of regional tau accumulation, a high Z-score value indicates significantly greater tau accumulation compared to the control group. A higher value suggests potential pathological change in that region.

2. Functions

NEXT-Cue provides the following functions to support automated analysis workflow, patient record review, result interpretation, and system operation.

2.1. User Account and Access Control

NEXT-Cue provides the following main functions:

- Automated analysis of T1-weighted brain MRI images and demographic/clinical data
- Display of the worklist and case status in the dashboard
- Search and review of the patient worklist and analysis history
- Generation of the NEXT-Cue report and saving the report to the hospital PACS system

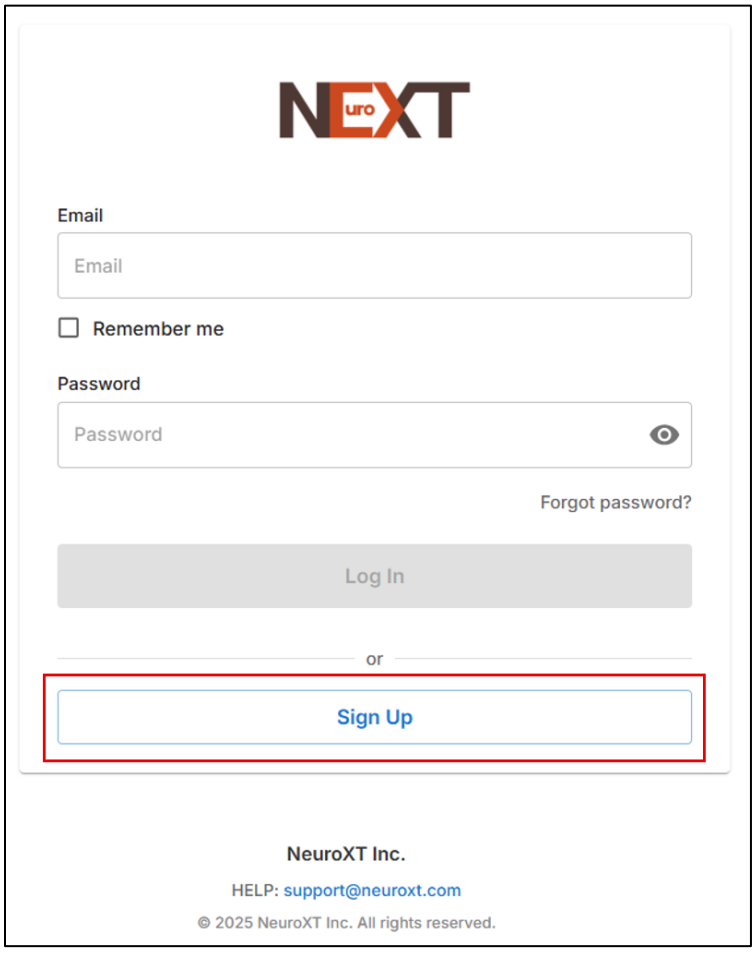
3. How to use NEXT-Cue

NEXT-Cue is designed to support an automated clinical analysis workflow by integrating with EHR and PACS systems. After the required patient information and MRI data are available, the system performs analysis automatically and provides the analysis result through the dashboard and PACS/PDF report. This section explains how to use each function in the order it is typically used during operation.

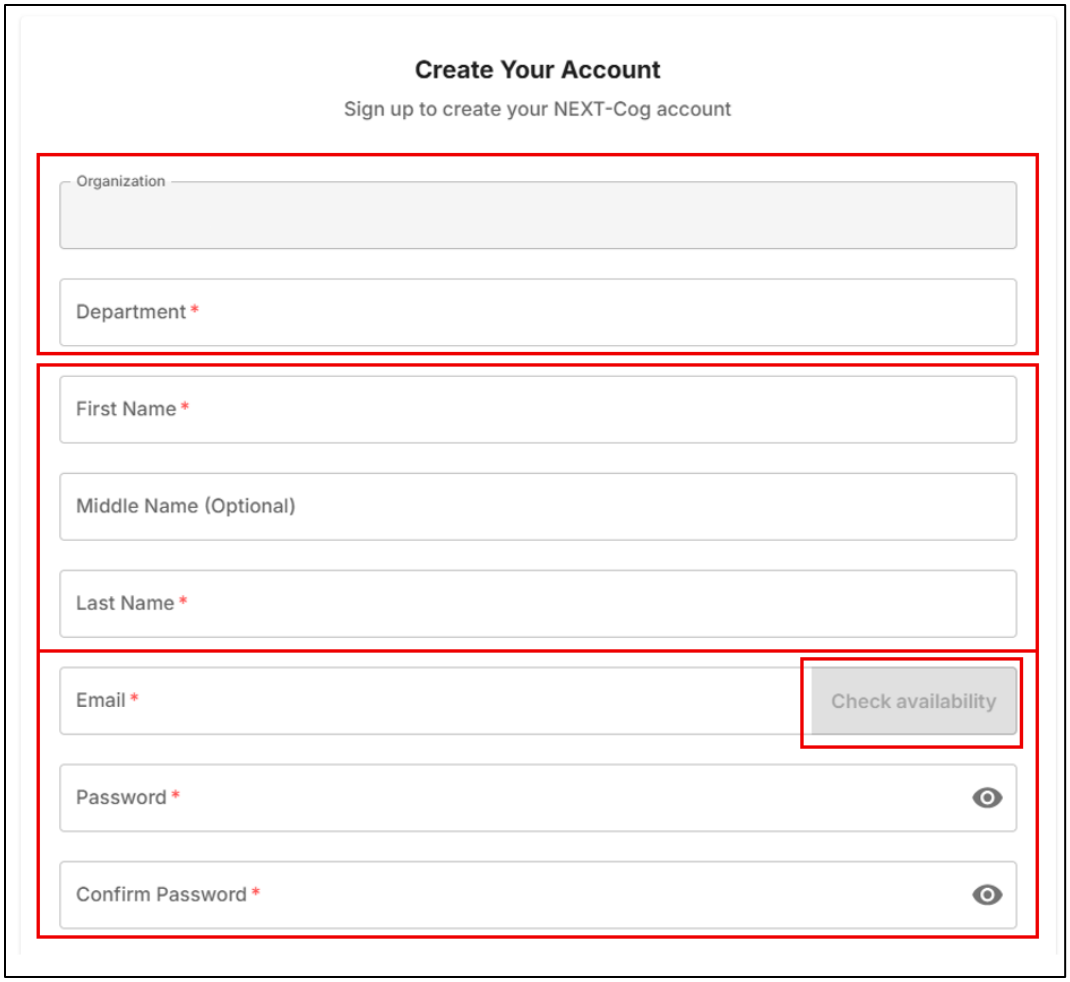
3.1. Access NEXT-Cue

1. Launch a web browser (Google Chrome 90 or later recommended).
2. Enter the unique URL given by NeuroXT Inc.

3.1.1. Sign up



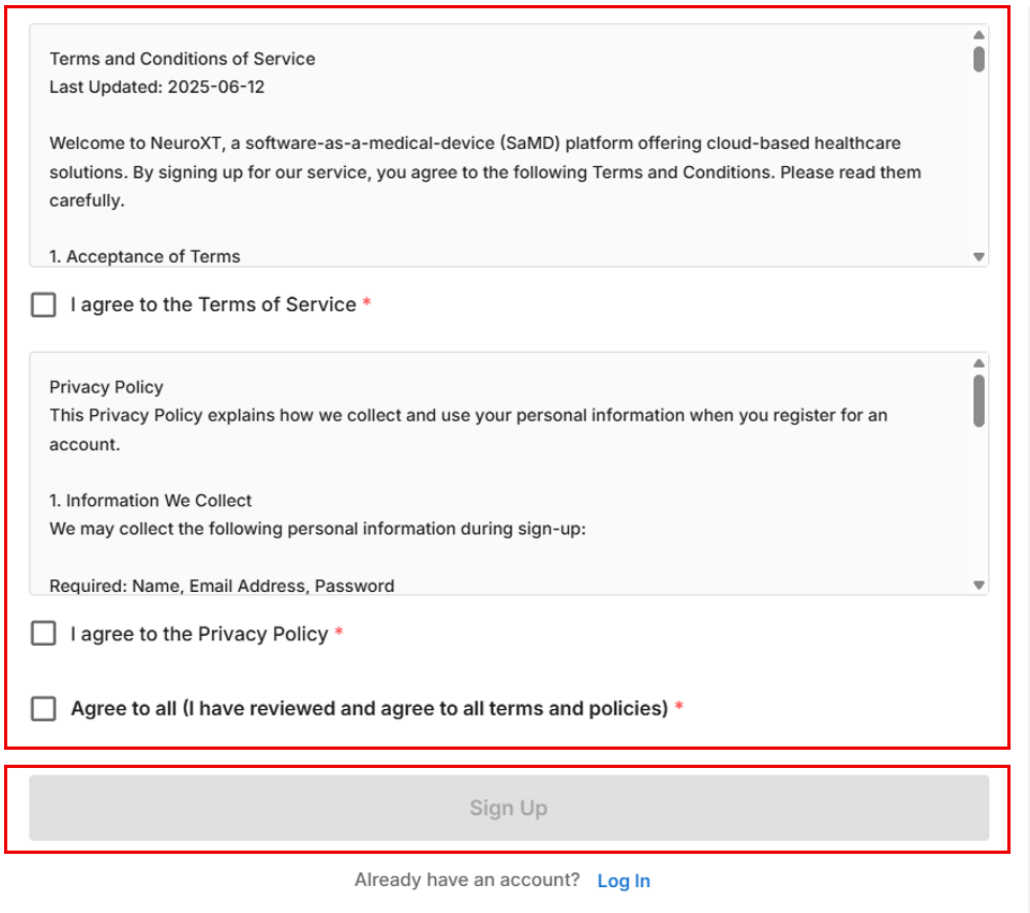
If the user does not have an approved account, click Sign Up on the login page and complete the registration request.



1. Confirm the automatically displayed Organization information.
2. Enter the user's Department.
3. Enter the user's First Name, optional Middle Name, and Last Name.
4. Enter the Email address to be used as the login ID.
5. Click Check availability to confirm whether the email can be used.
6. Enter the Password and Confirm Password.

Note

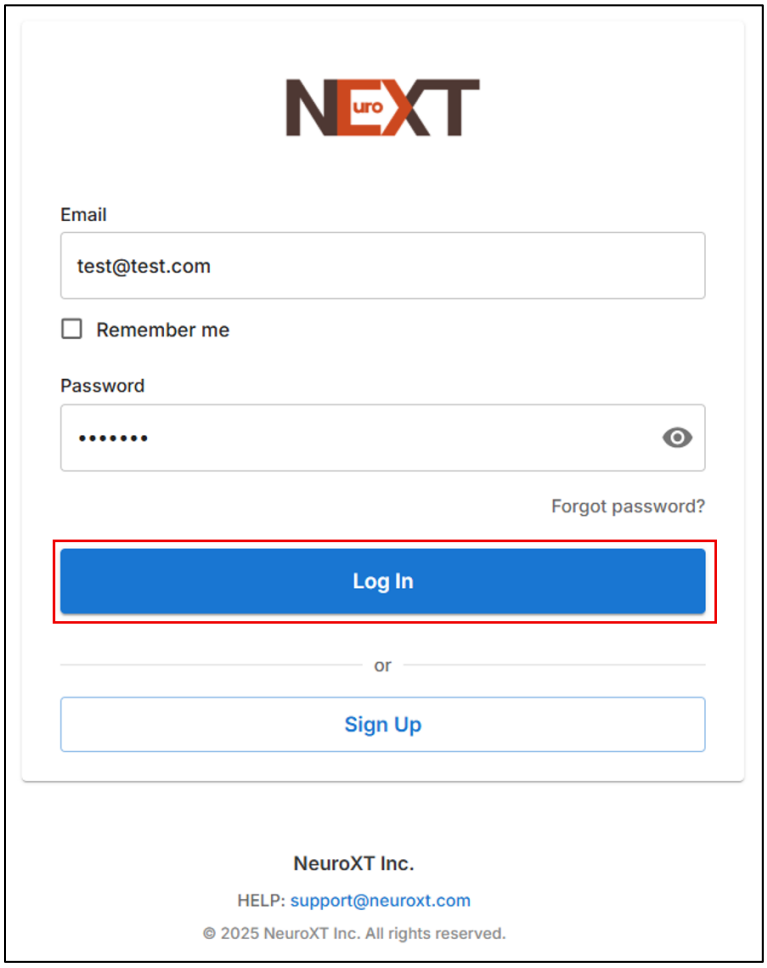
- The sign-up process must be completed prior to login.
- Make sure your password satisfies security guidelines, such as including letters, numbers, and special characters. It should be at least 8 characters long and cannot be the same as or contain your email ID.



7. Review and agree to the Terms of Service and Privacy Policy or select Agree to all.
8. Click Sign up to submit the account request.

System access is granted only after the manufacturer reviews and approves the registration request.

3.1.2. Log in



1. On the login page, enter your approved Email ID and password.
2. Click the Log In to access NEXT-Cue.

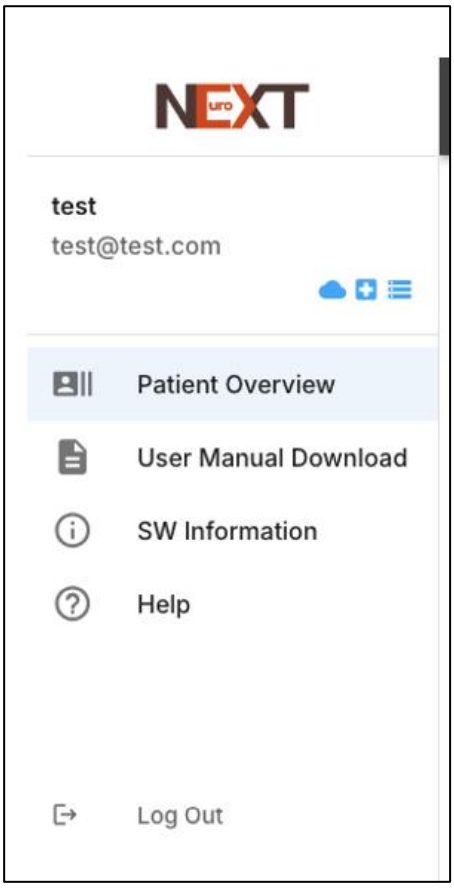
Use only an account that has been registered and approved by the manufacturer. Do not share the Email ID or password with anyone.

Note	**- The account is automatically locked after five consecutive failed login attempts to prevent unauthorized access.** **- For security purposes, passwords must be changed every 90 days. If 90 days have passed since the last password change, the system blocks the login attempt and redirects the user to the password reset page.**

3.2. Main Dashboard

After a successful login, NEXT-Cue automatically opens the main dashboard. The dashboard is used to review patient cases, check input data, monitor analysis status, access reports, and use system support functions.

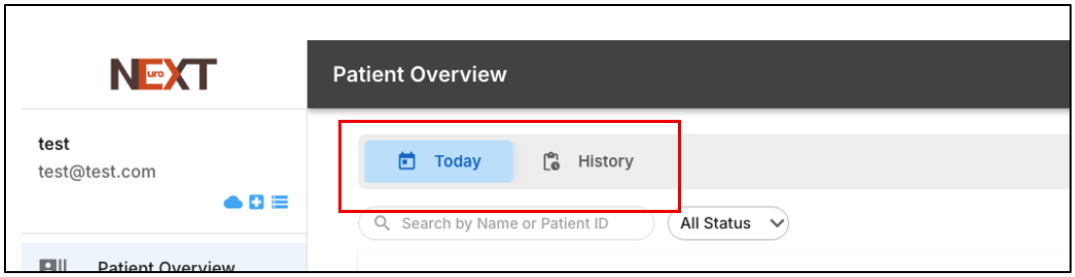
3.2.1. Menu



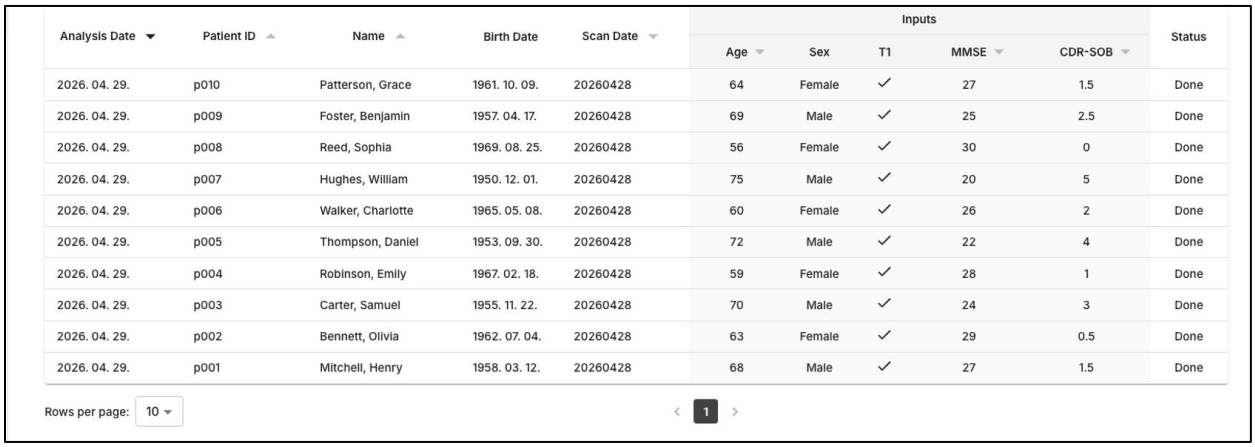
1. Network connection Icon: Check the Connection Status Icon to confirm the connectivity status of NEXT-Cue, EHR, and PACS systems.

Note	**- If any connection appears unavailable or unstable, verify the network environment before reviewing patient records or analysis results. If the issue persists, contact the manufacturer.**

2. Before using NEXT-Cue for the first time, **you must click User Manual Download to download and carefully review this manual.** Do not use the software until you have read and understood the instructions.
3. Click SW Information to view system information, including medical device label information.
4. Click Help to view the manufacturer's address, contact number, and contact email for product support and inquiries.



5. Use Patient Overview to choose which patient records to display.
   - Select Today to view cases analyzed on the current date.
   - Select History to view previously analyzed cases associated with the user or patient.



Analysis Date	Patient ID	Name	Birth Date	Scan Date	Inputs					Status
					Age	Sex	T1	MMSE	CDR-SOB	
2026. 04. 29.	p010	Patterson, Grace	1961. 10. 09.	20260428	64	Female	✓	27	1.5	Done
2026. 04. 29.	p009	Foster, Benjamin	1957. 04. 17.	20260428	69	Male	✓	25	2.5	Done
2026. 04. 29.	p008	Reed, Sophia	1969. 08. 25.	20260428	56	Female	✓	30	0	Done
2026. 04. 29.	p007	Hughes, William	1950. 12. 01.	20260428	75	Male	✓	20	5	Done
2026. 04. 29.	p006	Walker, Charlotte	1965. 05. 08.	20260428	60	Female	✓	26	2	Done
2026. 04. 29.	p005	Thompson, Daniel	1953. 09. 30.	20260428	72	Male	✓	22	4	Done
2026. 04. 29.	p004	Robinson, Emily	1967. 02. 18.	20260428	59	Female	✓	28	1	Done
2026. 04. 29.	p003	Carter, Samuel	1955. 11. 22.	20260428	70	Male	✓	24	3	Done
2026. 04. 29.	p002	Bennett, Olivia	1962. 07. 04.	20260428	63	Female	✓	29	0.5	Done
2026. 04. 29.	p001	Mitchell, Henry	1958. 03. 12.	20260428	68	Male	✓	27	1.5	Done

Rows per page: 10 1

6. In the patient list, review the displayed patient and analysis information.
   - Analysis Date: Date when the analysis was performed.
   - Patient ID: Unique patient identification number.
   - Name: Patient name.
   - Birth Date: Patient's date of birth.
   - Scan Date: Date when the MRI scan was acquired.
7. Click a sortable column header to reorder the list. Clicking the same header toggles between ascending and descending order. Sorting moves the user back to the first page of results.
   - Analysis Date: Date when the analysis was performed.
   - Patient ID: Unique patient identification number.
   - Name: Patient name.
   - Birth Date: Patient's date of birth.
8. Review the input data fields to confirm whether the required information is available for analysis.
   - Age: Patient age.

- Sex: Patient sex.
- T1 Image: T1 image path used for analysis.
- MMSE Score: Mini-Mental State Examination score.
    - When no MMSE value is entered, the MMSE field displays “Not available.” A completed case with MMSE displayed as “Not available” was generated without MMSE input.
- CDR-SOB: Clinical Dementia Rating – Sum of Boxes score.

Note	**Before analysis or report review, confirm that the demographic information, cognitive assessment values, and MRI study shown in NEXT-Cue are consistent with the source clinical records and the original imaging examination. If any mismatch is suspected, do not use the AI result until the discrepancy is resolved.**

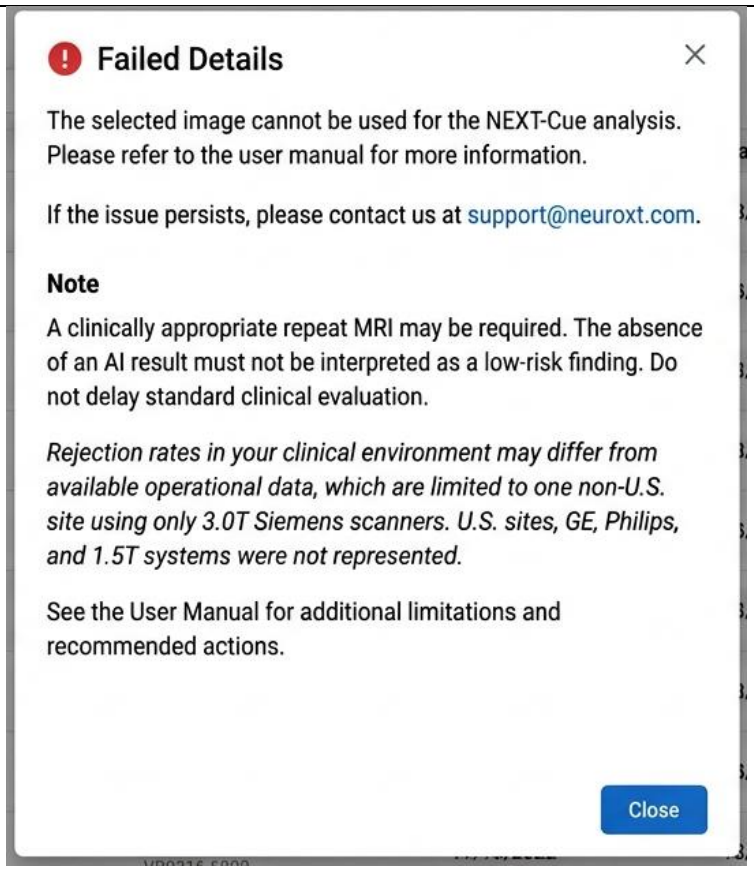
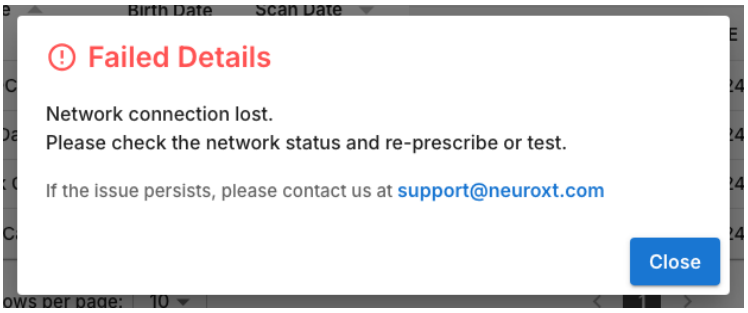
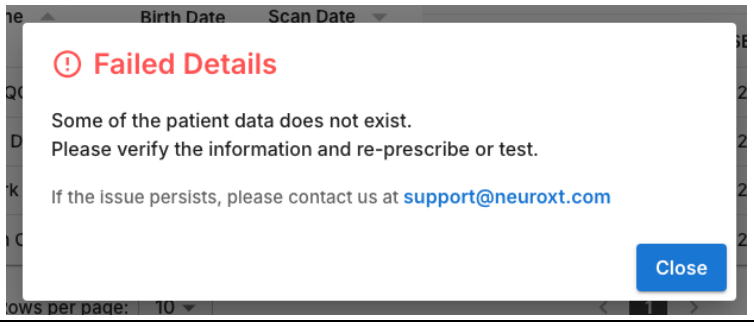
9. Use the **Status** column to monitor the progress of each case.

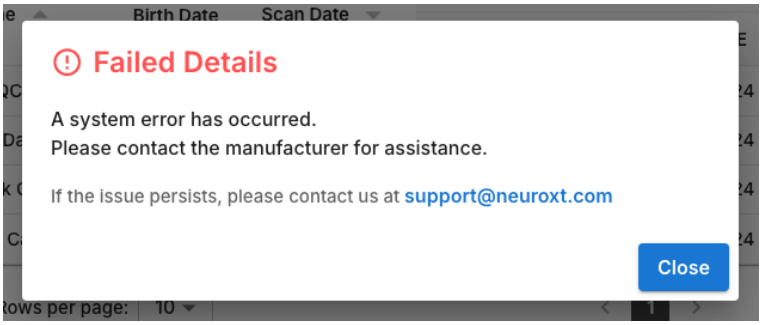
Status	Description	User Action
Completed	Analysis is complete. The report has been saved to the PACS system.	View the report through the PACS Viewer or PDF viewer.
Failed	Analysis could not be completed due to data, network, or system-related issues.	Click the Failed status text to view detailed failure information.
Processing	Analysis is in progress.	Wait until the analysis is completed.
Delivering	The report is being transmitted to the PACS system.	Wait until delivery to PACS is completed.

When the status changes to Completed, the report is automatically saved in the hospital’s PACS system.

When the status is Failed, click the Failed status text in the Status column. A Failed Details popup window will appear and display the reason for the failure. Review the message and take the appropriate action according to the failure category.

Failure Category	Popup Message	User Action
Image QC Error	The selected image cannot be used for the NEXT-Cue analysis. Please refer to the user manual for more information. If the issue persists, please contact us at support@neuroxt.com. The popup also displays a Note containing operational-data limitations and clinical guidance, as shown below.	Verify that the submitted study is a supported T1-weighted brain MRI and that required input information is complete and consistent. Review the MRI for image-

		quality issues. If clinically appropriate, submit a suitable study or obtain a repeat MRI according to local workflow. The absence of an AI result must not be interpreted as a low-risk finding. Continue standard clinical evaluation without delay.
Network Loss	Network connection lost. Please check the network status and re-prescribe or test. 	Check the hospital network, internet or intranet connection, and the connection status between PACS/EHR and NEXT-Cue. Re-prescribe or retest after the network connection is restored.
Missing Patient Data	Some of the patient data does not exist. Please verify the information and re-prescribe or test. 	Check whether essential patient information, such as sex or age, is available from EHR, EMR, or PACS. Correct or complete the missing information, then re-prescribe or retest.

Internal System Error	A system error has occurred. Please contact the manufacturer for assistance. 	This error cannot be resolved by the user. Contact the manufacturer for support.

If the issue persists after the recommended action, contact the manufacturer using the support information provided in the popup or in the **Help** menu.

Note	-	**ImageQC determines whether a submitted MRI study can proceed to NEXT-Cue analysis. A RED disposition means that the study is rejected and no Prognitor Score or clinical report is generated. Review the failure details and verify image suitability and required input completeness before resubmitting the study or obtaining a repeat MRI.**
	-	**A failed analysis may result from unsupported image conditions, missing or inconsistent required data, tissue segmentation or other preprocessing failure, or temporary system or network issues. Review the displayed failure details, verify input completeness and system connectivity, and resubmit or obtain a repeat MRI only when clinically appropriate. If the issue cannot be resolved, proceed with standard clinical evaluation and contact the manufacturer or system administrator as needed.**

Limitations of the SNU Operational Assessment

The SNU analysis is a retrospective operational assessment of a single non-U.S. tertiary-hospital cohort using only 3.0T Siemens MAGNETOM Skyra-family systems. The cohort does not include U.S. clinical sites, GE systems, Philips systems, or 1.5T systems.

The corrected SNU result is not asserted to represent the ImageQC RED rejection rate in all U.S. clinical environments, scanner vendors, field strengths, MRI protocols, patient populations, or clinical workflows. Rejection rates in a specific clinical environment may differ from the available operational data.

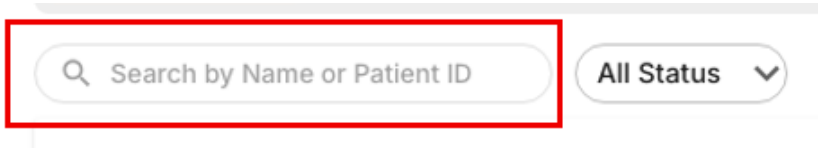
The cohort does not include prospective operational data on repeat-acquisition scheduling, patient inconvenience, or actual time to repeat MRI acquisition.

When ImageQC RED occurs, a clinically appropriate repeat MRI may be required. The absence of an AI result must not be interpreted as a low-risk finding and must not delay standard clinical evaluation.

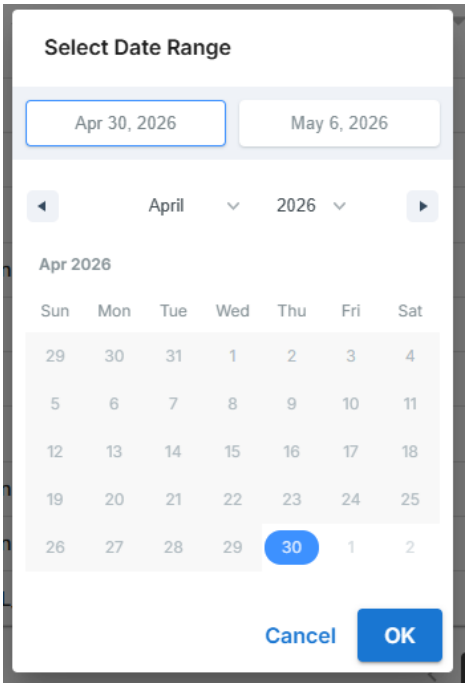
3.2.2. Search and Filter Records

Use the search and filter functions to locate specific records.

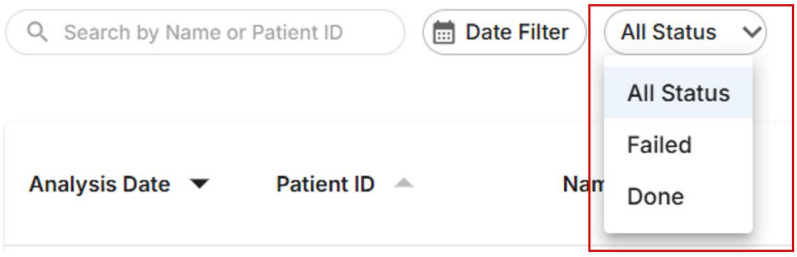
1. Enter a patient name or Patient ID in the Search Bar.



2. Select a Date Range to filter analysis data. Only data from the last 7 days can be viewed.



3. Use the Status Filter to display records by status.



3.2.3. Log Out

Click Log out to exit the system securely.

The system automatically logs out after 15 minutes of inactivity.

3.3. NEXT-Cue Report – Data Analysis Results

When a case is completed, the report is saved as a PDF in your hospital PACS system. You can then open and review the report using your existing PACS viewer or PDF viewer (e.g., Adobe Acrobat). The report contains patient information, analysis results, interpretation guidance, and supporting visual information.

Note	**The report is designed to display the Patient ID and Patient Name in an identifiable location. The intended clinical workflow provides access to the corresponding patient identity and relevant clinical information through the hospital EHR, EMR, and PACS systems, and the User Manual instructs users to verify consistency before interpreting the AI output.**

NEXT-Cue Report

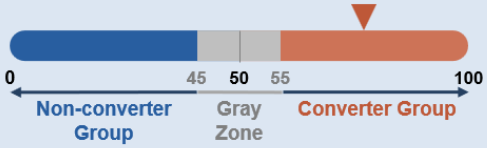
Hospital Name	Doctor Name
General Hospital	**Dr. John Doe**
Patient ID	Patient Name
P0025	**Jane Doe**

Age 84	Sex (F) / M
Date of Birth	1943-11-08
Date of Analysis	2026-03-11
Date of Scan	2026-03-06
CDR-SOB Score	2.5
MMSE Score	26

Prognitor Score

75

(Specificity: 95% · PPV: 96%)



A Prognitor Score of 75 indicates that this patient's profile is similar to the converter population in the reference MCI cohorts.

How to Interpret the Prognitor Score

Score interpretation is summarized below:

- **Score < 45: More similar to the non-converter group (lower scores within this range indicate even greater similarity).**
- **Score 45–55: Gray zone, intermediate range where patterns of converters and non-converters overlap.**
- **Score ≥ 56: More similar to the converter group (higher scores within this range indicate even greater similarity).**

The Prognitor Score is a scaled similarity score ranging from 0 to 100 that indicates how closely an individual patient's profile resembles the converter and non-converter populations in the reference MCI cohorts.

Scores in the gray zone may warrant additional follow-up, such as repeat cognitive testing (e.g., MMSE, CDR-SOB) and/or follow-up structural MRI, to support longitudinal clinical interpretation.

Warning: The Prognitor Score must not be used to diagnose Alzheimer's disease or to guarantee disease progression. It is a probabilistic similarity measure and must be interpreted in conjunction with clinical history, physician evaluation, and other diagnostic information.

How the Prognitor Score is Generated

Prognitor Score is the output of an AI model developed by NeuroXT that analyzes variables derived from T1-weighted (structural) brain MRI and clinical information. The model integrates regional atrophy measures, imaging-derived features of brain structural patterns, and cognitive and clinical indices, and compares these with patterns learned from reference MCI populations with known clinical outcomes to generate a scaled similarity score ranging from 0 to 100.

The predictive performance of the Prognitor Score was evaluated in a separate external, multicenter validation cohort of patients with MCI, where it demonstrated clinically meaningful levels of specificity and positive predictive value (PPV) for 5-year conversion to Alzheimer's disease dementia.

A total of 25 variables are used in the analysis, and the contribution of each variable to the score can be found in the Key Features table on page 2.

Health Recommendation

Maintain a healthy lifestyle, including regular physical activity, cognitive and social engagement, a Mediterranean-style diet, sufficient sleep, and stress management, to support overall brain health and function.
For individualized recommendations and care planning, consult your healthcare provider.

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NEXT-Cue Report

Patient ID	**P0025**
Patient Name	**Jane Doe**

Key Features

Priority	Factors	Values	Importance	Priority	Factors	Values	Importance
1	CDR-SOB	2.5	▲ + 0.46	7	T1/Hippocampus (R)	1.45	▼ - 0.38
2	AGE	84	▼ - 0.92	8	T1/Hippocampus (L)	1.58	▼ - 0.37
3	CDR-Memory	0.5	▲ + 0.72	9	CDR-Judgement	0.5	▲ + 0.35
4	CDR-Community	0.5	▲ + 0.71	10	T1/Inferiortemporal (R)	1.18	▼ - 0.30
5	T1/Parahippocampal (L)	0.87	▲ + 0.46	11	T1/PC01	0.72	▲ + 0.29
6	CDR-Orientation	0.5	▲ + 0.45	12	T1/Parahippocampal (R)	0.97	▲ + 0.27

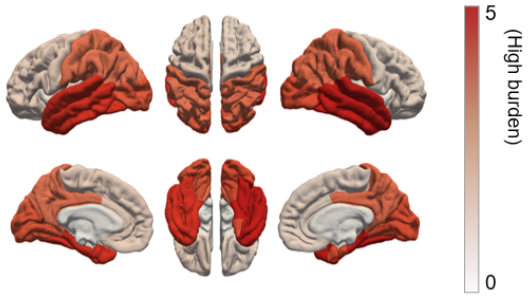
This table displays the **top 12 key features** that most strongly influenced the calculation of this patient's Prognitor Score.

- Value: Patient-specific input value
  - Demographic: Actual values such as Age, Sex, MMSE, and CDR-SOB
  - T1-driven features: Structural indicators derived from T1-weighted MRI, representing average cortical thickness values calculated from each brain region's volume and cortical surface area.
- Importance: Indicates how much each feature contributes to increasing or decreasing the Prognitor Score (▲ increase, ▼ decrease)

The contents of the above table may vary across patients.

Exploratory index, not for clinical decision-making.

Brain Status (Regional AD-related degeneration patterns)



Normalization to Control Group (Z-score)

Brain Status is an imaging-based heatmap that visually highlights regional brain change patterns associated with Alzheimer's disease, shown relative to a normal reference group across cortical regions. The color scale (0–5, displayed from white to red) represents the relative level of model-estimated change in each region compared with the normal reference group.
All values underlying this heatmap are normalized using Z-score transformation based on the normal reference group. A value of 0 corresponds to the mean of the normal reference group, and values are displayed from 0 to 5, with higher values indicating a greater degree of deviation from this mean.

⚠ **Warning**: **The Brain Status heatmap is provided for informational purposes only and is not used as an input to the NEXT-Cue model that generates the Prognitor Score. It should not be used as an independent basis for diagnosis or treatment decisions, and its values do not modify the Prognitor Score or its interpretation.**

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3.3.1. Hospital Information

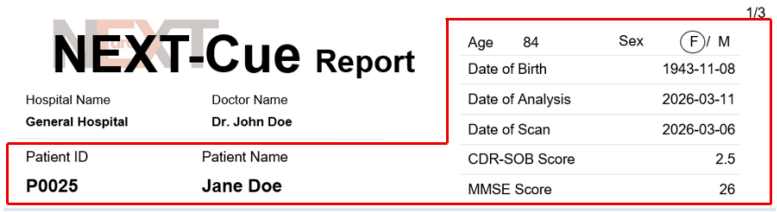
Check the hospital-related information.



- **Hospital Name**: Hospital where the patient was examined.
- **Doctor Name**: Attending physician.

3.3.2. Patient's Information

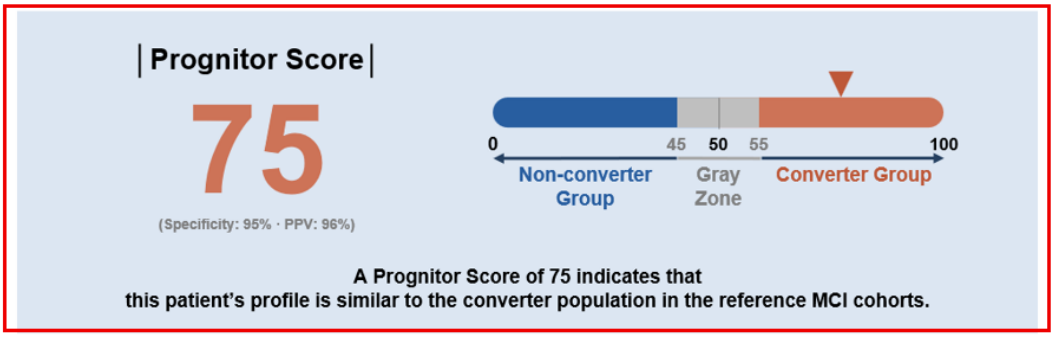
Check the patient's demographic and clinical information.

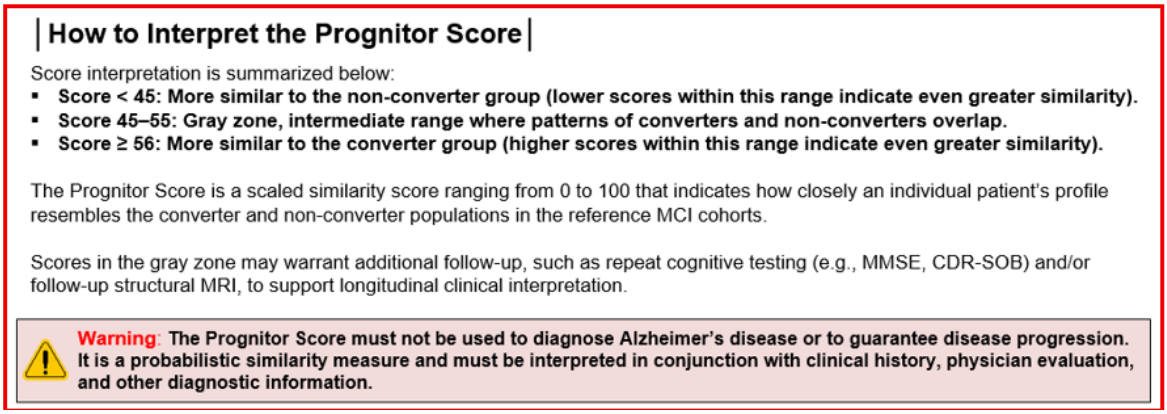


- Patient ID
- Patient Name
- Age
- Sex
- Date of Birth
- Date of Analysis
- Date of Scan
- CDR-SOB Score
- MMSE Score

3.3.3. Prognitor Score

Review the Prognitor Score, which is displayed as a scaled similarity score ranging from 0 to 100 with a bar visualization.





Score Range	Interpretation
Score < 45	More similar to the non-converter group (lower scores within this range indicate even greater similarity).
Score 45–55	Gray zone, intermediate range where patterns of converters and non-converters overlap.
Score ≥ 56	More similar to the converter group (higher scores within this range indicate even greater similarity).

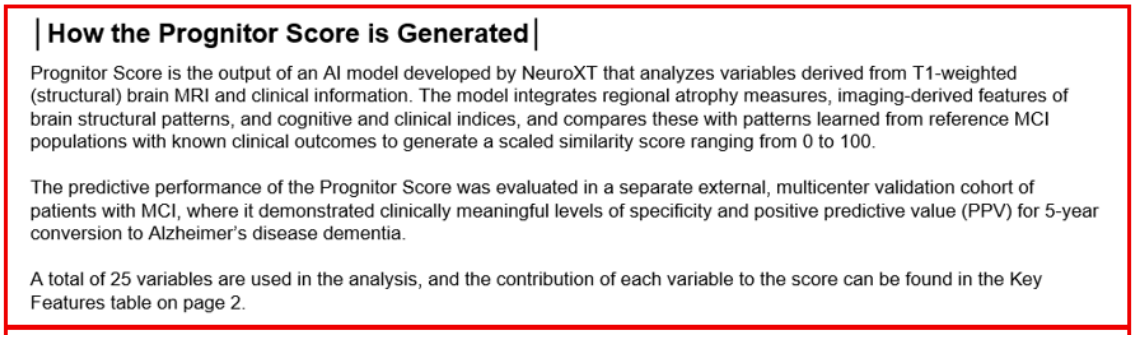
The Prognitor Score is a scaled similarity score ranging from 0 to 100 that indicates how closely an individual patient's profile resembles the converter and non-converter populations in the reference MCI cohorts.

The Prognitor Score is not an individual patient-specific probability of conversion to clinical Alzheimer's disease dementia and cannot be converted to an individual absolute five-year conversion-risk estimate.

Scores in the gray zone may warrant additional follow-up, such as repeat cognitive testing (e.g., MMSE, CDR-SOB) and/or follow-up structural MRI, to support longitudinal clinical interpretation. Gray-zone results should be interpreted with particular caution because converter and non-converter patterns overlap in this range. In these cases, follow-up clinical assessment, repeat cognitive evaluation, and/or follow-up structural MRI may be considered according to clinical judgment.

⚠ Warning	**- The Prognitor Score must not be used to diagnose Alzheimer's disease or to guarantee disease progression.** **- It is a scaled similarity measure and must be interpreted in conjunction with clinical history, physician evaluation, and other diagnostic information. It is not a probability, percentage probability, or calibrated individual absolute five-year conversion-risk estimate.** **-The Prognitor Score and score category are intended only to support MRI-based dementia risk assessment workflow and must not be used as the sole basis for diagnosis, follow-up discontinuation, or treatment decisions. Additional diagnostic testing, including invasive testing or treatment escalation, should not be determined solely on the basis of the AI result.**

3.3.4. How the Prognitor Score is Generated



How the Prognitor Score is Generated

Prognitor Score is the output of an AI model developed by NeuroXT that analyzes variables derived from T1-weighted (structural) brain MRI and clinical information. The model integrates regional atrophy measures, imaging-derived features of brain structural patterns, and cognitive and clinical indices, and compares these with patterns learned from reference MCI populations with known clinical outcomes to generate a scaled similarity score ranging from 0 to 100.

The predictive performance of the Prognitor Score was evaluated in a separate external, multicenter validation cohort of patients with MCI, where it demonstrated clinically meaningful levels of specificity and positive predictive value (PPV) for 5-year conversion to Alzheimer's disease dementia.

A total of 25 variables are used in the analysis, and the contribution of each variable to the score can be found in the Key Features table on page 2.

Review the explanation of how the Prognitor Score is generated. The score is produced by an AI model that analyzes variables derived from T1-weighted structural brain MRI and clinical information, including regional atrophy measures, imaging-derived structural patterns, and cognitive or clinical indices.

3.3.5. Health Recommendation

Review the automatically generated recommendation according to the Prognitor Score range.

Score Range	Recommendation Use
Score < 45	Maintain a healthy lifestyle, including regular physical activity, cognitive and social engagement, a Mediterranean-style diet, sufficient sleep, and stress management, to support overall brain health and function. **Routine clinical follow-up may be considered as appropriate.**
Score 45–55	Scores in the gray zone may warrant additional follow-up, such as repeat cognitive testing (e.g., MMSE, CDR-SOB) and/or follow-up structural MRI, to support longitudinal clinical interpretation.
Score ≥ 56	Maintain a healthy lifestyle, including regular physical activity, cognitive and social engagement, a Mediterranean-style diet, sufficient sleep, and stress management, to support overall brain health and function. **For individualized recommendations and care planning, consult your healthcare provider.**

3.3.6. Key Features

Key Features

Priority	Factors	Values	Importance	Priority	Factors	Values	Importance
1	CDR-SOB	2.5	▲ + 0.46	7	T1/Hippocampus (R)	1.45	▼ - 0.38
2	AGE	84	▼ - 0.92	8	T1/Hippocampus (L)	1.58	▼ - 0.37
3	CDR-Memory	0.5	▲ + 0.72	9	CDR-Judgement	0.5	▲ + 0.35
4	CDR-Community	0.5	▲ + 0.71	10	T1/Inferiortemporal (R)	1.18	▼ - 0.30
5	T1/Parahippocampal (L)	0.87	▲ + 0.46	11	T1/PC01	0.72	▲ + 0.29
6	CDR-Orientation	0.5	▲ + 0.45	12	T1/Parahippocampal (R)	0.97	▲ + 0.27

This table displays the **top 12 key features** that most strongly influenced the calculation of this patient's Prognitor Score.
- Value: Patient-specific input value
  - Demographic: Actual values such as Age, Sex, MMSE, and CDR-SOB
  - T1-driven features: Structural indicators derived from T1-weighted MRI, representing average cortical thickness values calculated from each brain region's volume and cortical surface area.
- Importance: Indicates how much each feature contributes to increasing or decreasing the Prognitor Score (▲ increase, ▼ decrease)

The contents of the above table may vary across patients.

Review the **top 12 key features** that most strongly influenced the calculation of this patient's Prognitor Score.

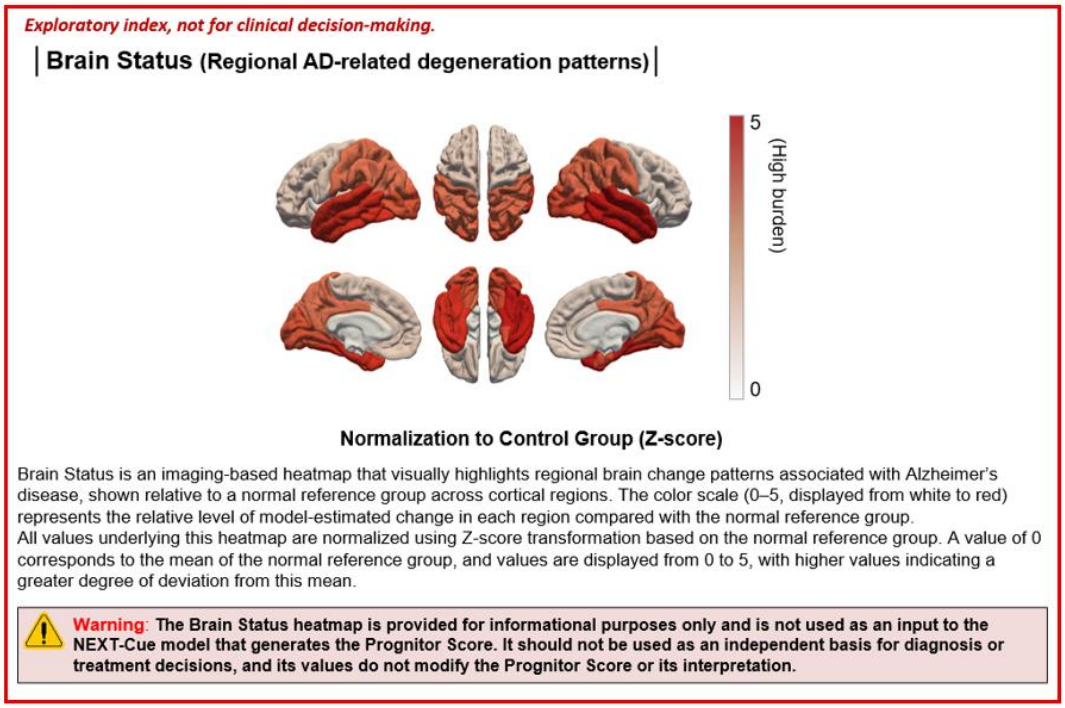
- Value shows the patient-specific input value.
  - Demographic: Actual values such as Age, Sex, MMSE, and CDR-SOB
  - T1-driven features: Structural indicators derived from T1-weighted MRI, representing average cortical thickness values calculated from each brain region's volume and cortical surface area.
- Importance Indicates how much each feature contributes to increasing or decreasing the Prognitor Score (▲ increase, ▼ decrease)

Key Features are provided as supplementary explanatory information to help users understand factors associated with the generated Prognitor Score. They are not intended to represent an independent diagnostic conclusion and must not be used alone as the basis for clinical decision-making.

Refer to the Abbreviations section on page 3 for definitions of the abbreviations used in the report.

3.3.7. (supplemental information) Brain Status

The Brain Status heatmap provides an imaging-based visualization of regional brain values relative to a normal reference group. It is intended to highlight relative differences in regional brain signals across cortical areas in an easy-to-view format.



The heatmap displays regional values across cortical areas, normalized using Z-score transformation. Color intensity (0–5) represents the degree of deviation from the normal reference group, with higher values indicating greater deviation.

The Brain Status heatmap is provided for exploratory and informational purposes only. It is not used as an input to the model that generates the Prognitor Score, does not affect the score or score category, and must not be used as an independent basis for diagnosis, treatment, or follow-up decisions.

4. Performance

NEXT-Cue is designed to provide quantitative analysis results to support clinical assessment of patterns associated with progression from mild cognitive impairment (MCI) to clinical Alzheimer's disease (AD) dementia within 5 years. This section describes the key performance characteristics of the model, validation outcomes, and important considerations for clinical application.

Performance Metrics

NEXT-Cue has undergone validation testing to evaluate its predictive performance for progression from MCI to Alzheimer's disease (AD) dementia.

The performance metrics are summarized below:

Metric	Performance
Specificity	97.80%
AUROC	0.9142
Sensitivity	71.91%
Positive Predictive Value (PPV)	96.97%
Negative Predictive Value (NPV)	78.07%
Processing Time	2-5 minutes per case

The reference outcome used for performance evaluation was based on clinically derived follow-up classification within the validated study framework. As with other clinical reference standards, some uncertainty may remain in outcome labeling, follow-up completeness, or case classification, and this should be considered when interpreting reported performance values.

Report availability and interpretation depend on adequate input quality, required data completeness, and successful system processing. If analysis is delayed, unavailable, or fails, users should continue patient evaluation according to standard clinical practice rather than waiting for or inferring meaning from the absence of an AI result.

Performance When MMSE Is Not Entered

When no MMSE value is entered, NEXT-Cue may generate a reduced-input result when all other required input and image-quality conditions are satisfied. The following estimates are from a simulated MMSE-masking analysis conducted in the 180-subject external-validation cohort and do not represent prospective validation in a population with actually unavailable MMSE data.

Metric	Full Input	Simulated MMSE-Masked Input
Sensitivity	71.91%	73.03%
Specificity	97.80%	94.51%
AUROC	0.9142	0.9000

In the simulated MMSE-masking analysis, sensitivity was 73.03% (95% CI: 63.64%–82.05%), specificity was 94.51% (95% CI: 89.29%–98.86%), and AUROC was 0.9000 (95% CI: 0.8517–0.9414).

Under simulated MMSE masking, specificity was 3.29 percentage points lower than under full-input processing, corresponding to a higher false-positive classification rate in the simulated analysis.

Note	**- Performance metrics are based on testing conducted using an independent site-level external-validation cohort that was not used for model development, model fitting, retraining, threshold selection, or post hoc operating-point modification.** **- Observed performance in clinical practice may differ from test performance and can be influenced by the quality and completeness of the input data and by clinical use conditions.** **- The model output is a scaled similarity score and must be interpreted together with clinical findings and professional judgment.** **- Study Population Limitation: Clinical performance was evaluated using an independent ADNI-derived site-level external-validation cohort. The cohort was predominantly White and was collected in a controlled research environment. Accordingly, the reported performance estimates may not be equally precise across all demographic groups, MRI acquisition workflows, scanner-protocol combinations, or follow-up conditions. The available premarket data were insufficient to reliably estimate performance in Black/African American, Hispanic/Latino, Asian, and other underrepresented racial and ethnic populations. Clinical performance in these populations has not been established.**

Clinical performance evidence may not be equally precise across all racial and ethnic subgroups because some subgroups were underrepresented in the performance study.

5. Cybersecurity

NEXT-Cue must be used only by authorized users with approved accounts. User accounts must not be shared, and users must log out after use. NEXT-Cue must be accessed only through the official URL provided by NeuroXT Inc. and used within a hospital-managed environment with appropriate security controls. Users and administrators must not alter, disable, or bypass security-related functions or approved configurations.

If a cybersecurity incident or suspicious activity is suspected, the event must be reported promptly according to hospital procedures and to NeuroXT Inc. using the support contact information provided in this manual. Manufacturer-authorized updates should be applied through approved procedures. Delayed application of security-relevant updates may increase cybersecurity risk.

Only manufacturer-approved configurations of the software, AI model, preprocessing, thresholds, and related labeling are permitted for clinical use. Changes to approved configurations require evaluation and re-validation under the manufacturer's quality system before clinical deployment. Users must not apply local, ad hoc, or site-specific modifications to the software, AI model, preprocessing, thresholds, report logic, or explanatory output.



- **Warning**
  Do not use shared accounts or leave NEXT-Cue open and unattended while patient information is displayed.



- **Caution**
  Do not use unauthorized URLs, unsupported interfaces, or unapproved software or configuration changes with NEXT-Cue.
  Note
  If suspicious activity, unauthorized access, or a possible cybersecurity issue is identified, report it immediately through hospital procedures and to NeuroXT Inc. support.

5.1. Shared Cybersecurity Responsibilities

NEXT-Cue operates under a shared cybersecurity responsibility model between NeuroXT Inc. and the healthcare delivery organization (HDO). Both parties must fulfill their respective obligations for the system to operate securely within its intended environment.

NeuroXT-managed responsibilities include:

- Secure configuration and operation of NeuroXT-controlled cloud services for NEXT-Cue, including appropriate network segmentation and isolation of protected components.
- Protection of communication between the NEXT-Cue Launcher and NeuroXT cloud services using mutually authenticated and encrypted transport protocols.
- Secure software and AI model update mechanisms, including cryptographic signing, integrity verification of update artifacts, and controlled release processes.

- Protection of manufacturer-controlled cryptographic materials and signing keys used for authentication, encryption, and software or model signing.
- Centralized logging, monitoring, and security alerting for cloud-hosted components under NeuroXT control.
- Processes to receive, assess, and respond to cybersecurity vulnerabilities, including issuance of security advisories and recommended mitigations when appropriate.

HDO-managed responsibilities include:

- Endpoint protection and anti-malware controls on hospital-managed systems that host or access the NEXT-Cue Launcher.
- Local identity and access management for NEXT-Cue user accounts, including provisioning, deprovisioning, and periodic review of access privileges.
- Network segmentation and firewall configuration within the hospital environment, including configuration of outbound connectivity for the Launcher as described in this section.
- Physical security of workstations and on-premise hardware that host the Launcher or are used to access NEXT-Cue.
- Secure configuration of remote-access and VPN solutions that are used to access hospital systems interacting with NEXT-Cue.
- Timely application of NeuroXT-issued security updates and recommended mitigations for NEXT-Cue.
- Compliance with hospital information security policies for systems that integrate with NEXT-Cue and handling of any hospital-side incidents that may affect those systems.

5.2. Network and IT Configuration Requirements

NEXT-Cue consists of an on-premise Launcher deployed within the hospital environment and cloud-hosted application and AI services operated by NeuroXT. The Launcher initiates all outbound communication to NeuroXT cloud services over mutually authenticated TLS, and no inbound connections from NeuroXT cloud services to the Launcher are required for normal operation.

For correct and secure operation, the hospital environment must meet the following network and IT configuration requirements:

- **Outbound connectivity**
  The Launcher workstation must have outbound HTTPS connectivity to NeuroXT cloud service endpoints required for NEXT-Cue operation. Outbound access must not be blocked by firewall rules or proxy configurations that prevent establishment of a secure, mutually authenticated TLS connection.

- **TLS requirements**
  All Launcher-to-cloud communications must use TLS 1.2 or higher. Configurations that downgrade TLS below version 1.2 are not supported and may prevent system operation.
- **Network segmentation**
  The Launcher should be deployed on a hospital-managed network segment that provides internet access to NeuroXT cloud endpoints while restricting unnecessary lateral access to other hospital systems. Direct exposure of the Launcher workstation to untrusted networks or the public internet is not permitted.
- **Firewall rules**
  Hospital firewall rules should allow outbound HTTPS traffic from the Launcher workstation to NeuroXT-designated cloud endpoints required for operation. Inbound traffic to the Launcher workstation from external networks should be restricted according to hospital security policy, and direct inbound connections from the public internet are not required.
- **Proxy configuration**
  If the hospital network uses an outbound proxy, the proxy must be configured to allow NEXT-Cue traffic to establish end-to-end TLS connections to NeuroXT cloud services. TLS-intercepting proxies that break and re-establish TLS sessions are not supported and may prevent correct operation.
- **EHR and PACS integration**
  Where NEXT-Cue is integrated with hospital EHR or PACS systems, integration interfaces must be configured to use encrypted communication channels consistent with hospital security policies. Unencrypted integration paths are not supported.
- **Endpoint security requirements**
  The workstation hosting the NEXT-Cue Launcher must meet the following minimum security requirements: a supported operating system version receiving security updates from the OS vendor; an active, up-to-date endpoint protection or anti-malware solution; regular application of operating system and application security patches consistent with the hospital's patch management policy; no installation of unapproved or unrelated software; no use of untrusted removable media; and administrative and monitoring interfaces accessible only to authorized personnel through approved secure channels.

5.3. Features

NEXT-Cue incorporates the following cybersecurity features to help protect patient data, system integrity, and clinical workflow security:

Feature	Description
Mutual TLS authentication	All communications between the Launcher and NeuroXT cloud services use mutually authenticated TLS 1.2 or higher, so that both parties are authenticated before data is exchanged.
Encryption in transit	Data transmitted between the Launcher and NeuroXT cloud services is encrypted in transit using industry-standard TLS.
Encryption at rest	Patient data and AI-relevant data stored within NeuroXT-controlled cloud infrastructure is encrypted at rest in accordance with NeuroXT security standards.

Cryptographically signed updates	NEXT-Cue software and AI model updates are cryptographically signed by NeuroXT. The Launcher verifies update signatures and version information before installing update artifacts.
Role-based access control	Access to NEXT-Cue functions is controlled by role-based access control. Users are assigned least-privilege roles appropriate to their clinical or administrative responsibilities.
Audit logging	Security-relevant events, including user authentication, data access, configuration changes, and update events, are logged within NeuroXT-controlled environments to support post-market surveillance and incident investigation.
Session management	User sessions are automatically terminated after a period of inactivity to reduce the risk of unauthorized access to patient information on unattended workstations.
Software Bill of Materials	NeuroXT maintains a Software Bill of Materials (SBOM) for cybersecurity-relevant components of NEXT-Cue. The SBOM is available to qualified customers and healthcare delivery organizations upon request.

5.4. Residual risks

Even when NEXT-Cue is deployed and operated in accordance with this manual and applicable hospital security policies, certain residual cybersecurity risks may remain. Users and hospital IT administrators should be aware of the following:

- **Compromised hospital user accounts** – If a NEXT-Cue user account is compromised through phishing, credential theft, or password reuse, an unauthorized party may gain access to patient data and clinical reports accessible to that account. Hospitals should enforce strong authentication, account monitoring, and prompt deprovisioning of accounts for departing personnel.
- **Malware or ransomware on hospital systems** – Malware or ransomware affecting the Launcher workstation or hospital network infrastructure may disrupt NEXT-Cue operation or compromise data integrity. Maintaining current endpoint protection and OS patches on the Launcher workstation reduces this risk.
- **Misconfigured hospital infrastructure** – Misconfiguration of hospital infrastructure such as directory services, VPNs, firewalls, or network segmentation may expose NEXT-Cue components to unauthorized access or disrupt secure communications. NEXT-Cue should be deployed in accordance with the network configuration requirements described in this section and hospital security standards.
- **Delayed application of security updates** – Failure to apply NeuroXT-issued security updates or recommended mitigations within a reasonable timeframe may leave known vulnerabilities unmitigated. NeuroXT recommends applying security-relevant updates promptly upon notification.
- **Operation outside validated configuration** – Operating NEXT-Cue outside the documented assumptions, configurations, or supported environment described in this manual may increase cybersecurity risk and may fall outside the validated and supported use of the product.

NeuroXT recommends that hospitals conduct a site-specific risk assessment prior to deployment and periodically review cybersecurity controls for systems that interact with NEXT-Cue.

5.5. Reporting & advisories

If you observe suspected cybersecurity vulnerabilities, incidents, or abnormal product behavior that may indicate a security issue, report the concern to NeuroXT promptly. When reporting, please provide a description of the observed behavior or suspected vulnerability, the NEXT-Cue software version and deployment environment, the date and time the issue was first observed, and any relevant log entries, error messages, or screenshots if available. Cybersecurity-related concerns may be reported using the NeuroXT support contact information provided in this manual, such as support@neuroxt.com or the designated support channel for your site.

NeuroXT may issue security advisories, field safety notices, or other communications related to cybersecurity vulnerabilities or required mitigations affecting NEXT-Cue. Hospitals should ensure that the primary IT and clinical contacts registered with NeuroXT are kept up to date so that security communications are received promptly. Upon receipt of a NeuroXT security advisory, customers should review the advisory and apply any recommended updates or mitigations within the timeframe specified.

A Manufacturer Disclosure Statement for Medical Device Security (MDS2) for NEXT-Cue is available upon request. NeuroXT also maintains a Software Bill of Materials (SBOM) for NEXT-Cue, which is available to qualified customers and healthcare delivery organizations upon request. Requests for MDS2 or SBOM information can be made using the NeuroXT support contact information provided in this manual.

5.6. Decommissioning

When NEXT-Cue is decommissioned or the hospital's use of the system is discontinued, the following steps should be performed to help ensure secure decommissioning and protection of patient data:

i. **Notify NeuroXT**
   Contact NeuroXT using the support information provided in this manual to initiate the decommissioning process. NeuroXT will coordinate deactivation of the hospital's NEXT-Cue account and associated cloud-side data handling in accordance with applicable agreements.

ii. **Revoke user accounts**
   Deactivate or delete all NEXT-Cue user accounts associated with the hospital prior to or at the time of decommissioning to prevent unauthorized access to historical patient data through retained credentials.

iii. **Uninstall the Launcher**
   Uninstall the NEXT-Cue Launcher application from the hospital workstation using the standard operating system application removal process. Confirm that Launcher application files have been removed according to hospital procedures.

iv. **Remove local data**
Confirm that no patient data or NEXT-Cue configuration files remain on the Launcher workstation following uninstallation. If the workstation is to be repurposed or disposed of, apply data sanitization procedures consistent with hospital policy and applicable regulatory requirements.

v. **Update firewall rules**
Remove firewall rules or network configurations that were created specifically to allow outbound NEXT-Cue traffic from the Launcher workstation to NeuroXT cloud endpoints, as appropriate for the hospital's network policy.

vi. **Retain documentation**
Retain records of the decommissioning process, including the date, responsible personnel, and confirmation of data deletion or sanitization, in accordance with hospital records retention policies.

6. Trouble Shooting

Troubleshooting guidance is intended to support restoration of normal operation, but it does not replace clinical judgment. If the report is unavailable, delayed, or failed, patient care decisions should be based on standard clinical assessment and the available clinical record until a valid report is generated.

Trouble	Guide	Description
The software does not close properly.	Follow the proper termination procedure.	Check if any processes are still running. Ensure all tasks are completed before clicking the "Logout" or "Exit" button within the software. If the issue persists, contact the system administrator.
Patient data is not syncing.	Check EHR integration status.	NEXT-Cue automatically retrieves patient data from the EHR system. Ensure that patient information is correctly entered into the EHR. If data is not syncing, contact the system administrator.
The PC is not connecting to NEXT-Cue.	Check firewall and network settings.	Ensure that firewall settings or security programs are not blocking the connection. Verify network settings. If the issue persists, contact the IT administrator.

Is it possible to modify already entered patient information?	Verify EHR integration status.	If the information is updated in the EHR, it will sync automatically. If manual modification is required, contact the system administrator.
Where to check the analysis report?	Verify PACS integration status.	The analysis report can be viewed in the PACS Viewer. Ensure PACS integration is working correctly.
Data upload is taking too long.	Check file size and server status.	Large files may take longer to upload. Check network connectivity and server status. If the issue persists, contact the system administrator.
Login error occurs.	Verify account credentials and password.	Ensure Caps Lock is off and re-enter the password. If the issue persists, reset the password or contact the manufacturer for assistance.
Login error or automatic redirection occurs.	Check password expiration (90-day policy).	If 90 days have passed since your last password change, login will be blocked for security. You will be automatically redirected to the password reset page. Please follow the instructions to set a new password.
Analysis is not progressing.	Check for missing required inputs.	Ensure that the T1 Image are uploaded. The analysis will not proceed if required fields are missing.
An error message appears.	Check the error code and log files.	If an error code appears, record it and contact the manufacturer support team. If available, submit log files for faster troubleshooting.
Data loading failure	Network disruption or missing input files	Check the network connection and confirm that the hospital system (PACS or EHR) is properly linked.

		Click the 'Failed' text to view specific network or data error details.
Analysis failure	Corrupted data or incomplete patient information	Ensure that T1 images are correctly uploaded. Verify that required patient demographic data, including Age, Sex, and CDR-SOB, is provided. If an MMSE value is entered, verify that it is within the valid range. When MMSE is not entered, the MMSE field displays “Not available” and a reduced-input result may be generated when all other required conditions are satisfied. For more specific error messages, click the 'Failed' text to open the 'Failed Details' popup. Refer to the Failed Details popup and the failure-handling instructions in this User Manual.
Report not appearing in PACS	Connectivity issue with PACS integration	Verify that the PACS server is online and correctly configured. Ensure that the analysis has reached the "Done" status in NEXT-Cue. If necessary, restart PACS synchronization.

7. Maintenance

NEXT-Cue is maintained by NeuroXT Inc. through controlled software, AI model, and configuration updates to help ensure security, performance, and reliable operation.

1. **Software and model updates**

Manufacturer-managed updates may include security patches, performance improvements, feature enhancements, and other approved changes. Updates are deployed through controlled release processes, and only updates provided by NeuroXT Inc. through approved mechanisms are supported. Hospitals should apply manufacturer-authorized updates and related instructions promptly in accordance with their internal change-control and maintenance procedures.

2. **System performance monitoring**

The performance and availability of NeuroXT-controlled cloud services are monitored by the manufacturer to help maintain reliable operation. A stable internet connection is required for cloud-based analysis, data processing, and delivery of results.

3. **Troubleshooting and technical support**

If an analysis does not complete, users should check the **Analysis Status** column and any associated error messages displayed in the user interface. If issues persist or cannot be resolved using the troubleshooting guidance in this manual, users should contact NeuroXT technical support and provide relevant details, such as error messages, timestamps, and other information needed to investigate the issue.

8. Quality Assurance

NeuroXT Inc. warrants against defects in the design and manufacturing process for a warranty period of **1 year** from the product's receipt by the customer. In the event of a dispute, it shall be resolved in accordance with the settlement procedures established by the Fair-Trade Commission regarding consumer disputes.

NeuroXT Inc. does not provide any guarantees for the following items:

- Damage caused by external factors, including accidents, misuse, fire, earthquakes, and other influences.
- Products modified without the written consent of NeuroXT Inc.
- Damage resulting from services provided by an engineer or service provider not authorized by NeuroXT Inc.

Refer to the user manual before requesting a warranty service, then contact customer support.

▶ Customer Support:

Company name: NeuroXT Inc.

Company Address: 917-919, 48, Achasan-ro 17-gil,

Seongdong-gu, Seoul, Republic of Korea

Contact: support@neuroxt.com