Configuration Guide – Patient Source

Below you will find a guide for the following which need to be completed to integrate MEMORI into your hospital EHR. Installation shall be done by the customer's technical/IT team, with this guide and support provided by the manufacturer.

Software version

This configuration guide is applicable with the following devices:

- 20240719_infection-risk-predictor
- 20240719_user-helper
- 20240719_model-helper
- 20240719_ehr-connector

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Before configuration

Before starting the configuration, Sanome will provide:

- the API Usernames, used in step 2
- the API passwords, used in step 2
- URL of the instance (e.g. rhntest.patientsource.co.uk)

The instructions in this configuration guide should be implemented in a staging or test environment initially to allow for sufficient testing.

Step 0: Pre-requisites

The device runs on infrastructure and in a network managed by the manufacturer. The requirements for the infrastructure and network are as follows:

The requirements for the running of the device are as follows:

- The device must be run on infrastructure and in a network managed by the manufacturer (managed via infrastructure-as-code-tool) so that it can be easily maintained and deployed.
- The manufacture will ensure that any infrastructure that runs the device is specifically reserved for this purpose to avoid interference with other processes.
- The manufacturer will ensure that there are robust virus scans on all virtual machines.
- The device must be managed by the manufacturer (via an orchestration tool) so that the device can be easily stopped, started or updated as required.
- The infrastructure running the device must have at least 4 CPUs and 16G of RAM.
- This infrastructure must be able to run containerised workloads (to avoid risk of bugs cause by inconsistent deployment environments)
- The infrastructure containing patient data needs to be isolated via a custom virtual network

There are no security options for the device that are set by the customer at installation time. All security requirements are pre-configured by the manufacturer before deployment. All the installation requirements and restrictions are laid out in the steps below.

Step 1: EHR Data Egress

To ensure that tabular data can be read from the EHR via SQL, the customer IT team must setup a replica EHR database in the network managed by the manufacturer. In addition to setting up the replica EHR database, the customer's IT team must also configure the network settings to enable secure, reliable, and uninterrupted data exchange between the hospital's EHR system and the manufacturer's network.

- The customer's IT team must configure Azure Virtual Network Peering to securely link the hospital's EHR network with the manufacturer's network, ensuring that the two virtual networks can communicate without exposing sensitive data to the public internet.
- The customer IT team should verify that firewalls and network security groups (NSGs) are configured to allow necessary inbound and outbound traffic between

the EHR network and the manufacturer's network, specifically for the MariaDB database connection.
- It is crucial that the port (default 3306 for MariaDB) and protocols required for database access are open in the network security settings to enable uninterrupted data flow. The customerIT team should work with the manufacturer to verify these configurations.
- The manufacturer's device will leverage the customer's existing security measures to ensure that the data flow operates securely within the customer's network. The customer's IT team is responsible for ensuring that appropriate protections against malware are in place within the network, including the use of firewalls, anti-malware software, and other necessary security protocols. The manufacturer will work with the customer IT team to ensure these security measures are compatible with the health software's operational requirements.

The following hazardous situations result from a failure of the customer's IT network to provide characteristics required for the running of the device (these are listed in the manufacturer):

- The user lacks information regarding the patient's health state
- Unintended people have access to confidential patient data

Database details (such as the host, username, password, port) should be shared with the manufacturer.

The manufacturer will monitor this replica database to ensure continuity of data flow. Any disruption in data transmission will trigger an alert to the manufacturer to ensure timely investigation.

Step 2: EHR Data Ingress

The risk category must be able to be pushed back to the EHR. In addition to the risk category, the associated observation set ID, observation type, risk category timestamp, and patient ID, should be sent to the REST API as part of the request payload.

The manufacturer will monitor this API to be alerted on any downtime (via the Grafana user below) and so to ensure continuity of data flow. Any disruption in data transmission will trigger an alert to the manufacturer to ensure timely investigation. The settings below have been configured to grant the manufacturer's device access only to the specific endpoint for transmitting the risk score to the EHR.

To configure the API, the customer IT team should follow the below steps:

2.1 Set up the API users – Sanome

- In ***Admin settings***, go to **Api users** and select ***+ Add***.
- Fill in as below:

Screenshot of settings

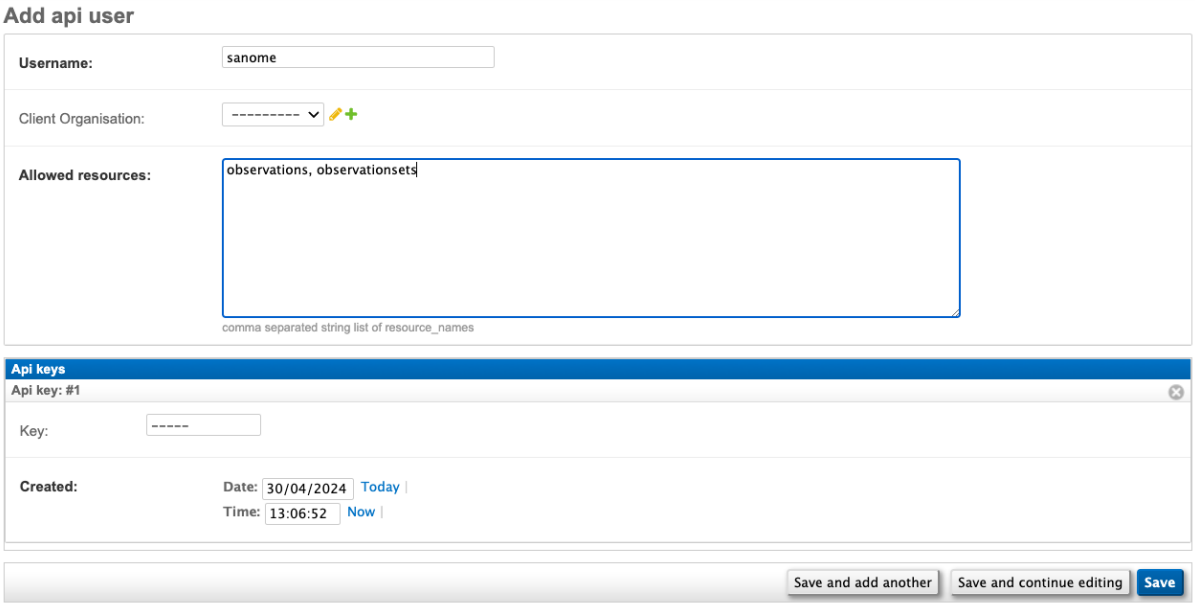


Table of settings (for readability/copy pasting)

Username:	Sanome (or whatever user is provided by Sanome)
Client organisation:	*[Hospital Name] (selected via the dropdown)* ***– this is important to include so that scores entered via the API can be shown on the ward board***
Allowed resources:	observations, observation sets

API KEYS

Key	*[password provided by Sanome]*

2.2 Set up the API users – Grafana

We use Grafana for testing the availability of the API, and it should only have access to 'groups'. Groups (which are observation groups) have been chosen as it is not possible to push anything with this resource to minimise risk.

- In ***Admin settings***, go to **Api users** and select ***+ Add***.
- Fill in as below:

Screenshot of settings

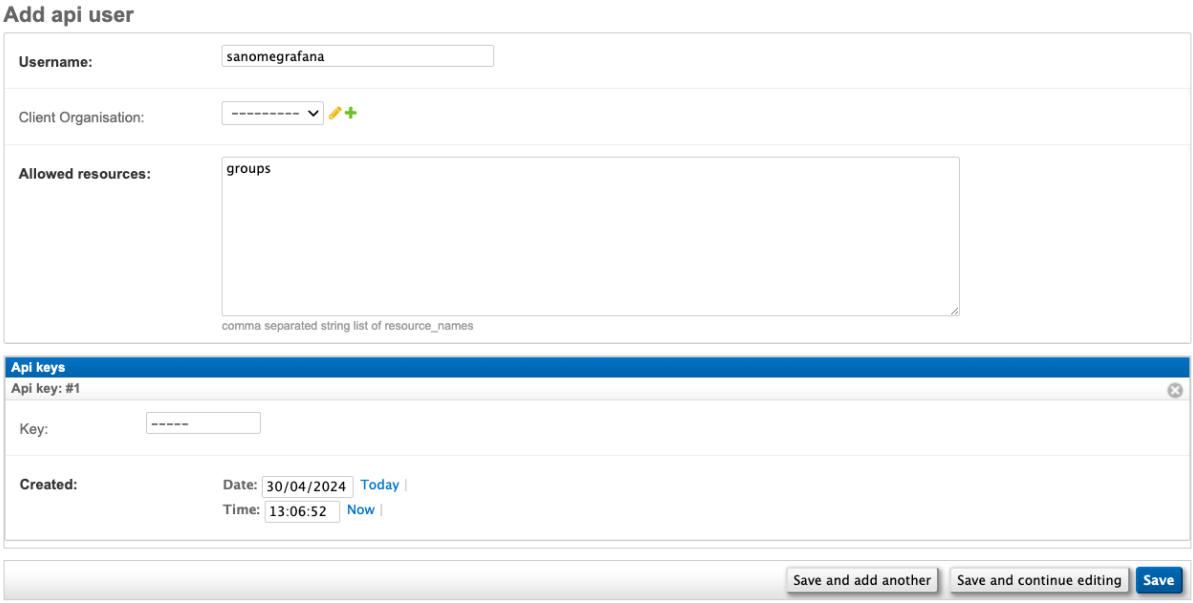


Table of settings (for readability/copy pasting)

Username:	sanomegrafana *(or whatever user is provided by Sanome)*
Client organisation:	*If you have 'Sanome' already created you can enter this, or create a new oragnisation for Sanome, but can also leave blank.*
Allowed resources:	groups

API KEYS

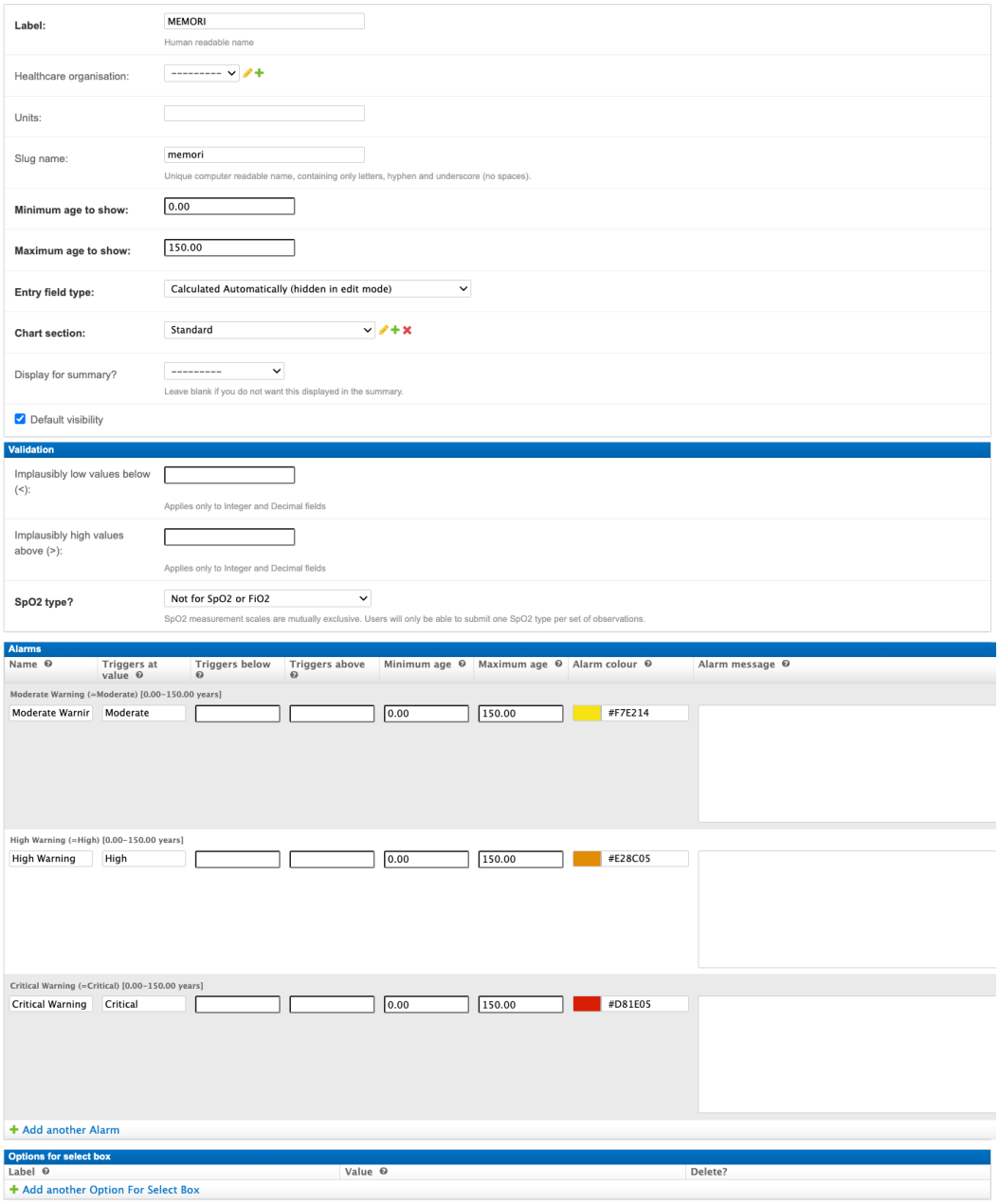
Key	*[password provided by Sanome]*

Step 3: EHR Front-end Configuration

3.1 Add MEMORI observation type

- In ***Admin settings,*** go to **Observation types** and select ***+Add***.
- Fill in as below:

Screenshot of settings


Label:
MEMORI
Human readable name
Healthcare organisation:

Units:
Slug name:
memori
Unique computer readable name, containing only letters, hyphen and underscore (no spaces).
Minimum age to show:
0.00
Maximum age to show:
150.00
Entry field type:
Calculated Automatically (hidden in edit mode)
Chart section:
Standard
Display for summary?

Leave blank if you do not want this displayed in the summary.
Default visibility
Validation
Implausibly low values below (<):
Applies only to Integer and Decimal fields
Implausibly high values above (>):
Applies only to Integer and Decimal fields
SpO2 type?
Not for SpO2 or FiO2
SpO2 measurement scales are mutually exclusive. Users will only be able to submit one SpO2 type per set of observations.
Alarms
Name
Triggers at value
Triggers below
Triggers above
Minimum age
Maximum age
Alarm colour
Alarm message
Moderate Warning (=Moderate) [0.00-150.00 years]
Moderate Warnir
Moderate
0.00
150.00
#F7E214
High Warning (=High) [0.00-150.00 years]
High Warning
High
0.00
150.00
#E28C05
Critical Warning (=Critical) [0.00-150.00 years]
Critical Warning
Critical
0.00
150.00
#D81E05
Add another Alarm
Options for select box
Label
Value
Delete?
Add another Option For Select Box

Table of settings (for readability/copy pasting)

Label	MEMORI
Healthcare organisation	
Units	
Slug name	memori
Minimum age to show	0.00
Maximum age to show	150.00
Entry field type	Calculated Automatically (hidden in edit mode)
Chart section	Standard
Display for summary?	
Default visibility	✅

Validation

Implausibly low values below (<):	Standard
Implausibly high values above (>):	
Spo2 type	Not for SpO2 or FiO2

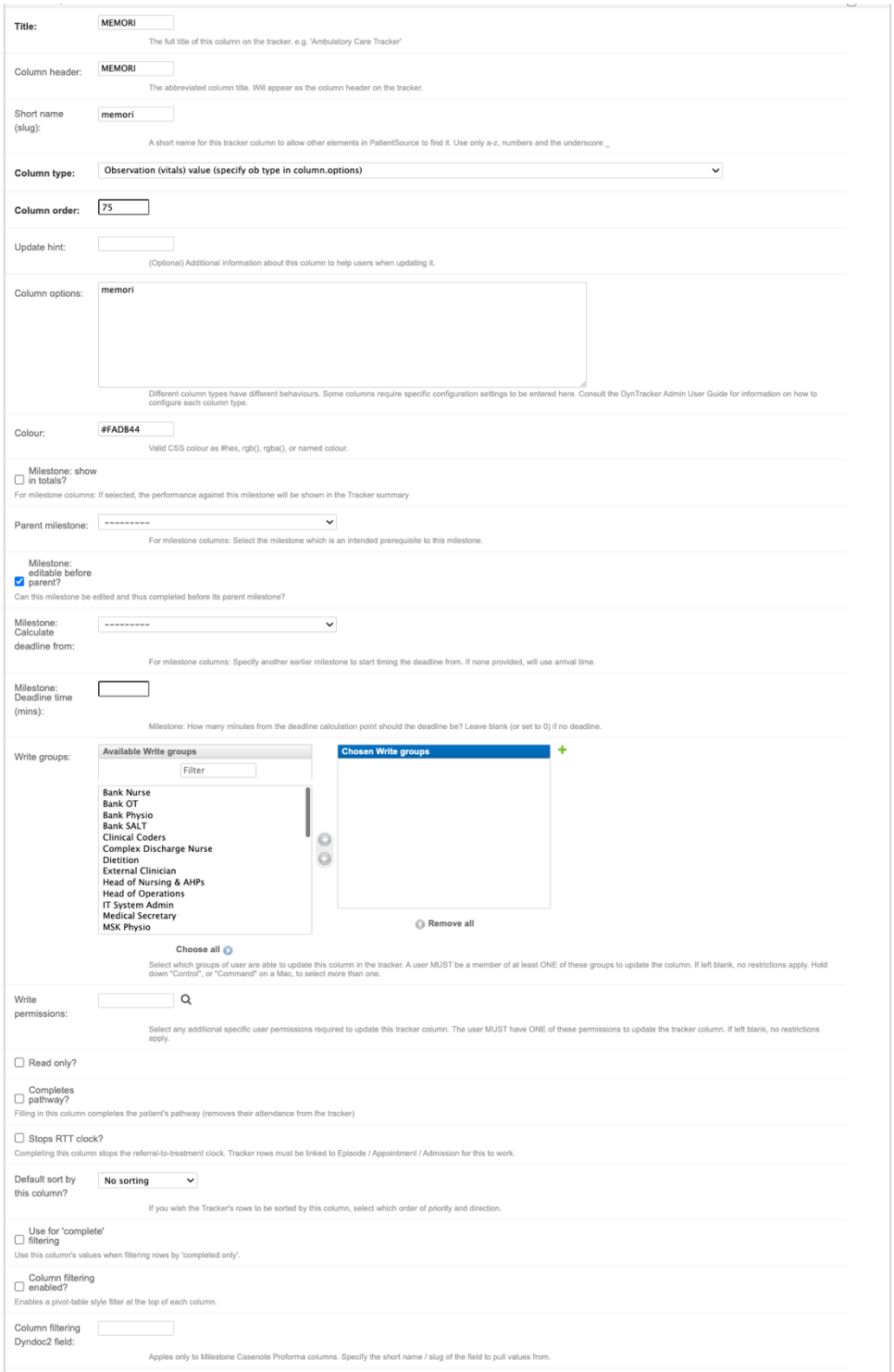
Alarms

Name	Triggers at Value	Triggers Below (years)	Triggers Above (years)	Minimum Age	Maximum Age	Alarm Colour	Alarm Message
Moderate Warning	Moderate			0.00	150.00	#F7E214	
High Warning	High			0.00	150.00	#E28C05	
Critical Warning	Critical			0.00	150.00	#D81E05	

3.2 Add MEMORI level to the ward board

- In ***Admin settings***, go to **Tracker configs** and select 🖍️. ***Change***.
- Select ***Ward view*** for the relevant ward(s) in the pilot
- Scroll to the bottom and select ***+Add another Tracker Template Column***
- Fill in as below:

Screenshot of settings


Title:
MEMORI
The full title of this column on the tracker. e.g. 'Ambulatory Care Tracker'
Column header:
MEMORI
The abbreviated column title. Will appear as the column header on the tracker.
Short name (slug):
memori
A short name for this tracker column to allow other elements in PatientSource to find it. Use only a-z, numbers and the underscore _
Column type:
Observation (vitals) value (specify ob type in column.options)
Column order:
75
Update hint:
(Optional) Additional information about this column to help users when updating it.
Column options:
memori
Different column types have different behaviours. Some columns require specific configuration settings to be entered here. Consult the DynTracker Admin User Guide for information on how to configure each column type.
Colour:
#FADB44
Valid CSS colour as #hex, rgb(), rgba(), or named colour.
Milestone: show in totals?
For milestone columns: If selected, the performance against this milestone will be shown in the Tracker summary
Parent milestone:

For milestone columns: Select the milestone which is an intended prerequisite to this milestone.
Milestone: editable before parent?
Can this milestone be edited and thus completed before its parent milestone?
Milestone: Calculate deadline from:

For milestone columns: Specify another earlier milestone to start timing the deadline from. If none provided, will use arrival time.
Milestone: Deadline time (mins):
Milestone: How many minutes from the deadline calculation point should the deadline be? Leave blank (or set to 0) if no deadline.
Write groups:
Available Write groups
Filter
Bank Nurse
Bank OT
Bank Physio
Bank SALT
Clinical Coders
Complex Discharge Nurse
Dietition
External Clinician
Head of Nursing & AHPs
Head of Operations
IT System Admin
Medical Secretary
MSK Physio
Choose all
Chosen Write groups
Remove all
Select which groups of user are able to update this column in the tracker. A user MUST be a member of at least ONE of these groups to update the column. If left blank, no restrictions apply. Hold down "Control", or "Command" on a Mac, to select more than one.
Write permissions:
Select any additional specific user permissions required to update this tracker column. The user MUST have ONE of these permissions to update the tracker column. If left blank, no restrictions apply.
Read only?
Completes pathway?
Filling in this column completes the patient's pathway (removes their attendance from the tracker)
Stops RTT clock?
Completing this column stops the referral-to-treatment clock. Tracker rows must be linked to Episode / Appointment / Admission for this to work.
Default sort by this column?
No sorting
If you wish the Tracker's rows to be sorted by this column, select which order of priority and direction.
Use for 'complete' filtering
Use this column's values when filtering rows by 'completed only'.
Column filtering enabled?
Enables a pivot-table style filter at the top of each column.
Column filtering Dyndoc2 field:
Apples only to Milestone Casenote Proforma columns. Specify the short name / slug of the field to pull values from.

Table of settings (for readability/copy pasting)

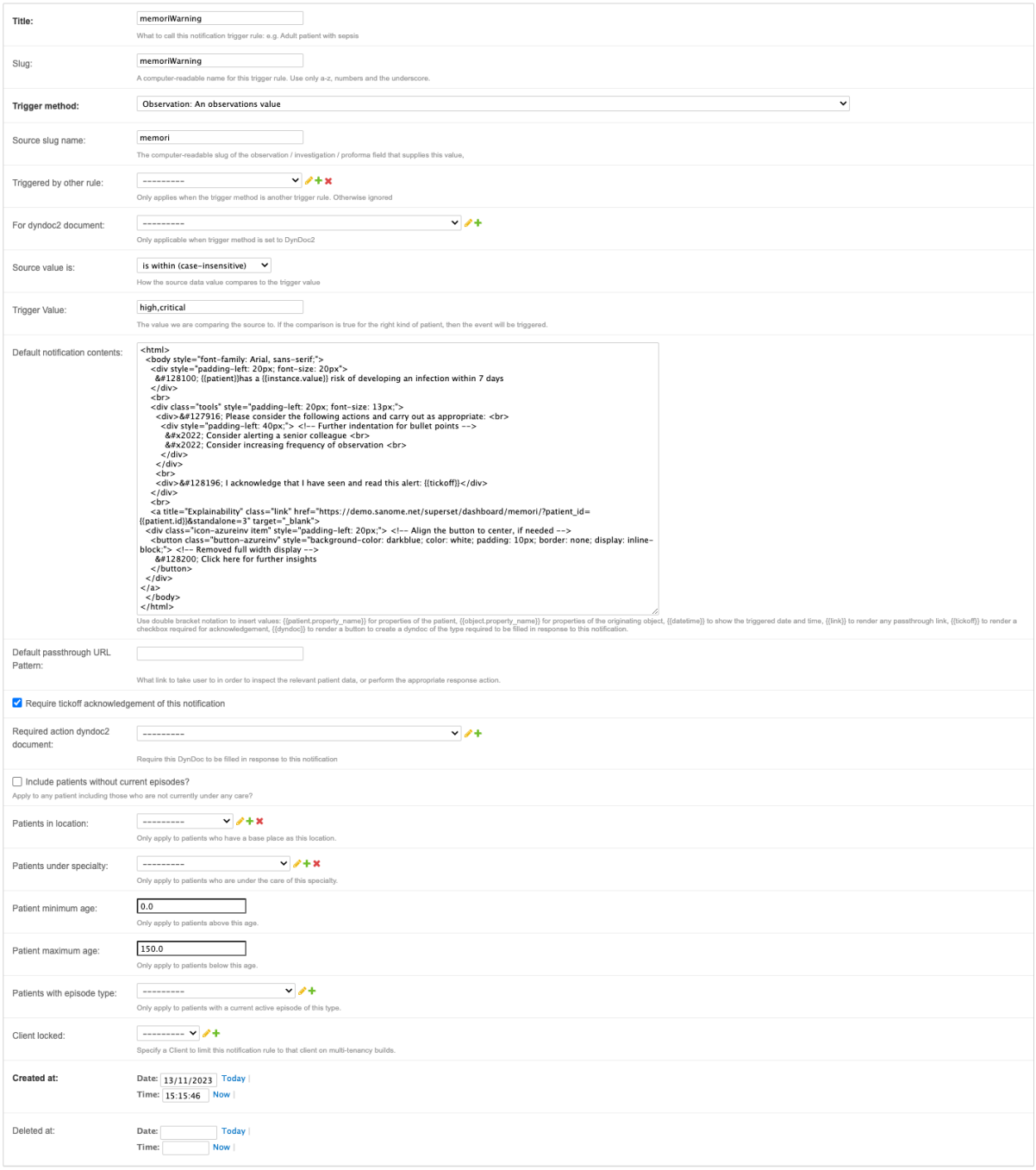
Field	Value
Title	MEMORI
Column header	MEMORI
Short name (slug)	Memori
Column type	Observation (vitals) value (specify ob type in column.options)
Column order	75 *(possible that it needs to be different your side – just needs to be larger than the number for NEWS2)*
Update hint	
Column options	memori
Colour	#FAD844
Milestone: show in totals?	
Parent milestone	------
Milestone: editable before parent?	✅
Milestone: Calculate deadline from:	------
Milestone: Deadline time (mins):	
Chosen Write Groups	
Write Permissions	
Read Only?	
Completes Pathway?	
Stops RTT Clock?	
Default Sort by This Column?	No sorting
Use for 'Complete' Filtering	

Column Filtering Enabled?	
Column Filtering Dynodoc2 Field:	

3.3 Add trigger rule (alert)

- In ***Admin settings***, go to **Trigger rules** and select ***+ Add***.
- Fill in as below
- (Make sure to click ***+ Add another Trigger Rule Action*** to reveal input section for warning-test)
- **Be sure to amend the 'demo.sanome.net' in the HTML below to either the staging or production URL provided by Sanome (e.g. rhntest.sanome.net)**

Screenshot of settings



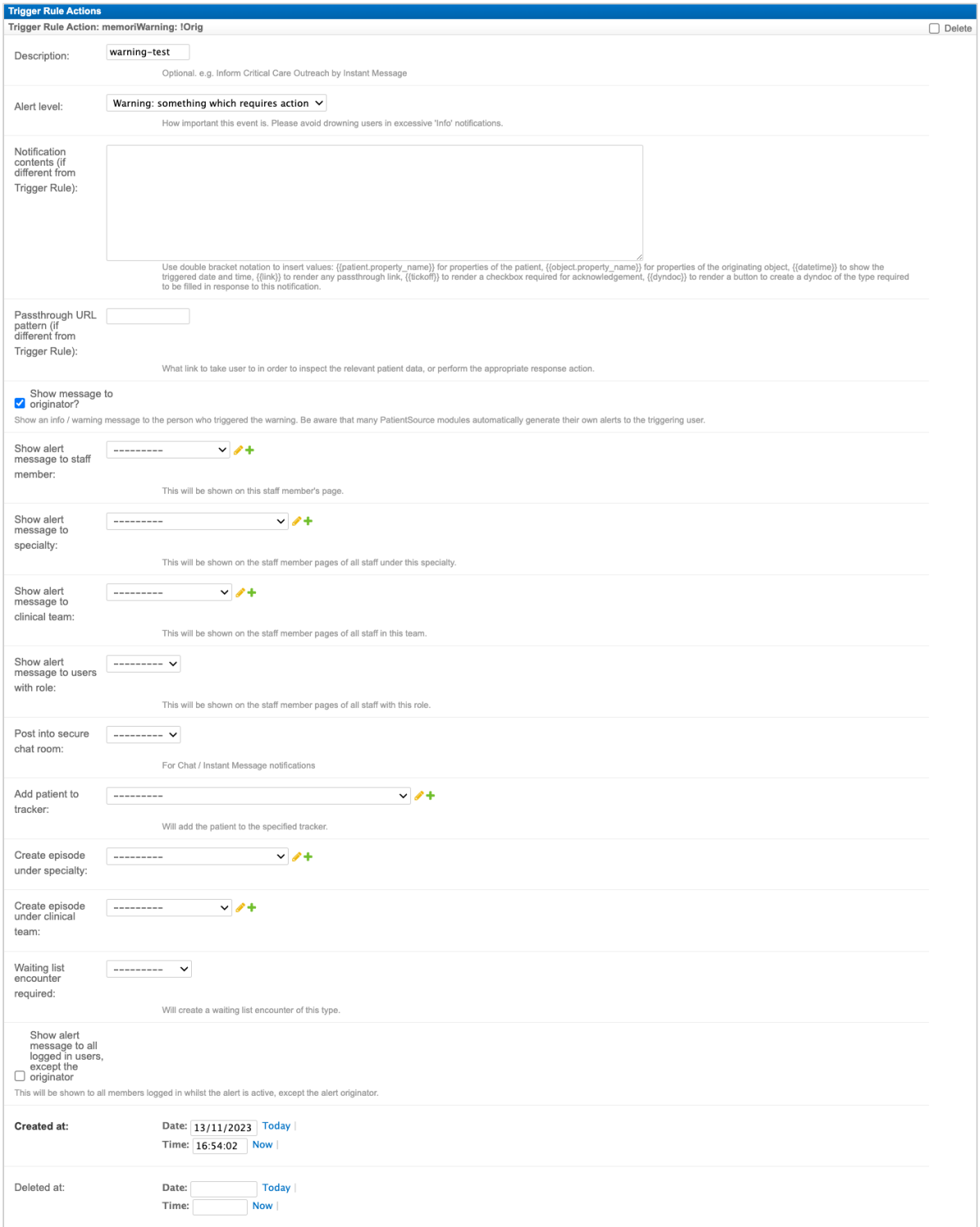

Trigger Rule Actions
Trigger Rule Action: memoriWarning: !Orig
Delete
Description:
warning-test
Optional. e.g. Inform Critical Care Outreach by Instant Message
Alert level:
Warning: something which requires action
How important this event is. Please avoid drowning users in excessive 'Info' notifications.
Notification contents (if different from Trigger Rule):
Use double bracket notation to insert values: {{patient.property_name}} for properties of the patient, {{object.property_name}} for properties of the originating object, {{datetime}} to show the triggered date and time, {{link}} to render any passthrough link, {{tickoff}} to render a checkbox required for acknowledgement, {{dyndoc}} to render a button to create a dyndoc of the type required to be filled in response to this notification.
Passthrough URL pattern (if different from Trigger Rule):
What link to take user to in order to inspect the relevant patient data, or perform the appropriate response action.
Show message to originator?
Show an info / warning message to the person who triggered the warning. Be aware that many PatientSource modules automatically generate their own alerts to the triggering user.
Show alert message to staff member:
This will be shown on this staff member's page.
Show alert message to specialty:
This will be shown on the staff member pages of all staff under this specialty.
Show alert message to clinical team:
This will be shown on the staff member pages of all staff in this team.
Show alert message to users with role:
This will be shown on the staff member pages of all staff with this role.
Post into secure chat room:
For Chat / Instant Message notifications
Add patient to tracker:
Will add the patient to the specified tracker.
Create episode under specialty:
Create episode under clinical team:
Waiting list encounter required:
Will create a waiting list encounter of this type.
Show alert message to all logged in users, except the originator
This will be shown to all members logged in whilst the alert is active, except the alert originator.
Created at:
Date: 13/11/2023 Today |
Time: 16:54:02 Now |
Deleted at:
Date: Today |
Time: Now |

Table of settings (for readability/copy pasting)

Title	memoriWarning
Slug	memoriWarning
Trigger method	Observation: An observation's value
Source slug name	memori
Triggered by other rule	------
For dynodoc2 document	-------
Source value is	is within (case-insensitivity)
Trigger Value	high,critical
Default notification contents	<html> <body style="font-family: Arial, sans-serif;"> 👤 {{patient}}has a {{instance.value}} risk of developing an infection within 7 days 🎬 Please consider the following actions and carry out as appropriate: <!-- Further indentation for bullet points --> • Consider alerting a senior colleague • Consider increasing frequency of observation 📄 I acknowledge that I have seen and read this alert: {{tickoff}} <!-- Align the button to center, if needed --> <button class="button-azureinv" style="background-color: darkblue; color: white; padding: 10px; border: none; display: inline-block;"> <!-- Removed full width display --> 📈 Click here for further insights

	</button> </body> </html>
Default passthrough URL Pattern	
Require tickoff acknowledgement of this notification	✅
Required action dynodoc2 document	--------
Include patients without	

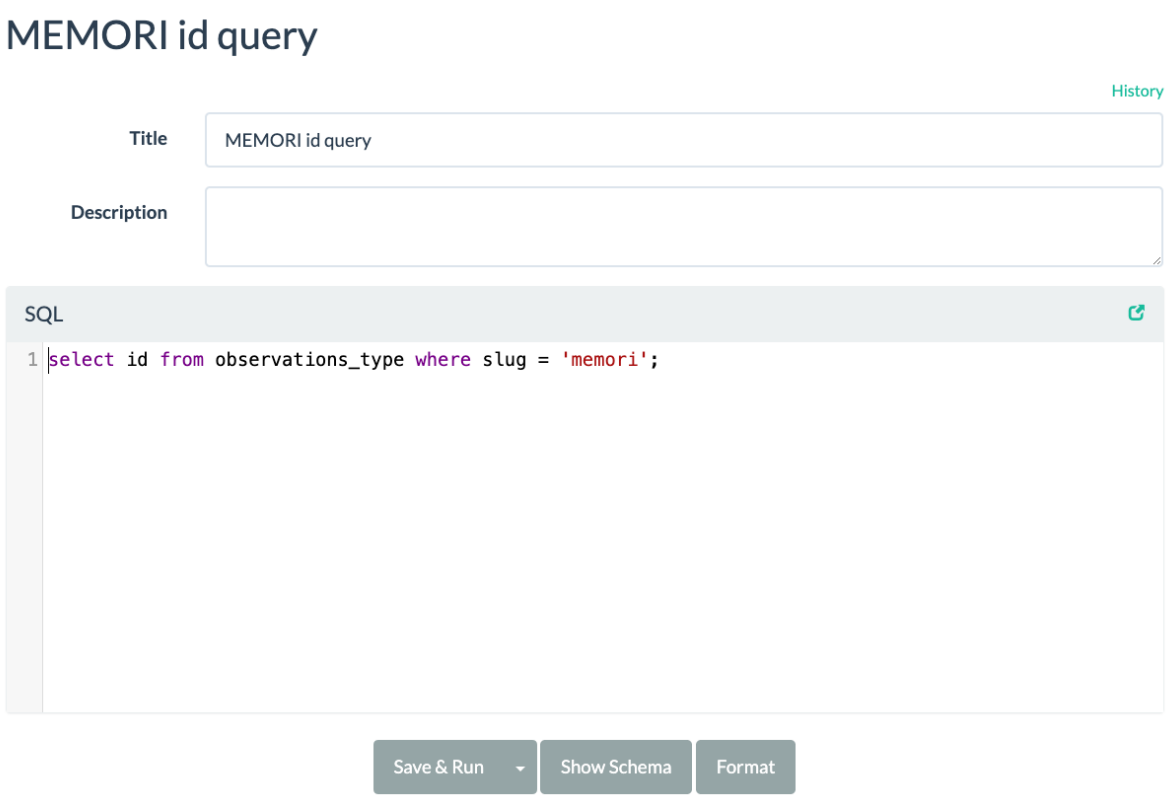
current episodes?	
Patients in location	----------
Patients under specialty	----------
Patient minimum age	0.0
Patient maximum age	150.0
Patients with episode type	----------
Client locked	----------

Trigger rule actions

Description	warning-test
Alert level	Warning: something which requires action
Notification contents (if different from Trigger Rule)	
Passthrough URL pattern (if different from Trigger Rule)	
Show message to originator?	☑
Show alert message to staff member:	----------
Show alert message to specialty:	----------
Show alert message to clinical team:	----------
Show alert message to users with role:	----------
Post into secure chat room:	----------
Add patient to tracker:	----------
Create episode under specialty:	----------
Create episode under clinical team:	----------
Waiting list encounter required:	----------
Show alert message to all logged in users, except the originator	

3.4 Get observation type ID for newly created 'memori' observation

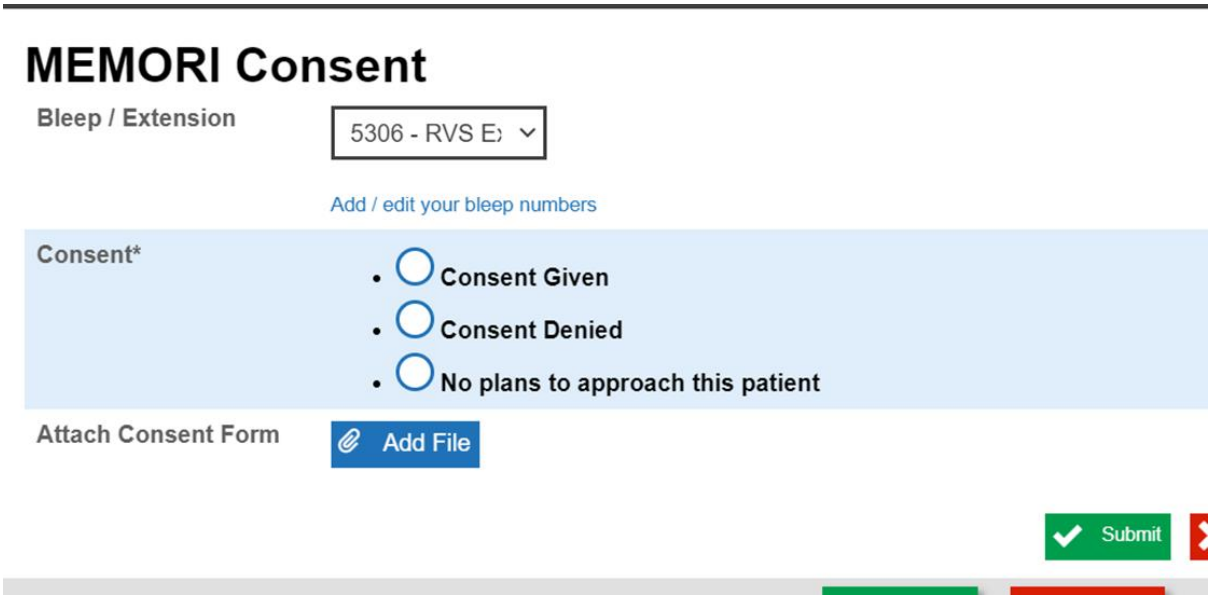
- Go to ***SQL explorer*** in the left hand navigation pane of PatientSource
- At the top of the page, select ***New Query***
- Add an appropriate title, e.g. 'MEMORI ID query'
- Enter `select id from observations_type where slug = 'memori';` in the **SQL** box, and select **Save & Run.**
- Record the id number that appears at the bottom and send to Sanome.



3.5 Consent Patients on the Current Ward Board

This step is only required if patient consent is required for example during a study. This is not required for use of approved MEMORI medical device.

- Fill out the 'MEMORI Consent' Dyndoc for all of the patients on the ward board in question (assuming that this dyndoc already exists)
- For half the patients on the ward board, tag them as 'Consent Given'. For the other half of the patients, tag them as 'Consent Denied' / 'No plans to approach this patient'



Step 4: SSO Configuration

The manufacturer will provide the following parameters ahead of the application being setup:

- *Redirect URI* – for example, https://oauth.[hospital_name].sanome.net/oauth2/callback
- *Scope*: openid

The customer IT team member with administrator access to the customer identify provider will conduct the following steps:

- *Register the Application*: Setup an application in the hospital's identity provider, using the Oauth2 authentication method. The redirect URI and scope should be entered as provided by the manufacturer. the name, a client ID and a client secret should be generated as part of the registration process
- *Access to Specific Groups* – Specific groups should be assigned in the application such that access to the dashboard is only available to specific roles at the hospital (groups to be determined with EHR / clinical teams)
- *Share Details:* the client ID and client secret should be shared with the manufacturer

Step 5: Device Deployment

One the above steps have been completed, the manufacturer should setup the infrastructure (using infrastructure-as-code tool) and then deploy the device using the orchestration management tool.

The manufacturer will then add enter some historic observations for 2 patients via the EHR API to assist with testing (one patient that will generate an alert, one patient that will not generate an alert).

The manufacturer will conduct some basic checks to ensure that the infrastructure and device has been setup correctly.

If required, the manufacturer will conduct initial local calibration of the device prior to first use.

Step 6: Testing

For the 2 patient IDs (one low risk, one high risk) that have been provided by the manufacturer, a member of the customer IT team will conduct the following steps:

For the low-risk patient:

1. A set of normal vital signs for a patient should be entered, such that the patient has a NEWS2 score of 0
2. They should check that a MEMORI score of 'Low' appears in both the Ward View and Observations View after no more than 5 minutes. No alert should be visible

For the high-risk patient:

1. A set of abnormal signs for a patient should be entered, such that the patient has a NEWS2 score of greater than 5.
2. They should check that a MEMORI score of 'High' or 'Critical' appears in both the Ward View and Observations View after no more than 5 minutes. An alert should pop up with this information.
3. The user should click on the button in the alert 'Click here for further insights' and go through to the explainability dashboard, signing in via SSO if necessary. They should check that the MEMORI score on the explainability dashboard matches that on the EHR and that all the graphs contain data

Step 7: Maintenance & Decommissioning

No ongoing maintenance is required for the device to function as intended.
If the device requires an update that would impact this configuration, the manufacturer will contact you as the customer to provide details and any necessary steps to carry out to complete the update.

The manufacturer maintains logs and visibility of the version of the device in use by the customer.

If a security event is detected (such as a virus is detected on one of the virtual machines running the device), the software will continue to run as normal. In this event, the manufacturer will be alerting via their monitoring system and take appropriate steps, keeping the relevant stakeholders at the hospital informed.

Decommissioning, if or when relevant, will be managed by the manufacturer. If any steps are required to be completed by the customer, the manufacturer will provide clear guidance for the customer.

Intended Use Statement

MEMORI is a modular software as a medical device (SaMD) which may utilize compatible software to obtain patient data collated from Electronic Health Record systems (EHR) and deliver a risk score (Memori Risk Score) to inform clinical management through the use of a proprietary Machine Learning model to categorise and stratify the risk of patients developing hospital acquired infections (HAIs) and predicting a set time frame of onset in the patient population. The MEMORI score and the information displayed on the explanatory dashboard can be used by a clinician to inform the management of a patient. Potential next actions may be displayed based on national guidelines and/or local policies as appropriate.

MEMORI is intended for use by trained healthcare professionals, including doctors, nurses, and healthcare assistants, for adult patients aged over 18 and under 90 years with acute neurological injuries and/or neurological conditions.

It is to be used within secondary care settings, including but not limited to:

- Acute brain injury wards
- Stroke units
- Complex neuro-rehabilitation units
- Prolonged Disorders of Consciousness (PDOC) units
- Ventilation and complex respiratory wards
- Neuro-behavioural wards
- Neurosurgical intensive care units (Neuro SICU)
- Intermediate neurological wards
- Neurological stepdown units

Use is restricted to the specified patient population and the defined clinical environments such as the above.

MEMORI is viewed on the care facility IT system through the EHR provider. Data from patients entered in the EHR both physiological and non-physiological, is processed by the Memori algorithm and the generated risk score is displayed to the clinicians via the EHR or Memori explainability dashboard. As patient data is updated with more monitoring inputs, so the risk score is updated and displayed. If the MEMORI score falls within a predetermined threshold, an alert message appears to inform the clinician regarding the change in metrics and MEMORI score. On the alert message, the clinician will also be able to access the explainability dashboard where they will be able to visualise patient-information including, but not limited to, vital sign trends, MEMORI score trend, recent investigations, drug history.

MEMORI is designed to predict the onset of HAIs and subsequently **INFORM** the clinician of this, to allow them to consider further investigations. This timely detection will translate into a clinician considering an appropriate intervention thereby significantly reducing the risk of complications and shortening the extra length of stay usually associated with the development of HAIs. Memori is **NOT** intended to replace clinicians or multi-disciplinary team members, drive clinical management, be used in replacement of new observations, investigations or treatment decisions, be used as the sole driver for discharge of patients from the hospital or to replace local or national guidelines.

Appendix:

Configuration Version	Description	Date
v1.0	Initial version of Configuration	01/05/2024
v1.1	Add details around consent	09/05/2024
v1.2	Tidying up various issues to do with the configuration, and clarification about what is provided initially and what is required to complete setup	15/05/2024
V1.3	Clarifying that PatientSource ID is needed for adding dashboard URL in section 6.	15/05/2024
V1.4	Removed section 6 “Add hyperlink” which is no longer required. Clarified consent requirement. Added maintenance & decommissioning details.	14/09/2024
V1.5	Adding additional steps to clarify the steps required in addition to the frontend configuration. Adding the intended use and software versions for clarity	09/06/2025