

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:

- 20250929_infection-risk-predictor
- 20250929_user-helper
- 20250929_model-helper
- 20250929_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 Next Best Actions form that has been signed off by the deployment site

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 customer IT 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

Add api user


Username:

Client Organisation:  

Allowed resources:

comma separated string list of resource_names

Api keys

Api key: #1 

Key:

Created: Date: [Today](#) | Time: [Now](#) |

Table of settings (for readability/copy pasting)

Username:	Sanome (or whatever user is provided by Sanome)
Client organisation:	<i>[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</i>
Allowed resources:	observations, observation sets

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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

Add api user

Username:	<input type="text" value="sanomegrafana"/>
Client Organisation:	<input type="text" value="-----"/>  
Allowed resources:	<input type="text" value="groups"/> <small>comma separated string list of resource_names</small>


Api keys	
Api key: #1 	
Key:	<input type="text" value="-----"/>
Created:	Date: <input type="text" value="30/04/2024"/> Today Time: <input type="text" value="13:06:52"/> Now
<input type="button" value="Save and add another"/> <input type="button" value="Save and continue editing"/> <input type="button" value="Save"/>	

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 organization for Sanome, but can also leave blank.
Allowed resources:	groups

API KEYS

Key	<i>[password provided by Sanome]</i>
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Step 3: EHR Front-end Configuration

3.1 Add MEMORI observation type

- In **Admin settings**, go to **Observation types** and select **+Add**.
- **Be sure to amend the 'example.sanome.net' in the HTML below to either the staging or production URL provided by Sanome (e.g. rhntest.sanome.net)**
- Fill in as below:

Screenshot of settings

The screenshot shows the configuration form for the MEMORI observation type. The form is divided into several sections:

- Basic Information:** Label (MEMORI), Healthcare organisation (dropdown), Units (text), 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? (dropdown), and Default visibility (checked).
- External Link:** External link template (https://dev.patientsource.nonprod.sanor) and Tooltip (text).
- Validation:** Implausibly low values below (<:), Implausibly high values above (>:), and SpO2 type? (Not for SpO2 or FIO2).
- Alarms:** A table with columns for Name, Triggers at value, Triggers below, Triggers above, Minimum age, Maximum age, Alarm colour, and Alarm message. It lists three alarm types: Moderate Warning (Moderate), High Warning (High), and Critical Warning (Critical).
- Options for select box:** A section for configuring the select box options, including Label, Value, and Delete?.

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	NEWS2 (This will vary depending on your PatientSource configuration. Typical chart section names are 'NEWS2' or 'Standard'.)
Display for summary?	
Default visibility	<input checked="" type="checkbox"/>
External link template	https://example.sanome.net/dashboard/patients/{patient.id} (Be sure to change this to the correct base URL.)
Tooltip	

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	

After adding the MEMORI observation type, go back to the observation types page and click 'Change Order'. Drag and drop 'MEMORI' to the desired position on the obs chart. Our recommendation is to put it immediately below NEWS2.

Record the observation type ID for newly created 'memori' observation. This is the number visible in the URL, e.g.:

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<https://example.patientsource.co.uk/admin/observations/type/254/change/>

Send this number to Sanome: it is essential that we know the observation type ID so that MEMORI scores can be sent to PatientSource system.

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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) which are part of the rollout
- Scroll to the bottom and select **+Add another Tracker Template Column**
- **Be sure to amend the** 'example.sanome.net' **in the HTML below to either the staging or production URL provided by Sanome (e.g. rhntest.sanome.net)**
- Fill in as below:

Screenshot of settings

Title: The full title of this column on the tracker. e.g. 'Ambulatory Care Tracker'

Column header: The abbreviated column title. Will appear as the column header on the tracker.

Short name (slug): 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:

Column order:

Update hint: (Optional) Additional information about this column to help users when updating it.

Column options: 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: 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.

Milestones: editable before parent? Can this milestone be edited and thus completed before its parent milestone?

Milestones: 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? 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: Applies 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?	<input checked="" type="checkbox"/>
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	

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Column Filtering Enabled?	
Column Filtering Dynodoc2 Field:	
External link template for new entries	
External link template for editing entries	https:// example.sanome.net /dashboard/patients/{patient.id}

3.3 Add trigger rules (alert)

Alerts in MEMORI are triggered for patients that have a high or critical MEMORI scores. For each risk level, the below steps will need to be followed:

- In **Admin settings**, go to **Trigger rules** and select **+ Add**.
- Complete the configuration as per the text below. The highlighted text in 3.3.1 and 3.3.2 can be found in the Next Best Actions form specified in the 'Before Configuration' section at the top of the document
- (Make sure to click **+ Add another Trigger Rule Action** to reveal input section for warning-test)
- **Be sure to amend the 'example.sanome.net' in the HTML below to either the staging or production URL provided by Sanome (e.g. rhntest.sanome.net) in the table in 3.3.1 and 3.3.2.**
-

Screenshot of settings

Title:	<input type="text" value="memoriWarning"/>
	<small>What to call this notification trigger rule: e.g. Adult patient with sepsis</small>
Slug:	<input type="text" value="memoriWarning"/>
	<small>A computer-readable name for this trigger rule. Use only a-z, numbers and the underscore.</small>
Trigger method:	<input type="text" value="Observation: An observations value"/>
Source slug name:	<input type="text" value="memori"/>
	<small>The computer-readable slug of the observation / investigation / profoma field that supplies this value.</small>
Triggered by other rule:	<input type="text" value="-----"/>
	<small>Only applies when the trigger method is another trigger rule. Otherwise ignored</small>
For dyndoc2 document:	<input type="text" value="-----"/>
	<small>Only applicable when trigger method is set to DynDoc2</small>
Source value is:	<input type="text" value="is within (case-insensitive)"/>
	<small>How the source data value compares to the trigger value</small>
Trigger Value:	<input type="text" value="high,critical"/>
	<small>The value we are comparing the source to. If the comparison is true for the right kind of patient, then the event will be triggered.</small>
Default notification contents:	<pre> <html> <body style="font-family: Arial, sans-serif;"> <div style="padding-left: 20px; font-size: 20px"> &#128100; {{patient}}has a {{instance.value}} risk of developing an infection within 7 days </div>
 <div class="tools" style="padding-left: 20px; font-size: 13px;"> <div style="padding-left: 40px;"> <!-- Further indentation for bullet points --> &#x2022; Consider alerting a senior colleague
 &#x2022; Consider increasing frequency of observation
 </div> </div>
 <div> <div>&#128196; I acknowledge that I have seen and read this alert: {{tickoff}}</div> </div>
 <div class="icon-azureimv item" style="padding-left: 20px;"> <!-- Align the button to center, if needed --> <button class="button-azureimv" style="background-color: darkblue; color: white; padding: 10px; border: none; display: inline-block;"> <!-- Removed full width display --> &#128200; Click here for further insights </button> </div> </body> </html> </pre> <small>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 dyndoc of the type required to be filled in response to this notification.</small>
Default passthrough URL Pattern:	<input type="text"/>
	<small>What link to take user to in order to inspect the relevant patient data, or perform the appropriate response action.</small>
<input checked="" type="checkbox"/> Require tickoff acknowledgement of this notification	
Required action dyndoc2 document:	<input type="text" value="-----"/>
	<small>Require this DynDoc to be filled in response to this notification</small>
<input type="checkbox"/> Include patients without current episodes?	
	<small>Apply to any patient including those who are not currently under any care?</small>
Patients in location:	<input type="text" value="-----"/>
	<small>Only apply to patients who have a base place as this location.</small>
Patients under specialty:	<input type="text" value="-----"/>
	<small>Only apply to patients who are under the care of this specialty.</small>
Patient minimum age:	<input type="text" value="0.0"/>
	<small>Only apply to patients above this age.</small>
Patient maximum age:	<input type="text" value="150.0"/>
	<small>Only apply to patients below this age.</small>
Patients with episode type:	<input type="text" value="-----"/>
	<small>Only apply to patients with a current active episode of this type.</small>
Client locked:	<input type="text" value="-----"/>
	<small>Specify a Client to limit this notification rule to that client on multi-tenancy builds.</small>
Created at:	Date: <input type="text" value="13/11/2023"/> Today Time: <input type="text" value="15:15:46"/> Now
Deleted at:	Date: <input type="text"/> Today Time: <input type="text"/> Now

Trigger Rule Actions

Trigger Rule Action: memoriWarning: 1Orig Delete

Description: Optional, e.g. Inform Critical Care Outreach by Instant Message

Alert level: 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: [Today](#) | Time: [Now](#) |

Deleted at: Date: [Today](#) | Time: [Now](#) |

3.3.1 - Table of settings (for readability/copy pasting) – for a HIGH Alert

Below is an example setting for a trigger which has been specified for a high MEMORI score. Two trigger rules should be set up: memoriWarningHigh and MemoriWarningCritical.

Default Notification Contents: update the yellow text in this section, with the first yellow text corresponding to unindented text and the subsequent yellow text corresponding to each bullet point. Note that if there are additional bullet points to what is displayed below, the subsequent text should be copied for each bullet point ‘• [instruction from Next Best Action sheet]
’

Title	memoriWarningHigh
Slug	memoriWarningHigh
Trigger method	Observation: An observation's value
Source slug name	memori
Triggered by other rule	-----
For dynodoc2 document	-----
Source value is	contains (case-insensitive)
Trigger Value	high

Default notification contents	<pre> <html> <body style="font-family: Arial, sans-serif;"> <div style="padding-left: 20px; font-size: 20px"> &#128100; {{patient}}has a {{instance.value}} risk of developing an infection within 3 days </div>
 <div class="tools" style="padding-left: 20px; font-size: 13px;"> <div>&#127916; Probable infection
 <div style="padding-left: 40px;"> &#x2022; Immediately assess ABCDE
 &#x2022; Inform nurse in charge/ward manager/Clinical Response Service (OOH) via SBAR
 &#x2022; Consider increasing observation frequency
 </div> </div>
 <div>&#128196; I acknowledge that I have seen and read this alert: {{tickoff}}</div> </div>
 <div class="icon-azureinv item" style="padding-left: 20px;"> <!-- 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 --> &#128200; Click here for further insights </button> </div> </body> </html> </pre>
Default passthrough URL Pattern	
Require tickoff acknowledgment of this notification	<input checked="" type="checkbox"/>
Required action dynodoc2 document	<p>-----</p>

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?	<input checked="" type="checkbox"/>
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	

3.3.2 - Table of settings (for readability/copy pasting) – for a CRITICAL Alert

Below is an example setting for a trigger which has been specified for a critical MEMORI score. A few points to note:

1. **Default Notification Contents:** update the yellow text in this section, with the first yellow text corresponding to unindented text and the subsequent yellow text corresponding to each bullet point. Note that if there are additional bullet points

to what is displayed below, the subsequent text should be copied for each bullet point ‘• [instruction from Next Best Action sheet]
’

Title	memoriWarningCritical
Slug	memoriWarningCritical
Trigger method	Observation: An observation's value
Source slug name	memori
Triggered by other rule	-----
For dynodoc2 document	-----
Source value is	contains (case-insensitive)
Trigger Value	critical
Default notification contents	<pre> <html> <body style="font-family: Arial, sans-serif;"> <div style="padding-left: 20px; font-size: 20px"> &#128100; {{patient}}has a {{instance.value}} risk of developing an infection within 3 days </div>
 <div class="tools" style="padding-left: 20px; font-size: 13px;"> <div>&#127916; Infection very likely
 <div style="padding-left: 40px;"> &#x2022; Immediately assess ABCDE
 &#x2022; Call for help (colleague) now
 &#x2022; Confirm Treatment Escalation Plan
 &#x2022; In hour: contact ward manager/CRS via SBAR
 &#x2022; Out of hours: contact Clinical Response Service using SBAR and request urgent bedside review
 </div> </div> </div>
 <div>&#128196; I acknowledge that I have seen and read this alert: {{tickoff}}</div> </div>
 <div class="icon-azureinv item" style="padding-left: 20px;"> <!-- 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 --> </pre>

	<pre> &#128200; Click here for further insights </button> </div> </body> </html> </pre>
Default passthrough URL Pattern	
Require tickoff acknowledgment of this notification	<input checked="" type="checkbox"/>
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?	<input checked="" type="checkbox"/>
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	

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](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

Once 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
3. For this patient, click their MEMORI score in the ward board and check that this links through to the explainability dashboard for this patient.

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. In the alert, confirm that the tickbox acknowledgement appears
4. 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
5. Back in Patient Source, tick to acknowledge the alert and refresh the page to check that the alert disappears. Confirm that there are audit log trails detailing the user and timestamp for the alert, for traceability

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.

Ensure that any changes to the EHR configuration including upgrades, renaming fields, modifying observation types or altering structures are communicated to Sanome. These changes can break the MEMORI integration silently, so advance notice is essential to prevent data flow or alert failures. Likewise, an disruption in data flow must be escalated via standard incident reporting pathways.

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
V1.6	Adding steps to incorporate next best actions as directed by hospital Adding extra detail for clarity on access to explainability dashboard and maintenance requirements	