

# **Operation Manual**



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### 1 Introduction

### 1.1 About the Software

The Calantic<sup>™</sup> Marketplace and My Apps is part of the Calantic Digital Solution. The Calantic Digital Solutions encompasses multiple parts in addition to the Calantic Marketplace and My Apps:

- Calantic Viewer
- Calantic Cloud platform
- Calantic Edge Device

The Calantic Marketplace and My Apps provides customers, such as radiologists, access to review a curated set of clinical applications, such as AI-enabled solutions, that can help simplify and drive efficiencies throughout the radiology workflow and as part of a larger disease management strategy. Customers can browse for applications (apps) and packages on the Calantic Marketplace by specialty or vendor and purchase apps to integrate into their workflow. The Calantic Marketplace and My Apps allows Bayer representatives to configure the apps customers have purchased and track utilization and performance.

The Calantic Viewer is an image review software tool for exploration of the results of image post-processing applications (IPPAs), for example, those that automatically detect and size lung nodules. It is a zero-footprint (web-application) viewer designed to be operated as part of the radiologist's standard workflow. The Calantic Viewer displays results only as a viewing tool and is not intended for diagnosis. It is a support tool that provides relevant clinical data as a resource to the clinician. It is not intended to replace the clinician's review of the image or his or her clinical judgement.

The Calantic Cloud platform and the Calantic Edge Device are the backend infrastructure that enable the day-to-day running of the Calantic Marketplace and My Apps.

The Calantic Edge Device allows a seamless and secure interface of the Calantic Cloud platform with various applications. The Calantic Edge Device is a virtual machine (software) that is deployed at the customer site and acts as the router between the hospital systems and the AI applications.

#### 1.2 Intended Users

Intended users of the Calantic Marketplace and My Apps are the radiologist administrators, or practice leaders, and practicing radiologists. For setup and configuration, other users of the Calantic Marketplace and My Apps include a hospital's IT administrators.

#### 1.3 Disclaimers

This Operation Manual is intended for global markets. Feature and clinical application availability may vary by market or by configuration in the same market; contact your authorized Bayer representative for more information per the information listed in 1.8 Contact of this manual.

Screen images in this manual are for illustration purposes only. Actual screens may vary.

# 1.4 Interoperability Requirements

The Calantic Marketplace and My Apps application runs on 64-bit web browsers including Chrome, Safari, Firefox, and Edge (current version and previous-to-current version).

If the Calantic Marketplace and My Apps is launched on an unsupported browser such as Internet Explorer, a blank screen (black) will be presented. Exit from the unsupported browser and launch the application on a supported browser.

# 1.5 Decommissioning and Disposal

In scenarios where decommissioning and disposal of application is required, contact an authorized Bayer representative or a designated site contact.

### 1.6 Contraindications

None known.

# 1.7 Required Training

The device is intended to be used by qualified healthcare professionals, administrators, and IT staff.

#### 1.8 Contact

To provide feedback or request support, please use the contact form provided on <a href="https://www.radiologysolutions.bayer.com/contact">https://www.radiologysolutions.bayer.com/contact</a>.

Report any serious incident that has occurred in relation to this device to Bayer (<a href="https://www.radiologysolutions.bayer.com/contact">https://www.radiologysolutions.bayer.com/contact</a>) and to your local European competent authority (or, where applicable, to the appropriate regulatory authority of the country in which the incident has occurred).

# 1.9 Catalog Numbers

	Catalog Number
Calantic Cloud Platform	CAL-CLOUD
Calantic MyApps	CAL-MYAPPS
Calantic Platform	CAL-PLATFORM
Calantic Viewer (measurement enabled)	CAL-VIEWER
Calantic Viewer (measurement disabled)	CAL-VIEWER-NO-M
Calantic Edge Device	CAL-EDGE

# 2 Creating an Account

Before logging in and using the Calantic $^{\text{TM}}$  Marketplace and My Apps, a new user must first register and create an account.

1. Go to the Calantic Marketplace and My Apps Login page. Click Sign up.

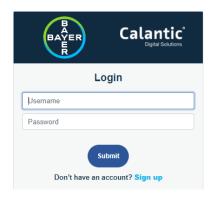


Figure 1: Sign up

**2.** The following screen will be displayed:

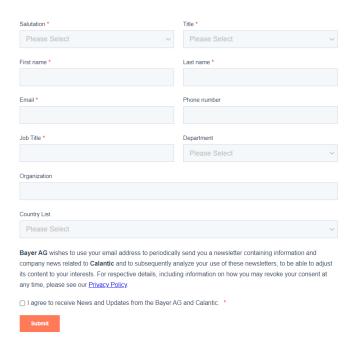


Figure 2: Sign up screen

3. Enter appropriate information in the respective fields, then click **Submit**. The details will be sent to Bayer Support for creating the new user account. A registration confirmation email will be sent to the user's email address.

**Note:** Click the **Privacy Policy** link to view the privacy policy. Checking the box to accept the policy terms will enable the **Submit** button.

4. Once the registration is processed by Bayer Support, the user will receive another email with their account details. The email will contain a username and a link to initialize the account. Click the link and the following screen will be displayed:

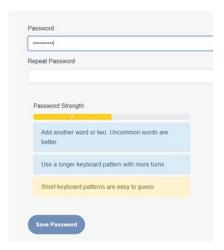


Figure 3: First time login - Setting a password

**Note:** The reset password link is valid for 60 minutes. After this time, the link is expired and the user should contact the Hospital IT Administrator.

**5.** Enter the new password in the appropriate fields. The **Save Password** button will be enabled only when all criteria for the password are met. Click **Save Password**.

A message will be displayed to indicate that the password has been set successfully. Click **Return to Login**.

**6.** Log in with the updated credentials.

# 3 Logging In

Enter the username and password on the Login screen, then click **Submit**.

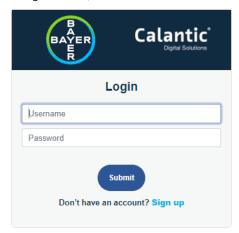


Figure 4: Login Screen

**Note:** A user has access to use functionalities per the default permissions.

**Note:** The application will automatically log out when user is inactive for one hour.

# 4 Calantic Marketplace and My Apps Home Page

After a successful login, the Calantic™ Marketplace and My Apps Home page will be displayed.

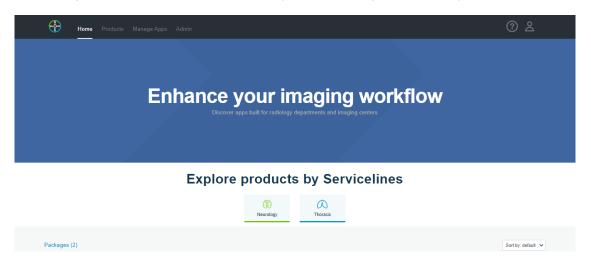


Figure 5: Calantic Marketplace and My Apps Home Page

The Home page presents a list of products in two sections: Packages and Applications. These products can be filtered using the filter icons under "Explore products by Servicelines." (Refer to 4.1.1 Filtering by Serviceline.)

The left-side bottom of the Home page displays a "Featured Application" area. Click the **Learn More** button in this area to view details for the featured application. The right-side bottom of the Home page displays a video link of the featured application. Click the link to open an informational video of the application.

#### 4.1 Main Menu

The Main Menu is accessible from all pages of the Calantic Marketplace and My Apps application. It allows for navigation between different tabs (Figure 6, Item 1): Home, Products, Manage Apps, and Admin. The Admin tab is only available for users with applicable access rights. By default, the landing page after logging into the application is the Home screen.



Figure 6: Main Menu

In addition to the tabs, there are two icons on the Main Menu:

• Knowledge Library icon (Figure 6, Item 2): Click to access the Knowledge Library.

The Knowledge Library page displays tiles for various document resources like FAQ's, Operation Manuals, etc. Click **View** on the respective tile to view/download the document.

- **User Access** icon (Figure 6, Item 3): Click to display these options:
  - The username of the currently logged in user.
  - **Reset Password:** Click to send an email to the registered ID of the logged in user for password reset.
  - Privacy Policy: Click to view the privacy statement.
  - **Sign out:** Click to sign out of the application.

# 4.1.1 Filtering by Serviceline

The icons under "Explore products by Servicelines" can be used to filter the displayed products.

All filter icons have a toggle functionality; this allows a user to enable/disable (select/deselect) the respective filter. When all filters are disabled, all products will be displayed.

# **Explore products by Servicelines**



Figure 7: Explore products by Servicelines

# 4.1.2 Favoriting Products

Packages and applications can be marked as Favorite. This feature allows for quick return to the favorited product(s).

To mark a product as a Favorite, click on the Favorite (heart) icon.

The **Favorite** icon has a toggle functionality that allows the user to favorite (select) or unfavorite (deselect) the product. When a product is favorited/selected, the heart will be solid blue. When a product is not favorited, the heart will be a gray outline.

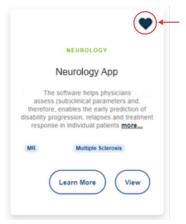


Figure 8: Marking a Favorite

# 4.1.3 "Sort By" Selector

The **Sort by** drop-down menu allows users to sort products by A to Z (alphabetical order of package or application name) or by Favorite. The default sorting is A to Z.

Selecting **Favorite** will list favorited products first, followed by the unfavorited products.

Sorting options are selected and applied to the Packages section and Applications section individually. Packages and applications can also be sorted on the Products page (refer to 4.2 Products).

### 4.1.4 Learn More

A Learn More button is available on each product tile. The Learn More page displays more information including:

- Package or application description
- Package or application title
- Package or application marked as Favorite or not
- Tags associated with the package or application

Click **Learn More** to re-direct to a page that provides specific information about the respective package or application. It also displays videos related to use of the respective application and allows users to view testimonials.

Click **Request Quote** to open a new window with a form that, once submitted, will send a request to Bayer for more information or a quote on the respective package or application.

### 4.2 Products

The Products tab of the application consists of two sub-tabs: Packages and Applications. The landing page of the Products tab is the Packages sub-tab.

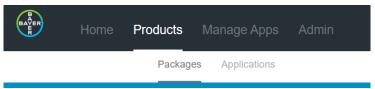


Figure 9: Products Tab - Packages and Applications

# 4.2.1 Packages

The Packages sub-tab displays tiles of all available packages.

Each product tile displays the logo of the company supplying the product (if available), the Serviceline (e.g., Pulmonology, Neurology etc.), the name of the product, a description and offerings of the product, and tags for identifying the packages.

For details on the Sort by drop-down menu function, refer to 4.1.3 "Sort By" Selector.

# 4.2.2 Applications

The Applications sub-tab displays tiles of all available applications.

Each product tile displays the logo of the company supplying the product (if available), the Serviceline (e.g., Pulmonology, Neurology etc.), the name of the product, a description and offerings of the product, and tags for identifying the applications.

For details on the Sort by drop-down menu function, refer to 4.1.3 "Sort By" Selector.

# 4.3 Manage Apps

The Manage Apps tab of the Calantic Marketplace and My Apps consists of three sub-tabs: Dashboard, My Apps, and Edge Config. The landing page of the Manage Apps tab is the Dashboard sub-tab.

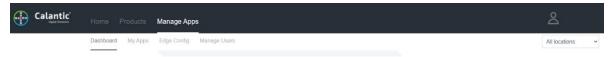
### 4.3.1 Dashboard

The following image displays the Dashboard sub-tab of the Manage Apps tab. The Dashboard summarizes data across all applications.



Figure 10: Manage Apps - Dashboard

Note: The Manage Users sub-tab will be visible only for users with the RadiologistAdmin role.



From the Manage Users sub-tab, a RadiologistAdmin can manage users and select one or all locations from which to view the dashboard data from the drop-down menu. Refer to 4.4.1 Manage Users.

Each user has their own Dashboard that presents information related to their use of the system. The Dashboard page allows the user to view performance information in relation to the products that the institution has subscribed to and the use of those products.

If a user is logged in as a RadiologistAdmin, the Dashboard will display KPI tickers showing statistics for Active Apps, Active Users, and Studies Processed (YTD).

# 4.3.2 Performance

On the Dashboard sub-tab, the Performance section presents summary information about the products and their usage pattern and performance.



Figure 11: Performance

### **Date Range Selector**

The Date Range drop-down menu allows users to view all the telemetry metrics across a variety of time periods. From the drop-down menu, select appropriate date range.

### Calantic Edge Device Selector

Note: This drop-down menu will be visible only for users with a RadiologistAdmin role.

The Edge Device Range drop-down menu allows the user to view the telemetry metrics for either a single Calantic Edge Device or all Calantic Edge Devices associated with that RadiologistAdmin.

#### **Studies Processed**

This tile shows the total number of studies which have been processed by all of the applications. The count for studies processed increases for every study detected by the Calantic Edge Device.

# Average Time to Review AI Results (Minutes)

This tile shows the average user accept/reject time (in minutes) between opening a study in the Calantic Viewer and marking it as accepted, partially accepted, or rejected.

# Accepted, Partially Accepted, Rejected Findings

This section shows the percentage rate of acceptance, partial acceptance, or rejection by radiologists for the findings generated by all the clinical applications.

A finding includes clinical information (i.e., images and imaging measurements) acquired by the operation of the clinical application(s). For instance, a clinical application may identify three lesions on a CT scan and each lesion would be deemed a finding. The type of finding may vary by clinical application depending on the applications' output.



Figure 12: Accepted, Partially Accepted, Rejected Findings

The Calantic Viewer allows radiologists to review the findings and to accept or reject the findings. In some cases, a radiologist may agree with some of a finding, but not the complete finding (partially accept).

# Top 5 Apps

This section displays a tabulated list of metrics. It displays a list of the top 5 applications:

- 1. Number of studies processed by the application
- 2. Percentage rate of accepted/partially accepted/rejected findings (illustrated by the bar graph)



Figure 13: Top 5 Apps

# Tab: Average Time to Review AI Results (minutes)

This graph displays the average time (in minutes) to review AI results from clinical applications for each application over a selected date range.



Figure 14: Average time to review AI results

### **Tab: Findings**

The Findings tab provides performance information for the products that the institution has subscribed to. It consists of three sub-tabs: Accepted, Partially Accepted, and Rejected. Within each sub-tab is a graph displaying the number of accepted, partially accepted, or rejected findings over a selected date range.

**Note:** In line with the Accepted/Partially Accepted/Rejected sub-tabs is a title that contains a list of the clinical applications for the findings. Should there be more than five applications available, the full list is visible within the tooltip, which is accessed via hovering over any location on the title (application title) itself.



Figure 15: Findings

# **4.3.3 My Apps**

My Apps is a sub-tab of the Manage Apps tab. When viewing the tiles, it allows the user to select a specific application and view the data only for that application.

# Selected Apps and Packages

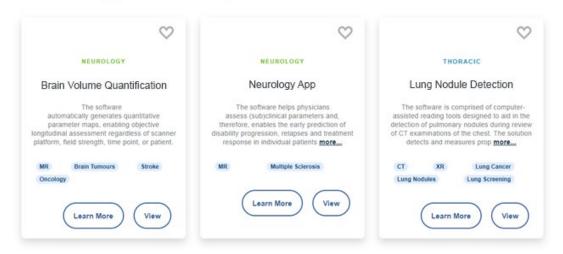


Figure 16: My Apps

Click **Learn More** to access the product details. For more information, refer to 4.1.4 Learn More.

Click **View** to access detailed performance information about the respective application. Click **View** to open the Performance, Configuration, and App Detail tabs.

#### **Performance Tab**

Telemetry data is recorded for each application in the system and this information can be viewed by clicking the **View** button on the application summary tile. This will display data related to the selected application. The following page will be displayed:



Figure 17: Clinical Application Detail

The telemetry summary sections show the number of studies processed, the average user accept/reject time in minutes, and the accepted, partially accepted, and rejected findings percentages for all users in the institution.

There are three sub-tabs that display respective graphs:

- 1. Average Time to View AI results
- 2. Total Time to View AI results vs Availability of AI results
- 3. Findings

### Average Time to Review AI Results Graph

This graph displays User Accept/Reject Time and allows the user to compare times with the average accept/reject times of peers (other radiologists in the institution). It also displays the average for all users (radiologists).

**Note:** For a Radiologist user role, other users will be anonymous. Only a user with RadiologistAdmin role will be able to compare non-anonymous usage.

### Total Time to Review AI Results vs. Availability of AI Results Graph

This graph displays the total time to review AI results vs. availability of AI results time (in minutes) for the selected application:

- **Total time to review AI results:** The total processing time (in minutes) of a study by an application, from when the application started processing to when it returns with results.
- **Availability of AI results:** The total processing time (in minutes) from when the Calantic Edge Device detected a study for processing to when the results were sent to the PACS or reporting system. This time will therefore be inclusive of the inference time and the time spent by a user using the Calantic Viewer (if applicable).

Hovering over any of the points will display total time to review AI results and availability of AI results time.

### **Findings Graph**

The Findings graph displays the number of times clinical findings have been accepted, partially accepted, or rejected using the Calantic Viewer.

It also allows to compare statistics with the other users from the same institution.

**Note:** For a Radiologist user role, other users will be anonymous. Only a user with RadiologistAdmin role will be able to compare non-anonymous usage.

# **Triage Only Applications**

Triage only applications do not offer accept/reject workflow. A triage only application only has one Performance tab and one Average AI processing time graph.

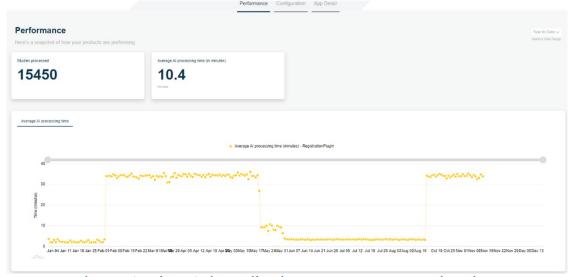


Figure 18: Triage Only Application - Average AI Processing Time

# **Configuration Tab**

The Configuration tab displays configuration details of the respective application.

### App Detail Tab

The App Detail tab will land on the Learn More page of the respective application. For more information, refer to  $\frac{4.1.4}{1.4}$  Learn More.

### 4.4 Admin

The Admin tab of the application consists of two sub-tabs: Manage Institutions and Manage Users. The landing page of the Admin tab is the Manage Institutions sub-tab.

# 4.4.1 Manage Users

Manage Users sub-tab allows admins to create, edit, and delete users. There are two types of admin roles:

- 1. Admin
- 2. RadiologistAdmin

Both admin roles have access to the Manage Users sub-tab, where users can be created, edited, or deleted.

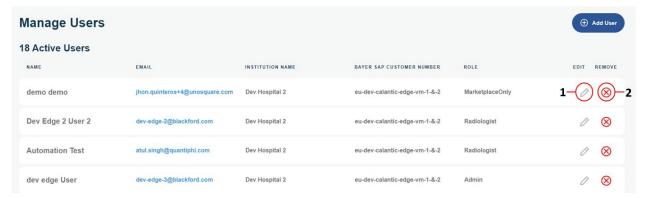


Figure 19: Manage Users Sub-tab

1 Edit 2 Remove
-----------------

#### **Create User**

Only admin users can create new users.

- 1. To add a new user, click Add User.
- 2. Enter the required information on the Create User page. All of the fields are validated and invalid fields are flagged with validation messages. The Institution field is automatically populated and assumed to be the same as that of the admin user creating the new user.



Figure 20: Create User

- 3. Click the **Submit** button to submit the details and create the user.
- 4. After the user has been created, an email with a password reset link will be sent to the registered email address of the user.

**Note:** The reset password link is valid for 30 minutes. After this time, the link is expired and a new password reset link will be required. A new link can be resent from the Edit User page.

#### **Edit User**

1. To edit an existing user, click the **Edit** icon (Figure 19, Item 1) in the row of the user to be edited.



Figure 21: Edit User page

- 2. Edit the user information as needed. The process for editing a user is similar to that for creating a user all fields are validated and invalid fields are flagged with validation messages.
- 3. To exit the Edit User page without saving changes, click Cancel.
- 4. Once all required fields have been edited, click **Update**. A message will be displayed to indicate that the update was successful.

#### **Reset Password**

The password of an existing user can be reset from the Edit User page.

To reset the password, click the **Reset Password** button on the Edit User page. An email with a password reset link will be sent to the registered email address of that user.

**Note:** The reset password link is valid for 30 minutes. After this time, the link is expired and the user should contact the administrator.

#### **Delete User**

To delete an existing user, click on the **Remove** icon (Figure 19, Item 2) beside the user to be deleted. The application will prompt a message to confirm the Delete operation.

Click **Yes** to confirm user deletion and return to the Manage Users screen. Click **No** to return to the Manage Users screen without deleting the user.

# **5 Cybersecurity**

The Calantic<sup>™</sup> Digital Solutions, including the Calantic Marketplace and My Apps, contains software and is subject to cybersecurity concerns. Depending on the licensed software features, it may also contain data that is subject to privacy laws or is of a sensitive nature which should be protected. This section covers the following aspects of cybersecurity and information security:

- Cybersecurity Protection
- Information Security
- Expected Security Environment
- External Interfaces and Interoperability
- Decommissioning of Equipment

**Note:** In the event of a suspected or known cybersecurity breach, or for any cybersecurity related questions, please contact Bayer Service at radiology.bayer.com/contact.

# **5.1 Cybersecurity Protection**

The design of the system includes technical measures that secure it against attackers. These are intended to protect the system against current and future threats. Calantic software updates are available periodically for the Calantic Solution and it is the client's responsibility to install security updates on the Calantic Edge Device. In addition, Bayer has a cloud service agreement with Google for security software updates. New cyber-attacks may require new technical controls. Bayer's cyber response policy ensures that software updates are developed and released when high-risk threats arise. Both planned updates and unplanned software patches are made available to authorized Bayer representatives for immediate deployment.

Google is responsible for updating Google managed services and the underlying infrastructure. Bayer is responsible for managing the VMs, containers, and Bayer-designed applications. Due to technical training requirements on device calibration and its operational checkout, Bayer is responsible for obtaining software or firmware and updating for Google Cloud Platform. Bayer is responsible for ensuring security maintenance with Google. Please refer to 5.8 Expected Security Environment and Security Control Provided by the Hospitals.

# **5.2 Cybersecurity Protection - Technical Controls**

The technical controls for cybersecurity are built into the design of the system and do not require any user configuration. They include:

- Built-in authentication and secure tokenization of the user when accessing the Marketplace application.
- Built-in encryption in transit using SSH and TLS; encryption at rest in Google Cloud Platform using AES 256.
- Continuous real time code and vulnerability scanning of containers, code (Static Analysis/SAST) and VM
  vulnerability scanning using daily updated scan engines.
- Container hashing to ensure supply chain integrity.
- Third Party Penetration testing to include API fuzzing.
- Google Cloud Platform (GCP) Virtual Private Cloud (VPC) Firewalls.
- Enterprise Azure AD integration for development environment which require Two Factor Authentication (2FA);
   restricted production code repository access.
- Robust threat modeling of all attack surfaces to ensure attack surface are not exposed.
- Modern web application firewall (Google Cloud Platform Cloud Armor) is used to prevent advanced attacks.

- Google Cloud Platform Security Command Center for threat detections.
- Third party Compliance tools for near real time gap detection and management.
- Viewer Cross Site Scripting XSS Attacks (and other web/software attacks) prevention using built in mitigation using JSX library for React.
- Audit logs are maintained and reviewed on a periodic basis.
- Databases are restricted by VPC firewall, require authentication and credentials are hashed and salted to provide a layer security approach.
- Masking/anonymization of patient data on transmission to external systems is provided as an option.
- Unique SSH keys used on The Edge Device for each client.
- Current Cloud Identity Access Management (IAM) solution.

# **5.3 Cybersecurity Protection - Operational Controls**

The system software must be maintained and be kept up to date to ensure that it remains secure in the face of new cyber threats. For the Calantic Marketplace application, the customer is responsible for the security. This includes patching, anti-virus, firewall, VM host security, network security, and Intrusion Prevention Systems or Intrusion Detection Systems (IPS/IDS). Bayer is responsible for updating the Calantic Marketplace application.

Bayer plans and releases one or more software updates per year which include cumulative security patches, and for the Calantic GCP instance Bayer plans to release software updates one or more times a year. Any new active cybersecurity threat that poses a risk to the operation of the system will trigger additional software releases to provide patches to the system.

During the subscription period, Bayer will provide maintenance and support services from a remote location via VirtualCare® Remote Support. Customers should plan for and accommodate system software updates, which may require on-site visits by an authorized Bayer representative or via VirtualCare® Remote Support. The system license includes software support including updates. Customers should plan for and accommodate system software updates.

# 5.4 Cybersecurity Protection - Known Vulnerabilities

Keeping system software up to date is part of the operational controls and will help to reduce security risks due to known vulnerabilities. The system software will undergo periodic penetration testing and fuzz testing by a third-party test lab as well as automated vulnerability scanning. A full listing of all CVEs is available on request.

# 5.5 Cybersecurity Protection - Software Bill of Materials

Software Bill of Materials are available on request.

# **5.6 Information Security**

The system contains information that may be either considered sensitive (e.g., network IP addresses), potentially governed by privacy laws (e.g., patient names), or which should be protected from access or accidental changes (e.g., protocols, product configuration). Information security depends on both technical controls embodied in the design of the system and operational controls which are the responsibility of the user to configure. Information in the Google Cloud Platform and the Calantic on-premises components is protected by the following:

 All data on Google Cloud is automatically encrypted in transit and at rest within Google Cloud. GCP uses AES 256 for data at rest and TLS 1.2 for data in transit.

- Data transmitted to GCP is encryption in transit using SSH and TLS.
- Masking/pseudo-anonymization of patient data on transmission to external systems is provided as an option in the Calantic Edge Device.
- The Viewer can display ePHI but only after a user authentication and authorization.
- The Viewer uses TLS to encrypt ePHI and does not store ePHI in cache.

# 5.7 Information Security - Operational Controls

The system, as part of normal use, makes information available through a variety of means. The Marketplace application requires authentication prior to granting access.

The following operational controls are provided to allow the product to be configured to close the above listed information security access paths:

- VirtualCare environment is ISO/IEC 27001:2013 compliant, requires a username and password, and encrypts all
  connections via TLS.
- The Marketplace application access is controlled by authentication and authorization, established by a TLS
  connection for data transmission.

# 5.8 Expected Security Environment and Security Control Provided by the Hospitals

Healthcare ecosystem stakeholders share responsibility for protecting patients and safeguarding data. As a healthcare device and solutions manufacturer, Bayer invests in infrastructure and developing policies and procedures that support evolving cybersecurity requirements and industry best-practices. At end user sites, cybersecurity protection and defense against the latest attack is strengthened through proper maintenance of networks and environments in which medical products and solutions are deployed. Hospital networks that are monitored and patched quickly provide the first line of defense for deployed medical solutions.

System owners must explicitly request that an authorized Bayer representative create the first user account on their behalf. After that point, the system owner is responsible for managing their own set user accounts.

As such, the customer is responsible for providing and securing the Edge Device VM, OS, and hospital network per their hospital policies to ensure further mitigations. It is the customer's responsibility to actively monitor security events that pertain to the Edge Device and surrounding network environment. In addition to keeping the system software updated, the following additional operational controls are suggested:

- Limit physical access to the Calantic Edge Device system as much as possible.
- Customers employ best security practice security measures (refer NIST 800-53 and NIST CSF) on their own
  network and their own virtual environments, especially around the Calantic Edge Device hosted in their data
  center. In addition, if the option to use a browser is used to connect to the Calantic Marketplace and My Apps,
  follow browser and OS best security practices.
- Snapshots/backups of the Calantic Edge Device are strongly suggested to be done by the customer.
- Encryption to internal resources, like PACS, is not enabled by default but can be enabled by the client.
- Antivirus, advanced endpoint detection, software security patches, and security configurations are not installed by default but can be installed and monitored by the client
- Physical access to the Calantic Viewer and Edge Device should not be in public spaces nor where non-staff people are unsupervised. Use of a privacy screen is advised.
- Rooms are secured when staff are not present.

- Periodic inspection and maintenance of equipment is performed.
- Enable encryption, when possible, for any connection to the client environment. For example, RIS and PACS.
- Install, configure, and thoroughly test application whitelisting also known as AppLocker to prevent malicious code execution.
- Enable disk encryption on the VM OS and ensure strong key management practices are in place.
- Client can run vulnerability scans on the VM only in their data center and are responsible for those remediations.
- Proper placement in the client's datacenter virtual environment should be considered since the VM interfaces and works with ePHI.
- Monitoring of application security events is strongly encouraged. Logs are in a standard format, commaseparated format (CSV) and are located at Drive:\Calantic Edge\Blackford Platform\BlackfordPlatformAudit.log for Security Information and Event Management (SIEM) ingestion via the client's log collector infrastructure.
- In the event that a customer detects a cyber signal event on the Calantic Edge Device and/or Calantic
  Marketplace and My Apps, it is strongly recommended that the customer stops using the product, follows
  institution best practices for incidence response, and notifies their authorized Bayer representative promptly.

## 5.9 Authentication and Authorization

The Marketplace application requires authentication for all roles.

If a user forgets their password, Bayer Support can assist as needed.

# 5.10 External Interfaces and Interoperability

The Calantic Solution has limited exposure to external interfaces. All interfaces were evaluated in the threat model as attack surfaces. They are:

- Connection to RIS system(s)
- Connection to PACS system(s)
- API Gateway for service-to-service connections
- Browser access to the Calantic Marketplace and My Apps
- VirtualCare (Bayer reports support access via a secure internet connection)
- Bayer GitLab access
- Worklist access
- Reporting access

# 6 Glossary

AES	Advanced Encryption Standard
API	Application Programming Interface
API SDK	Application Programmable Interface Software Development Kit
CVE	Common Vulnerabilities and Exposures
ePHI	Electronic Protected Health Information
IDS	Intrusion Detection System
IE	Internet Explorer
IEC	International Electrotechnical Commission
IPPA	Image Post-Processing Applications
IPS	Intrusion Prevention System
ISO	International Organization for Standardization
JSX	JavaScript XML
KPI	Key Performance Indicator
OS	Operating System
PACS	Picture Archiving and Communications System
PHI	Protected Health Information
RIS	Radiology Information System
SAST	Static application security testing
SSH	Secure Shell
Telemetry	Usage and diagnostic data captured from the Calantic Edge Device and user interactions; the data is emitted by the Calantic Edge Device during processing activities
TLS	Transport Layer Security
TM	Trademark
VM	Virtual Machine
VTD	Vear-to-Date

### 7 Licenses

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## **Jest**

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#### **SASS** Loader

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# Webpack

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# Yup

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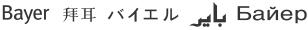
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