Clinical Insights Manager (release 2.0) Technical Data Sheet

Document Information

MKT0552
Revision 3.0
2023-173

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Manufacturer

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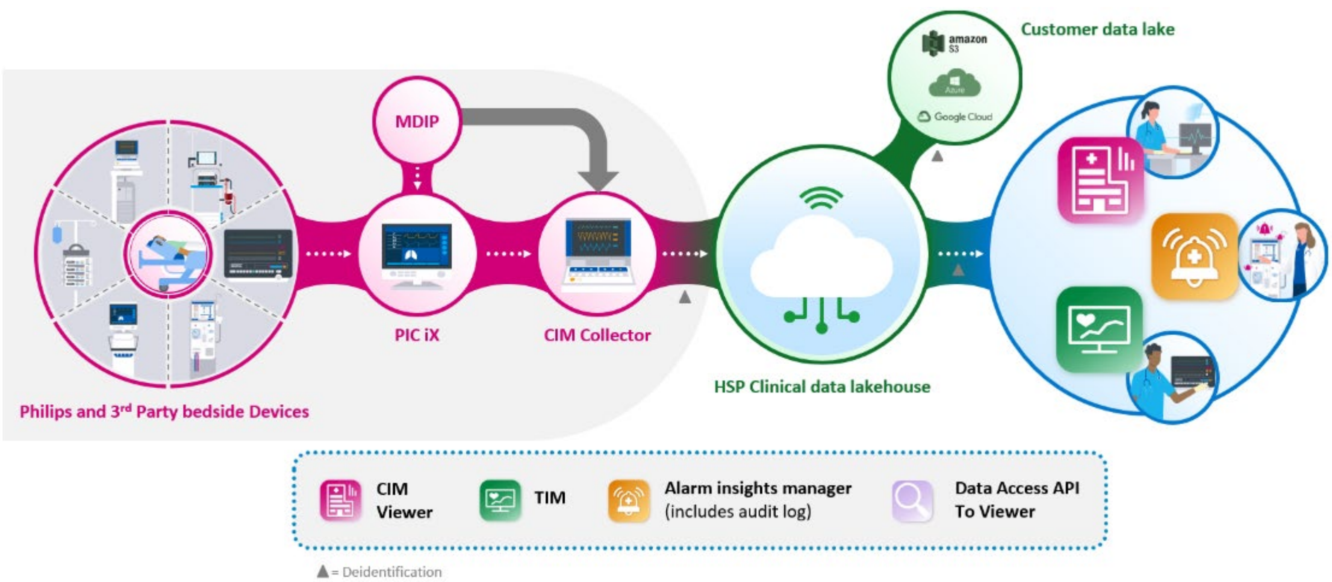
Contents

Intended Purpose

- The Clinical Insights Manager solution is not designed to drive clinical decisions on patients.
- Store patient monitoring data (including but not limited to physiologic waves, parameters, alarms, and events) from multiple patients in a repository.
- Provide the ability to analyze the stored data for quality improvement, clinical research, alarm management or operational improvements.
- Provide the customer a test bed for algorithms before it is deployed for real-time clinical decisions.
- Provide the customer a platform for retrospective analytics and prospective predictions based on multi-year, multi-patient data.
- Provide the customer a platform for collaboration with other institutions on research or Quality Improvement (QI) programs.
- Enable IT/Data Optimization Services: These services will be delivered on top of the Clinical Insights Manager product. The services team will leverage available APIs and options from CIM to create interoperability.
- Clinical Insights Manager is intended for use in professional healthcare and research facilities by professionals working in healthcare and related research areas.

Introduction- Philips Clinical Insight Manager

Philips Clinical Insights Manager (CIM) is a service-oriented end-to-end solution enabling high-resolution physiological and third-party bedside device data acquisition, access and archival. It also facilitates the transformation of this data into insights by offering applications that were developed collaboratively with customers, aiding in data visualization, clinical innovation, standardizing care, and conducting research on extensive databases.



Philips CIM features

- Captures and stores data from the Philips Information Center (PIC iX) as well as other bedside devices for up to 1024 beds at high resolution. A single CIM collector can capture data from multiple Primary Servers. CIM can capture data for up to 1,024 beds per collector. The 1,024 beds can be spread across multiple PIC iX servers.

- Stores patient monitoring physiological data from bedside monitors, IntelliBridge bedside, IntelliBridge System, telemetry, and other devices in the Philips HealthSuite Platform. HealthSuite is powered by Amazon Web Services (AWS).
- Stores data in HealthSuite for 1 year.
- High-resolution data stores all captured data to meet future “big data” needs as well as training AI models on high fidelity data and developing insightful analytics.
- Supports continuous capture of diagnostic quality (Dx) ECG for all patients monitored at the bedside. High resolution must be turned on at the bedside.
- CIM Data Analysis and Review includes 3 browser-based applications: Clinical Insights Manager (CIM) Viewer, Alarm Insights Manager (AIM) Dashboard and Telemetry Insight Manager Dashboard.
- Data continuity: If data cannot be exported to the HealthSuite cloud, it is stored in a local database and will be sent once the connection is restored. For a healthcare facility with 1,000 beds, CIM can store up to 6 hours of patient data locally, assuming a payload size of 1 GB every 5 minutes. If the connection to the cloud is not restored and the local storage reaches its maximum capacity, any additional data will be discarded.

Number of beds	**Downtime Stored Data (hours)**
25	240
100	60
250	24
500	12
1000	6

Stored data elements

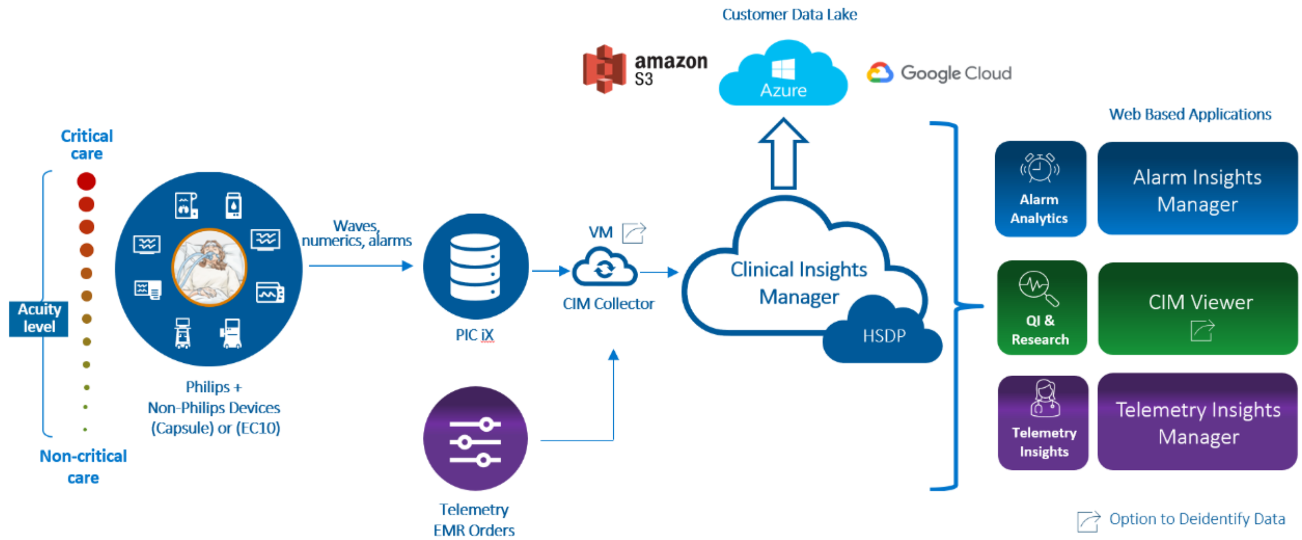
CIM captures and retains the following data elements:

- Patient admission, discharge, and transfer (ADT) information, including names, IDs, bed numbers, and demographics obtained from the monitoring system. This ADT information can create a continuous record for a patient as they move within the hospital.
- Alarms with various details, such as event start time, alarm announcement time, scrolling or escalating alarm text, and the time when the alarm is acknowledged.
- Derived numeric parameters at 1-second intervals and irregular numerics, such as NBP, with detailed status for each parameter (such as current alarm limits and ongoing alarms). These parameters encompass complex numerics like calculations and Early Warning Scores.
- CIM captures each beat-to-beat heart rate with a resolution of one-half millisecond for use in heart rate variability calculations, providing a unique benefit for neonatal research.
- Raw, non-derived waveforms, with a limit of 24 waveforms:
- Default ECG waveforms are stored at 250 samples per second (sps) with a monitoring bandwidth ranging from 0.05 or 0.5 Hz to 20, 40, 55, or 125 Hz, adjustable at the patient bedside.
- With the Diagnostic Quality option, ECG waveforms are stored at 500 sps with a bandwidth from 0.05 to 150 Hz.
- A maximum of two limb leads, along with all chest leads, are stored. The other four limb leads can be mathematically computed.
- Arrhythmia monitoring information from the ST/AR algorithm, providing details on current rhythms, location and classification of beats and pacemaker pulses, and a continuous assessment of signal quality.
- Alarms, numerics, and waveforms from IntelliBridge hubs and module-interfaced devices, such as

ventilators, pumps, and NIRS (near-infrared spectroscopy) cerebral oximetry.
- Comprehensive information about all source devices.
- Non-ECG waves (Pleth/SpO2, Pressure) are stored at the highest possible acquisition rate of 125 samples/s.
- Slow moving waves (Resp) are stored at the highest possible acquisition rate of 62.5 samples/s.

Deployment

There are four elements to a successful CIM deployment:
- A virtual machine (VM) aggregates data from multiple PIC iX systems and sends the data to HealthSuite for storage and analysis.
- Installation and setup of CIM software on the VM.
- Configuration of PIC iX/MDIP to export data to CIM.
- Onboarding users on HealthSuite for data access.



CIM Viewer

The capabilities of the CIM Viewer include:

- Authentication using HealthSuite Identity Access Management (IAM).
- Patient, time, and event-based navigation and visualization of data.
- Data export to standard formats, including CSV for numeric and textual data and PhysioNet for waveforms and related metadata.
- Users can export parameters, alarms, consolidate alarms, waveforms, and patient information in .zip format.
- Data Access API enables programmatic access to CIM data.

Alarm Insight Manager Dashboard

The AIM Dashboard is a web-based application that offers insights into the overall alarm situation through an interactive and intuitive dashboard.

- It includes authentication using HealthSuite IAM.
- It may help identify actionable insights related to the hospital alarm system quality; aiming to reduce noise, enhance alarm accuracy, establish and share care standards, and manage sentinel events effectively.
- It allows the creation of standard and ad-hoc alarm reports that can be automatically generated and shared across the enterprise.
- The Alarm Audit Log Migration (AALM) tool enables a one-time migration of the PIC iX Alarm Audit log (up to 90 days) to Alarm Insights Manager (AIM). Once migrated, AIM can be used to investigate and

address alarm issues. This migration is conducted by Philips field services in coordination with R&D DevOps.

- It requires a license for AIM that covers the same clinical unit(s) from which the data is migrating from the PIC iX Clinical Audit Log. The PIC iX version must be C.03 or higher, and its language and regional settings must be one of the supported locales.

Language	Regional Setting
en-US	English (US)
zh-CHN	Chinese (Simplified China)
zh-TW	Chinese (Traditional, Taiwan)
cs-CZ	Czech (Czechia)
da-DK	Danish (Denmark)
nl-NL	Dutch (Netherlands)
fi-FI	Finnish (Finland)
fr-FR	French (France)
de-DE	German (Germany)
el-GK	Greek (Greece)
hu-HU	Hungarian (Hungary)
it-IT	Italian (Italy)
ja-JP	Japanese (Japan)
nb-NO	Norwegian Bokmål (Norway)
ro-RO	Romanian (Romania)
ru-RU	Russian (Russia)
es-ES	Spanish (Spain International Sort)
pl-PL	Polish (Poland)
pt-BR	Portuguese (Brazil)
sv-SE	Swedish (Sweden)

Telemetry Insight Manager (TIM) Dashboard

The Telemetry Management Dashboard allows customers to transmit numerical and alarm data to the Clinical Insights Manager Cloud storage (which includes 1-year cloud storage) to facilitate daily and retrospective analytics programs related to telemetry management within the organization. Additionally, TIM features an IBE connection for bringing telemetry orders from HIS/EMR systems, with PIC IX sending physio patient information including telemetry alarms. The minimum supported PIC IX version for TIM is 4.2.

Telemetry Insights Manager is a solution that offers visual insights for managing telemetry patients and utilization. It provides various key performance indicators (KPIs) for evaluating and improving telemetry device utilization on a daily and retrospective basis. TIM utilizes an analytics framework to visualize data and KPIs, providing an intuitive platform for analyzing data from different perspectives to derive insights that aid in the daily and retrospective management of telemetry patients.

This tool integrates information from the EMR and telemetry devices to assist in monitoring telemetry demand over time and identifying areas for improvement in overall performance. Supporting daily telemetry management by highlighting:
Patients with Sinus Rhythm
Device Inventory
Telemetry length of stay
Patients without tele orders
Patients without active monitoring.
Current Patient Report

Data Analysis and Review

The capabilities of CIM Data Analysis & Review entail the following:

- Verification through Philips HealthSuite Identity Access Management (IAM).
- Navigation and visualization of data based on patients, time, and events.
- Exporting data to standard formats such as CSV for numeric and textual data, and PhysioNet for waveforms and accompanying metadata.
- Users can export parameters, alarms, consolidate alarms, waveforms, and patient information in ZIP format.
- Auto Export of Patient Data with Multi-Cloud Integration. Users can schedule export tasks for a unit operating on a predetermined frequency. The scheduled task integrates with cloud storage accounts that are owned and managed by the customer. The integration is currently available with the following vendors:
    - AWS S3
    - Azure Blob Storage
    - Google Cloud Storage

Security

Security by Design

For details on Philips product security, please visit:
https://www.usa.philips.com/healthcare/about/customer-support/product-security

Data Security

Data at rest on premise is encrypted using AES-256.

All communication uses protocol TLS v1.3.

All inbound communications to the application are via HTTPS only.

Application Security

- HSDP OAuth provides unique authentication for each individual to access web applications.
- To enhance security, multifactor authentication (MFA) is implemented for all user access to web applications.
- Every HTTPS request to HealthSuite necessitates a valid web token.
- A token is generated through an Identity Management Service (OAuth/IAM). Each application instance has an identity registered in HealthSuite.
- The token issued against the identity remains valid for 30 minutes, after which the application must refresh the token.

Cloud Security

- Internal microservices are displayed in a virtual private cloud within HealthSuite.
- API Gateway Architecture is implemented to prevent internal microservices from being publicly exposed via the Gateway service.
- All communication within cloud microservices is encrypted with HTTPS.

Operational Security

- The application auditing and logging framework gathers metrics for vulnerability, health, and audit log analysis to identify and notify about potentially suspicious activity.
- CIM and its components undergo monitoring for new vulnerabilities, which are evaluated, and necessary recommendations and/or updates are provided.
- Philips InCenter communicates security-related software updates that necessitate customer action to the customers.

Data Warehouse Connect migration

Philips facilitates the migration of DWC version C.03+ data to CIM in HealthSuite using tools that are executed and validated by Philips personnel.

System Health Monitoring

The CIM cloud infrastructure is monitored 24x7 by the HealthSuite operations team. This includes monitoring

database uptime and AWS services. The CIM application suite and data store are monitored and maintained by a dedicated DevOps team. Monitoring includes:

Proactive monitoring and support

- The built-in watchdog services constantly monitor bottlenecks, performance issues, or unplanned shutdowns of core solution services and applications, sending alerts to the DevOps team through email and dedicated Microsoft Teams channels.
- The DevOps team addresses these alerts proactively to prevent any potential issues.

Reactive diagnostics and support

- A collection of application dashboards keeps track of log events, performance counters for applications and services, offering a comprehensive overview of system health.
- Kibana offers a unified display of logs from various sources within the application suite, displaying the problem and any significant related events.

Privacy

The Global Privacy Team completes a Privacy Impact Assessment to assure that no personal data is processed for secondary purposes. CIM provides two configuration options to ease privacy concerns:

- Send ePHI information to HealthSuite. All ePHI information is encrypted using TLS v1.3 certificates over HTTPS. ePHI information is encrypted in flight and at rest in HealthSuite.
- Do not send ePHI information to HealthSuite. No ePHI information is sent to HealthSuite; only bed and unit labels are sent. The CIM Viewer application displays the patient by bed and clinical unit only. The AIM Dashboard is not affected since it does not have ePHI-related views.

Privacy for data export

For data export, CIM provides a configuration option to automatically de-identify ePHI information. If the user chooses to de-identify before data export, CIM removes all ePHI information. Only unidentified data is exported. In addition, a password field is provided to encrypt the exported data files.

On premise VM specifications

For proper operation of the CIM software, the on-premises VM must be dedicated and not shared with other software. The following table lists the hardware specifications based on the CIM licensed product options:

Requested Data	Bed range	RAM	Virtual CPUs	Speed (GHz)	Disk Size (SSD)	Network upload bandwidth	Payload
Alarms only	<512	16 GB	4 vCPUs	2.2	172 GB	10 Mbps	<= 3 MB
Alarms only	512-1024	32 GB	6 vCPUs	2.2	172GB	10 Mbps	<= 6 MB
All Data (Waves+Numerics+ Alarms+Events)	<512	32 GB	4 vCPUs	2.2	172GB	50 Mbps	<= 1 GB
All Data (Waves+Numerics+ Alarms+Events)	512-1024	64 GB	10 vCPUs	2.2	172GB	100 Mbps	<= 2 GB

Firewall: On-Premise Customer-Provided Windows Virtual Machines

- Windows Firewall is enabled for all network profiles.
- The following ports and applications are exclusions for all network profiles on all hosts (inbound)**:**
  - Remote Desktop (TCP 3389), NetBIOS (UDP 137, 138), SMB (TCP 445), DNS (UDP 53)**.**
  - Microsoft .NET framework and WCF are open, regardless of license (TCP 8050, 8051, and 9912)
  - Windows Time (UDP 123)
  - HTTPS (TCP 443)
- Incoming data is allowed for Philips.ACP.ServiceHost.exe (UDP and TCP).

Virtualization Software

Software	Version	Operating system
VMware ESXi	6.5, 6.7, 7.0	Windows Server 2019 or higher
Microsoft Hyper-V Server	2019	Windows Server 2019 or higher
Nutanix AHV	5.10.4 or higher	Windows Server 2019 or higher

Antivirus support

Philips tested and verified McAfee 10.6.1 antivirus software for use with CIM. The customer can install other third-party antivirus software. The customer is responsible for ensuring the antivirus software does not interfere with the product's intended use.

Browser Support

CIM supports the following web browsers:

- Google Chrome version 80 and higher
- Microsoft Edge version 80 and higher

Philips Product Compatibility

Product (CIM)	PIC iX Requirement	IBE Requirement	MDIP
Patient Data Viewer	PIC iX C.03	IBE B.21	Not Compatible
Alarm Insights Manager	PIC iX C.03	IBE B.21	2023-2 and above
Telemetry Insights Manager	PIC 4.2 and above	IBE B.21	Not Compatible
Cloud Data Storage	PIC iX C.03	IBE B.21	2023-2 and above*

*For future use with Alarm Insights Manager and Telemetry Insights Manager with Upcoming version of CIM.

Screen Resolution

Full 1280 x 1080 or Higher at 100% scale or lower.

Third party software

The following software is required and installed with CIM:

Software	Version
PostgreSQL	14
VC++ 2013 Redistributable Package	X64
.Net Framework	4.8
Postman	V8.0.10
Fiddler	v5.0.20204
Wireshark	v2.4.5

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MKT0552, DCN 2023-173 Rev 3.0 Published 2024-Aug
00000511-00-00 * AUG 2024