

# 操作手册



# 本页特意将左侧留空

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# Calantic<sup>™</sup> Marketplace and My Apps 操作手册

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# 1 简介

# 1.1 关于软件

Calantic™ Marketplace and My Apps 是 Calantic 数字解决方案的一部分。除了 Calantic Marketplace and My Apps 之外,Calantic 数字解决方案还包含多个组成部分:

- Calantic Viewer
- Calantic 云平台
- Calantic Edge Device

客户(如放射科医生)可以利用 Calantic Marketplace and My Apps,查看包括 AI 解决方案在内的一系列精心设计的临床应用程序,这有助于简化并提升整个放射工作流程的效率,促进整体疾病管理策略的制定。客户可在 Calantic Marketplace 上按专业或供应商浏览应用程序和套件,以及购买要集成到自身工作流程中的应用程序。Calantic Marketplace and My Apps 允许 Bayer 代表对客户购买的应用程序进行配置,并跟踪应用程序的使用情况和性能表现。

Calantic Viewer 是一个图像查看工具软件,用于查看图像后处理应用程序 (IPPA) 的结果,例如自动检测和测量肺结节的大小。该工具为 Web 应用程序,不占用任何空间,作为放射科医生标准工作流程的一部分进行设计。作为查看工具,Calantic Viewer 仅显示结果,不可用于诊断。该支持工具可为临床医生提供相关的临床数据。它不可替代临床医生对图像的专业评估或临床判断。

Calantic 云平台和 Calantic Edge Device 将作为后端基础设施,支持 Calantic Marketplace and My Apps 的日常运行。

Calantic Edge Device 支持 Calantic 云平台与各种应用程序实现安全的无缝对接。Calantic Edge Device 是一个部署在客户场所的虚拟机(软件),相当于医院系统和 AI 应用之间的路由器。

# 1.2 目标用户

Calantic Marketplace and My Apps 的目标用户为放射科管理员(或实践主管)和具备执业资格的放射科医生。在设置和配置方面,Calantic Marketplace and My Apps 的其他用户还包括医院的 IT 管理员。

# 1.3 免责声明

本操作手册面向全球市场。提供的具体功能和临床应用程序可能因市场或同一市场中的配置而异。如需了解详细信息,请使用本手册 <u>1.8</u> 所列的<u>联系信息</u>,联系 Bayer 授权代表。

本手册中的屏幕图像仅供说明之用。实际的屏幕图像可能不同。

# 1.4 互操作性要求

Calantic Marketplace and My Apps 可在 64 位 Web 浏览器上运行,包括 Chrome、Safari、Firefox 和 Edge(最新版本和次新版本)。

如果在不支持的浏览器上运行 Calantic Marketplace and My Apps,如 Internet Explorer,将显示空白屏幕(黑色)。此时请退出不支持的浏览器,然后在支持的浏览器上启动应用程序。

# 1.5 停用和弃置

如需停用并弃置应用程序,请联系 Bayer 授权代表或指定的站点联系人。

# 1.6 禁忌

未知。

# 1.7 所需培训

仅供合格的专业医护人员、管理员和IT人员使用。

# 1.8 联系信息

若要提供反馈或需要支持,请使用 https://www.radiologysolutions.bayer.com/contact 上提供的联系表。

请向 Bayer (https://www.radiologysolutions.bayer.com/contact) 和您当地的欧洲主管机构(或如果适用,向事故发生所在国家/地区的相应监管机构)报告所发生的任何与本设备有关的严重事故。

# 1.9 目录号

目录号

Calantic 云平台 CAL-CLOUD

Calantic MyApps CAL-MYAPPS

Calantic Platform CAL-PLATFORM

Calantic Viewer(测量已启用) CAL-VIEWER

Calantic Edge Device CAL-EDGE

# 2 创建帐户

登录和使用 Calantic™ Marketplace and My Apps 前,新用户须先注册并新建帐户。

**1.** 前往 Calantic Marketplace and My Apps 登录页面。单击**注册**。

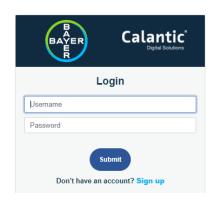


图 1: 注册

2. 将显示以下屏幕:

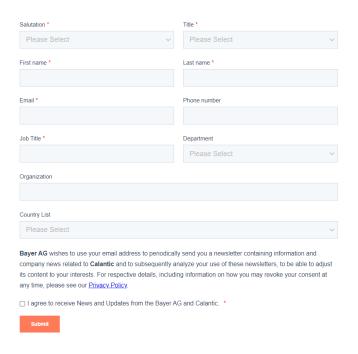


图 2: 注册屏幕

- **3.**在各个字段中输入相应信息,然后单击**提交**。这些信息将被发送至 Bayer 支持中心,用于创建新帐户。将向用户的电子邮件地址发送注册确认邮件。
  - 注:单击隐私政策链接查看隐私政策。选中复选框接受政策条款将启用提交按钮。

**4.**注册经 Bayer 支持中心处理后,用户将收到另一封包含帐户信息的电子邮件。该电子邮件中将包含用户名和一个链接,用于对帐户进行初始化处理。单击此链接,将显示以下屏幕:

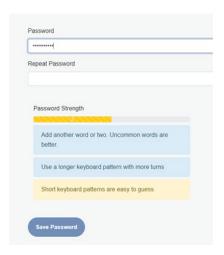


图 3: 首次登录 - 设置密码

- 注:密码重置链接的有效时间为60分钟。之后密码将失效,用户需联系医院IT管理员。
- **5.**在相应字段中输入新密码。只有满足密码的所有要求,才会激活**保存密码**按钮。单击**保存密码**。 然后将显示一条消息,提示密码已设置成功。单击**返回登录**。
- 6.使用新凭据登录。

# 3 登录

在登录屏幕上输入用户名和密码, 然后单击提交。

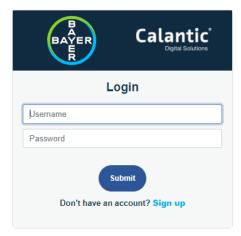


图 4: 登录屏幕

注: 用户可以按照默认权限使用功能。

注: 如果用户一小时内不进行任何操作,应用程序将自动注销。

成功登录后,将显示 Calantic™ Marketplace and My Apps 主页。

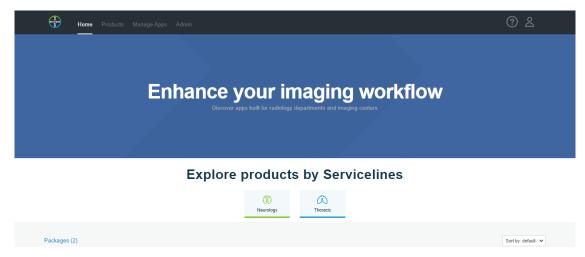


图 5: Calantic Marketplace and My Apps 主页

主页将显示产品列表,包含两个部分: "套件"和"应用程序"。可使用"按服务线浏览产品"下的筛选图标筛选产品。(请参阅 4.1.1 按服务线筛选。)

主页左侧底部为"特色应用程序"区域。单击该区域的**了解更多**按钮,了解特色应用程序的详细信息。主页右侧底部为特色应用程序的视频链接。单击该链接将打开应用程序的介绍视频。

# 4.1 主菜单

可从 Calantic Marketplace and My Apps 应用程序的所有页面访问主菜单。在主菜单中,可以切换不同的选项卡(图 6,项目 1):"主页"、"产品"、"管理应用"和"管理员"。仅具有相应访问权限的用户可以访问"管理员"选项卡。登录后默认显示 Calantic Marketplace and My Apps 主页。



图 6: 主菜单

除选项卡外,主菜单中还有两个图标,分别为:

• 知识库图标(图 6,项目 2):单击可访问知识库。

知识库页面显示各种文档资源的磁贴,如常见问题解答、操作手册等。单击相应磁贴上的**查看**可查看/下载文档。

- 7. 用户访问权权限图标(图 6,项目 3): 单击可显示以下选项:
  - 当前登录用户的用户名。
  - 重置密码:单击后将向登录用户的注册电子邮件地址发送一封邮件,用于重置密码。
  - 隐私政策: 单击可查看隐私声明。
  - 注销:单击可注销应用程序。

# 4.1.1 按服务线筛选

可使用"按服务线浏览产品"下的图标筛选已显示的产品。

所有筛选图标均有开关功能,用户可启用/禁用(选择/取消选择)各个筛选条件。如禁用所有筛选条件,将显示全部产品。

# **Explore products by Servicelines**





图 7: 按服务线浏览产品

# 4.1.2 收藏产品

用户可以收藏套件和应用程序。收藏后,用户可以快速回到自己收藏的产品。

要收藏产品,请单击收藏(心形)图标。

**收藏**图标有开关功能,用户可以收藏(选择)或取消收藏(取消选择)产品。收藏/选择产品后,图标将变为实心蓝 色。如未收藏产品,心形图标将变为空心灰色。

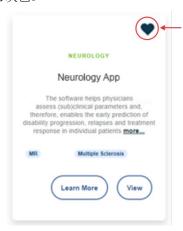


图 8: 收藏

# 4.1.3 "排序"选择器

用户可使用**排序**下拉菜单,按"从A到Z"的顺序(套件或应用程序名称的字母顺序)或按"收藏"情况对产品进行排序。默认排序方式为"从A到Z"。

选择收藏将首先列出收藏的产品,然后列出未收藏的产品。

用户可对"套件"部分和"应用程序"部分分别选择和应用排序选项,也可在产品页面上对套件和应用程序进行排序(请参阅  $\frac{4.2 \, \text{产品}}{\text{O}}$ )。

# 4.1.4 了解更多

每个产品磁贴上都有一个了解更多按钮。"了解更多"页面将显示更多信息,包括:

- 套件或应用程序的描述
- 套件或应用程序的名称
- 套件或应用程序是否已收藏
- 与套件或应用程序关联的标签

单击**了解更多**将打开一个页面,显示相应套件或应用程序的具体信息。此外,还会显示使用各应用程序的相关视频,并且用户可以查看客户评价。

单击**请求报价**可打开一个新窗口,其中包含一个表单,提交后将向 Bayer 发送请求,以获取更多有关套件或应用程序的报价信息。

# 4.2 产品

"产品"选项卡包含两个子选项卡: "套件"和"应用程序"。"产品"选项卡的登录页为"套件"子选项卡。

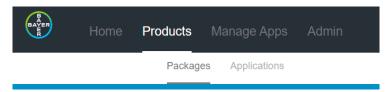


图 9: "产品"选项卡 - 套件和应用程序

# 4.2.1 套件

"套件"子选项卡显示所有可用套件的磁贴。

产品磁贴会显示产品提供商的徽标(如适用)、服务线(如肺脏、神经等)、产品名称、产品描述,以及用于识别套件的标签。

有关"排序"下拉菜单功能的详细信息,请参阅4.1.3"排序"选择器。

# 4.2.2 应用程序

"应用程序"子选项卡显示所有可用应用程序的磁贴。

产品磁贴会显示产品提供商的徽标(如适用)、服务线(如肺脏、神经等)、产品名称、产品描述,以及用于识别应用程序的标签。

有关"排序"下拉菜单功能的详细信息,请参阅4.1.3"排序"选择器。

# 4.3 管理应用程序

Calantic Marketplace and My Apps 的"管理应用程序"选项卡包含三个子选项卡: "控制面板"、"我的应用程序"和 "Edge 配置"。"管理应用程序"选项卡的登录页为"控制面板"子选项卡。

# 4.3.1 控制面板

下图显示"管理应用程序"选项卡的"控制面板"子选项卡。控制面板汇总了所有应用程序的数据。

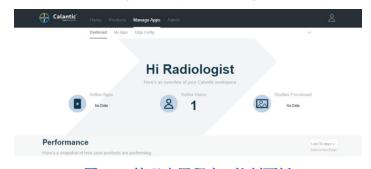
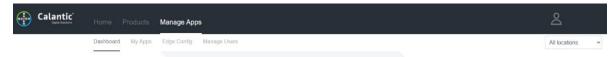


图 10: 管理应用程序 - 控制面板

注: "管理用户"子选项卡仅对拥有"放射科管理员"权限的用户显示。



在"管理用户"子选项卡中,"放射科管理员"可以管理用户,并从下拉菜单中选择一个或多个可查看控制面板数据的位置。请参阅 4.4.1 管理用户。

每个用户都有自己的控制面板,其中会显示其系统使用情况的相关信息。用户可通过"控制面板"页面查看机构所购产品的相关性能表现以及这些产品的使用情况。

如果用户以"放射科管理员"的身份登录,控制面板将显示 KPI 动态,展示活动应用程序、活动用户和年初至今已处理的检查等统计数据。

# 4.3.2 性能

在"控制面板"子选项卡上,"性能"部分汇总显示了产品及其使用情况和性能表现的相关信息。



图 11: 性能

#### 日期范围选择器

用户可通过"日期范围"下拉菜单查看各种期间的所有遥测指标。从下拉菜单中选择所需的日期范围。

#### Calantic Edge Device 选择器

注:该下拉菜单仅对拥有"放射科管理员"角色的用户可见。

用户可通过 "Edge Device 范围"下拉菜单查看单个或所有与该放射科管理员关联的 Calantic Edge Device 的遥测指标。

#### 已处理的检查

该磁贴显示所有应用程序已处理的检查总数。Calantic Edge Device 每检测到一个检查,已处理的检查数量就会随之增加。

#### AI 结果平均审核时间(分钟)

该磁贴显示从在 Calantic Viewer 中打开一个检查,到将检查标记为已接受、部分接受或拒绝的平均用户接受/拒绝时间(分钟)。

#### 接受、部分接受、拒绝的结果

该部分显示放射科医生对于临床应用程序所生成结果的接受率、部分接受率或拒绝率。

结果包括临床应用程序操作获取的临床信息(即图像和成像测量数据)。例如,临床应用程序在一次 CT 扫描中发现三处病灶,则每处病灶即视为一个结果。结果类型因临床应用程序及其输出而异。



图 12:接受、部分接受、拒绝的结果

放射科医生可通过 Calantic Viewer 查看结果,并选择接受或拒绝结果。某些情况下,放射科医生可接受结果的一部分,而非整个结果(部分接受)。

#### 前 5 个应用程序

该部分列出以下指标,其会显示排名前5的应用程序列表:

- 1. 应用程序处理的检查数量
- 2. 结果的接受/部分接受/拒绝率(如条形图所示)



图 13: 前 5 个应用程序

# 选项卡: AI 结果平均审核时间(分钟)

该图显示所选日期范围每个临床应用程序的 AI 结果平均审核时间(分钟)。



图 14: AI 结果平均审核时间

# 选项卡:结果

"结果"选项卡显示了机构所购产品的相关性能表现。该选项卡包含三个子选项卡: "接受"、"部分接受"和 "拒绝"。每个子选项卡下都有一个图,显示在选定日期范围内已接受、部分接受或拒绝的结果的数量。

**注:**与"接受"/"部分接受"/"拒绝"子选项卡并排显示一个标题,其中列出了获取结果的临床应用程序。如果应用程序超过五个,可将鼠标置于标题的任意位置,将在工具提示中显示所有应用程序。



图 15: 结果

# 4.3.3 我的应用程序

"我的应用程序"是"管理应用程序"选项卡的子选项卡。用户可以通过查看该磁贴选择特定的应用程序,从而仅 查看该应用程序的数据。

# Selected Apps and Packages

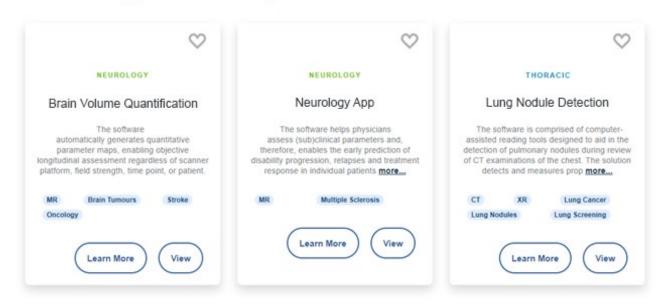


图 16: 我的应用程序

单击了解更多可查看产品详细信息。有关详细信息,请参阅4.1.4了解更多。

单击查看可查看各应用程序的详细性能信息。单击查看可打开"性能"、"配置"和"应用程序详细信息"选项卡。

#### "性能"选项卡

系统会记录每个应用程序的遥测数据,可单击应用程序摘要磁贴上的**查看**按钮进行查看。这将显示所选应用程序的相 关数据。将显示以下页面:



图 17: 临床应用程序详细信息

遥测数据摘要部分显示已处理的检查数量,平均用户接受/拒绝时间(分钟)以及机构中所有用户的接受、部分接受和 拒绝结果比例。

三个子选项卡将显示图表:

- 1. AI 结果平均审核时间
- 2. AI 结果总审核时间与 AI 结果可用性
- 3. 结果

#### AI 结果平均审核时间图

该图显示用户接受/拒绝时间,用户可通过该图比较同行(机构中的其他放射科医生)的平均接受/拒绝时间。该图还显示所有用户(放射科医生)的平均值。

**注:** 对于放射科医生用户角色,其他用户将匿名显示。仅拥有放射科管理员角色的用户可以比较非匿名的使用情况。

#### AI 结果总审核时间与 AI 结果可用性图

该图显示所选应用程序的 AI 结果总审核时间与 AI 结果可用时间(分钟):

- AI 结果总审核时间: 应用程序处理检查的总时间(分钟), 从应用程序开始处理到返回结果。
- **AI 结果可用性:** 从 Calantic Edge Device 检测到要处理的检查,到将结果发送至 PACS 或报告系统的时间。 因此,该时间包含处理时间和用户使用 Calantic Viewer(如适用)所花费的时间。

将鼠标悬停在任意点上都将显示 AI 结果总审核时间和 AI 结果可用性。

#### 结果图

结果图显示使用 Calantic Viewer 接受、部分接受或拒绝临床结果的次数。

用户还可比较同机构内其他用户的统计数据。

**注**: 对于放射科医生用户角色,其他用户将匿名显示。仅拥有放射科管理员角色的用户可以比较非匿名的使用情况。

#### 仅分诊应用

仅分诊应用不提供接受/拒绝工作流。仅分诊应用只有一个"性能"选项卡和一个"平均 AI 处理时间"图。



图 18: 仅分诊应用 - 平均 AI 处理时间

# "配置"选项卡

"配置"选项卡显示各应用程序的详细配置信息。

# "应用程序详细信息"选项卡

"应用程序详细信息"选项卡将转至各应用程序的"了解更多"页面。有关详细信息,请参阅4.1.4了解更多。

# 4.4 管理员

"管理员"选项卡包含两个子选项卡: "管理机构"和"管理用户"。"管理员"选项卡的登录页为"管理机构"子选项卡。

# 4.4.1 管理用户

管理员可使用"管理用户"子选项卡创建、编辑和删除用户。管理员权限分为两种:

- 1. 管理员
- 2. 放射科管理员

两种管理员角色都可以访问"管理用户"子选项卡,并创建、编辑或删除用户。

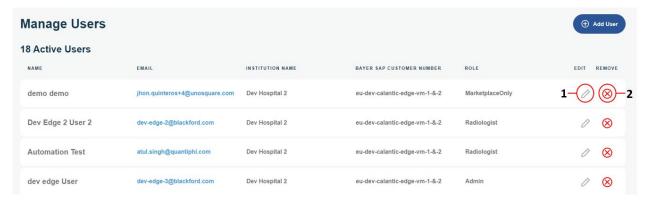


图 19: "管理用户"子选项卡

<b>1</b> 编辑	2	移除
-------------	---	----

# 创建用户

仅管理员用户可以创建新用户。

- 1. 要添加新用户,请单击添加用户。
- 2. 在"创建用户"页面上输入所需的信息。将验证所有字段,无效字段将标注验证消息。"机构"字段会自动填充并假定为与创建新用户的管理员用户所在的机构相同。



图 20: 创建用户

- 3. 单击**提交**按钮,提交详细信息并创建用户。
- 4. 创建用户后,将向用户注册的电子邮箱发送一封电子邮件,里面带有密码重置链接。

**注:** 密码重置链接的有效时间为 30 分钟。之后该链接将过期,用户需要一个新的密码重置链接。可以通过"编辑用户"页面重新发送新链接。

#### 编辑用户

1. 要编辑现有用户,请单击要编辑的用户所在行的编辑图标(图 19,项目 1)。



图 21: "编辑用户"页面

- 2. 根据需要编辑用户信息。用户编辑过程与创建用户类似,所有字段都会进行验证,并标注无效字段。
- 3. 要退出"编辑用户"页面而不保存更改,请单击**取消**。
- 4. 编辑完所有必填字段后,单击**更新**。将显示一条消息,提示已成功完成更新。

#### 重置密码

可以通过"编辑用户"页面重置现有用户的密码。

要重置密码,单击"编辑用户"页面上的**重置密码**按钮。随后将向用户注册的电子邮箱发送一封电子邮件,里面带有密码重置链接。

注:密码重置链接的有效时间为30分钟。之后密码将失效,用户需联系管理员。

#### 删除用户

要删除现有用户,请单击要删除的用户旁边的**删除**图标(图 19,项目 2)。应用程序将显示一条确认删除的消息。 单击**是**确认删除用户并返回"管理用户"屏幕。单击**否**返回"管理用户"屏幕而不删除用户。

# 5 网络安全

Calantic™ 数字解决方案(包括 Calantic Marketplace and My Apps)包含软件,受到网络安全问题的影响。视许可的软件功能而定,其中也可能包含需遵守隐私法或属于敏感性质的数据,应予以保护。本节介绍以下网络和信息安全方面的信息:

- 网络安全保护
- 信息安全
- 所需的安全环境
- 外部接口和互操作性
- 设备停止使用

注:如果出现疑似或确定的网络安全漏洞,或任何与网络安全相关的问题,请联系 Bayer 服务中心 (radiology.bayer.com/contact)。

# 5.1 网络安全保护

系统的设计包括用来保护系统免受攻击者攻击的技术措施,这些措施旨在保护系统应对当前和未来的安全威胁。 Calantic 解决方案定期提供 Calantic 软件更新,客户自行负责在 Calantic Edge Device 上安装安全更新。此外,Bayer 已与 Google 签订了一份云服务协议,用于软件安全更新。新的网络攻击可能需要新的技术控制措施。Bayer 网络响应政策可确保在出现高风险威胁时开发和发布软件更新。将向 Bayer 授权代表提供计划内的软件更新和计划外的软件补丁,以用于快速部署。

Google 负责更新 Google 托管服务和底层基础架构。Bayer 负责管理虚拟机、容器和 Bayer 设计的应用程序。由于设备校准及其操作检验需要进行技术培训,因此 Bayer 负责获取软件或固件并更新 Google Cloud Platform。Bayer 负责与 Google 一起进行安全维护。请参阅 5.8 预期由医院提供的安全环境和安全控制措施删掉。

# 5.2 网络安全保护-技术控制措施

用以保障网络安全的技术控制措施内置于系统设计中,不需要任何用户配置。其中包括:

- 内置访问 Marketplace 应用程序时的身份验证和用户安全令牌化。
- 内置数据传输 SSH 和 TLS 加密; Google Cloud Platform AES 256 静态数据加密。
- 持续实时代码和容器漏洞扫描,使用每日更新的扫描引擎进行代码(静态分析/SAST)和VM漏洞扫描。
- 容器哈希以确保供应链完整性。
- 第三方渗透测试,包括 API 模糊测试。
- Google Cloud Platform (GCP) 虚拟私有云 (VPC) 防火墙。
- 开发环境集成 Enterprise Azure AD,要求双重身份验证 (2FA);限制访问生产代码库。
- 所有攻击面的强大威胁建模,确保不暴露攻击面。
- 使用现代化的 Web 应用程序防火墙 (Google Cloud Platform Cloud Armor) 阻止高级攻击。
- Google Cloud Platform 安全命令中心检测威胁。
- 第三方合规工具,几乎实时地检测和管理漏洞。
- 通过使用 React ISX 库的内置迁移功能阻止 Viewer 跨站脚本 (XSS) 攻击(及其他网络/软件攻击)。

- 定期维护和审查审计日志。
- 数据库受 VPC 防火墙限制,要求对身份验证和凭据进行哈希加盐,以确保层安全性。
- 可以选择在将患者数据传输到外部系统时对其进行掩码/匿名化处理。
- 在 Edge Device 上对每个用户使用唯一的 SSH 密钥。
- 最新的云身份访问管理 (IAM) 解决方案。

# 5.3 网络安全保护 - 操作控制措施

系统软件必须进行维护和更新,以确保其在遇到新的网络威胁时仍能保持安全。对于 Calantic Marketplace 应用程序,客户自行负责确保安全性。安全措施包括补丁、防病毒、防火墙、虚拟机安全、网络安全和入侵防护防系统或入侵检测系统 (IPS/IDS)。Bayer 负责更新 Calantic Marketplace 应用程序。

Bayer 计划每年发布一次或多次软件更新(包括累积安全补丁)。对于 Calantic GCP,Bayer 计划每年发布一次或多次软件更新。 如有任何对系统运行构成威胁的新的活跃网络安全威胁,将追加发布软件,以提供系统补丁。

订阅期间,Bayer 将通过 VirtualCare® Remote Support 远程提供维护和支持服务。用户应针对系统软件更新制定计划并作出妥善安排,可能需要 Bayer 授权代表亲自到场或通过 VirtualCare® Remote Support 远程访问。系统许可证涵盖包括更新在内的软件支持。用户应针对系统软件更新制定计划并作出妥善安排。

# 5.4 网络安全保护 - 已知漏洞

让系统软件保持最新状态是操作控制措施的一部分,将有助于降低因已知漏洞而产生的安全风险。系统软件将定期由第三方测试实验室进行渗透测试和模糊测试,并进行自动漏洞扫描。可根据需要提供所有 CVE 的完整列表。

# 5.5 网络安全保护 - 软件物料清单

可根据需要提供软件物料清单。

# 5.6 信息安全

系统中包含的信息可能属于敏感信息(如网络 IP 地址)、受隐私法的管辖(如患者姓名),或应受到保护以防止访问或意外更改(如治疗方案、产品配置)。信息安全取决于以下两项:系统设计中内置的技术控制措施,用户负责配置的操作控制措施。Google Cloud Platform 和 Calantic 本地组件中的信息通过以下方式进行保护:

- Google Cloud 上的所有数据在传输中和在 Google Cloud 中处于静态时均自动加密。GCP 使用 AES 256 加密静态数据,使用 TLS 1.2 加密传输数据。
- 传输至 GCP 的数据在传输中使用 SSH 和 TLS 进行加密。
- 可以在 Calantic Edge Device 中选择在将患者数据传输到外部系统时对其进行掩码/伪匿名化处理。
- Viewer 可以显示 ePHI, 但用户须进行身份验证并获得授权。
- Viewer 使用 TLS 加密 ePHI, 并且不会缓存 ePHI。

# 5.7 信息安全 - 操作控制措施

通过各种方式提供信息属于系统的正常功能。Marketplace 应用程序需要在授权访问之前进行身份验证。

提供以下操作控制措施,以便将产品配置为关闭上述信息安全访问路径:

- VirtualCare 环境符合 ISO/IEC 27001:2013 标准,需要用户名和密码,并对所有 TLS 连接加密。
- Marketplace 应用程序访问通过身份验证和授权(通过 TLS 数据传输连接建立)进行控制。

# 5.8 预期由医院提供的安全环境和安全控制措施

医疗保健生态系统利益相关方共同负责保护患者和保护数据。作为一家医疗器械和解决方案制造商,Bayer 投资建设基础架构和制定政策和程序,力求满足不断发展的网络安全要求并支持行业最佳实践。在最终用户场所,通过妥善维护部署医疗产品和解决方案的网络和环境,加强网络安全保护,防御最新攻击。医院网络受到监控且能快速打补丁,为部署的医疗解决方案提供了第一道防线。

系统所有者必须明确要求 Bayer 授权服务代表代表他们创建第一个用户帐户。此后,系统所有者负责管理自己设置的用户帐户。

因此,用户应负责根据医院政策提供并保护 Edge Device 虚拟机、操作系统和医院网络,以确保进一步降低安全风险。客户自行负责主动监测与 Edge Device 和周围网络环境相关的安全事件。除了不断更新系统软件外,还建议采取以下其他操作控制措施:

- 尽可能限制对 Calantic Edge Device 系统的物理访问。
- 客户对自身的网络环境和虚拟环境采取最佳安全实践(NIST 800-53 和 NIST CSF),尤其是在其数据中心中托管的 Calantic Edge Device 周围。此外,如果使用浏览器连接 Calantic Marketplace and My Apps,应遵循浏览器和操作系统的最佳安全实践。
- 强烈建议用户对 Calantic Edge Device 制作快照/进行备份。
- 内部资源加密功能(如 PACS)默认不启用,但用户可自行启用。
- 默认不会安装防病毒、高级端点检测、软件安全补丁和安全配置,但用户可自行安装并监测。
- 不得在公共场所或非工作人员不受监督的情况下物理访问 Calantic Viewer 和 Edge Device。建议使用防窥屏幕。
- 工作人员不在时,房间会上锁。
- 对设备进行定期检查和维护。
- 如果可以,请对与用户环境的任何连接进行加密。例如,RIS 和 PACS。
- 安装、配置并全面测试应用程序白名单(也称为AppLocker),以组织恶意代码执行。
- 在虚拟机操作系统上启用磁盘加密,并确保采取强大的密钥管理措施。
- 用户仅可在其数据中心的虚拟机上进行漏洞扫描,并应负责修复漏洞。
- 由于虚拟机与 ePHI 连接并一起工作,因此应考虑其在客户数据中心虚拟环境中的放置是否妥当。
- 强烈建议监测应用程序安全事件。 日志分为标准格式和逗号分隔格式 (CSV), 位于 Drive:\Calantic Edge\Blackford Platform\BlackfordPlatformAudit.log, 用于通过用户的日志采集器架构进行安全信息和事件管理 (SIEM) 的数据收集。
- 如果客户在 Calantic Edge Device 和/或 Calantic Marketplace and My Apps 上检测到网络信号事件,强烈建议用户停止使用产品,采取机构关于事件响应的最佳实践,并立即通知 Bayer 授权代表。

# 5.9 身份验证和授权

Marketplace 应用程序的所有角色都需要进行身份验证。 如果忘记了密码,Bayer 支持中心可以根据需要为用户提供帮助。

# 5.10 外部接口和互操作性

Calantic 解决方案对外部接口进行了限制。所有接口均作为攻击面在威胁模型中进行评估。这些可选功能包括:

- 连接 RIS 系统
- 连接 PACS 系统
- API 网关(用于服务对服务连接)
- 通过浏览器访问 Calantic Marketplace and My Apps
- VirtualCare (支持通过安全的互联网连接访问 Bayer 报告)
- 访问 Bayer GitLab
- 访问白名单
- 访问报告

# 6 术语表

AES 高级加密标准

API 应用程序编程接口

API SDK 应用程序编程接口软件开发套件

CVE 常见漏洞和暴露

ePHI 电子保护健康信息

IDS 入侵检测系统

IE Internet Explorer

IEC 国际电工委员会

IPPA 图像后期处理应用程序

IPS 入侵防护系统

ISO 国际标准化组织

JSX JavaScript XML

KPI 关键绩效指标

OS 操作系统

PACS 图像存档与通信系统

PHI 保护健康信息

RIS 放射信息系统

SAST 静态应用程序安全测试

SSH 安全外壳

遥测 从 Calantic Edge Device 和用户交互中捕获使用和诊断数据;数据由 Calantic Edge Device 在处理活动过程中发出

TLS 传输层安全

TM 商标

VM 虚拟机

YTD 年初至今

# 7许可证

The following third-party software is included as part of the Calantic Marketplace and My Apps and the license terms for such software are outlined below.

#### **MailKit**

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