Instructions for Use

ComeoCare User Guide

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Document	
Product:	ComeoCare
Editions:	Data Center / Cloud
Versions:	ComeoCare v4.3.x, v4.2.x, v4.1.x, v4.0.x, v3.71.3, v3.70.3 CytoWeb v3.68.1, v3.54.4
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Document History

Version	Date	Change Description
1.0	30/09/2020	Baseline for ComeoCare v4.0.x
1.1	25/03/2021	Changed Deployment Manual to Installation Manual; Support for paper copy
		This revision was not issued for safety reasons.
1.2	24/08/2022	Added Swiss Authorized Representative (CH-REP); Copyright; Typos fixed; Rename tariffication;
		This revision was issued for safety reasons: Added precaution about patient monitoring
1.3	12/10/2022 - 08/11/2022	Replace “should” by “must” and “shall” where applicable; Added cloud center Internet dependance in precautions; Clarified regimen validation; Included supported codes for scanning; Support of v4.1 version
		This revision was issued for safety reasons: Added user profile, user environment, indications, contra-indications, and side effects
1.4	22/11/2023 - 05/01/2024	Adapted the template to the new version; Updated the support information; Rename Service Desk to Support and updated email; Moved Service Desk to a new document; Add new integrations; Rename Azure AD to Azure Entra ID; Add Regulatory Information; Remove information regarding deprecated releases;
		This revision was not issued for safety reasons.
1.5	12/02/2024	Updated Regulatory Information (use of correct symbols); Updated support information.
		This revision was not issued for safety reasons.
1.6		Reconsidered some warnings as limitations

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	15/05/2024 - 28/05/2024	This revision was not issued for safety reasons.
1.7	15/01/2025 - 30/01/2025	Updated to latest template version; Added clinical benefits to be expected, and Performance characteristics; Detailed Applications that can be used together with protocol, safe combination and known restrictions, System, error and fault messages, Security considerations, Specific precaution regarding training; Completed Intended use environment with Restrictions on locations or environments; Added placeholders for change for safety reasons in the History of changes; Mention of retention duration in Paper copy; Included guidance for skills and limitations in Intended user profiles; Updated support email; added product misuse warning; added software validation precaution.
		This revision was issued for safety reasons: Added new warnings and a new precaution
1.8	07/03/2025 – 25/03/2025	Support of version v4.3.x; Removed reference to Installation Manual as it has been merged into Operations Manual; Added new integrations ECS, RMB and DBX; Added hazardous situations for ECS and DBX.
		This revision was issued for safety reasons: Modified the details of a precaution by adding new hazardous situations

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Table of Contents

1 Introduction

1.1 Purpose

This document aims at guiding the users for the safe use of the ComeoCare software.

It delivers important notices, limitations, contraindications, precautions, and warnings, regarding the use of ComeoCare, that must be considered carefully by all users before any use.

1.2 Scope

This document is the entry point to the ComeoCare User Guides series.

It is meant to deliver general information, precautions and warning for the physicians, pharmacists, and nurses. It also enumerates the technical requirements of the user's computer devices qualifying for the use of ComeoCare.

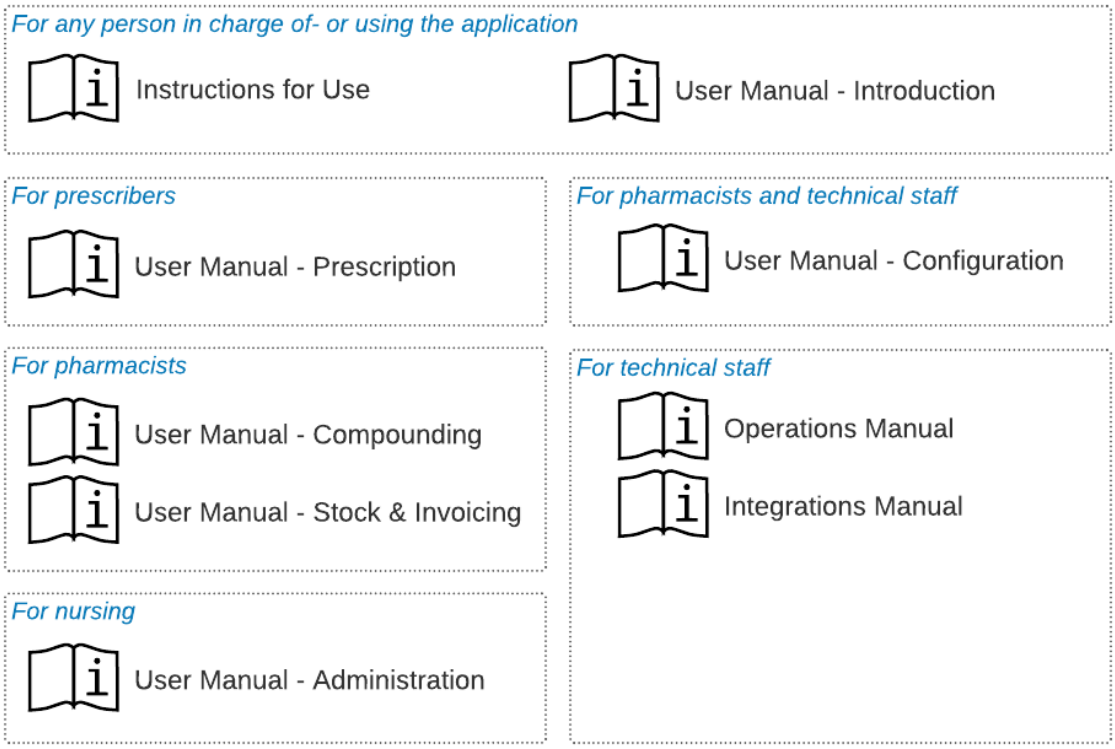
This document is part of the ComeoCare User Guides series whose reading is mandatory in function of the person's roles:

- The [REL3] **ComeoCare - User Manual – Introduction** document delivers general information about the general principles of use of the application. It's a mandatory reading for any person in charge of- or making use of the application;
- The [REL4] **ComeoCare – User Manual – Prescription** document presents the prescription module. It's a mandatory reading for any prescriber making use of the application;
- The [REL5] **ComeoCare – User Manual – Compounding** document presents the compounding module. It's a mandatory reading for any pharmacist making use of the application;
- The [REL6] **ComeoCare – User Manual – Administration** document presents the administration module. It's a mandatory reading for any nurse making use of the application;
- The [REL7] **ComeoCare – User Manual – Stock and Invoicing Management** document presents the pricing and billing module. It's a recommended reading for any pharmacist making use of the application;
- The [REL8] **ComeoCare – User Manual – Configuration** document presents the settings and parameterization module. It's a recommended reading for any pharmacist making use of the application;
- The [REL1] **ComeoCare - Operations Manual** describes the minimum IT requirements and initial installation procedures for the ComeoCare system. This manual also provides guidance to ensure the ComeoCare operating environment performs correctly, safely and efficiently;

- The [REL2] **ComeoCare - Integration Manual** explains the general integration architecture and the configuration of the available integrations.

The [REL1], [REL2] and [REL8] document are a mandatory reading for the Hospital Information Technology team in charge of ComeoCare.

This is illustrated on the next diagram:



1.3 Applicability

The information in this document applies to the editions and versions of ComeoCare mentioned on the first page of this document, for all markets where it is distributed, unless specifically mentioned otherwise in the text. When a certain chapter or subchapter is limited to an edition, version, or market, this is the case for all paragraphs within this section and its subsections.

Sections limited to specific markets will be indicated by the 2 letter ISO 3166-1 code of the country between brackets, such as [BE] for Belgium and [CH] for Switzerland.

The versions lower than v3.70 are branded “CytoWeb”, and the versions as from v3.70 and above are branded “ComeoCare”. In the remainder of this document, the product will be referred to as “ComeoCare” regardless of the version.

The version of the product can be found on the logon page and on the about page of the application.

1.4 Audience

Intended audience of this document are:

- Hospital Healthcare professionals that are users of ComeoCare;
- Hospital Information Technology team in charge of configuration and maintenance;
- Any other person in charge of- or making use of the application.

1.5 Paper copy

The present Instructions for Use deliverable is distributed electronically and is accessible through the link in the “About” page of the application. In conformity with the (EU) 2021/2226 Regulation on Electronic Instructions for Use of Medical Devices, it will be available from the manufacturer for 15 years after the last device has been placed on the market.

Users requiring a paper copy can submit a request to:

E-mail:	Online: https://support.comeo.com E-Mail: support@comeo.com

Paper copies will be received by the requesting user to the latest within 7 calendar days.

1.6 Support

Any complaint about **ComeoCare** or any incident that has occurred in relation to **ComeoCare** should be reported with no delay to the manufacturer or its distributor.

The contact details for the different regions are listed below:

Region	**Support**
[BE] Belgium	Online: https://support.comeo.com E-Mail: support@comeo.com
[CH] Switzerland	Online: https://support.comeo.com E-Mail: support@comeo.com
[ES] Spain	Online: https://www.bbraun.es/es/productos-y-soluciones/soluciones/gestion-de-tratamientos-oncohematologicos.html E-Mail: service-osrc@bbraun.com

[DE] Germany	Online: https://www.bbraun.de/de/produkte-und-loesungen/loesungen/digitale-arzneimitteltherapie-in-der-haemato-onkologie.html E-Mail: service-osrc@bbraun.com
[NL] Netherlands	Online: https://www.bbraun.nl/nl/oplossingen-en-producten/oplossingen/medicatiemanagement-voor-oncologie.html E-Mail: service-osrc@bbraun.com

Functional and Technical support is available from the same contact point. To help understanding and remediating the situation, please explain the circumstances and observed conditions.

Any **serious incident** that has occurred in relation to **ComeoCare** should be reported with no delay to the manufacturer and the Competent Authority of the state in which the user and or patient is established:

Serious incident reporting	
Manufacturer:	support@comeo.com
[BE] Belgium	FAGG Portal in Dutch: https://www.fagg.be/nl/MENSELIJK_gebruik/gezondheidsproducten/medische_hulpmiddelen_hulpstukken/materiovigilantie/wat_0 AFMPS Portal in French: https://www.afmps.be/fr/humain/produits_de_sante/dispositifs_medicaux/materiovigilance/que_notifier/professionnel_de_la
[CH] Switzerland	Swissmedic Portal in French: https://www.swissmedic.ch/swissmedic/fr/home/dispositifs-medicaux/declaration-des-incidents---des-fsca/utilisateurs---exploitants.html Swissmedic Portal in German: https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/vorkommnisse---fsca-melden--materiovigilance-/anwender---betreiber.html Swissmedic Portal in Italian: https://www.swissmedic.ch/swissmedic/it/home/dispositivi-medici/notificare-eventi---fsca/utilizzatori.html
[DE] Germany	BfArM Portal in German: https://www.bfarm.de/DE/Medizinprodukte/Antraege-und-Meldungen/Vorkommnis-melden/Hersteller-und-Bevollmaechtigte/_node.html
[ES] Spain	AEMPS Portal in Spanish:

	https://notificaps.aemps.es/enviotelematico/notificaps/notifica/inicio.do
[NL] Netherlands	IGJ Portal in Dutch: https://www.igj.nl/zorgsectoren/medische-technologie/toezicht-op-producten/vigilantie-medische-technologie/melden-als-fabrikant

To help understanding and addressing the Serious Incident, please explain the circumstances and observed conditions.

1.7 Related documents

ID	Reference	Description
REL1	CCR-OPM	ComeoCare - Operations Manual
REL2	CCR-ITM	ComeoCare - Integration Manual
REL3	CCR-USM-01	ComeoCare - User Manual - Introduction
REL4	CCR-USM-02	ComeoCare - User Manual - Prescription
REL5	CCR-USM-03	ComeoCare - User Manual - Compounding
REL6	CCR-USM-04	ComeoCare - User Manual - Administration
REL7	CCR-USM-05	ComeoCare - User Manual – Stock & Invoicing Management
REL8	CCR-USM-06	ComeoCare - User Manual - Configuration

1.8 Glossary of terms

Term	Definition
SPOC	Single Point of Contact. A person or a department serving as the coordinator or focal point of information concerning an activity or program.
LIS	Laboratory Information System
Scanning	Physically capturing information contained in a barcode, which is then decoded and sent to ComeoCare. ComeoCare uses this technique in different areas: scanning patient bracelet to identify the patient and scanning the product label to identify the prepared product.
Bedside scanning	The complete flow of using scanning to identify the patient and the product to administer to the patient and verify that the scanned preparation is meant to be administered to the identified patient.

EPR	Electronic Patient Records. An application that includes information about the patient within one health care organization that can be created, managed, and consulted by authorized users within that organization. The EPR includes support for the process of care delivery by that organization (such as a hospital).
Four eyes principle	The Four eyes principle is a requirement that two individuals approve some action before it can be taken. The Four eyes principle is sometimes called the two-man rule or the two-person rule
Active Directory	Active Directory (AD) is Microsoft's proprietary directory service. It runs on Windows Server and enables administrators to manage users, groups, and their permissions.
SSO	Single sign-on or SSO is an authentication method that enables users to securely authenticate with multiple applications and websites by using just one set of credentials.
OpenID	OpenID is a decentralized authentication mechanism to enable Single Sign-on on the Internet.
Azure AD	Azure AD is the obsolete name for Azure Entra ID. See Azure Entra ID.
Azure Entra ID	Azure Entra Id is a cloud-based identity and access management service. Applications can outsource the authentication to Azure Entra ID so that the user identification is entirely handled by Microsoft’s Cloud platform.
Contextual Call	A contextual call or contextual link is a link within an application that directs the user from the source of the call to another webpage relevant to the initial page the user is consulting.
Timestamping	Timestamping is a system that allows to keep proof of the existence of a document and its content on a given date. The term "proof" indicates that no one, not even the owner of the document, can modify the timestamping certificate (non-repudiation).
HTTPS	Hypertext Transfer Protocol Secure is a protocol that secures communication and data transfer between a user's web browser and a website. HTTPS is the secure version of HTTP. The protocol protects users against eavesdroppers and man-in-the-middle (MitM) attacks.
DRP	A Disaster Recovery Plan (DRP) is a documented process outlining procedures to recover and restore critical infrastructure and operations after an incident or disaster.
BCP	A Business Continuity Plan (BCP) is a documented strategy outlining the procedures an organization follows to maintain essential functions and operations during and after a disruption or incident

2 Intended Application

2.1 Intended use

ComeoCare is an integrated web application intended to be used by hospital healthcare professionals for the prescription and management of complex regimen-based customizable medicine treatments with dose calculation, pharmaceutical compounding, and controlled nursing administration.

2.2 Intended indications

ComeoCare is indicated for medication management of complex treatments involving all or part of the following aspects: regimen-based prescription, personalized dose calculation, pharmaceutical compounding, controlled nursing administration.

2.3 Intended use environment

The use environment of ComeoCare is integrated in a hospital, as support to medication prescription.

Restrictions on locations or environments in which the software can be used: the software may only be used in locations and environment qualified for the purpose by the responsible organization.

2.4 Intended user profile

ComeoCare is intended to be used exclusively by healthcare professionals that have been trained for using the application.

These healthcare professionals must have followed a ComeoCare training and have read the [REL3-7] ComeoCare - User Manual documents as defined in section 1.2.

These healthcare professionals must carry the right qualifications:

- The role of physician can only be attributed to persons carrying a degree of Doctor of Medicine.
- The role of pharmacist can only be attributed to people carrying a degree in the field of pharmacy.
- The role of nurse can only be attributed to people carrying a nursing degree.

Persons in charge of performing the ComeoCare configuration, including authorization management, must follow a ComeoCare configuration training and read the [REL8] ComeoCare - User Manual – Configuration deliverable as defined in section 1.2, before configuring ComeoCare.

2.5 Target population

ComeoCare targeted population encompasses any human patient being treated in a hospital or medical institution.

3 Important Notices

3.1 Contra-Indications

The following is a non-limitative list of conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit.

ComeoCare is contraindicated for automatic dose calculation in treatments for children, and more specifically for pediatric oncology.

3.2 Side effects

There are no known side effects from the use of ComeoCare.

3.3 Warnings

The following is a non-limitative list of important attention points to be reviewed and understood by the hospital staff and its application developer's suppliers before considering using ComeoCare as a prescription system within their institution.

3.3.1 Authenticate users

> **Applicability notes**:
> - OpenID integration with Azure Entra ID is available in v4.0 and higher.

ComeoCare supports different authentication methods, integration with Active Directory or Azure Entra ID must be activated in the production environment to guarantee the most secure authentication. Users may never share user credentials and must always log out after using ComeoCare.

By integrating ComeoCare with Active Directory or Azure Entra ID, the hospital makes sure that the authentication and password policy adhere to the security policy of the institution.

Whatever the selected authentication method, users may never share credentials or use another user's credentials, since these credentials define which actions the user is allowed to perform. Since all actions are traced back to the executing user, all users must uniquely and exactly be identified and authenticated to guarantee full traceability.

For the same reason, every user must log off after any ComeoCare activity so that no other person can perform actions in the name of the logged user.

3.3.2 Avoid SuperUser role

The use of the SuperUser role must be avoided and only be activated for specific actions. Users must immediately switch back to their regular role after the use of the SuperUser role.

ComeoCare offers a special SuperUser role, which allows a user to perform and override standard actions, including actions not possible for regular roles, ignoring the need of specific permissions, and allowing to bypass necessary states.

The SuperUser role can only be attributed to a limited number of people, carrying a degree of Doctor of Medicine, a degree in the field of pharmacy or nursing, to unblock situations that might have occurred after misuse of the application or data corruption. The Super User role may never be used to override any medical or pharmaceutical validation, for drug administration purposes or to consult and modify information not accessible by the user's regular role.

When used, the SuperUser role can be selected only to perform specific actions requiring this intervention, and the user must immediately switch back to her/his standard attributed role. All user actions are logged for traceability, and therefore all misuse of this role will be logged in the audit trail.

3.3.3 Display patient's identification in clear

ComeoCare must be configured by the hospital so that the patient is identifiable on all printed or displayed material.

ComeoCare displays the patient information in different locations and screens, including on the printable reports and labels. The hospital can configure how the patient identification is structured and formatted, including which information will be shown. The hospital must make sure that the patient identification configuration always contains enough information to uniquely identify the patient and is human readable. This means that the patient label must at least include in clear writing the last name, first name and date of birth of the patient. This warning is equally valid for all printed label and reports concerning the patient.

3.3.4 Exposure to software malfunction

ComeoCare is subject to present defects (i.e. bugs) or vulnerabilities that could affect its performance.

The manufacturer has performed extensive set of verifications and tests and has deployed the highest level of security infrastructure to prevent cyber-attacks and contamination by malwares. However, as all technologies, it's always possible that despite all the precautions and verifications there could be a residual risk of defect present in the software.

This risk can be reduced by the hospital and users by:

a. Executing additional verification procedures of all integrations involved.
b. Make sure you are using the latest version of the Software. Contact the support in case of doubt.
c. Always ensure that your digital equipment is protected for malware and anti-virus contaminations.
d. Always pay attention to messages and information displayed by the software.

The Electronic Instructions for Use are packaged in the software itself, so there is only one latest version accessible.

However, it's always possible that the Electronic Instructions for Use will not be visible to the Healthcare Professionals despite all the precautions and verifications. This risk can be reduced by:

a. Providing required documentation separately.
b. Verifying the availability of the latest version of the Electronic Instructions for Use (a paper version can be obtained within 7 days if necessary).
c. Using a device compatible with the display of the Electronic Instructions for Use.
d. Always consulting the label of ComeoCare through the About page.

3.3.5 Protect from product misuse

Product misuse, including off-label use, might have severe consequences for the patient health.

It is essential for all users to carefully and meticulously verify all entered data. While the application provides tools such as validation ranges and warnings to assist in ensuring accurate data and use of the application, human error may still result in inappropriate actions being made on treatment information.

Misuses can lead to reducing the effectiveness of patient's treatment, or have irreversible toxic effects on their health, possibly resulting in mortality.

It is the responsibility of the hospital to make sure that product misuses are prohibited, and that the product is solely used within the scope of the intended application as described in section 2.

3.3.6 Compounding monitoring

Applicability notes:

- The optional ComeoBox module for compounding monitoring is available in v3.68 and higher;

Warnings related to the setup of the optional module ComeoBox in the Compounding area:

- Physical access to the Compounding area must be restricted to authorized hospital staff
- Only supported devices must be connected to the box. Connecting other devices can cause malfunction or even damage.
- The cables and connectors of all peripherals used with this product must have adequate insulation so that relevant safety requirements are met.

Warnings related to the communication box:

- The box shall only be connected to the supplied external power supply. Any external power supply used with the box shall comply with relevant regulations and standards applicable in the country of intended use.
    - Non-approved power supplies may cause electric shock. Serious injury or death may occur.
    - Non-approved power supplies may cause fire and burns.
- Prevent liquid, flammable, or metallic substances from entering the housing of the box or connected devices. Operating the box with foreign substances inside may lead to malfunction, failure, or fire.

Warnings related to the camera and mounted lens:

- Do not place the lens under direct sunlight. This may cause fire.
- Do not look at the sun or other strong light sources through the lens. This may cause injury to the eyes.

3.4 Precautions

ComeoCare may partially or completely malfunction if it is not installed, configurated, maintained, operated, and used in accordance with the complete Instruction set, containing this document and the [REL1] to [REL8] User Manuals series of documents. To ensure that the product operates properly and safely, it must be installed, maintained, operated and used in accordance with the instructions provided in these documents.

Besides the guidelines in the instruction set, this section contains a mandatory but non-limitative list of precautions to be taken by the hospital staff and its application developer's suppliers in the integration and deployment of ComeoCare within their institution.

3.4.1 Trained and qualified professionals

ComeoCare must only be used by trained and qualified professionals.

ComeoCare is intended to be used exclusively by healthcare professionals that have been trained for using the application.

These healthcare professionals must have followed a ComeoCare training and have read the [REL3-7] ComeoCare - User Manual documents. They must carry the right qualifications:

- The role of physician can only be attributed to persons carrying a degree of Doctor of Medicine.
- The role of pharmacist can only be attributed to people carrying a degree in the field of pharmacy.
- The role of nurse can only be attributed to people carrying a nursing degree.
- The SuperUser role can only be attributed to a limited number of people, carrying a degree of Doctor of Medicine, or a degree in the field of pharmacy or nursing.

Persons in charge of performing the ComeoCare configuration, including authorization management, must follow a ComeoCare configuration training and read the [REL8] ComeoCare - User Manual – Configuration document, before configuring ComeoCare.

3.4.2 Network availability

Applicability notes:

- The optional ComeoBox module for compounding monitoring is available in v3.68 and higher;

ComeoCare is a web application, i.e., relying and dependent on the hospital's internal and possibly external network.

Hospital staff must be aware that the application is physically running on a server – and not on the user device – and accessed through the hospital network.

In case of the Data Center edition of ComeoCare, the network traffic is limited to the hospital's internal network. When external applications are integrated, a part of the information is transported externally on the network segments required by these applications whose technical requirements are complementary to the present instructions. These requirements include scalability, adaptability, extensibility, and manageability.

In case of the Cloud edition of ComeoCare, all information is transported over the internet. Therefore, the hospital must provide a high availability internet infrastructure that addresses the best-in-class requirements of the enterprise - such as providing for security, real-time availability, and performance.

In addition, connected hardware devices integration with ComeoBox requires Internet access, both for the Data Center and for the Cloud edition. In this case the hospital must also foresee a high availability internet infrastructure as described in previous paragraph.

It is in all cases advised to Hospital IT staff to consider the risks of using such a system and take any relevant mitigation measures as appropriate to ensure an acceptable level of availability of their networking infrastructure.

3.4.3 Business continuity and disaster recovery

The hospital must possess of a business continuity and disaster recovery plan in case ComeoCare is temporarily unavailable.

The hospital must have a Business Continuity Plan to keep all essential aspects of the hospital functioning despite significant disruptive events. ComeoCare continuity must be included in this plan.

ComeoCare allows to export the treatments as individual PDF files. The hospital must use this feature to store a copy of the treatments in another independent file location. In the case the application becomes unavailable for whatever reason, the current treatment details will still be available on this file location. Based on the evaluated criticality of this data, these treatment files can also be printed in advance to avoid unavailability during a total network outage.

The hospital must have a set of policies, tools, and procedures to enable the recovery or continuation of vital technology infrastructure and systems following a natural or human-induced disaster. ComeoCare recovery must be included in this Disaster Recovery Plan.

The data stored in the ComeoCare databases must be backed up regularly and be an integral part of the hospital's backup strategy. The selected backup rotation scheme and backup location shall follow the hospital's requirements and internal policy.

All external systems involved through integration with ComeoCare in the treatment process must be considered by the Hospital Information Technology team as critical and therefore be included in the Disaster Recovery Plan and their continuity must be guaranteed by including them in the hospital's Business Continuity Plan.

3.4.4 Verified data sources

Product and regimen data entered in ComeoCare must be based on published scientific information and validated by another healthcare professional than the author of the information.

The hospital builds a thesaurus of products and regimens in ComeoCare, which is then used for further treatment selection and personalization. ComeoCare does not offer any guarantee about any

existing products or regimens. Additions and modifications must only be done by trained and qualified healthcare professionals and based on validated and published scientific articles and information. All product and regimen information must be double checked and validated based on the Four eyes principle by another healthcare professional besides the author of the changes.

3.4.5 Verified integrations

Applicability notes:

- The optional ComeoBox module for compounding monitoring is available in v3.68 and higher;
- Laboratory results import is available in v3.70 and higher;
- Patient height and weight import through webservice is available in v3.70 and higher;
- Treatment Administration integration is available in v3.71 and higher;
- Smart cabinets control is available in v4.0 and higher;
- Export of structured treatment data and digitalized treatment reports is available in v4.0 and higher;
- The External Administration System integration mentioned in this section, consisting of the ADF, EAS and PRO integrations, is available in v4.2 and higher.
- Automatic Data Export integration is available in v4.3.0 and higher.
- The External Compounding Control System integration is available in v4.3.0 and higher.

An incorrect integration of ComeoCare with the other software systems of the hospital might cause a harmful situation for the patient.

For any system integrated with ComeoCare in the hospital's application landscape, the integrated system is considered as the data master for its capability/domain. In case of an incomplete or incorrect integration of ComeoCare, it is possible that a software failure could arise and cause a harmful situation potentially impacting the patient health.

The table below lists these situations:

Integration	Description	Hazardous situation
CBX	Compounding Monitoring	Compounding monitoring measures are not propagated correctly because of a software failure, causing the user to base decisions on wrong information.
CTC	Contextual Call	A user is logged with the wrong identity while using the contextual call, does an inappropriate action on treatment information.

DBX	Automated Data Export	If corrupted or incomplete data is exported due to a software failure, it could affect future treatment administered to the patient.
EAS	External Administration System	If corrupted or incomplete data is sent to the external administration system, the nursing team might not be able to perform the administration activities safely as expected.
ECS	External Compounding Control System	If corrupted or incomplete data is sent to the external compounding control system, incorrect compounding instructions could be shown to the pharmacist.
EPO	Patient Height and Weight	Patient height and weight results are not propagated correctly because of a software failure, causing the user to base decisions on wrong information.
FBE	Fluid Balance Export	Fluid Balance data are not propagated correctly because of a software failure, causing the user to base decisions on wrong information.
LAB	Laboratory Result	Laboratory results are not propagated correctly because of a software failure, causing the user to base decisions on wrong information.
PRO	Product Details	Product data are not propagated correctly because of a software failure, causing the user to base decisions on wrong information.
SCA	Smart Cabinet Integration	If corrupted or incomplete data is sent to the smart medicine distribution cabinet, the patient might not receive the correct treatment in time.
TAE	Treatment Administration Export	Treatment administration data are not propagated correctly because of a software failure, causing the user to base decisions on wrong information.
TRR TRD TRH	Treatment Report Treatment Data Treatment History	ComeoCare treatment is wrongly or with delay communicated to the electronic patient record (EPR) application, causing the users accessing the EPR to take wrong decisions.

To mitigate the probability of such events, it is advised that the Hospital Information Technology team plans, executes and reports on a defined verification of the implementation effectiveness, including but not limited to:

- Integration testing of the relevant system components;
- System testing based on defined scenario and test data covering a representative set of all possible situations including nominal cases, various alternative cases, and exception cases;
- Acceptance testing by healthcare professional user representatives.

3.4.6 Validated software

The software must successfully pass a comprehensive validation test before being used in the production environment of the hospital.

Before deploying any new version of the software in the production environment, it is critical to perform thorough acceptance testing. This ensures that the new version meets the specified requirements and functions as intended, and meets all operational, regulatory, and safety standards.

In collaboration with the manufacturer, the Hospital Information Technology team must plan, execute and report on acceptance testing by healthcare professional user representatives.

Failure to complete these validation steps may result in undetected issues that could impact the safety of patients as well as the performance or compliance of the software.

3.4.7 Patient identification

All nursing staff must identify the patients before administering any products as proposed by ComeoCare.

ComeoCare guides the nursing staff during the administration of products to the patients. Failure to correctly identify patients in this phase constitutes a serious risk to patient safety. The hospital's patient identification policy must always be applied to ensure the correct identity of the patients before administering any products, based on the information and guidance displayed in ComeoCare.

Accurate patient identification is the responsibility of all staff involved in the admission, clinical and administrative processes to ensure correct details are obtained. As a minimum staff must check the patient's name and date of birth. This information is typically mentioned on the patient bracelet.

ComeoCare provides bedside scanning to uniquely identify the patient by scanning the bracelet, but even in the case this functionality is used, the administering nurse must always double check the identity of the patient.

3.4.8 Patient monitoring

All patients must be monitored before and after administration of any product proposed by ComeoCare.

Monitoring patients is integral to medicines administration because it can enable potential medicines-related harms to be identified. Monitoring patients for adverse drug reactions is a crucial part of the administration process.

ComeoCare guides the nursing staff during the administration of products to the patients, but it remains the full responsibility of the hospital staff to monitor the patient for any adverse reactions to the products proposed by ComeoCare.

3.4.9 Page translation

Translation of the page through the browser could lead to weird incorrect translations of the application data.

All external extensions (e.g., Google Translate) in the browser that translate the data in the application must be deactivated. The translation of these extensions is not always correct and could even be misleading in some situations. If another language is desired, use the built-in languages of the application to switch languages.

3.4.10 Compounding monitoring

> **Applicability notes:**
> - The optional ComeoBox module for compounding monitoring is available in v3.68 and higher;

Special precautions must be taken when using the ComeoBox module to connect hardware devices for capturing photographic and/or gravimetric evidence during the compounding.

Carefully respect the box and device usage instructions mentioned in the [REL1] ComeoCare – Operations Manual.

Precautions regarding the general ComeoBox setup in the Compounding area:

- Do not open the housing of the box or connected devices. Touching internal components may damage them.
- Prevent liquid, flammable, or metallic substances from entering the housing of the box or connected devices. If operated with any foreign substances inside, the camera may fail or cause a fire.
- Do not operate the box or connected devices in the vicinity of strong electromagnetic fields. Avoid electrostatic charging.
- Ensure compliance with the instructions mentioned in the [REL1] ComeoCare – Operations Manual.

Precautions to be taken related to the communication box:

- The box shall be operated in a well-ventilated environment.

- Whilst in use, the box must be placed on or attached to a stable, flat, non-conductive surface and must not be in contact with conductive items.
- Do not expose to water or moisture, or place on a conductive surface whilst in operation.
- Do not expose to heat from any source; the product is designed for reliable operation at normal ambient temperatures.
- Take care whilst handling to avoid mechanical or electrical damage to the printed circuit board and connectors.
- Whilst it is powered, avoid handling the box, or only handle it by the edges to minimize the risk of electrostatic discharge damage.

Precautions to be taken related to camera usage:

- Only use the supplied camera mount to set up the camera in the preparation cabinet.
- The lens thread length is limited. If a lens with a very long thread length is used, the lens mount will be damaged or destroyed, and the camera will no longer operate properly.
- Do not disassemble or modify the lens. This may impair the performance of the lens.
- The lens is not intended for use in environments where strong vibrations can occur.

3.5 Limitations

The following is a non-limitative list of relevant factors that may affect the device's performance or safety.

3.5.1 Not a diagnosis tool

ComeoCare manages the complete lifecycle of complex medication treatments, but it does not provide any guidance regarding diagnosis and treatment selection.

Before a patient treatment can be started in ComeoCare, the first critical step in the management of complex diseases is to establish the diagnosis based on pathological examination. Although the diagnostic process is not managed in ComeoCare is it a vital prerequisite before the treatment can start. The physician using ComeoCare must use all necessary pathology and laboratory medicine services to determine the diagnosis and select the right medication treatment.

ComeoCare manages medication therapy treatments. The treatments managed in ComeoCare do not exclude any other forms of therapy such as surgery or radiotherapy.

3.5.2 Not a human replacement

ComeoCare is a software intended to complement the healthcare professional expertise with an extra level of verification, but not to replace him/her.

As any software, and despite all measures taken to ensure the availability and the connectivity to

ComeoCare, it is possible that ComeoCare will not be able to assist the complex treatment lifecycle or does not contain the correct information.

In all situations, the physician must carefully review and validate the doses calculated and proposed by ComeoCare. The pharmacist must perform a pharmacological and physicochemical validation of the proposed preparation and verify all printed material. The nurse must always verify the products and dose to be administered.

If for any reason ComeoCare is not available during administration, the nurse must check other sources containing information about the treatment and administration before administering a product. These other sources can be, but are not limited to, generated PDF versions of the treatment stored in an independent file location or structured treatment data exported by ComeoCare to the Electronic Patient Record at a previous time. If these sources are also unavailable at the time of administration, the product can only be administered when the nurse is accompanied by another qualified healthcare professional who performs a double check of the product and dose to be administered before the administration – the so-called Four eyes principle.

3.6 System, error and fault messages

The following table categorizes the different types of system messages, their purpose, and descriptions to help users understand their context, causes, and potential actions required to address them.

Class	Form	Purpose			Description
		Notify	Raise awareness	Alert	
Non-persistent	Toaster	Yes	No	Yes	Used to notify the users. They stay visible during a sufficient time to ensure the user's awareness and readability.
Semi-persistent	Dynamic validation messages	Yes	Yes	No	Usually placed around input fields or at the bottom of a form. They are intended to notify or raise user's awareness
Persistent	Static text with background color	No	Yes	Yes	Messages remaining on the screen until manually dismissed or addressed
	Banners	No	Yes	Yes	Used to alert users about a situation that can severely impede

					the application process (e.g. the end of license) or that does not follow regulation (e.g. a pharmacist validating their own preparation). Banners can either be displayed on one relevant screen or throughout the whole application, depending on the severity.

3.7 Lifetime, decommissioning and disposal of ComeoCare

3.7.1 Device lifetime

The device lifetime is defined to 3 years after the release date of the version to the market. The release date is mentioned on the About page.

Extended support is possible for a maximum period of 2 additional years after which an update must be performed. The institution must contact the manufacturer for detailed terms and conditions to obtain extended support.

3.7.2 Device decommissioning and disposal

After the end of the subscription period, a limited license for read-only access may be granted to allow institutions to consult data in its original format without modification, using the ComeoCare application during the period leading up to disposal. The institution must contact the manufacturer for detailed terms and conditions to obtain a limited read-only license.

If the subscription of a Data Center edition of ComeoCare is terminated or not renewed, the institution must dispose of the software and the data. Disposal of the software involves erasing installations and destroying all security copies and backups. Disposal of the data involves exporting the data managed by ComeoCare and then erasing the original data stores.

The Manufacturer handles the disposal of the software and data for terminated Cloud Edition subscriptions. Before erasing the data, the manufacturer exports the data managed by ComeoCare and transfers this data securely to the institution.

The institution is responsible to securely store the exported data managed by ComeoCare in accordance with legal retention terms and confidentiality requirements and must ensure cyphering and access security for this exported data.

4 Device Description

4.1 How ComeoCare achieves its intended use

ComeoCare achieves its goal as a web application managing the complete lifecycle of complex regimen-based treatments by the mean of several core features that are described below. The following explanation details how ComeoCare will fulfills its purpose independently, without requiring integration with any other applications.

4.1.1 Products and regimens management

Applicability notes:
- The availability of some dose calculation safety parameters is varying per version; check the user manual of your version for details.
- The control enforced by the 4 eyes principle is available in v3.70 and higher.

The application allows the hospital to define and maintain a thesaurus of products and regimens through two modules.

- **Products**: In this module, pharmacists manage the list of products that can be used for treatments, as well as the properties and options of each type of products, such as dose calculation method, maximum allowed doses, available packages, stability parameters… This information forms the base for configuring and optimizing the treatments lifecycle.
- **Regimens**: This module supports the definition, validation, and update of a library of structured treatment regimens. These regimens consist of different lines, representing prescriptions and administrations of a certain product at a given time. When the cross-validation option is activated, all changes to a regimen always require the plan to be re-validated based on a 4 eyes principle before it can be used for treatments.

The products and regimens management modules are further described in the [REL3] ComeoCare - User Manual – Introduction user guide.

4.1.2 Treatment management workflows

Applicability notes:
- The availability of the patient safety controls is varying per version; check the user manual of your version for details.
- Step by step compounding is available in v3.68 and higher;

Based on the hospital thesaurus defined in 4.1.1, the application guides the healthcare professionals through the patient treatment. ComeoCare tracks and displays the progress of the patient treatments.

The major workflow modules are:

- **Prescription**: In this module, the physician selects the right regimen or treatment plan for the patient. At that moment the doses of the products within the regimen are calculated according to the patient's clinical data. Extra checks are being performed to ensure the patient's safety, such as cumulative dose warnings or glucose warnings for diabetics. The physician can adapt the standard regimen by adding or removing medication prescriptions to the treatment or by applying dose reductions. When a prescription is validated by the physician, the product preparation or delivery can be ordered.

The prescription module is further described in the [REL4] ComeoCare - User Manual – Prescription user guide.

- **Compounding**: In this module, the pharmacist is alerted of the prescriptions requiring handling while being provided with a guidance for the compounding activities. Based on the prescribed dose and concentration of the available packages, the correct packages and diluents for the compounding are selected. After a medication appropriateness check, the picking can start based on a generated picking list. Once the products are picked, a step-by-step guidance for the preparer is displayed inside the laminar flow or isolator. The pharmacy can then release the preparation for administration after a post-preparation validation and print the product label to uniquely identify the preparation. A barcode or QR or Data matrix code can be added to this label to uniquely identify the preparation. Once the pharmacy updates the status of the products, nursing is alerted that the products are ready for administration.

The compounding module is further described in the [REL5] ComeoCare - User Manual – Compounding user guide.

- **Administration**: In this module, the nursing staff is provided with a daily overview of the preparations to be administered to each patient. The patient safety is guaranteed through bed-side scanning: by scanning the patient bracelet, a first validation checking if this patient requires treatment is done. By scanning the barcode on the printed product label, the application verifies if the product corresponds to the right patient. When the nurse registers that a product has been administered, the status of the corresponding prescription is changed, which allows the physician to be informed that the process has been correctly carried out and allows a precise history of the administered products.

The administration module is further described in the [REL6] ComeoCare - User Manual – Administration user guide.

4.2 Clinical benefits to be expected

The clinical benefits of the ComeoCare software medical device system that may be expected are:

1. **Safe and Effective Use**: ComeoCare supports healthcare professionals in medication dose calculation, pharmaceutical compounding, and controlled nursing administration, ensuring these processes are performed safely and effectively.
2. **Reduction in Medication Errors**: The system reduces the margin for medication errors by at least 38%, enhancing patient safety and improving the overall quality of care.

4.3 Performance characteristics of ComeoCare

The following table contains a non-exhaustive list of the device performance characteristics:

Topic	Characteristics
Access Management	• Authentication for users in on-premises Active Directory • Authentication for Entra ID users through Open ID (**Applicability**: v4.0 and higher) • Built-in Role Access Control • Automatic Group provisioning with on-premises Active Directory (**Applicability**: v4.2 and higher) • Automatic Group provisioning with Entra ID through SCIM (**Applicability**: v4.2 and higher)
Product configuration	• Customizable Product Form and Type lists • Drug identification based on International Nonproprietary Name (INN) • Dose calculation method management based on fixed dose, on weight, body surface and AUC values (Creatinine Clearance) • Range management for dose banding • Management of compounding practices, including administration device and diluents per administration route and dose range (**Applicability**: v4.3 and higher) • Provisioning and linking of actual available packages in the institution • Traceability of all changes
Regimen configuration	• Regimen versioning (**Applicability**: v3.68 and higher) • 4-eyes regimen validation (**Applicability**: v3.68 and higher) • Customizable regimen types, tags and color codes • Add drugs from the product configuration and override specific values if needed for specific regimen

	• Comment and question management • Regimen duplication • Regimen creation based on patient treatments
Treatment prescriptions	• Customizable status- and transition management • Real-time status updates • Traceability of individual prescriptions • Regimen based prescriptions • Automatic dose calculation based on patient clinical parameters • Personalize treatment by adding, removing and updating prescriptions, comments and questions • Duplication of existing treatments for extra cycles • Dose reduction propagation • Previous administration feedback visualization (**Applicability**: v3.68 and higher) • Automated alerts for dose and cumulative dose limits and sugar intake for diabetics • Automatic agenda generation
Compounding Guidance	• Picking support with barcode scanning (**Applicability**: v4.1 and higher) • Standard GTIN code support (**Applicability**: v4.1 and higher) • Automatic package calculation and proposal for least number of packages • Step-by-step guidance for preparing compounded medications • Customizable labels for prepared medication • Drug Vial Optimization (**Applicability**: v4.1 and higher) • Invoicing overview of all consumed packages per patient
Administration Management	• Overview of daily administrations • Traceability and documentation of administration actions and events • Fine-tuned (re)scheduling and delay management • Notification for upcoming or overdue administrations • Barcode scanning at the bedside to verify patient identity and medication, and dosage • User interface responsiveness making administration screens available for Computer on Wheels and handheld devices

Data Security and Reporting	• Encrypted data at rest through secure data storage protocols • Encrypted data transfer with anonymization support • Automatic treatment report generation for Business Continuity • Customizable reports with self-service report management

4.4 Applications that can be used together with ComeoCare

The sections below list the information flows that are supported by ComeoCare and the applications that can be used together to provide extra functions.

4.4.1 User authentication

Applicability notes:
- User authentication through Open ID with Azure Entra ID is available for the Cloud edition in v4.0 and higher.

ComeoCare supports external/central users' authentication through Active Directory integration. This means that the user credentials needed to log on to ComeoCare are synchronized with the users managed in the hospital's Active Directory, ensuring that the authentication and password policy adhere to the security policy of the institution.

The application can also use the OpenID protocol to outsource the user authentication to Azure Entra ID, so that even the login page is handled and configured by the hospital.

Read more on how to set the authentication mode in the [REL2] ComeoCare - Integration Manual.

4.4.2 Automated user authorization through group membership

Applicability notes:
- User authentication through Open ID with Azure Entra ID is available for the Cloud edition in v4.0 and higher.
- Automated user authorization is available in v4.2 and higher.

ComeoCare can copy group memberships defined in the Directory (Entra ID or LDAP) to the groups defined in ComeoCare. This automated authorization allows users to log into ComeoCare and automatically assign the appropriate permissions.

For more information about the setup of the groups in ComeoCare, please refer to the [REL2] ComeoCare - Integrations Manual.

4.4.3 Contextual calls

ComeoCare exposes different contextual calls or links, which can be called by an external system to directly display specific information, such as patient or treatment information for a given patient.

These integrations, typically with the Patient Electronic Record (EPR) system, can be used by sharing and relying on the patient's unique identification number.

Read more on Contextual Calls in the [REL2] ComeoCare - Integration Manual.

4.4.4 Incoming and outgoing information flows

The table below lists the information flows that are supported by ComeoCare and the applications that can be used together with ComeoCare to contribute to the achievement of the intended use. he applicability of each integration is indicated within the corresponding row of the table. For a more detailed technical view on how to integrate an application with ComeoCare, please refer to the [REL2] ComeoCare - Integration Manual document.

Integration	Application	Description
Incoming information		
ADF External Administration Feedback	Dedicated Managing Drug Administration System Hospital Information System (HIS) or Electronic Patient Record (EPR)	**Intended purpose:** This integration allows the Administration Management System to send administration feedback such as adverse effects to ComeoCare after administration. **Supported protocols:** HL7 (RAS messages) **Qualified software for safe combination:** OncoSafety a.k.a. OSRC (B. Braun) **Known restrictions or constraints:** the external system must be able to send RAS messages through TCP or deposit the messages as a file on a location available to ComeoCare. **Applicability:** v4.2 and higher

ADT Patient and Visit information	Hospital Information System (HIS) or Electronic Patient Record (EPR)	**Intended purpose:** Patient and Visit information can be self-managed in the application but they are typically imported and linked to the hospital's central patient management software system. The patient information is used by the physician to personalize the prescriptions. This visit information gives nurses insight in the current location of the patients and helps planning the daily administrations. Visit information is also used to support the nursing in the administration flow and for the stock management and invoicing. **Supported protocols:** HL7 (ADT messages) **Qualified software for safe combination:** Oazis (Zorgi), Wish (IBM), Amaron (Amaron), CARAD-RT, Opale (Opale Solutions). **Known restrictions or constraints:** the external system must be able to send ADT messages through TCP or deposit the messages as a file on a location available to ComeoCare. **Applicability:** v3.71 and higher
ART Article and Product Information	Pharmacy Management System	**Intended purpose:** The hospital's standard drug library can be imported into ComeoCare and linked to the defined products. This allows to store the internal product references, later used by the TAR integration for invoicing. **Supported protocols:** HL7 (MFN messages) **Qualified software for safe combination:** Infohos Pharmacy (Zorgi), APO (MedSoc), CCA, GCL/Win, Opale (Opale Solutions). **Known restrictions or constraints:** the external system must be able to send MFN messages through TCP or deposit the messages as a file on a location available to ComeoCare. **Applicability:** v3.71 and higher

CBX Compounding Monitoring	System for Compounding Monitoring	**Intended purpose:** ComeoCare can be integrated with the ComeoBox system to support the gravimetric or photographic validation of the compounding process. A hardware communication box linked to the hardware devices is installed for each preparation cabinet – either an isolator or a laminar flow cabinet. Because compounding usually involves the use of gloves and limited room for mouse and keyboard manipulation, user actions can be registered by pressing a foot pedal. A camera connected to the communication box allows to display a live video stream during preparation and to take single pictures of the preparation step for validation. When connected to a precision balance ComeoBox can also send the current preparation weight to ComeoCare for gravimetric validation of the preparation step. The camera pictures and gravimetric information are then used in ComeoCare to enhance 4-eyes compounding validation. **Supported protocols:** REST Web Service **Qualified software for safe combination:** ComeoBox (Comeo). **Known restrictions or constraints:** • The boxes, cameras and pedals must be installable physically within the compounding area. • Only precision balances of the Mettler Toledo brand are supported. **Applicability:** v3.68 and higher

EPO Patient Height and Weight	Hospital Information System (HIS) or Electronic Patient Record (EPR)	**Intended purpose:** ComeoCare can fetch the latest height and weight data for a patient at prescription time, so that the doses are calculated based on the last known clinical data. **Supported protocols:** SOAP Web Service. **Qualified software for safe combination:** C2M (Cegeka). **Known restrictions or constraints:** the web service must adhere to the standard method signature and message layout. **Applicability:** v3.70 and higher
LAB Laboratory Results	Laboratory Information System (LIS)	**Intended purpose:** External laboratory results can be displayed in ComeoCare and used as input in the application. The physician can accept the incoming results, and after acceptance, clinical data can be used to either automatically (re)calculate the doses for the patient or be used as guidance for dose adaptations. **Supported protocols:** HL7 (ORU messages). **Qualified software for safe combination:** Glims (Mips), Molis (CGM), Jade, Labo400. **Known restrictions or constraints:** the external system must be able to send ORU messages through TCP or deposit the messages as a file on a location available to ComeoCare. **Applicability:** v3.70 and higher
Outgoing information		

BCP Business Continuity Plan	File System	**Intended purpose:** ComeoCare can export a digitalized patient treatment report into a dedicated folder. If for any reason ComeoCare is temporarily unavailable, the patient treatments can be continued based on these reports. **Supported protocols:** PDF export. **Qualified software for safe combination:** File System. **Known restrictions or constraints:** ComeoCare must have access to the file system to store the PDF files. **Applicability:** v3.68 and higher
DBX Database Export	Business Intelligence (BI) and Data Analysis tools	**Intended purpose:** ComeoCare exports its database tables in an open source format allowing compression. Thes files are typically used for data analysis. **Supported protocols:** Parquet files. **Qualified software for safe combination:** Power BI (Microsoft). **Known restrictions or constraints:** ComeoCare must have access to the file system to store the Parquet files. **Applicability:** Cloud edition v4.3 and higher
EAS External Administration System	Dedicated System Managing Drug Administration or Hospital Information System (HIS) or Electronic Patient Record (EPR)	**Intended purpose:** ComeoCare sends administration data to an external administration system to externalize the administration flow. **Supported protocols:** HL7 (RDS messages). **Qualified software for safe combination:** OncoSafety a.k.a. OSRC (B. Braun). **Known restrictions or constraints:** the external system must expose a TCP endpoint or file system location to receive RDS messages. **Applicability:** v4.2 and higher

ECS External Compounding System	Dedicated System Managing Drug Compounding	**Intended purpose:** ComeoCare sends compounding information to an external compounding system to externalize the compounding flow. **Supported protocols:** Custom XML and HL7 (RDS messages). **Qualified software for safe combination:** DrugCam (Eurekam), Mundus HD robot (Equashield), Vuzix Smart glasses. **Known restrictions or constraints:** the external system must expose a TCP endpoint or file system location to receive RDS messages. **Applicability:** v4.3 and higher
FBE Fluid Balance Export	Hospital Information System (HIS) or Electronic Patient Record (EPR)	**Intended purpose:** ComeoCare exports fluid balance information for a specific patient (= the volume of fluids administered through ComeoCare) to the Electronic Patient Record. **Supported protocols:** SOAP Web Service. **Qualified software for safe combination:** H++ (Zorgi), XCare (Zorgi). **Known restrictions or constraints:** the web service must adhere to the standard method signature and message layout. **Applicability:** v4.0 and higher

[BE] HDT Hospital Data	Dedicated Nurse Action Reporting System or Government eHealth platform	**Intended purpose:** All information about administration times and volumes collected by ComeoCare can be exported directly or indirectly to the Belgian eHealth platform. This information is required by eHealth for compliancy reasons. **Supported protocols:** SOAP Web Service. **Qualified software for safe combination:** Othello (Calidos). **Known restrictions or constraints:** the web service must adhere to the standard method signature and message layout. **Applicability:** v4.0 and higher
PRO Product Details	Dedicated System Managing Drug Administration Hospital Information System (HIS) or Electronic Patient Record (EPR)	**Intended purpose:** ComeoCare sends updates of product management to an external application, including all new products, product modifications and deleted products. **Supported protocols:** HL7 (MFN messages). **Qualified software for safe combination:** OncoSafety a.k.a. OSRC (B. Braun). **Known restrictions or constraints:** the external system must expose a TCP endpoint or file system location to receive MFN messages. **Applicability:** v4.2 and higher

[BE] RCP Recip-e	Government eHealth Platform Aggregator	**Intended purpose:** This integration allows various healthcare prescribers to send prescriptions electronically and securely to a Belgian e-Health server. The prescriptions are encoded and can then be used upon the patient's request by a pharmacist to prepare and deliver the correct medicines for this prescription. **Supported protocols:** XML (KMEHR format). **Qualified software for safe combination:** Infohos Connect (Infohos), HealthConnect (HealthConnect). **Known restrictions or constraints:** the external system must expose a TCP endpoint, file system location or webservice to receive KMEHR messages. **Applicability:** v4.0 and higher
[BE] RMB Reimbursement Requests	Government eHealth Platform Aggregator	**Intended purpose:** ComeoCare sends digitized prescription information to another application. This prescription information is then used for automated handling of medicine reimbursement requests. **Supported protocols:** HL7 (ORM messages). **Qualified software for safe combination:** Workflower (Amaron). **Known restrictions or constraints:** the external system must expose a TCP endpoint or file system location to receive HL7 messages. **Applicability:** v4.3 and higher

SCA Smart Cabinets	Smart Medication Cabinets	**Intended purpose:** Smart dispensing systems can be connected, and all prescription information known in ComeoCare can be exported, allowing nurses to use these systems with the correct medicine proposal per patient. **Supported protocols:** HL7 (RAS messages). **Qualified software for safe combination:** VANAS, Ethilog. **Known restrictions or constraints:** the external system must expose a TCP endpoint or file system location to receive RAS messages. **Applicability:** v4.0 and higher
[BE] SIG Electronic Signature	Government eHealth Platform Aggregator	**Intended purpose:** Electronic prescription timestamping can be obtained from the Belgian Governmental eHealth platform to freeze prescription content and achieve nonrepudiation. **Supported protocols:** XML (KMEHR format) **Qualified software for safe combination:** Amaron (Amaron), Infohos connect (Infohos), HealthConnect, MediBridge (Digital Wallonia), XConnect (RSW). **Known restrictions or constraints:** the external system must expose a TCP endpoint, file system location or webservice to receive KMEHR messages. **Applicability:** v4.0 and higher

TAE Treatment Administration	Hospital Information System (HIS) or Electronic Patient Record (EPR)	**Intended purpose:** ComeoCare can export treatment administration data to the Electronic Patient Record to have a real time view about treatment administrations. **Supported protocols:** SOAP Web Service. **Qualified software for safe combination:** H++ (Zorgi), XCare (Zorgi). **Known restrictions or constraints:** the web service must adhere to the standard method signature and message layout. **Applicability:** v4.0 and higher

TAR Stock Management and Invoicing	Pharmacy Management System	**Intended purpose:** Pharmacy management is supported for two main aspects: • **Stock Management**: products that have been administered can be notified to the pharmacy stock management system to adapt the stock availability numbers. • **Invoicing**: at the time of a – configurable – state change of an administration/ prescription, the application can be configured to send the number and type of used packages, and the patient visit information to the hospital invoicing system to be handled. The stock and invoicing module is further described in the [REL8] ComeoCare - User Manual – Stock and Invoicing user guide. **Supported protocols:** HL7 (RAS messages) or XML **Qualified software for safe combination:** Infohos Pharmacy (Zorgi), APO (MedSoc), CCA, GCL/Win, Opale (Opale Solutions). **Known restrictions or constraints:** the external system must expose a TCP endpoint, file system location or webservice to receive RAS messages. **Applicability:** v3.71 and higher

[BE] TRA Treatment Analytics	Walloon Health Network	**Intended purpose:** ComeoCare exports treatment data in a specific format for the INAH project, aiming at creating a Walloon entity for enabling the ethical use of electronic health information based on the infrastructure provided by the Walloon Health Network. **Supported protocols:** XML. **Qualified software for safe combination:** Cetic – INAH. **Known restrictions or constraints:** the external system must expose a TCP endpoint, file system location or webservice to receive XML messages. **Applicability:** v4.0 and higher
TRD Structured Treatment Information	Hospital Information System (HIS) or Electronic Patient Record (EPR)	**Intended purpose:** ComeoCare sends treatment information in a structured message to another application. This data can then be read, interpreted, and used as required. **Supported protocols:** HL7 (ORM messages). **Qualified software for safe combination:** Millenium (Cerner), C2M (Cegeka), H+ Result (Zorgi). **Known restrictions or constraints:** the external system must expose a TCP endpoint, file system location or webservice to receive ORM messages. **Applicability:** v4.0 and higher

TRH Structured Treatment History	File System	**Intended purpose:** ComeoCare sends digitized reports of previous treatments to another application. These reports can then be added to the medical record of the patient. **Supported protocols:** PDF Export. **Qualified software for safe combination:** File System. **Known restrictions or constraints:** the external system must expose a TCP endpoint, file system location or webservice to receive ORM messages. **Applicability:** v4.2 and higher
TRR Digitalized Treatment Report	Hospital Information System (HIS) or Electronic Patient Record (EPR)	**Intended purpose:** ComeoCare sends digitized treatment reports to another application. These reports can then be added to the medical record of the patient. **Supported protocols:** HL7 (ORU messages). **Qualified software for safe combination:** Millenium (Cerner), C2M (Cegeka), H+ Result (Zorgi), Nexuzhealth (Cegeka), Primuz (CtG), Carefolio. **Known restrictions or constraints:** the external system must expose a TCP endpoint, file system location or webservice to receive ORU messages. **Applicability:** v4.0 and higher

4.5 Configuration

ComeoCare can be configured by the means of settings influencing the way of working within the application modules.

The configuration parameters are further described in the [REL8] ComeoCare - User Manual – Configuration user guide.

5 User Device Technical requirements

Applicability notes:

- The optional ComeoBox module for compounding monitoring is available in v3.68 and higher;
- Photographic validation is available in v3.68 and higher.

5.1 Minimum Hardware Requirements

The computer, tablet or handheld device used for ComeoCare must meet minimum technical requirements.

The device must have an integrated or external keyboard, and a pointing device. This can either be a computer mouse, touchpad, or touchscreen. If ComeoCare is used together with ComeoBox, the device on which ComeoCare runs in the preparation room must not be equipped with a keyboard or pointing device, since these actions are performed by using the linked ComeoBox foot pedal.

ComeoCare is a responsive web application which implies that the content adapts to the available screen size and resolution. Therefore, ComeoCare will display on all device screens, but the minimum requirements are set to use the application fluently: the screen resolution must at least be 1280*1024 in 4/3 aspect ratio and 1280*720 in 16/9 aspect ratio.

The device must have a network interface, wired or wireless, to establish the communication with the ComeoCare server.

If scanning is enabled during the preparation or prescription flow, a barcode scanner must be attached to or integrated in the device. This barcode scanner must be able to at least scan Code 128 barcodes. If labels generated by other software, such as patient bracelet codes, use different code formats, the scanner must support these barcode types as well.

The device must have access to a printer if the printing capabilities of ComeoCare are needed. The printer must be able to print on A4 paper format for the reports. Most standard paper-roll label printers are supported for the product labels.

The communication from the device to the ComeoCare server is fully based on HTTPS requests. Therefore, the outbound 443 HTTPS port must be opened in the device's firewall if any.

5.2 Minimum Software Requirements

All users of ComeoCare need a web browser to use the application, regardless of the operating system or device the user is using. All web browsers used for ComeoCare must support JavaScript and cookies, and these settings must be turned on.

For the pharmacy preparation with live imaging feature (requires ComeoBox), the browser must also support the "multipart/x-mixed-replace" content-type.

Browser	Minimum Version	"multipart/x-mixed-replace" support
Microsoft Edge	40	Yes
Mozilla Firefox	60	Yes
Google Chrome	60	Yes
Google Chrome for Android	74	No

If the user wants to read or print reports from the client device, a PDF reader software must also be installed on the device. If no PDF reader is available, the reports will be saved to the disk, but the user will not be able to view or print them.

If the user wants to export query results to an Excel file, the Microsoft Excel software must be installed on the device. If no Microsoft Excel reader is available, the reports will be saved to disk, but the user will not be able to view or print them.

5.3 Security considerations

When using ComeoCare, it is essential to follow security best practices to ensure the safety of patient data and the proper functioning of the system. The next table contains a non-exhaustive list of security considerations:

Topic	Considerations
Secure Access to the System	• Always use unique login credentials and never share them with others. • Ensure multi-factor authentication (MFA) is enabled and complete the authentication process for every login. • Do not allow unauthorized individuals to view or access the application while it is in use. • Lock your device or application screen if you step away from your workstation • Log out of the system when not in use
Use of Approved Devices	• Access ComeoCare only from devices that are approved and compliant with your organization's security policies. • Keep your devices updated with the latest operating system and security patches.
Data Handling and Export	• Avoid exporting sensitive patient data unless strictly necessary and authorized. • Ensure exported data is stored securely, encrypted, and deleted when no longer required.

	• Use data anonymization techniques to remove identifiable information before exporting or sharing data, in compliance with privacy regulations. • Do not transfer sensitive data using unsecured channels such as email
Responding to Alerts	• Take all system alerts and notifications seriously. • If you encounter a security alert, follow the recommended action steps provided by the system or notify your IT/security team immediately.
Reporting Suspicious Activity	• Report any suspicious activity, such as unexpected account logins or data anomalies, to your organization's IT/security team promptly. • Use the designated incident reporting system to log potential breaches or concerns.
Compliance with Organizational Policies	• Follow your organization's security policies and guidelines while using ComeoCare. • Participate in regular security awareness training to stay informed about potential risks and best practices.
Keep Personal Information Secure	• Do not save passwords or sensitive information in unsecured locations (e.g., sticky notes, text files). • Use password managers if needed, ensuring they comply with organizational security requirements.

6 Regulatory Information

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	[BE] **Comeo sa/nv** - Rue Boulvint 54, 1400 Nivelles, Belgium [CH] **Comeo sa/nv** - Rue Boulvint 54, 1400 Nivelles, Belgium [DE] **B. Braun Melsungen AG** - Carl-Braun Str. 1, 34212 Melsungen, Germany [ES] **B. Braun Melsungen AG** - Carl-Braun Str. 1, 34212 Melsungen, Germany [NL] **B. Braun Melsungen AG** - Carl-Braun Str. 1, 34212 Melsungen, Germany
CH REP	**Veranex Switzerland sa** Chemin de Rovéréaz 5 1012 Lausanne, Switzerland
CE	ComeoCare v4.3.x, v4.2.x, v4.0.x, v3.71.3, v3.70.3 CytoWeb v3.68.1, v3.54.4
CE 2797	ComeoCare v4.1.x
MD	ComeoCare is a Medical Device