comeo·care

Instructions for Use
ComeoCare User Guide

Product:	ComeoCare
Basic-UDI:	++B886COMEOCAREGX
Editions:	Data Center / Cloud
Versions:	ComeoCare v4.1.x, v4.0.x, v3.71.x, v3.70.3
	CytoWeb v3.69.x.y, v3.68.1, v3.65.1, v3.54.4, v3.48.0, v2.10.x
Manufacturer:	**Knoware sa/nv**
	Rue Boulvint 54
	1400 Nivelles - Belgium
Swiss Authorized Representative (CH-REP):	**Medidee Services sa**
	Chemin de Rovéréaz 5
	1012 Lausanne – Switzerland
Reference:	CCR-IFU-01

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Document Description

Title:	ComeoCare Instructions for Use
Sub-Title:	ComeoCare User Guide
Author(s):	Frederic Costenoble
Reviser(s):	Jean Auquier, Olivier Vanekem, Sidney Barclay, Laurent Taymans
Date:	08/11/2022

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
1.2	24/08/2022	Added Swiss Authorized Representative (CH-REP); Copyright; Typos fixed; Rename tariffication; Added precaution about patient monitoring
1.3	12/10/2022 – 08/11/2022	Replace "should" by "must" and "shall" where applicable; Add cloud center Internet dependance in precautions; Clarify regimen validation; Include supported codes for scanning; add user profile, user environment, indications, contra-indications, and side effects; support of v4.1 version

Table of Contents

1 Introduction

1.1 Purpose

This document aims at guiding the users in the use of the ComeoCare application. It delivers important notices, 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 [REL4] **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 [REL5] **ComeoCare – User Manual – Prescription** document presents the prescription module. It's a mandatory reading for any prescriber making use of the application;
- The [REL6] **ComeoCare – User Manual – Compounding** document presents the compounding module. It's a mandatory reading for any pharmacist making use of the application;
- The [REL7] **ComeoCare – User Manual – Administration** document presents the administration module. It's a mandatory reading for any nurse making use of the application;
- The [REL8] **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 [REL9] **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 - Installation Manual** describes the minimum IT requirements for the Data Center edition and initial installation procedures for the ComeoCare system;
- The [REL2] **ComeoCare - Operations Manual** provides guidance to ensure the ComeoCare operating environment performs correctly, safely and efficiently;

- The [REL3] **ComeoCare - Integration Manual** explains the general integration architecture and the configuration of the available integrations.

The [REL1], [REL2], [REL3] and [REL9] document are a mandatory reading for the Hospital Information Technology team in charge of ComeoCare.

This is illustrated on the next diagram:

For any person in charge of- or using the application

Instructions for Use   User Manual - Introduction

For prescribers   *For pharmacists and technical staff*

User Manual - Prescription   User Manual - Configuration

For pharmacists   *For technical staff*

User Manual - Compounding   Installation Manual

User Manual - Stock & Invoicing   Operations Manual

                                   Integrations Manual

For nursing

User Manual - Administration

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 document is distributed electronically ("eIfU") and is accessible through the link in the "About" window of the application.

Users requiring a paper copy can submit a request to:

E-mail:	servicedesk@comeocare.com

1.6 Authorized Representatives and Support

The authorized representative for the different regions in which ComeoCare is distributed is mentioned in the table below.

Functional and Technical support is available for the ComeoCare application from the ComeoCare Service Desk. The contact information for this Service Desk in the different regions is also mentioned in this table.

Region	Authorized Representative	Service Desk
EU	Knoware sa/nv Rue Boulvint 54 1400 Nivelles – Belgium (Manufacturer)	Online: https://support.comeocare.com E-mail: servicedesk@comeocare.com
CH	Medidee Services sa Chemin de Rovéréaz 5 1012 Lausanne - Switzerland	Online: https://support.comeocare.com E-mail: servicedesk@comeocare.com

Please refer to section 5 to find out more on how to contact and use the service desk.

1.7 Related documents

ID	Reference	Description
REL1	CCR-ISM	ComeoCare - Installation Manual
REL2	CCR-OPM	ComeoCare - Operations Manual
REL3	CCR-ITM	ComeoCare - Integration Manual
REL4	CCR-USM-01	ComeoCare - User Manual - Introduction
REL5	CCR-USM-02	ComeoCare - User Manual - Prescription
REL6	CCR-USM-03	ComeoCare - User Manual - Compounding
REL7	CCR-USM-04	ComeoCare - User Manual - Administration
REL8	CCR-USM-05	ComeoCare - User Manual – Stock & Invoicing Management
REL9	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 Active Directory (Azure AD) is a cloud-based identity and access management service. Applications can outsource the authentication to Azure AD 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.

2 ComeoCare 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.

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 [REL4-8] 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.

Persons in charge of performing the ComeoCare configuration, including authorization management, must follow a ComeoCare configuration training and read the [REL9] ComeoCare - User Manual – Configuration document, before configuring ComeoCare.

2.5 Target population

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

2.6 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.

2.6.1 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.
- Four eyes principle control is available in ComeoCare 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 administration 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 four-eye principle before it can be used again for treatments.

The products and regimens management modules are further described in the [REL4] ComeoCare - User Manual – Introduction user guide.

2.6.2 Treatment management workflows

Applicability notes:
- The availability of some patient safety controls is varying per version; check the user manual of your version for details.
- Step by step compounding is available in ComeoCare v3.68 and higher;
- The optional ComeoBox module for enhanced compounding control is available in ComeoCare v3.68.x and higher;
- Barcode scanning is available in ComeoCare v3.54 and higher.

Based on the hospital thesaurus, 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, based on the diagnosis, the physician selects the right regimen or treatment plan for the patient, causing that 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 and signed electronically by the physician, the product preparation or delivery can be ordered.

The prescription module is further described in the [REL5] 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 pharmacological validation, 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 Datamatrix 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 optional ComeoBox module allows to connect hardware devices to ComeoCare to control the compounding process through photographic and gravimetric validation steps, enabling extra machine validations. 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 four eyes compounding validation.

The compounding module is further described in the [REL6] 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 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 [REL7] ComeoCare - User Manual – Administration user guide.

2.7 Applications that can be used together with ComeoCare

Applicability notes:

- User authentication through AD is available for the Data Center edition in ComeoCare v3.46.x and higher.
- User authentication through Open ID with Azure AD is available for the Cloud edition in ComeoCare v4.0.x and higher.
- Patient information import is available in ComeoCare v3.46 and higher;
- Patient visit management is available in ComeoCare v4.0.x and higher;
- Electronic Patient Records integration is available in ComeoCare v3.71 and higher;
- Laboratory results import is available in ComeoCare v3.70 and higher;
- **[BE]** Electronic prescription Recip-e export is available in ComeoCare v4.0.x and higher;
- Smart cabinets control is available in ComeoCare v4.0.x and higher;

ComeoCare allows the hospital to set up integrations with other software systems running in the hospital, to enhance the information available and to integrate the performed activities in the complete hospital flow.

The sections below are giving a quick overview of the main integration possibilities.

2.7.1 User authentication

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 completely outsource the user authentication to Azure AD, so that even the login page is handled and configured by the hospital.

Read more on how to set the authentication mode in the [REL1] ComeoCare - Installation Manual.

2.7.2 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 [REL3] ComeoCare - Integration Manual.

2.7.3 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. For a more detailed technical view on how to integrate an application with ComeoCare, please refer to the [REL3] ComeoCare - Integration Manual document.

Integration	Application	Description
Incoming information		
ADT Patient and Visit information	Hospital Information System (HIS) or Electronic Patient Record (EPR)	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.
ART Article and Product Information	Pharmacy Management	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 channel for invoicing.
LAB Laboratory Results	Laboratory Information System (LIS)	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 automatically (re)calculate the doses for the patient.
Outgoing information		
BCP Business Continuity Plan	Business Continuity Plan	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.
HDT Hospital Data	[BE] Nurse Action Reporting System or Government eHealth platform	[BE] 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.

RCP Recip-e	**[BE]** Government eHealth platform	**[BE]** 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.
SCA Smart Cabinets	Smart Medication Cabinets	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.
SIG Electronic Signature	**[BE]** Electronic signature	**[BE]** Electronic prescription timestamping can be obtained from the Belgian Governmental eHealth platform to freeze prescription content and achieve nonrepudiation.
TAR Stock Management and Invoicing	Pharmacy Management System	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.
TRA Treatment Analytics	**[BE]** Walloon Health Network	**[BE]** 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.
TRD Structured Treatment Information	Hospital Information System (HIS) or Electronic Patient Record (EPR)	ComeoCare sends treatment information in a structured message to another application. This data can then be read, interpreted, and used as required.

TRH Structured Treatment History	Hospital Information System (HIS) or Electronic Patient Record (EPR)	ComeoCare sends digitized reports of previous treatments to another application. These reports can then be added to the medical record of the patient.
TRR Digitalized Treatment Report	Hospital Information System (HIS) or Electronic Patient Record (EPR)	ComeoCare sends digitized treatment reports to another application. These reports can then be added to the medical record of the patient.

2.8   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 [REL9] ComeoCare - User Manual – Configuration user guide.

3   Important Notices

3.1   Contra-Indications

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:
- Active Directory integration is available in ComeoCare v3.46.x and higher.
- OpenID integration with Azure AD is available in ComeoCare v4.0.x and higher.

ComeoCare supports different authentication methods, integration with Active Directory or Azure AD 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 AD, 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 what 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   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.

3.3.5   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 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.

3.3.6 Compounding control

Warnings regarding the general ComeoBox setup in the Compounding area:

- 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.
  - o Non-approved power supplies may cause electric shock. Serious injury or death may occur.
  - o Non-approved power supplies may cause fire and burns.
- 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.

Warnings related to the camera and mounted lens:

- 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 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, configured, maintained, operated, and used in accordance with the complete Instruction set, containing this document and the [REL1] to [REL9] 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   Network availability

> **Applicability notes**:
> - The optional ComeoBox module for enhanced compounding control is available in ComeoCare v3.68.x 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 DataCenter 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.

3.4.2   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.

If the hospital uses the ComeoBox module, it must be included in the Disaster Recovery Plan and its continuity must be guaranteed by including it in the hospital's Business Continuity Plan.

3.4.3   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.

3.4.4   Verified integration

> **Applicability notes**:
> - The integrations mentioned in this section are available in ComeoCare v3.48.x and higher.

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

In case of an incomplete or incorrect integration of ComeoCare in the hospital's application landscape, it is possible that a software failure could arise and cause a harmful situation potentially impacting the patient health.

Examples of such situations could be the following ones, but are not limited to these:

Integration	Description	Hazardous situation
LAB	Laboratory Result	Laboratory results are not propagated correctly because of a software failure, causing the user to base decisions on wrong information.
TRR TRD	Treatment Report Treatment Data	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.
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.

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.

3.4.5 Patient identification

Applicability notes:
- Bedside scanning is available in ComeoCare v3.54.x and higher.

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.

3.4.6   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.

3.4.7   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.

3.4.8   Compounding control

Applicability notes:
- The optional ComeoBox module for enhanced compounding control is available in ComeoCare v3.68.x and higher;

Special precautions must be taken when using the ComeoBox module to connect hardware devices for enhanced compounding control.

Precautions regarding the general ComeoBox setup in the Compounding area:
- Physical access to the Compounding area must be restricted to authorized hospital staff
- 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.

Precautions to be taken related to the communication box:
- 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.
- Carefully respect the box and device usage instructions mentioned in the [REL2] ComeoBox – Quick Guide.

Precautions to be taken related to camera usage:
- Do not place the lens under direct sunlight. This may cause fire.
- 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.

4 User Device Technical requirements

Applicability notes:
- Patient and Product scanning is available in ComeoCare v3.54.x and higher.
- The optional ComeoBox module for enhanced compounding control is available in ComeoCare v3.68.x and higher;
- Photographic validation is available in ComeoCare v3.68.x and higher.
- Responsive web and screen size adaptability is available in ComeoCare v3.x and higher.

4.1 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.

4.2   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.

Applicability notes:
- CytoWeb v2.10 supports the browsers mentioned in the next table:

Browser	Supported versions
Microsoft Internet Explorer	8, 9, 10 and 11

Applicability notes:
- ComeoCare v3.0x and higher supports the browsers mentioned in the next table:

Browser	Minimum Version	"multipart/x-mixed-replace" support
Microsoft Internet Explorer	11	No
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 Service Desk Requests

5.1 Service Desk Access

ComeoCare provides an online portal to the hospital to submit all ComeoCare related requests.

The hospital requests must be centralized in the hospital first and handled by several dedicated SPOC (single point of contact). This role is typically played by:
- Application Responsible within the hospital;
- Technical Responsible of the ComeoCare installation in the hospital;
- Functional representative of each role.

By doing this, known internal technical issues and recurring functional requests are addressed in the hospital first and answered or solved quickly. This way of working also bundles similar requests which makes the follow-up much easier, both for the hospital and for the ComeoCare service desk.
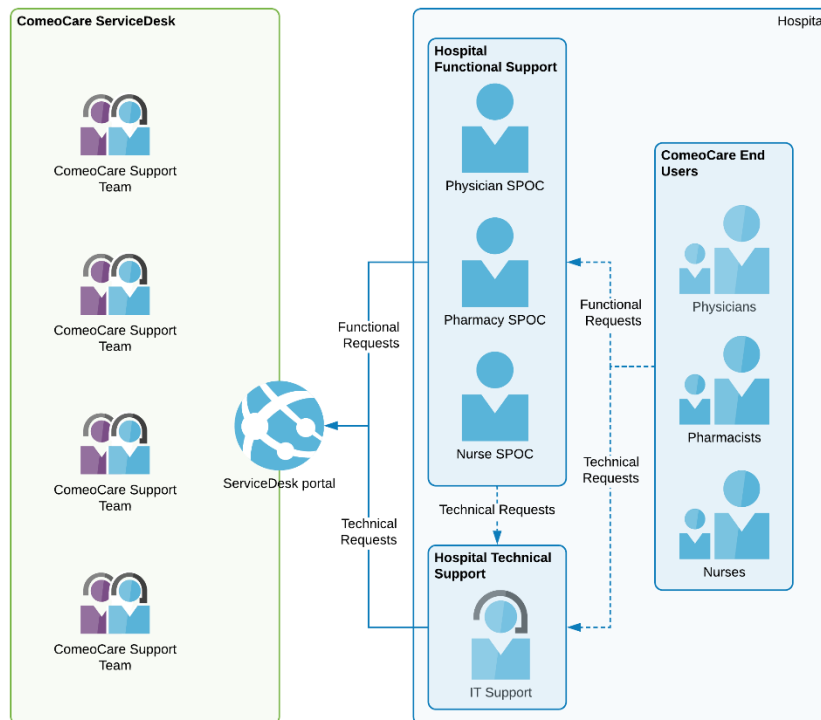
The details of all the SPOCs must be sent to servicedesk@comeocare.com :
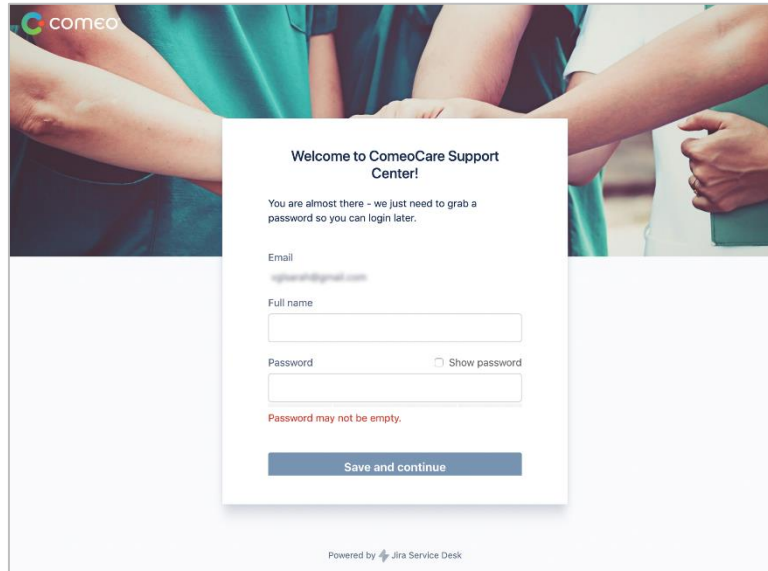
- Last name;
- First name;
- Email address.

Each SPOC will receive an individual invitation email to create their own account with which (s)he can access the ComeoCare Service Desk portal.
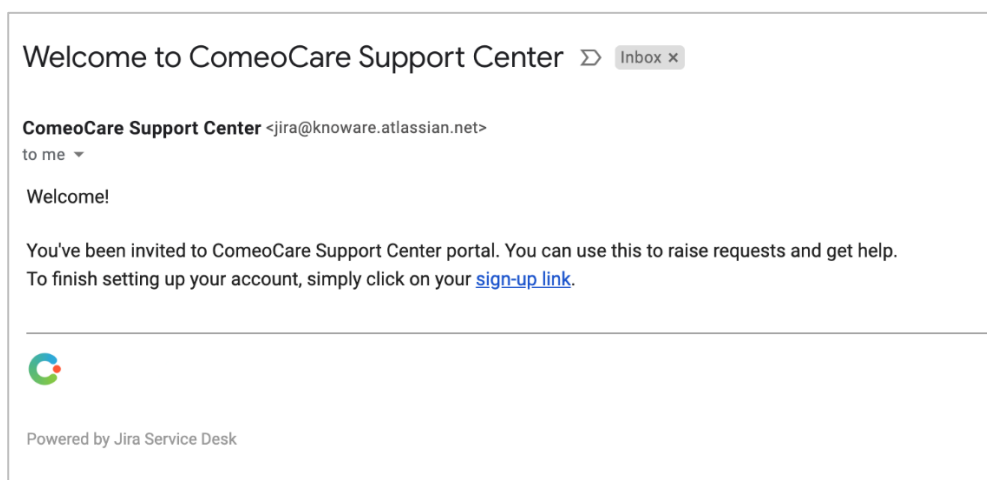
By clicking on the link in the mail, the SPOC will be redirected to a page to create the Service Desk account.

5.2   Home screen

The Service Desk can be reached at https://support.comeocare.com. By clicking on the Comeo logo in the left-hand upper corner the user is navigated to this home screen.
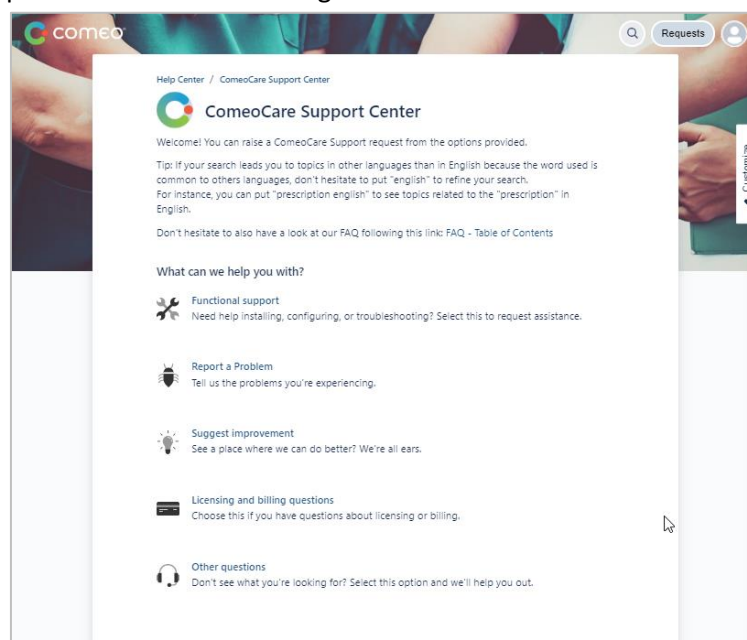
Possible actions:

- Search the available help articles by keyword - click on the magnifying glass;

- Browse all requests entered personally or all requests of the organization – click on the "Requests" button;
- Access the user profile to change the parameters or log off - click on the person icon (can be replaced by the user's initials);
- Create a new request – click on of the topics in the list.

5.3 Browse help articles

The browse screen appears when clicking on the magnifying glass icon in the home screen:
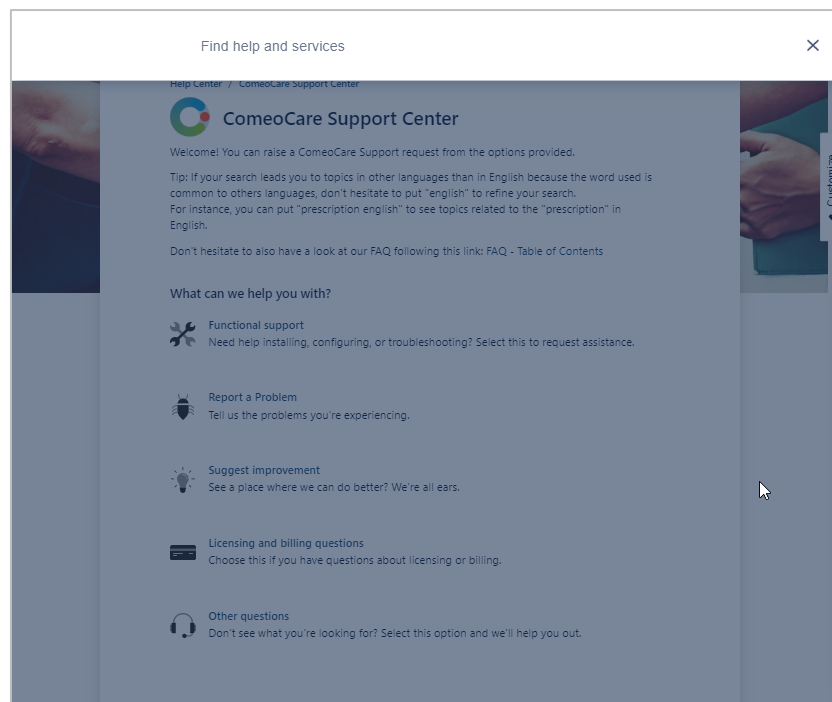
By entering one or more keywords in the displayed field, the results as displayed while typing:
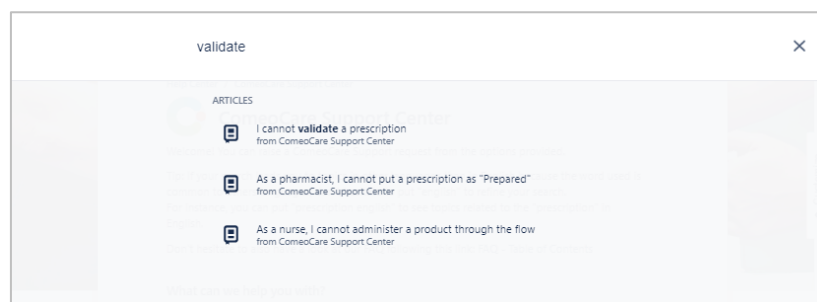
The article is displayed by clicking on the title:
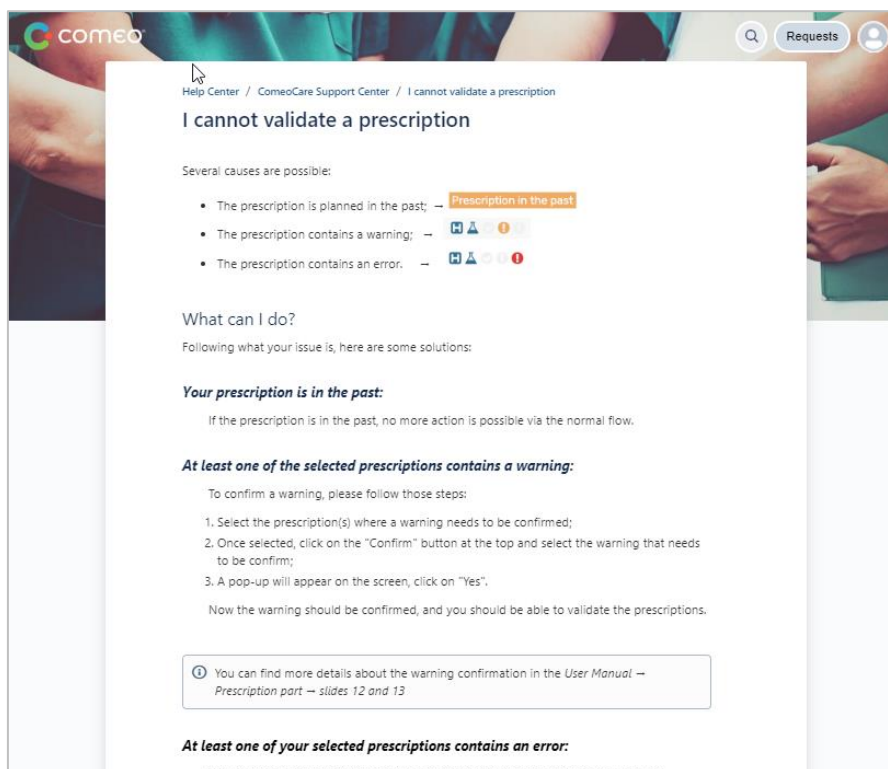
Note: a link to the table of contents can be found at the bottom of each article. This table of contents lists all available articles. This Table of Content link is also available on the home screen.

5.4   Enter a request

If the solution to the problem or question is not found in the available articles, a new request can be entered by clicking on the right category in the home screen.

A new window will be opened where all the information of the request can be entered. A print screen can be attached to clarify the request. All available information must be entered, including but not limited to:

- The user who raised the request.
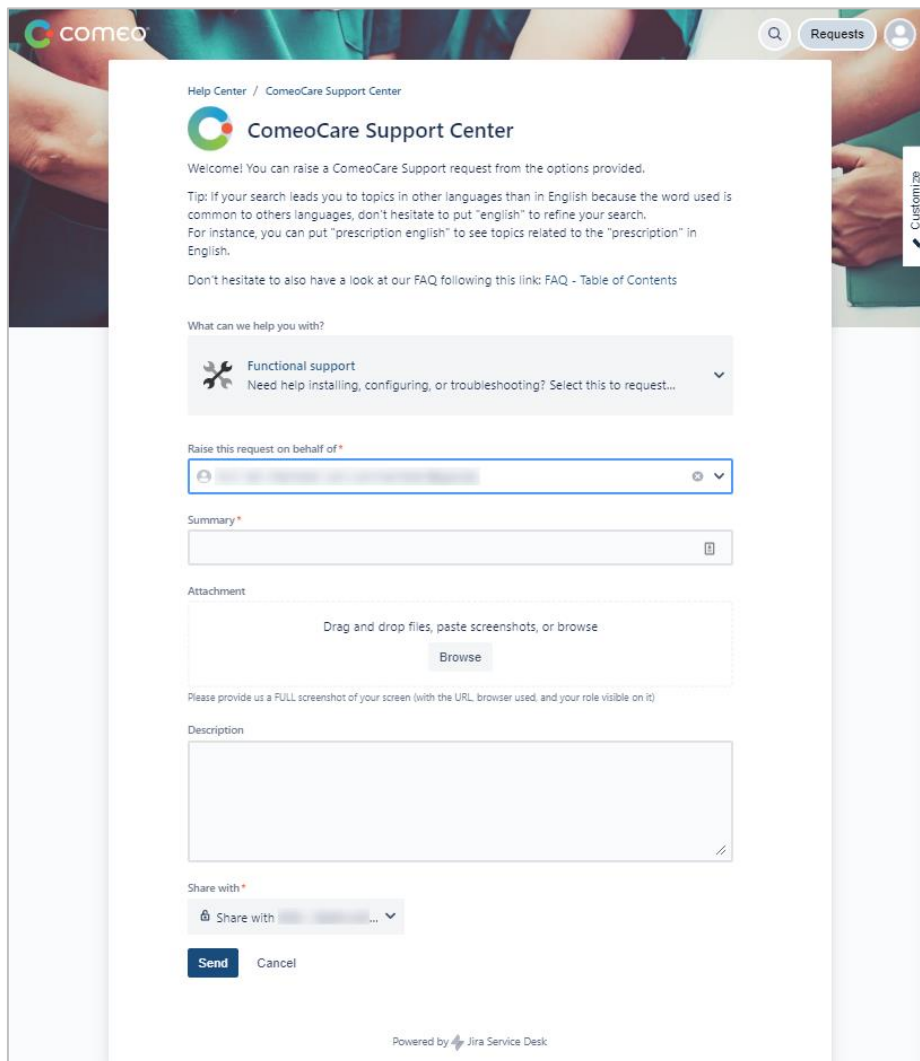
In case of bug reports, this information must be also added:

- The date and time of the problem;
- The impacted treatment;
- The flow that was used;
- A print screen of the complete screen, including the address bar, username and date and time at the bottom right of the screen.

Notice that the Service Desk proposes a list of existing articles while typing. Based on the title the Service Desk tries to find a related article which might already help with the request.

The request must always be shared with the complete organization, so other stakeholders can follow the lifecycle of the request.

5.5 Request follow-up

Clicking the Request button on the home screen brings up the Request Follow up screen. The top of this page displays the different filter possibilities:

- Request Status;
- Request Creator;
- Request type.
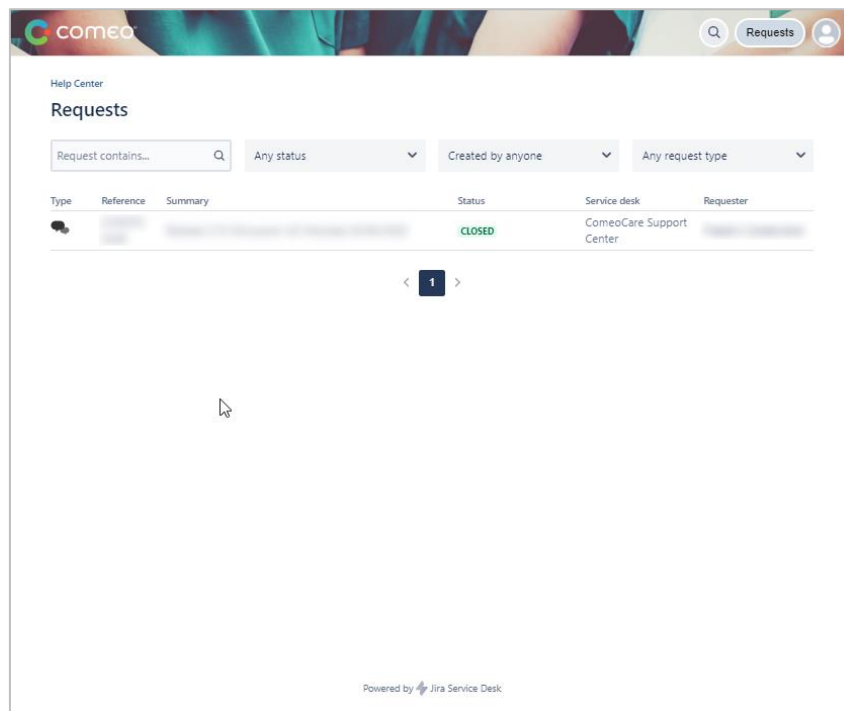
Clicking on a request brings up the Request Detail window, where the status of the request can be followed. Further communication with the ComeoCare Service Desk members is also possible by adding a comment. All information about the request is available centrally to be followed up by the organization.

On the menu on the right the request can also be cancelled or marked as solved if in the meanwhile the organization has found the solution, or if the problem does not occur anymore.

The request can be shared with other members of this organization – if this was forgotten during the request creation - by clicking the plus icon or the Share link. These people can then also intervene in this request by adding their comment.
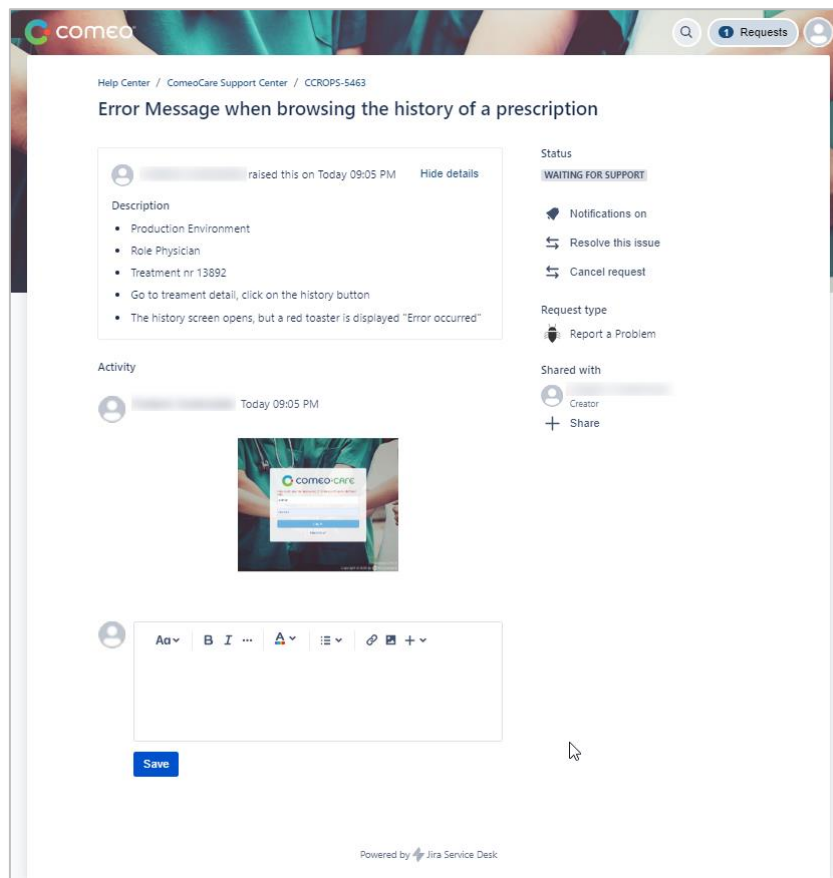
The Status label indicates in which state the request is currently. This allows to follow up on the progression of the request. A notification will be sent every time a status of one of the requests changes. In all cases, a comment will be added to the request to explain more about the status change. The next table contains the possible status values.

Status	Description
Waiting for Support	The request is waiting to be picked up by the ComeoCare Service Desk.
In Progress	The Service Desk is handling the request
Canceled	The request was canceled. The reason is mentioned in the comment.
Resolved	The request/problem was solved.
Closed	The request is closed.