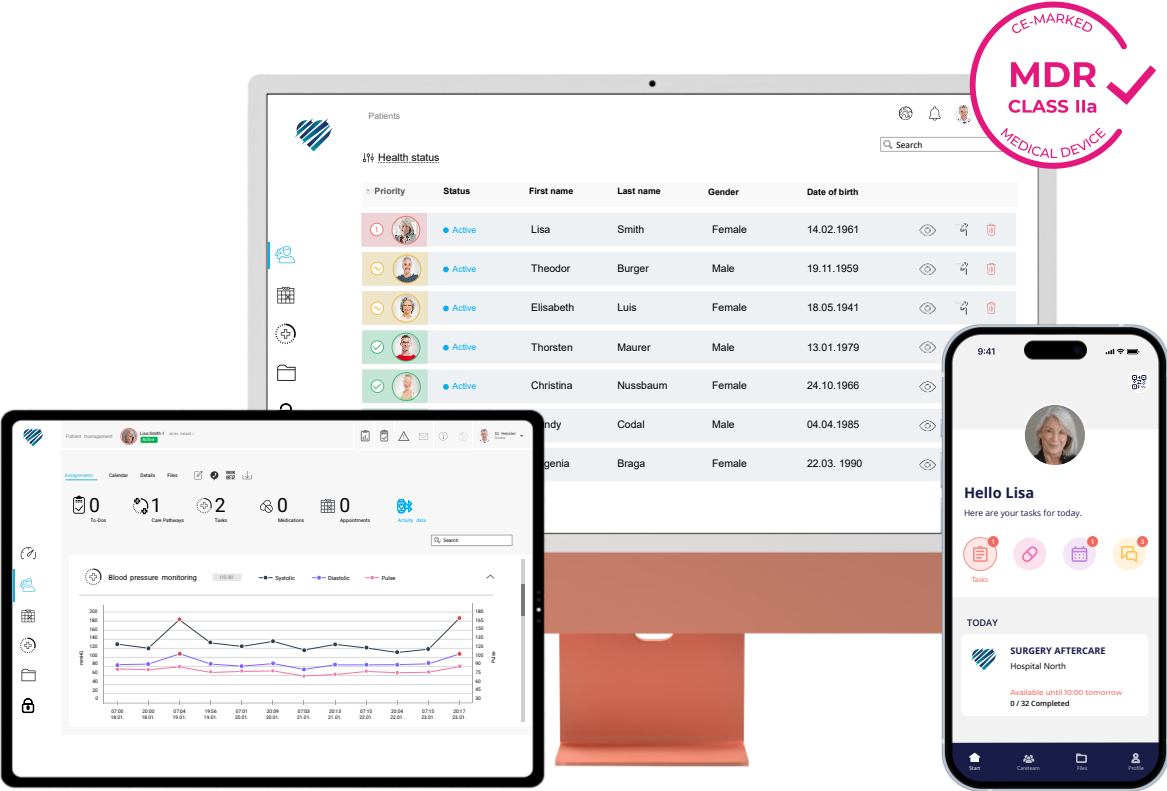


THE DIGITAL HEALTH PLATFORM



SW User Guide - myoncare v.1.11

- **Device name/ trade name:** myoncare
- **Version:** 1.11 and upcoming third- and fourth-digit releases
- **FDA code:** Medical device data system. The FDA has recommended enforcement discretion for this device.
- **IFU Release date:** 2024-10-29



CE 0123

Rx only



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If you require a printed version of the instructions for use, please contact us via email at service@myoncare.com. You will receive it within 7 working days.

In case information required to resolve specific questions cannot be obtained within this guide, or if questions or problems exceed the contents of this guide or you have any feedback/ suggestion to improve this guide please contact ONCARE support at:

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Ticketing System:



Regarding data privacy related topics, please contact the following ONCARE support:

E-mail: privacy@myoncare.com

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1. General Information

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Copyright

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Patent information

This product may be covered by one or more patents or pending patent applications.

Disclaimer

myoncare is NOT intended to be used for medical emergencies. We, as a service provider, assume no liability for transmitted or stored third party information or the consequences arising from it. ONCARE GmbH neither owns, nor originates the data points and content which is created by healthcare professionals, patient journeys or other activities relating to myoncare. ONCARE does neither own the created content, nor assume liability for the creation or use of standardized questionnaires or treatment plans which are copyrighted. This holds especially true for standardized questionnaires for ANY medical indication and further content which might be similar or identical to any existing and copyrighted content. No copyright claims apply.

This device is not available for commercial distribution in all markets. Contact sales@myoncare.com for further information on the availability for specific countries.

Expected lifetime

ONCARE provides no fixed-term lifetime for myoncare. Its support will automatically be discontinued following a significant change (second-digit change). During this period, updates, as well as support, are offered (if not automatically included via subscription). Any second-digit change might affect the compatibility to mobile Operating System (OS) versions. Customers will be informed of any changes to the compatibility before these become effective. ONCARE does not support rollback (i.e. reverting to a previous version) of myoncare.







Sales configuration of the product








The basic configuration for myoncare Careplan Manager as a medical device will require healthcare professionals to always acquire the module BASIC (which contains Patients, including sub-services such as Medication and Sensor data, Careplans, Administration, Appointments and Asset Management). Given that Careplan Manager will generate and collect data points to and from Mobile services, patients can either download the PatientApp from the AppStores or access the PWA (Progressive Web App). The same configuration can be used as a non-medical variant of the product or for underage patients when disabling threshold management and health calculation. Further optional modules or services, such as an HL7 interface and Telemedicine, can be added, but are not mandatory.

Variants of the product

This product is available as a medical device but can also be made available in a non-medical variant (which does not allow users to set thresholds or use the health indicator functionality).

2. Symbols

	Warnings		Lot number
	Precautions		Version number
	Information		Consult instructions for use or consult electronic instructions for use

	Manufacturer		Swiss Authorized Representative
	Country of manufacture The date of manufacture may be added adjacent to this symbol.		CE mark – Indicates that the medical device is CE marked
	Unique Device Identifier		Caution: Federal law restricts this device to sale by or on the order of a physician
	Medical Device		

3. Device Description

myoncare is the brand name for a Platform-as-a-Service (PaaS) software application, which consists of several mandatory as well as some optional modules. Every module fulfills a distinct purpose within the software framework, which will be briefly described in the list below. myoncare is designed for clinical practice and follow-up care of patients as indicated in subsequent chapters. The interface enhances the patient-healthcare professional interaction as well as the remote monitoring of patients by facilitating the distribution of content created by medical professionals to their patients. Thereby it supports to track a patient's health condition in their care journey and enabling early intervention or therapy adjustment.

NOTE: throughout this document, the term 'myoncare' is used to refer to both Careplan Manager (WebApp) and Mobile (PatientApp and Progressive Web App). When specifically referring to Careplan Manager, it will be mentioned 'myoncare Careplan Manager' or 'myoncare WebApp' and when referring to 'Mobile' (either PatientApp or PWA), it will be mentioned as 'myoncare PatientApp' or 'myoncare PWA' respectively.

Patients

Provides an overview of all registered patients of the specific site the user is logged into. The list of patients will be sorted by default pending on the health indicator but can also be sorted and filtered according to the selected sorting options and filters. Furthermore, it allows to show detailed patient data, including the assigned Care Pathways, Caretasks, files, activity data and responses when selecting an individual patient. Healthcare professionals (HCP's) can also initiate medication reminders and appointment requests for patients. Also, myoncare Careplan Manager facilitates interaction with patients via chat or video call. Additionally, the system allows healthcare professionals to compare a patient's scores with other scores or activity data over time, visualized through a graph view, enabling a more comprehensive analysis of the patient's progress within a specific timeframe.

Care Manager

- Serves as the central hub for creating and assigning content in form of Care Pathways, Caretasks and the respective components (i. e. questionnaires) or their corresponding templates.
- Enhances monitoring and traceability of answers by allowing customized reminders and export (or sharing) of components and Caretask templates or similar.
- Enables healthcare professionals to set threshold notifications for patient answers, which consequently results in notifications displayed in the WebApp (= browser-based healthcare professional interface).

Administration

Enables the healthcare professionals to add, edit, activate and deactivate myoncare Careplan Manager users, adjust sites, customize filters.

On the start page of this module, the healthcare professionals will see an overview of currently enrolled healthcare professionals with their mandatory data displayed as well as the list of created sites, satellites, custom filters, and roles (= permission sets of healthcare professionals). These are listed in different tabs on the top of the page. Within every tab (healthcare professional, site, custom filters, Satellites and roles), the healthcare professional has the possibility to search via the search bar displayed within the screens.

Note: Not all healthcare professionals will have access to the administration page. Furthermore, depending on the healthcare professionals' site permission set, specific tabs may not be available.

By clicking the action button within the administration page, the healthcare professional can add a healthcare professional, a site, a custom filter or define a role within the system. Within the following sections, the different options will be elaborated in more detail.

Users

Within the tab "Users" all HCPs of the respective site or installation (limitation depends on the permission set of the healthcare professional) will be listed. This view allows the User (Site Admin for example) to edit, view, activate or deactivate the HCPs. The list can be sorted by First name, Last name, Username and Email address. Furthermore, it displays the role of all users (e.g. HCPs) as well as the site they are in.

Adding or editing a healthcare professional

After opening the action menu by clicking the "+"-button, the healthcare professional has the possibility to add a healthcare professional by clicking on the respective symbol. This opens a mask, which must be filled out by the administrator. Besides the mandatory information, a password for the corresponding healthcare professional needs to be set. A "(De-)activate" toggle button on the far right of the overview page will allow administrators to (de-) activate healthcare professionals.

After initially setting up the healthcare professional, it can still be edited. Therefore, the displayed edit button within the healthcare professional list will lead to the healthcare professional's profile mask to edit the credentials or other information.

Adding or editing a site

Selecting "Add Site" from the action menu will trigger a mask with a couple of mandatory fields and the option to upload a site logo (optimal scaling at 40x40). A "(De-)activate" toggle button on the far right of the overview page will allow to (de-)activate sites. Sites can only be edited and (de-)activated by admins.

After initially setting up the site, the healthcare professional can still edit the site by clicking on the "edit"-symbol within the site list. A similar mask as within the creation of the site will be displayed and editable.

Adding a privacy policy

The healthcare professional has the possibility to upload a privacy policy within the add or edit site modal. The uploaded privacy policy will be shown to every patient who connects to the site via a personalized QR-Code generated from the patient overview or via the self-triggered registration workflow of the patient by scanning a QR-Code of a Care Pathway or Caretask. Furthermore, already connected patients will be informed about a privacy policy update.

Additionally, within the add or edit modal, the healthcare professional can define further texts the patient is required to consent to. Keep in mind that all the consent claims need to be defined within your uploaded privacy policy file since it is only possible to upload one file.

Once a privacy policy has been uploaded, the healthcare professional cannot detach the privacy policy without uploading a replacement. This shall ensure that a privacy policy is in place. Note: In case you uploaded a privacy by mistake and want to correct your mistake, please contact service@myoncare.com.

Note: In case you want to update or add one or more consent texts, you are required to upload a new privacy policy file. This is to ensure that the already existing consented privacy policy and its consents are appropriately documented within the patient files.

Once the healthcare professional uploaded a privacy policy, this document is also visible within the files section of the myoncare Careplan Manager.

To allow the healthcare professional to trace back if a patient consented to a privacy policy, the referenced file will be stored within the specific patient files. Within the patient overview underneath the section files, the healthcare professional can view which privacy policy the healthcare professional consented to. By clicking on the "view"-icon of the respective privacy policy file, the healthcare professional can review the time the patient consented to or revoked the privacy policy. Furthermore, all consents are shown within the view modal.

The patient is required to consent to all the defined texts. Otherwise, the patient cannot connect to your site. In case he revokes one of the consents, the patient will be logged out from your site.

Note: The patient can easily connect to your site again by scanning a personalized QR-Code or a QR-Code of a Caretask or Care Pathway – keep in mind that the Care-element will then be assigned again to the patient.

myoncare Careplan Manager does not review or check the privacy policy uploaded, nor the texts being defined within that modal and is therefore not liable for the document and its consents. To ensure legal coverage please consider contacting your site's Data Protection Officer.

Satellite

The Satellite streamlines the process of integrating "external healthcare professionals" (HCPs) into the myoncare Careplan Manager. Satellites can be mapped exclusively to users holding the "External HCP" role. Consequently,

patient information becomes accessible only to these specific external HCPs when the QR code associated with their Satellite is scanned by patients.

It is the responsibility of the customer to ensure that their terms and conditions and privacy policy are allowing to have “external HCP’s” within their site and if necessary, the customer must establish any required site contracts between their organization and external healthcare professionals (HCPs).

Selecting “Add Satellite” from the action menu will trigger a mask with a couple of mandatory fields. A “(De)activate” toggle button on the far right of the overview page will allow to (de)activate Satellite. Importantly, a Satellite can only be deactivated if there are no users mapped to it.

Files








Provides the healthcare professional the possibility to upload and download files such as documents, images, videos, and audios from / to myoncare Careplan Manager. The uploaded files can be shared to patients via chat or Caretasks.





Clicking on the “file”-symbol on the left side of the myoncare Careplan Manager, the healthcare professional will be directed to a file-module of myoncare.

The four categories (Documents, Images, Videos, Audios and Privacy Policies) provide the healthcare professional with an overview of his / her files by automatically grouping them in the defined categories. The supported data types and how they will be grouped can be taken from the table below.

Document types	Image types	Video types	Audio types	Privacy Policy
PDF	JPEG / JPG	MP4	WAV	PDF
	PNG	MOV	MP3	
	GIF	M4V	MP4	
	BMP			

Buttons and Symbols within files

	<p>Upload-button: redirects the healthcare professional to an explorer view which enables the healthcare professional to upload files to myoncare Careplan Manager file management module.</p> <p>Every upload will be checked for malicious content. A flash message at the top of the screen will inform the healthcare professional regarding the status of the update. Note: The maximum file size is 30 Mb. The maximum number of files being uploaded simultaneously is three (3).</p>
	<p>Share-button: within the files overview it is possible to share files with other institutions or sites the healthcare professional's site is connected to. To share files the healthcare professional needs to select files by clicking the checkboxes on the left side of the documents and click the “Share”-button. Note: The “Share”-button is just clickable in case the healthcare professional selected at least one file.</p>
	A file is selected.
	A file is not selected.
	<p>Search functionality: the search bar in the file management module provides the healthcare professional with search functionality within the respective data category. By searching for files, the matching files within the selected category will be displayed.</p>
	<p>Retry-button: the “Retry”-button will be shown within the tile of the respective file in case a file could not be uploaded due to an unstable internet connection, technical error or similar. By clicking this button, the healthcare professional is repeating his previously triggered action.</p>
	<p>Action in progress: to inform the healthcare professional that the current action is still progressing three dots will appear on the respective files until the action of uploading / editing or deletion is completed.</p>

Symbols to trigger actions	
	Download: download of the respective document to your computer / tablet.
	Preview-symbol: will open a file preview. Within the file preview, the healthcare professional can review the properties of the file as well as where the file is attached to or shared with.
	Edit symbol: opens a pop-up which enables the healthcare professional to edit the name, description as well as for whom this file is available. Furthermore, the healthcare professional can also preview the file or open it within the browser.
	<p>Delete-symbol: provides the healthcare professional with the possibility to delete a file from the file management module. Note: If a file is attached to a Caretask or shared with a patient, this file cannot be deleted. To delete it, the healthcare professional must delete or detach it within the respective Caretasks or patient views first. This prevents deleting files by mistake.</p> <p>Note: Uploaded Privacy Policies cannot be deleted within the myoncare Careplan Manager.</p>

Attach and detach files to / from Caretasks & Assessments

To attach a file to a Caretask or an Assessment, the healthcare professional needs to open the respective Caretask and select a component to which a file needs to be attached. Within the component settings for the respective component, the healthcare professional can select a file from the file management. If attached, it can also be easily removed via clicking the “-”-symbol next to the file attached to the component.

Sharing files with patients

Files can also be shared with patients. For this purpose, the healthcare professional needs to open the respective patient and share the file via the chat section. Within the chat view, the healthcare professional can choose between sharing files from the general file management module of myoncare Careplan Manager or directly uploading a file to the patient from the computer / tablet.

Another option is to define within a Caretask that the attached files shall be permanently available to the patient. This can be done by enabling the toggle button for “Allow patient to review files after conducting the Caretask” within the Caretask settings. After conducting the Caretask, the files will be available for the patients conducting the Caretask.

All files which have been shared between the healthcare professional and the patient will be displayed within the tab “Files” of the respective patient overview. Within this view the files can be previewed, edited, downloaded, removed, or deleted by using the symbols on the right side of the file tiles as described above.

Appointments

Provides an overview of scheduled appointments for the site of the Careplan Manager users.

Clicking on appointments will direct the healthcare professional to an overall calendar overview of the site with all the patient’s appointments.

On the left side of the screen, the healthcare professional has the possibility to filter the appointments by their types. Furthermore, the healthcare professional has also the possibility to apply a filter to review all appointments for specific peer groups. Therefore, the healthcare professional needs to click on the filter symbol on top of the calendar and select a specific filter group.

By hovering the mouse over an appointment, more details of the appointments will be displayed such as patient, Patient-IDs, specific time and address.

By clicking the action button, the healthcare professional can schedule a meeting with a patient. To adjust the appointment, the healthcare professional needs to edit the appointment within the respective patient.

Healthcare professionals can select from various appointment types including attending, consultation, discharge, follow-up, test, transportation, treatment, surgery date, video call, and others.

Importantly, for appointments categorized as video calls, an email containing the video call link is automatically sent to both the healthcare professional and the patient. In cases where an appointment is deactivated or directly deleted, a cancellation email is dispatched. Similarly, updating an appointment triggers an email notification for rescheduling, keeping all parties informed of any changes.

HL7 interface

Connects to the Hospital Information System (HIS). ONLY activated upon the institution's request. An HL7 interface is initialized on a data protocol level, there is no visible user interface.

Report Service

The report service is an optional module for remote report generation and storage. This module operates discreetly in the background, without a visible user interface, and is not part of the medical device itself. ONLY used upon the customer request.

Broker

Broker will handle all workflows which were dispatched into, or modeled within, the myoncare Careplan Manager and thus serves as a hub for healthcare professional interaction with myoncare.

Mobile (PatientApp and Progressive Web App)

Once assigned and sent to the patient, the corresponding Caretask will be pushed to the patient's device at the defined starting date. If allowed by patients within their preference settings, the patient will be informed about the content via push notification for PatientApp or email for Progressive Web App when the Caretask is starting. If not allowed, the patient will only see new information when opening Mobile, i.e. new Caretasks, messages or appointments. Furthermore, the patient will be asked to switch on the notifications.

3.1. Intended purpose

Careplan Manager: medical software for monitoring and diagnostic support.

The intended purpose of myoncare Careplan Manager non-medical is to facilitate information between healthcare professionals and their patients as well as to exchange and digitalize the communication. It shall provide healthcare professionals with an interface to manage their patients and enable tracking and visualization of their condition.

3.2. Intended user

Careplan Manager: the intended users are healthcare professionals such as doctors and their staff.

Considering the educational qualifications, it can be ensured that the healthcare professionals are trained to perform clinical activities in a clinical setting, which includes using software applications within the scope of patient treatment and familiarity with the use of handheld devices and mobile applications in general.

Further users: Service personnel responsible for installation, maintenance and customer support of myoncare (Careplan Manager and Mobile). IT administrators of clients performing limited IT-related maintenance for myoncare (Careplan Manager and Mobile).

3.3. Intended patient population

The intended patient population of myoncare (Careplan Manager) are adult patients (i.e. age over 18 years), excluding patients affected by the contraindications.

3.4. Place of use

Careplan Manager: clinical setting, i.e. within a clinical building or the building of a practice. Further places of use can be in a non-clinical setting (e.g. for review of available patient data).

Careplan Manager can be used throughout the day by the HCPs given that natural or artificial illumination is provided and through browsers on a workstation or on tablet devices.

3.5. Indications for use

myoncare (Careplan Manager) provides a system for Caretask management which allows the customization of the scoring of Caretask components according to the healthcare professionals requirements within the specifications of the system. The validation and scope of Careplan Manager includes the Caretask management and the scoring system as well as the associated notification system. It is designed to provide flexibility to the intended user in monitoring the health condition of patients by allowing the healthcare professionals to choose the content of Caretasks.

Therefore, the use of Caretasks for various indications which may be distributed over multiple medical specialties, except the ones listed in the contraindications, is possible at the healthcare professional's discretion.

However, the content of these Caretasks is not controlled or validated by Careplan Manager.

3.6. Clinical benefits

myoncare's (Careplan Manager) clinical benefit is the digitalization of follow-up care alongside the possibility to digitally monitor patients for their current condition while enhancing the early detection of complications and adverse events, thereby aiding the therapy monitoring and facilitating recovery.

3.7. Warnings



- myoncare does neither claim nor intend to replace a user's / healthcare professional's experience and expertise, regardless of the use scenario. It solely provides additional assistance to the user in monitoring the health status of patients. All content displayed and modeled within myoncare requires the user to perform a plausibility review prior to initiating further actions, treatments or assessing the medical devices as well as non-medical device's output.
- In case customers intend to collect health data from openly accessible registrations, e.g. by making the registration QR Codes or Deep links publicly available on a website in an anonymous fashion, customers need to proactively ensure that the legal basis for data processing is adequately established. Alternatively, the data shall always remain anonymous. ONCARE will not assume liability in such cases whatsoever.
- NEVER use the health indicator as the sole decision-making criteria for diagnosis and /or therapy. This is also indicated by the following warning in the system: "I am aware that scores and thresholds shall not be used as the sole basis for medical intervention / further medically relevant actions or prioritization of patients."
- Before assigning Care Pathways or Caretasks, all scores, thresholds and jumps should be verified for validity. In addition, at no time should a score lead to the sole basis of an intervention, relevant medical action, or prioritization of individual patients. This is described in the following warning: "I am aware that thresholds and scores shall not be used as the sole basis for medical intervention, further medically relevant actions or prioritization of patients". "I confirm that all thresholds, scores and logic jumps were validated and adequately address the purpose of the Caretask".
- As soon as the healthcare professional adds another component with scoring or adjusts an existing Scoring of a component to an existing Caretask, the overall scoring scheme of the Caretask needs to be reviewed and adjusted.
- It must be ensured that only patients who shall receive this Care Pathway or Caretask per the healthcare professional's intention are selected.
- It must be ensured that the reference type is selected correctly, as all Caretasks of the Care Pathway are defined in fixed relationship with the reference type. Otherwise, the Caretasks will be sent out to patients at a different time.
- If a start or end date is defined, the description of "before" and "after" defines the date in relation to the reference type (e.g., 9:00 o'clock, 3 days before the surgery).
- In case an appointment is rescheduled (but already connected with Care Pathways), the rescheduling scheme presents also potential conflicts with a red outline (e.g., a Caretask is in the past). Ensure that all Care Pathways and their Caretasks are still correct or adjust them accordingly (note: this must be done manually). The following warning will be displayed: "Highlighted Caretasks have a start date in the past and will therefore not be sent out to the patient. To send them to the patient, go to the specific patient and change the start date of the Caretask there". To adjust to a conflict within a Caretask (e.g., a Caretask is in the past), finish the workflow of appointment rescheduling and go to the specific patient, for which the appointment was rescheduled. Go to the specific Caretask and select "Edit assignment" and adjust the start date accordingly.
- In case an appointment and a Care Pathway were already connected (via reference type, and ICD-code), it is not possible to connect the same Care Pathway a second time. The following message is presented: "The Care Pathway '<name of care pathway>' is already active for this patient. You cannot assign a Care Pathway multiple times."
- When scanning a QR-Code or clicking on a Deeplink of a Caretask or Care Pathway, the most recent update of the content will be assigned and sent out to the patient.
- For data security and data privacy reasons, intended users are advised to change the initial password, which has been set as a default by ONCARE, immediately after the first login.
- In case the filter setting is selected so that not all patients are visible, a warning will be displayed: "Patient filter applied!".
- Users and medical professionals are hereby advised to not rely on threshold notifications alone for diagnosis / intervention or any subsequent adjustment in a patient's therapy.
- All template thresholds and scores must be removed in case one or more selected patients being below 18 years old.
- Caretasks and templates, which include thresholds or scores cannot be assigned to patients below the age of 18 years. This will be indicated by a warning on the bottom of the "patient selection" step and the "next" button will consequently be disabled.

- In case customers intend to collect health data via openly accessible registrations, e.g., by making the registration QR Codes or Deeplinks publicly available on a website in an anonymous fashion, customers need to proactively ensure that the legal basis for data processing is adequately established. Alternatively, the data shall always remain anonymous. ONCARE will not assume liability in such cases whatsoever.
- The displayed activity data can be inaccurate or incomplete. Please, consider this within your decision making.
- DO NOT USE myoncare's video call functionality FOR EMERGENCY CALLS or diagnosis. Call quality depends upon network availability and camera quality and might therefore be inadequate to diagnose or assess a patient's health condition.
- The Care Pathway may include Caretasks scheduled before the reference date. In that case a pop-up to make the user aware of reviewing the scheduling of Caretasks as well as the chosen reference date appears.
- In case the user wants to assign a Care Pathway based on an existing appointment of the patient, the user needs to ensure that the patient's appointment is marked with the corresponding reference type as well as ICD-Code. If this has not yet been done, a warning within the assignment process will be displayed mentioning that the patient has no accurate appointment scheduled yet. Therefore, the myoncare WebApp user cannot assign the appointment to the patient.
- By making QR Codes or Deeplinks publicly available on a website, flyers or as a display at clinics in an anonymous fashion, healthcare professionals or clinics shall proactively ensure that the Caretask or Care Pathway is only intended for general support but does not contain content individualized for a single patient. It is not intended to be a substitute for professional medical advice and should not be relied on as health or personal advice, nor intended to diagnose, treat, cure, or prevent any condition or disease. Be aware that the Caretasks could be answered by individuals of the general public, be aware not to create a doctor-patient relationship. Any medical information should be provided as general information only. Public means everyone, not members of a specific group, public does not include a specific doctor-patient relationship. ONCARE assumes no responsibility or liability for omissions or errors that may appear and for any misuse of the QR codes or Deeplinks that are made available publicly, and ONCARE cannot assure the availability of the service at any given time. As the use is at your own risk, you are fully encouraged to use all possible means and precautions to overcome any of the above factors. ONCARE makes no endorsement or guarantee regarding the safety or efficacy and shall be held harmless for any losses or damages that may result from the above-mentioned usage including, but not limited to, economic loss, injury, illness, or death.

3.8. Precautions



- In the event of malfunction of the myoncare Careplan Manager interface, ONCARE recommends healthcare professionals to refresh their browser or – if the malfunction persists – to restart the hardware. Should this not result in myoncare Careplan Manager resuming adequate functionality, healthcare professionals are hereby advised to log the date as well as the errored workflow and forward it to ONCARE support, ideally including a screenshot and a brief description of the malfunction.
- Deactivating a site will automatically render all user logins associated with this site invalid.
- Deleting a role will automatically render all logins associated with this role invalid. Users of this role/permission set will no longer be able to log in.
- Whenever components carry a score, the answers will affect the health indicator value accordingly, unless the box "Categorization via health indicator" remains unchecked / is greyed out.
- The health indicator is always present, but its use is optional. Patients will not see their "health status".
- The "Activate Scoring" feature is greyed out unless the toggle button is actively selected (indicated by turning blue). This means that assigned scores will not automatically be calculated unless this option is selected by the creator. If it remains deactivated, the Caretasks will be excluded from the calculation of the health indicator and do not show a score.
- Deleting a patient will only remove the patient from myoncare. Patient data, as well as the health record stored in the hospital information system (HIS), will still be accessible. Within back-up of the data, the deleted information can still be retrieved. To finally delete all data please contact your site admin.
- Please be aware of the duty to preserve records, if required by law.
- The deletion of patients will also remove the patient's access to the Mobile. Patients can also re-register with a site by scanning a new QR code as described in the invitation workflow.
- Deleting a Care Pathway completely removes it from the myoncare Careplan Manager, i.e., for all users who have access to this site. Deleted objects cannot be restored. The results for previously sent or answered Caretasks are still available in the patient module.
- Please do not enter confidential personal information in the consent texts.

- Working with myoncare Careplan Manager will require healthcare professionals to familiarize themselves with the use of the myoncare Care Manager module.
- Scoring needs to be enabled by activating the toggle button in the right sidebar for every component. The scoring of individual answers needs to be adjusted for each item.
- In case a start date was selected, and a weekly occurrence chosen, for example Mondays, then patients will get the Caretask on the first Monday after the start date for the first time.
- Deleting a component will remove it from the myoncare Careplan Manager entirely, i.e., for all users having access to a site's components. Deleted components cannot be restored.
- Deleting a Caretask template will remove it from the myoncare Careplan Manager entirely, i.e., for all users having access to a site's components. Deleted templates cannot be restored (unless they are re-imported). Results for previously sent or answered templates will still be accessible within the Patients module.
- Once the "Lifespan" begins, patients receive a push notification stating the title of the Caretask they were assigned. After the "Lifespan" has ended, patients can no longer access the Caretask to respond to it.
- Should healthcare professionals choose not to select the option "Send out immediately", the Caretasks will be assigned but still require to be actively sent to patients on the individual patient overview page.
- Thresholds set during the "assignment" workflow will not be saved to the template. These are only valid for the particular assignment cycle.
- A Caretask occurrence can only be displayed to the patient if an internet connection is ensured by the users as well as the patient. To prevent the patient overuses occurrences, we highly recommend an internet connection establishment at least once every 24 hours.
- Do not use video files which were previously converted using a third-party software. These converted video files are not supported by myoncare.
- After the patient is created, either by creating the patient within the myoncare Careplan Manager or by a self-registration process, it is possible to edit the demographic data of the patient. If these changes happen via the myoncare Careplan Manager, the changes are only reflected in the myoncare Careplan Manager and not in Mobile. If, on the other hand, a patient changes these data via Mobile it is reflected in myoncare Careplan Manager as well.
- To ensure optimal performance and provide patients with the best user experience, the number of caretask in a carepathway is limited to 200.
- Healthcare professionals should only choose to answer on behalf of a patient if it is confirmed that the patient is unable to respond independently. Additionally, it is recommended that healthcare professional seek permission from the patient before utilizing this option.

3.9. Contraindications

- myoncare shall not be used for patients whose CNS is affected by any disease or condition which results in them being unfit to use hand-held devices unsupervised due to physical or mental disability. myoncare shall also not be used if any other disease or condition leads to a patient's physical or mental unfitness to use hand-held devices unsupervised.
- myoncare shall not be used as the sole basis for diagnostic or therapeutic decisions by the intended user.
- myoncare is not intended to be used in emergency situations.

3.10. Undesirable side effects

No undesirable side-effects are expected or identified from the use of Careplan Manager. The application of myoncare (Careplan Manager and Mobile) in the clinical routine depends on the clinical content generated by intended users of Careplan Manager and the responses given by the patients. Patients trying to "trick" the system by providing erratic responses in an attempt to under-/ overreport their actual condition depend on their integrity and cannot be prevented from a manufacturer/ technical point of view.

4. Technical Requirements

4.1. Software & Hardware compatibility

Google Chrome is recommended to provide the best user experience and full functionality of the PaaS platform. Apple Safari and Mozilla Firefox are alternative browsers. Microsoft Internet Explorer and Edge are not supported. A stable internet connection is required. Healthcare professionals need to ensure to always use the latest browser versions available at the time of purchase.

OS (Desktop)	Browser (version)
--------------	-------------------

	Firefox	Safari	Chrome
Windows 10 (or higher)	OK	N/A	OK
MacOS 10.11 (or higher)	N/A	OK	OK
Ubuntu 20.0 (or higher)	OK	N/A	OK
iOS 13.0 (or higher)	N/A	OK	N/A
Android 11.0 (or higher)	N/A	N/A	OK

The use of myoncare Careplan Manager has been verified using officially released versions of smartphone operating systems, browsers, or desktop software. Testing software versions are not supported.

Server: 16 GB RAM required, 160 GB of extendable storage (or more) recommended. 4 CPU required (for on-premises).

Application (Screen, Tablet): A screen size of 10.5" or higher is required for adequate scaling.

Network and server connections must be stable and their speed at least 10Mbps. Restart is required if connection is unstable or is lagging. Latency must not exceed 200ms. Access to the server might require a dedicated port to be reserved for integrating myoncare Careplan Manager. WiFi / indoor mobile data connection is required for use among in-house patients.

Interfaces

myoncare Careplan Manager offers the possibility of an interface with various related software applications such as hospital information systems. For a reliable statement regarding a possible interface as well as the corresponding data flow diagrams and requirements for your IT network, please contact sales@myoncare.com.

Compatibility to other (medical) devices

myoncare Careplan Manager does not claim to be compatible to any other (non-)medical devices or any of their accessories available on any worldwide market other than myoncare Mobile.

The compatibility of myoncare Careplan Manager is always ensured by parallel development, verification, and validation.

4.2. e-IFU Technical Requirements

Refer to Section 4.1 for the information on the technical requirements to view the e-IFU.

4.3. Domain and ports

To ensure the intended functionality of the myoncare Careplan Manager in a local installation in the presence of a firewall or a reverse proxy, please make sure that the server with the myoncare Careplan Manager installation can request REST API calls and receive responses from the following domains:

1. https://*.myoncare.care
2. https://FIREBASE_URL.com
3. <https://hub.docker.com>

In addition, the following ports should be available for the myoncare Careplan Manager on the installation sever.

Function	Port
For the myoncare reverse proxy which funnels all communication from the intended user and forwards it to the correct service.	443
For the myoncare internal service communication.	3000, 3050, 3024, 3017, 3018, 3022, 3033, 3036, 3014, 3012, 3021, 3016, 3023, 3008, 3041, 6048, 6379, 3011, 3009, 8080, 3306, 8887, 3034, 3037, 3310, 3013, 5672, 3038, 161, 4040, 3039, 8090, 3306, 15672, 443, 80, 3044, 3081, 587, 3046, 27018, 8082, 8123, 3042, 3090, 3040.

4.4. Supported languages

Note: Depending on the selected language a different date format is applied in the myoncare Careplan Manager. The following date formats are being used:



- DE: DD-MM-YYYY
- EN: MM-DD-YYYY
- IT: DD-MM-YYYY
- PT: DD-MM-YYYY
- FR: DD-MM-YYYY
- AR: DD-MM-YYYY

4.5. IT Security and safety measures

- Token-based authentication and SSL encryption for accessing functions and data transmissions, i.e., the communication between doctors and patients through myoncare is protected by tokens and secure scripts, which will only allow transfer of data with the right authentication.
- Transmission of data is initialized by an encrypted transaction database (Firebase, as a NoSQL database, triggers the notification, which needs to be decrypted via the token authentication). Thus, patient responses are all end-to-end encrypted by dedicated tokens.
- Transmission of data is encrypted within the internal communication between myoncare services.
- The healthcare professional shall change the log-in data (password) after the first login.
- Logfiles can be found in the installation directory. For cloud-based installations, please contact service@myoncare.com. Only the site-admin has the rights to see the logfiles. The responsibility for the analysis of the logfiles lies with the support team of the ONCARE GmbH.
- Update strategy: As soon as a new version of the myoncare Careplan Manager is available, the support team of ONCARE GmbH will contact you to update your system.
- Each bug-fix version (update, which results for trouble-shooting reasons) will be installed for every customer by the ONCARE GmbH. Please be informed that bug-fix versions for versions earlier than myoncare Careplan Manager 1.9 are not supported. The ONCARE GmbH does not support backwards compatibility of versions before myoncare Careplan Manager 1.9 for either Careplan Manager nor Mobile. To guarantee the best possible user experience, it is mandatory to update the system on the newest available version of myoncare Careplan Manager.
- Without a stable internet connection, the myoncare Careplan Manager is not available.
- Please contact the site-admin in case the error message "Something went wrong" occurs or in case of problems with the product.
- ONCARE GmbH takes care of the data back-up for cloud-based installations. In case of a local installation, each customer is responsible to back-up the data regularly.
- In case of multiple failed log-in attempts of myoncare Careplan Manager users trying to log-in to the myoncare Careplan Manager, the account of this person will be deactivated due to security reasons. Deactivated user accounts can be easily reactivated through the site admin within the administration section of the myoncare Careplan Manager. To Activate / Deactivate a myoncare Careplan Manager user, the toggle button of the respective user shall be triggered. Until the account has been reactivated the user is not able to log-in to his account and therefore cannot monitor patients through myoncare Careplan Manager. We highly recommend communicating the responsibility of the site admin to the users of myoncare Careplan Manager within your organization.
- A security feature ensures that a myoncare Careplan Manager user account cannot be logged in multiple times at the same point of time. In case a user tries to log-in through a separate browser / tab or similar while an elder session is still ongoing, the elder session will end immediately. If the elder session contains unsaved changes (e.g. Caretasks, Care Pathways, Chats or similar), these changes will not be saved and cannot be retrieved. To avoid the loss of unsaved changes, please ensure that there is always just one active session. Furthermore, if you notice suspicious logouts of your active session, please change your password to protect your user account from being used by third parties.
- Locally maintained installations:
 - Ensure stable internet connection of at least 10 Mbps for all devices using myoncare Careplan Manager as well as the server on which myoncare Careplan Manager is installed.
 - Necessity of a firewall: It is mandatory to use an appropriate firewall and to allow communication of myoncare Careplan Manager clients with the associated database.
 - Proxy settings shall allow communication of myoncare Careplan Manager clients with the associated database.
 - The file path / storage location of the installation shall not be changed without prior consultation with ONCARE support.
 - The hard drives on which myoncare Careplan Manager is installed shall not be partitioned.

- Do not delete any files from the myoncare Careplan Manager installation folder.
- Enable adequate storage volume without moving data elsewhere.
- Ports required for communication with the Hospital Information System (HIS) shall not be blocked.
- Make sure appointments and Caretask components are initialized adequately within the HIS as well as myoncare Careplan Manager.
- Make sure HL7 connection remains functional if you modify network parameters within hospital IT.
- WiFi / indoor mobile data connection is required for use among in-house patients.
- Define the access rights to the log files in the installation directory.
- Please refer to the sections “domains and ports” below.
- To keep track of all actions which were carried out with myoncare, a historical view for each patient and each Caretask is presented in the myoncare Careplan Manager. This history view can be reviewed within the respective user view in the administration section.
- In case the system appears to not function properly / shows signs of security breaches or data inconsistencies, we highly recommend reporting the issues to ONCARE GmbH.

5. Training & Installation

In order to ensure safe and appropriate use of myoncare Careplan Manager, neither the software nor its features shall be used without proper instruction of healthcare professionals prior to the first use of the myoncare Careplan Manager in a clinical setting (i.e., involving patients). All training activities require to be conducted by ONCARE personnel or adequately trained / licensed partners (= ONCARE representative) and must result in a training record. This record must further be signed by both the ONCARE representative as well as all individuals trained in the use of the product as well as the scope of the training and the individual modules covered by it. Training documentation must be returned to ONCARE for archiving and filing.

User manual and IT guidelines will be handed out by ONCARE personnel after the training.

To ensure an adequate performance of the software, myoncare Careplan Manager will be installed / set up by qualified ONCARE representatives and the training will be conducted on the customers' installation. This must be done prior to the first use of the myoncare Careplan Manager in a clinical setting (i.e., involving patients).

6. Mode of use

The following paragraphs will explain how to use the software to its full capability and where to retrieve relevant data from. **Read through all sections before using myoncare Careplan Manager and refer to these instructions in case of questions.** Some of the functions described below are only available to selected users (e.g., administrators) and are therefore not visible to every user within the myoncare Careplan Manager.

General information and settings

Healthcare professionals have two options to access myoncare Careplan Manager. The default option is through the web browser, which can be accessed by navigating to the appropriate URL. Alternatively, healthcare professionals can download the Desktop version of myoncare Careplan Manager to access the platform.

The Desktop app is available for Windows (Version 10 or higher), macOS (Version 10.11 or higher) and Linux (Version 20.0 or higher) and can be downloaded from the myoncare Careplan Manager login screen. Once downloaded, the healthcare professional will be prompted to enter the domain to connect to the myoncare Careplan Manager. This screen will only be displayed once, immediately after the installation, and the healthcare professional will always land on the login screen. The domain can be changed later by clicking on the “change instance” link.

Log in to myoncare Careplan Manager

To access myoncare Careplan Manager, users can log in either through the web browser or the desktop application. To log in via the web browser, go to the login screen at [https://\[SITE ACRONYM\].myoncare.care](https://[SITE ACRONYM].myoncare.care) and enter your login credentials (= username and password), which were received and provided by either the site administrator or ONCARE upon successful completion of the training.

Recover and subsequently reset the password by clicking on “Forgot password”. Enter the email address, which is associated with the corresponding myoncare Careplan Manager account and submit. Follow the instructions contained in the email.

Switching to a different (supported) language is possible by clicking on the dropdown, which is located in the bottom bar on the right.

It will be required to agree to the data privacy policy at the first login of a healthcare professional.

Two-Factor-Authentication

To ensure a healthcare professional's IT-security, myoncare Careplan Manager offers a Two-Factor-Authentication functionality, which enables the user to verify himself with a second source of verification. Therefore, after entering the credentials and clicking on "login", the user will be asked to enter a "Verification Code" / "PIN". The verification code will be sent to the user's mail address which is used for the myoncare account. After confirming the code, the user will be logged in and can use the system.

The requested verification code is valid for 15 minutes after requesting the code by clicking on "login". In case the user does not enter the code within the given timeframe, the user can always request a new code by clicking on "Resend PIN" within the verification page.

The Two-Factor-Authentication can also be deactivated within the "Edit Profile" section.

Logout from myoncare Careplan Manager

To log out, the healthcare professional has the possibility to open a dropdown menu from the top right corner via clicking on the tile which displays his/ her name and role within myoncare Careplan Manager. Within this dropdown menu the healthcare professional can either edit his profile or log out.

Healthcare professionals are automatically logged out of myoncare Careplan Manager after 15 minutes of inactivity.

Maintenance page for myoncare Careplan Manager

When maintenance or an update process is initiated, the healthcare professional attempting to access the myoncare WebApp will be directed to a dedicated maintenance screen, providing them with clear information about the ongoing maintenance. All patients connected to this myoncare WebApp will temporarily not be able to use Mobile for technical reasons. They will be notified about this after logging in. ONCARE GmbH will proactively update the designated contact person for each customer regarding the anticipated update schedule.

General navigation through myoncare Careplan Manager

To provide user-friendly navigation within myoncare Careplan Manager, the navigation bar on the left side allows the healthcare professional to be redirected to the main modules as described in 1.4 as well as the following chapters.

QR codes & Deeplinks

Healthcare professionals can generate and provide QR codes to patients to register as new patients or to access new Caretasks and Care Pathways. By scanning the QR code, patients can initiate these actions.

A Deeplink is a hyperlink associated with a specific Caretask or Care Pathway that serves as an alternative to using QR codes. It can be opened on both mobile and desktop devices without requiring any app installations. When a patient clicks on a Deeplink, they are instantly directed to the designated Caretask or Care Pathway, and they can begin their tasks or pathways immediately after providing all the necessary consents. It's important to note that Deeplinks are supported exclusively by the Progressive Web Application of Mobile (PWAs).



User settings of myoncare









Next to the Two-Factor Authentication settings mentioned above, the healthcare professional is also able to edit his username, name, profile picture, email address as well as the consent of the terms and conditions within the "Edit Profile" page.




Furthermore, the healthcare professional can define which e-mail notifications he/ she wants to receive. In general, myoncare Careplan Manager offers to notify the healthcare professional via e-mail in case there are unseen messages, triggered thresholds or Caretasks to conduct for the day. Depending on the checkmark settings next to the respective notification category, the healthcare professional will receive an e-mail as a reminder at 8:00 AM (depending on the local server time) each day in case there are unread chat messages or Caretasks to conduct. In case a threshold has been triggered the healthcare professional will receive an e-mail notification immediately.








Note: The settings for e-mail notification are disabled by default. Roles without access to patient demographic data do not have access to this functionality.





Next to the profile dropdown menu in the top row on the right side of the myoncare Careplan Manager, the following symbols are being displayed.

	Language selection: Refer to Section 4.4.
	Notifications on new chat messages or video call requests. Exceeded threshold notifications will also be displayed within this segment within the medical device variant.

	When clicked, healthcare professionals are redirected to a section with two tabs: " To-dos Notifications " which lists all Caretasks assigned to HCPs and ready to be answered, and " All mention Notifications " which displays all notifications where the healthcare professionals have been tagged.
	List of reports ready for review. Each report in this list is accompanied by a dropdown menu and a 'Start Review' button. Users can select the appropriate "Review Caretask" from the dropdown.
	Information icon: the healthcare professional can access the instructions for use as well as the imprint of the respective device. Additionally, the system provides a 'Help and Support' feature that, when activated, opens a website where healthcare professionals can submit a ticket for help-related topics.
	Action button: located at the right bottom of every actionable page, serves as a starting point for any actions to be taken in the corresponding module or on the corresponding view.
	<p>Patient symbol: located on the left navigation bar or logging into myoncare Careplan Manager the healthcare professional will be redirected to the myoncare Careplan Manager patient's module.</p> <p>The patient's module will display all the new as well as the existing patients according to the applied filter; to switch between the new or existing patients the healthcare professional can use the tabs above the patient list. The list includes a comprehensive view of each patient's details, with fields such as Priority, Compliance, Patient-ID, First Name, Last Name, Gender, Date of Birth, and ICD Code. By clicking on the column headers is possible to sort patient data on the dashboard. Additionally, when logged in as an External HCP role, the module presents a list of patients mapped to the same Satellite as the user, facilitating focused care coordination.</p> <p>Note: In case a HL7 or similar interface from myoncare Careplan Manager to another system is established to exchange patient information, the healthcare professional needs to ensure that the Patient-ID within myoncare corresponds to the Patient-ID of the patient within the interfacing system. Otherwise, the patient data cannot be read or written accordingly.</p> <p>Compliance for each patient is calculated to reflect patient engagement with caretasks. The calculation includes only active expired caretasks that are assigned to patients from the past 12 months and excludes caretasks assigned to HCPs. Compliance is calculated by dividing the number of answered occurrences by the total number of caretasks due.</p> <p>In case the medical variant is in use the patients will be sorted according to the health indicators by default. When sorting the patient list by name or another criterion, the order of the patient list does not reflect the triaging anymore. When applying filters, the triaging is still the default value for sorting the patients.</p> <p>Within the patient module the healthcare professional is also able to search for specific patients via the search bar above the patient list. The healthcare professional can search for Patient-ID, first name, last name, e-mail address, reference-ID or ICD-code. Each patient is listed in a tile which directs the healthcare professional to the respective individual patient's overview by clicking on it.</p>
Additional symbols	
	Show symbol: it shows the patient information in a non-editable window, which also details the editing history of this patient record.
	Editing symbol: editing the patient allows the healthcare professional to update the medical information of the respective patients. If mandatory fields are left blank after editing, the changes will not be saved. The healthcare professional can see all patients and information such as Caretasks and Care Pathways of the site he is registered to.
	Delete symbol: deleting a patient will remove the patient from the myoncare Careplan Manager. Patient data, as well as the health record stored in the hospital information system (HIS), will still be accessible. Within back-up of the data, the deleted information can still be retrieved. To finally delete all data associated with the patient, please contact your site admin. The deletion of patients will also remove the patient's access to the Mobile. Patients can also re-register with a site by scanning a new QR code as described in the invitation workflow.

	<p>As soon as the patient updates personal information within the Mobile, the patient information is automatically updated within the myoncare Careplan Manager.</p> <p>If the user's installation uses the blockchain services, the myoncare Careplan Manager user can actively request synchronization of patient information by clicking on the "Synchronize" icon within the myoncare Careplan Manager. This is only visible if the patient has added or updated information. The information will not be updated automatically.</p>
Creating a patient	
 	<p>NOTE: In general, if a myoncare Careplan Manager installation includes an HL7 interface (non-mandatory module), parts of the patient data stored in the hospital information system (HIS) can automatically be imported into myoncare Careplan Manager and do not have to be entered manually.</p> <p>For creating a patient manually within the myoncare Careplan Manager, the healthcare professional needs to do the following steps:</p> <ul style="list-style-type: none"> • Click on the action button ("+"-button) within the patient overview. • Click on the "Add patient"-button. • Add the patient information in the mask accordingly. All input fields which are marked with a "*" are mandatory (First name, Last name, and Date of birth). <p>NOTE: Patient-ID is the unique identifying attribute to other systems (HIS/KIS) and needs to be identical to the medical record within interfacing systems. Reference-ID is an open pseudonym that each site can choose for its patients. It is not necessarily unique.</p> <p>Medical information such as patient ID, case number, OPS Reference or reference ID can be adjusted in the myoncare Careplan Manager at any time.</p> <p>In case no specific Patient-ID is defined for a patient within the creation process, the patient receives a standardized combination of 3 characters of the first name, last name and date of birth.</p>
Inviting/ associating a patient	
	<p>To register patients to your site, myoncare provides two possibilities:</p> <ul style="list-style-type: none"> • Link a patient to an existing patient within your site. To do this, patients require a QR code and a password, both of which are generated in myoncare Careplan Manager. Clicking on the QR code/ "generate registration letter" icon on the right side of the clickable fields will open a pre-filled invitation letter for the patient. A registration letter can also be exported within the QR-code screen, which includes a QR code and a password. Patients are required to – after downloading Mobile from the AppStore or Google PlayStore – register with a site by scanning the QR code and accepting ONCARE's data privacy policy as well as confirming the data as contained in the QR code. <p>NOTE: for data privacy reasons, the key and QR code will generate anew after every refresh of the page, meaning that prior credentials are rendered invalid (unless these were already used by the patient).</p> <ul style="list-style-type: none"> • Allow patients to register themselves to your site by scanning a QR-Code of a Caretask or Care Pathway. After scanning a QR-Code of a Caretask or Care Pathway, the patient is required to enter his credentials. In the next step, the patient is required to consent to the privacy policy as well as to other defined consents and agree to connect with your site. After that process the patient will be automatically displayed within your patient list and you can review the patient as well as provide him with content such as Caretasks, Care Pathways and further information.
Viewing a patient and answers/ result	
<p>By clicking on the line of a patient which has been created, or whose record shall be viewed, healthcare professionals are redirected to an overview page which provides all information on a specific patient.</p> <p>On the top row of the browser window, healthcare professionals can see the basic data of the patient, such as date of birth and Patient-ID. The "app status" indicator tells attending staff how (in-) active the patient is with the following color scheme:</p> <ul style="list-style-type: none"> • Unpaired – Mobile not installed / initialized • Offline – Mobile installed, patient is offline • Active now – Patient currently online in Mobile <p>Also, the health indicator is displayed around the profile picture of the patient.</p>	

	<p>Export symbol: patient responses to Caretask components can be exported in CSV or PDF format for a selectable date range.</p>
<p>Tab</p>	
	<p>Care Pathways: assigned Care pathways and their underlying Caretasks can be reviewed.</p> <p>After selecting “Assign Care Pathway” the healthcare professional can select a Care Pathway to be assigned. Within the assignment process the healthcare professional can add the selected Care Pathway to the assignments of the patient or send out the Care Pathway immediately.</p> <p>In case the Caretasks of the Care Pathway contain components with thresholds or jumps the healthcare professional will be asked to review these within the assignment process.</p>
	<p>Caretasks (for patients): assigned Caretasks and their results/ answers can be reviewed.</p> <p>When selecting “Assign Caretask” from the action menu within a patient’s detailed overview, the Caretask assignment workflow will automatically open, and healthcare professionals will be asked to assign from an existing template. Caretasks, as well as additional information, can be edited and customized, e.g. a Caretask’s lifespan, recurrence and ICD reference.</p> <p>Within the medical variant the healthcare professional is also able to edit the threshold notifications.</p> <p>NOTE: In the case where patients may be unable to respond to Caretasks, healthcare professionals have the option to answer on their behalf by utilizing the 'Answer on behalf' button. This feature is accessible from the patient overview area, specifically through the Caretask card. It is crucial to exercise this functionality judiciously.</p>
	<p>To-dos: A list of all assigned active assessment (caretask for healthcare professionals) awaiting responses from healthcare professionals for the patient. When an HCP selects 'Answer Now,' a right-side modal window appears, allowing the HCP to provide responses to the assessment components. Upon completion, the assessment will be removed from the 'To-Dos' section.</p> <p>There are three types of assessments:</p> <ul style="list-style-type: none"> • Assessments Triggered by Caretasks: these assessments are triggered automatically upon the completion of specific care tasks in a care pathway. The care pathway name and parent caretask are displayed. • Assessments Part of a Care Pathway: these assessments are triggered as a part of a predefined care pathway. • Manually Assigned Assessments: these assessments have been manually assigned to the HCP.
	<p>Medications: assigned medications and their details can be reviewed.</p> <p>Within the patient’s overview page, medication reminders can be set to remind patients of medication intake. Upon selecting “Assign Medication” from the action menu, a configuration page will appear.</p> <p>Always check previously assigned medications and their medication reminders to avoid overdoses or double medication assignments and contraindicated drug interactions (myoncare Careplan Manager does not check for contraindications).</p> <p>Medication Plan: the patient can scan the medication plan using Mobile. In this case, the current ongoing medication reminders will be deactivated, and medication reminders will be activated according to the medications provided in the plan. A reference to the medication plan PDF will also appear. The function for assigning new medication reminders will be deactivated.</p>
	<p>Appointments: scheduled appointments and their details are displayed within that section.</p> <p>After selecting "Add appointment" from the floating menu, a configuration page appears.</p> <p>This interface, allows you to configure the type of appointment (type, name, ICD reference, participants, location, start and end date, repetitions, and notes).</p>
	<p>Overview: enables users to select and compare up to two data points (such as caretask scores and health data) over a customizable timeframe, providing a clear visual representation alongside any relevant medications for that period.</p> <p>The graph view feature in the myoncare WebApp allows users to select up to two data points—either caretask scores, health data, or a combination of both. These selected data points are displayed as a graph for easy comparison and analysis. Users can adjust the displayed timeframe to focus on specific periods, such as daily, weekly, or monthly data. Beneath the graph, any medications assigned for the selected timeframe will also be displayed, providing a comprehensive view of the patient’s data in context.</p>

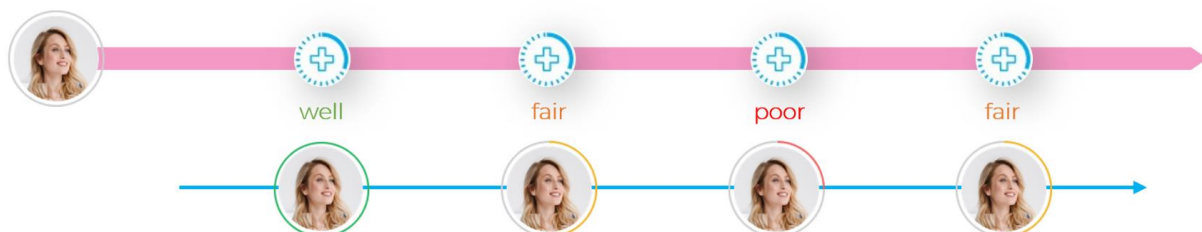
	<p>For health data, users can synchronize various health metrics, including weight, height, steps, calories burned, sleep patterns, distance traveled, heart rate, and blood pressure. These metrics are collected from wearables like smartphones and smartwatches, or from patient-reported data through caretask responses, such as BMI and blood pressure updates. Health data serves only for visualization, supporting contextual understanding of a patient's condition without influencing medical device functionality.</p> <p>Important considerations:</p> <ul style="list-style-type: none"> • Data synchronization requires patient consent and is contingent on the regular synchronization of data. It requires the use of Apple Health, Google Fit, or Withings Health Mate, with each platform offering different levels of data integration: • Apple Health and Google Fit can sync all available data points. • Withings Health Mate can sync only blood pressure values. • Patients can use only one of these applications at a time. • Patients have the right to withdraw their data-sharing consent at any time, which will stop the transmission of new data to healthcare professionals. <p>Note that this data synchronization feature is not available for users accessing the Progressive Web App (PWA).</p>
	<p>“Deactivate” will only remove future occurrences of the Caretask from the patient's queue. Completed items will not be affected.</p> <p>Upon clicking on “Results”, healthcare professionals can review individual answers to Caretask components and visualize a trending of these answers. If no answers are received yet, the “Results” field is not displayed and the Caretask could be deleted.</p>
	<p>Notes for medical staff</p> <p>The right-side bar modal within the patient view also includes a section, which allows the healthcare professional to take notes to the respective patient. These notes are only visible for the myoncare Careplan Manager healthcare professionals and will not be transmitted to the patient. Furthermore, the healthcare professional is allowed to upload files to that section via attaching a file and saving it with the displayed icon on the left.</p> <p>To simplify the traceability of notes, the healthcare professional can search for comments or files within the search bar of the Notes functionality for previously saved notes on the patient.</p> <p>Note: It is not possible to search for the name of the notes author.</p> <p>Healthcare professionals (HCPs) can now tag individual colleagues, specific roles, or an entire satellite (group of users) in their notes. When a tag is added, the tagged HCP(s) will receive a notification. These tags can be used to draw attention to specific notes or files uploaded in the notes section, ensuring that relevant team members are promptly informed.</p> <ul style="list-style-type: none"> • Tagging Individuals or Roles: HCPs can tag specific colleagues by their name, or they can tag a role (e.g., all doctors) to notify everyone in that role group. • Tagging a Satellite: HCPs can tag an entire satellite, which will notify all users within that satellite group. <p>All tagged notes can be reviewed under the “All mention notifications” section by clicking the To-Do icon in the notification bar. Tagged HCPs will also receive an email notification each time they are tagged in a note. If an HCP wishes to stop receiving these email notifications, they can configure this preference in the “Edit Profile” section of their account.</p>
	<p>Calendar: Shows a calendar view of assignments. Furthermore, multiple filter options are available.</p>
	<p>Files: Shows all files sent between patient and Careteam via the chat functionality. Furthermore, files, which were provided to the patient via Caretasks, with the enabled option “Allow patient to review files after conducting the Caretask” within the Caretasks settings, will be saved in this section. Every data privacy policy, which will be consented to by the patient, will be listed within the files section as well. Within the view file modal, the healthcare professional is able to see the date and time of the consent as well as of the revoke.</p>

Health Indicator

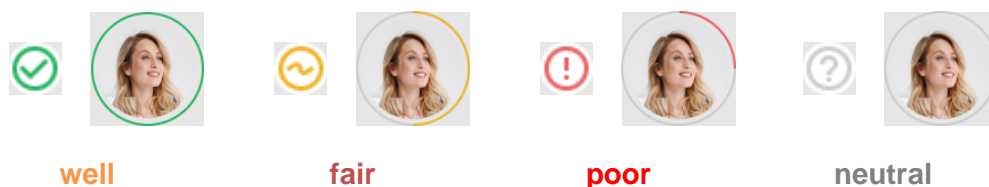
The health indicator in Careplan Manager is an optional feature visible only to medical professionals. This indicator is visible within the patient list as a color-coded ring around the profile picture of the respective patient. The order of the health indicators will be by default: **“Poor”**, **“Fair”**, **“Well”** and **“Neutral”**. It is calculated by taking a patient's

answers and the values, with which the Caretask components were scored (if applicable), into account. The indicator is a calculation based on the values of a patient's responses to the assigned components of all Caretasks for which the scoring function was activated.

The health indicator does not show the scores achieved by the patient but presents only whether the patient is in a "well", "fair" or "poor" condition. The value ranges of these three states are defined by the healthcare professional when creating the respective Caretask. The indicator represents the "worst" achieved value of a Caretask of this patient which is active and has upcoming occurrences. Meaning in case there are multiple Caretasks with recurring occurrences, the patients' health indicator represents the worst scoring of the currently active Caretask assignments.



To view the detailed results of the patient and his Caretask, click on the detail view of the corresponding patient, then select "Results" for the desired Caretask. The thresholds for the indicator's color scale are initialized with three colors: green indicates good health; orange is set for medium-to-below-average health and red shall alert healthcare professionals of a worsening or bad health condition (the scores of well, fair and poor needs to be defined by the healthcare professional). In case the patient did not answer any scored Caretask or did not connect to myoncare the color of the health indicator will be grey as shown below:



Zero value Caretasks and components are excluded from the calculation of the indicator. The health indicator in Careplan Manager color scale and range can be customized per Caretask.

In the patient overview, care tasks and assessments are visually differentiated by colors such as grey, blue, red, orange, or green. This applies to both the list of caretasks and care pathways, as well as the trend graph. Grey indicates that the task has not been answered. Blue signifies that the task has been answered but without categorization. Red denotes a categorization of poor, orange indicates fair, and green signifies well. Furthermore, when viewing the details of a caretask with multiple occurrences, the radio buttons used to select occurrences are color-coded accordingly, following the same logic.



Caretasks and individual components are not included in the scoring or health display by default. Only if an "Activate Scoring" is to be performed, the healthcare professional must actively select this. Whenever components carry a score, the answers will affect the health indicator value accordingly, unless the box "Categorization via health indicator" remains unchecked / is greyed out.

Filter functionality

myoncare Careplan Manager provides a filter functionality within the patient list which allows the healthcare professionals to filter out specific patients based on patient or Caretask related criteria. This functionality can be accessed within the patient list by clicking the button 'filter'. The healthcare professional can choose between creating a new 'on-demand filter' or to select a 'custom filter'.

- **On-demand filters**

By clicking 'Create filter' the healthcare professional interface to select and define filter criteria will be displayed above the list of patients showing two different criteria: Patient and Caretask criteria.

Within the respective modals for the patient or Caretask criteria, the healthcare professional can define different criteria as well as dependencies between the criteria such as "And" or "Or".

Furthermore, the healthcare professional can also select a dependency between the patients and Caretask criteria by selecting "And" or "Or" within the dropdown menu between the two criteria segments.



On-demand filters cannot be saved. Therefore, once they are cleared or the healthcare professional enters a different section of the myoncare Careplan Manager, the beforehand created filter is cleared and cannot be restored.

- **Custom filters (saved filters)**

Custom filters can be created, edited as well as deleted within the tab 'Custom Filters' within the administration section. This functionality is only accessible for healthcare professionals with the role 'Site Admin' (or in case the user has permissions for Custom filters within the role matrix enabled). The custom (saved) filters will be displayed within the patient list when clicking on 'Filter' for the user to select them.

While creating a custom filter the healthcare professional has the possibility to add rules and groups for filters. A rule includes a single filter criterion whereas the groups include a combination of filter criteria using the "And" or "Or" operators. The healthcare professional also has an option to add extra conditions such as intersect or exclude the results of some filter criteria.



In case the healthcare professional applied a filter and wants to export patient data, the export only contains content from patients which match the filter criteria.

Adding or editing a filter

When selecting "Add new filter" from the action menu, healthcare professionals will be taken to a blank filter template which can be customized. A filter name as well as the associated site(s) are mandatory, whereas a preset (i.e., an existing filter) may be used as a draft to adjust further before saving a new filter.

Within the mask the healthcare professional can add the following filter options:

- **Create Filter:** adds an additional parameter set to the already existing one(s). The healthcare professional has the possibility to define if the filter criteria should be intersecting or be excepted from the initial filter setup.
- **Add rule:** adds a new parameter for which the filter will search. Its exclusivity depends on the group's overall logic (AND/OR).
- **Add group:** adds a new level of logic behind the filter which is aligned with the previous group's setting (AND / OR). Introducing a new group will not extend but refine the custom filter to an in-depth detail level.

The main filter logic will display the criteria for which the filter will search. "AND" is the exclusive search logic which adds further details / additional criteria (i.e., "rules" or "groups") for the filter whereas "OR" is more inclusive and points towards optional parameters, all of which will be displayed as an output after running the filter.

Within the dropdowns, healthcare professionals can choose between multiple parameters (first input field) to search for and the mode (second input field) by which the patient database associated with the corresponding site is scanned for the parameters.

In order to see all patients associated with a specific site, healthcare professionals may choose to set a default site filter by adding only one rule, e.g., "Site-Name equal [SITE]" (i.e., has access to the patient's data). Equivalently, filtering for a particular ICD-10 Code or OPS-Code can be achieved by selecting "ICD-Code equal [CODE]".

Adding a group will automatically render the filter more complex, hence healthcare professionals are advised to double-check the logic before the filter is saved and used.

"Delete" will remove the rule or group from the advanced search filter. Rules or groups which were removed cannot be recovered unless the filter was saved previously.

"Reset" will return the filter customization to a blank form without saving.

myoncare's telemedicine functionality is comprised of a chat feature, which further enables patients and doctors to exchange text messages as well as attachments, and the option to perform a video call. Within the patient overview, healthcare professionals will see the chat / video chat section on the right side of the screen. At the bottom of the patient page, healthcare professionals can type a message, send an attachment, or call their patients directly. Patients can only request a call but not call their attending healthcare professionals directly.

Note: In case a patient starts a conversation or sends a message, doctors will be notified via the notifications on the header row of the myoncare Careplan Manager.

No video session will start if one of both parties does not have a camera available/ activated on/ from the device.

By clicking on the "hang up" button within the new window the healthcare professional will end the video call. Afterwards the window will remain open, even though you have ended the call. Please close the window after the call has ended manually.

Please make sure that the internet browser you use allows pop-ups of myoncare Careplan Manager to ensure that the window can be opened.

For iPads, the camera is not automatically opened but needs to be activated.

Care Manager

- **Creating a Care Pathway:**
 1. **Care Pathway Builder:**

- i) **General Settings & Caretask Selection:** When creating a Care Pathway in the Webapp, a new page will open. Start by defining the name of the Care Pathway. After clicking on "Care Pathway Settings" in the top bar, the right sidebar will open. Here, users can choose the reference type and associated ICD code. To add a Caretask to the Care Pathway, select "Add Caretask" in the top bar, and the right sidebar will open, allowing users to search and add Caretasks. Below the search field, select the type of caretask to add – Parent Caretask or Linked Caretask. The search results appear below, and the chosen caretask can be added to the main area of the care pathway by dragging and dropping. To remove a caretask, click on its card and then select the "trash" icon.
 - ii) **Caretask Configuration:** Each parent caretask requires specific configurations. Click on the selected caretask card to open the right sidebar. Define the duration of each Caretask in relation to the chosen reference date (selected when assigning the Care Pathway to a patient). Additionally, set the lifespan of the Caretask, indicating how long it will be accessible to the patient.
 - iii) **Linking Caretasks:** When a parent caretask is selected, either during care pathway creation or editing, the caretask card displays two to three dots. On top of these dots, the terms 'well,' 'poor,' and, depending on the health indicator of the selected caretask, 'fair' are shown (if a caretask is selected without a health indicator, nothing is displayed). As the next step, to create a Linked Caretask, the user must navigate to the right sidebar menu after clicking on 'Add Caretask.' Here, the user needs to change the radio button from 'Parent Caretask' to 'Linked Caretask.' Subsequently, the user can select any caretask for linking. Once a caretask is selected, the caretask card shows a dot on top. To establish a linkage, the user simply clicks on one of the dots, holds the left mouse button, and drags the line to the desired dot on the connected caretask.
2. **Components Configurations:** Overview of the scores and jumps of the Caretasks, which occur in the Care Pathway. Within the medical variant the healthcare professional is also requested to review the set thresholds. Furthermore, the thresholds shall also not be used as the sole basis of an intervention, relevant medical action, or prioritization of individual patients. The role of "Author" within the myoncare platform allows users to link specific components to analytics data labels. This feature facilitates consistency in tracking and analyzing patient data across care tasks. For further information or assistance with setting up and managing standard values, please contact the service team of myoncare
 3. **Save:** Within the last view of the Care Pathway creation, all Caretasks which are included are displayed with their scheduled occurrences. After reviewing the schedule, the Care Pathway can be saved.
 - **Editing:** after a Care Pathway has been created, it will appear within the Care Manager in the respective Care Pathways tab. On the right side of the screens, some buttons are available to the healthcare professional to interact with the respective Care Pathways (refer to the Section 'Additional symbols' in the table above for more details on the symbols). Within the patient overview of the respective patient the healthcare professional can identify whether the Care Pathway was set up via a reference date or, in case the functionality is enabled, via an appointment. Accordingly, the rescheduling of the Care Pathway is either done via the edit Care Pathway button on the respective Care Pathway or via the appointment the Care Pathway is connected to. Keep in mind that by rescheduling the Care Pathway to an earlier time, single occurrences of Caretasks might not be sent out. To avoid this from happening, please review the assignment within the last step of the assignment process, which is triggered via the assignment or editing of the Care Pathway.
 - **Reviewing a Care Pathway for a specific patient:** for reviewing the results of a Care Pathway and its tasks, the healthcare professional can go into a patient overview of a patient the Care Pathway was assigned to. Within the Care Pathway section in the patient overview the Care Pathway will be displayed as well as its result and its status.

Caretasks

Within the Caretasks tab & the Review Caretask tab of the Care Manager, all available Caretasks (items containing at least one question or task, which can subsequently be addressed or assigned to the patient) are listed and can be searched for / sorted by healthcare professionals. Only items to which the healthcare professional and / or site has access to, or is entitled to see, are displayed.

- **Adding or editing a Caretask template:** by clicking on "create caretask" button, the healthcare professional will be redirected to a configuration page. Within this page the healthcare professional can add a Caretask name (on the top center of the page) and adjust the Caretask settings.
 1. **Add the name of the Caretask to be created.**
 2. **Selection of the Caretask type: for patients or HCPs.**
 - i) **Review Caretask:** This field becomes visible only when 'medical' is selected to conduct the Caretasks within the myoncare Careplan Manager. By selecting this field, it transforms the Caretask into a special category, accessible to the HCP in a new tab within the Care Manager

called "Review Caretask". These specific Caretasks cannot be manually assigned to patients, nor they can be chosen during the creation of a care pathway. Additionally, there is no possibility to scan these Caretasks. Their sole purpose is to facilitate the review of reports.

ii) Template description

iii) Allow patient to review files after conducting the Caretask: Providing the attached documents of the Caretask to be permanently available to the patients

iv) ICD-10 references, OPS codes

v) Custom Formula

vi) Categorization via health indicator

vii) Creation of report of the answers for the patient

viii) Custom recurrence: the phase type for which the template is created and the start time repetition, number of occurrences and lifespan: "Start time specifies by which time the template shall be available for patients to answer. Distribution times will be based on the patient's time zone. "Repeat" allows healthcare professionals to set a detailed, custom recurrence. Available options are daily, weekly, monthly and yearly. Further options to specify recurrence are weekdays (only if "weekly" is selected) as well as the time by which the recurrence shall end, which can either be after a fixed number of occurrences or on a specific date (section "Ends").

- 3. "Categorization via health indicator":** triggers the associated component scores to be included in the health indicator calculation upon a patient's or healthcare professional's response to the Caretask, if the Caretask is recurring. To assign a rating to the value finally achieved, the areas corresponding to a "well, fair and poor" health status can be defined. Here it can be defined whether a high or low value corresponds to a "good" or "bad" result. To display the rating values to the patient in PatientApp, enable the option 'Share overall score with patient.'

The "Categorization via health indicator" feature is greyed out by default. This means that assigned scores for components will not automatically be calculated unless this option is enabled within the Caretask settings. If it remains deactivated, the Caretasks will be excluded from the calculation and will not show a score and therefore no health indicator will be assigned to patients.

If "Categorization via health indicator" is activated the interface allows to "add a component" to the three score categories. Depending on the result of the Caretask, the additional components will be triggered. To add additional components the healthcare professional must click on "Add component" which triggers a dropdown with 12 preset components. Each component can contain a question or a task-like description. In case the "Categorization via health indicator" option is not enabled; the health indicator will also not be displayed.

Note: In Caretasks that are supposed to be answered by healthcare professionals, the healthcare professional cannot define additional components to the categories 'well', 'fair' or 'poor'. This functionality is available for patient Caretasks only. Accordingly, any existing additional components will be eliminated if the role is changed from Patient to Medical.

Templates

In the "Care Manager"-module underneath "Caretasks", myoncare Careplan Manager displays all templates which are available to the healthcare professional's site and ready for assignment sorted by "Title".

Caretask templates can be exported / shared and (re-) imported to the interface. Refer to the ensuing sections for details on sharing or importing templates.

On the right side of the screen, healthcare professionals have several actionable buttons to interact with Caretask templates (refer to the table above for more information on the symbols 'Additional symbols').

Custom Score Formulas

Healthcare professionals can calculate multiple scores by creating custom formulas in the caretask settings screen. To get started, simply toggle the "Custom Score Formula" option to enable it. Once enabled, a button labeled "Add Section Formula" will appear on the right-hand side of the screen. Clicking this button will provide the healthcare professional with a section labeled "Section Score 1" and two textboxes to input a title and a valid formula.

A maximum of 10 section score formulas are allowed. To add another section score formula, click on the "Add Section Score" button again, and a new section labeled "Section Score n" (where "n" is a number between 2 and 10 and increments with each new section score added) will appear with its own title and formula textboxes. Clicking the delete button on any section will remove it from the list.

How to input a valid formula

To input a valid formula, the healthcare professional can use components, numbers, and operators. Components are represented as "C" followed by the component number, such as "C1" for the first component in the caretask. Operators that can be used for formula construction include plus ('+'), minus ('-'), multiplication ('*'), division ('/'), and brackets ('()').

Make sure that the components used in the formula exist in the caretask and have a score. Otherwise, an error message will appear under the formula text box. To avoid errors, refer to the list of components displayed in the "Available Components" section.

Please refer below for an example of a valid formula:

$(C1C2 \cdot C3) \cdot 100/3$, where C1, C2, and C3 are components with valid scoring schemes.

Below are some examples of invalid formulas:

1. $(C1 \cdot C2 \cdot Q3) \cdot 100/3$: Components can be represented using only "C" followed by a valid component number.
2. $(C1 \cdot C1)/5) \cdot 5$: The formula is missing an open bracket.
3. $C1000 + 5000$: The component "C1000" does not exist in the caretask.

Thresholds & Notifications

Threshold notifications are intended to inform healthcare professionals of specific answers to questions/ components of patients, to support early detection of adverse events and - accordingly - early intervention in the event of a deterioration in a patient's health status.

Within myoncare Careplan Manager Caretask configurator, healthcare professionals can opt to add "thresholds" to components before assigning a Caretask or saving a template.

Once healthcare professionals create components or templates, the option to set "thresholds" will appear on the right sidebar as a toggle button. To set a threshold, healthcare professionals need to activate it (indicated by the button turning blue) and select the response/ value of which they want to be notified for every component which shall carry a threshold. By clicking on the desired response option, this is defined as the threshold value. Once all thresholds were set according to the healthcare professional's preferences, the Caretask / template can be saved, and the workflow can be continued. Alternatively, thresholds can be (re-)set during the assignment workflow, so that individual thresholds can be set for this template.

Setting thresholds for pain location charts or multiple-choice answers is not recommended. Thresholds for Free text, Ranking, Information and File Request cannot be set.

Exceeded threshold values will appear as threshold notifications on the home screen, where healthcare professionals can review further information on the details. Thresholds included in templates are preset but can be changed when assigning them to multiple healthcare professionals.

As soon as a threshold value is selected from the threshold notifications (top right corner of the myoncare Careplan Manager), the patient and his or her corresponding Caretask is displayed with the threshold value. As soon as this has been viewed, the threshold notification disappears from the threshold notification display or is reduced to the threshold values, which have not yet been viewed.

In the non-medical variant of myoncare Careplan Manager, the threshold notification will not be displayed and only the notification center for messages can be viewed.

Adding jumps

As soon as the healthcare professional is in the component settings, the option for "jump" appears on the right sidebar as a slider. This is applicable to only Single choice, Numeric Range, Numeric Value, Information & Blood pressure components. To insert jumps (to other components of this Caretask), the healthcare professional must activate this option for each component that is supposed to have a jump. By clicking on the desired response option, it is defined as a jump. After activation, the component to which the jump shall be made must be defined for at least one response option of the component concerned. The answer is selected by clicking on the arrow symbol. Then the component to which the jump is to be made can be specified. This procedure can be repeated with any number of possible answers of the component. Jumps can only be initialized chronologically (i.e., progressively within the Caretask; jumping back to a previous question is not possible).

Linked Caretasks

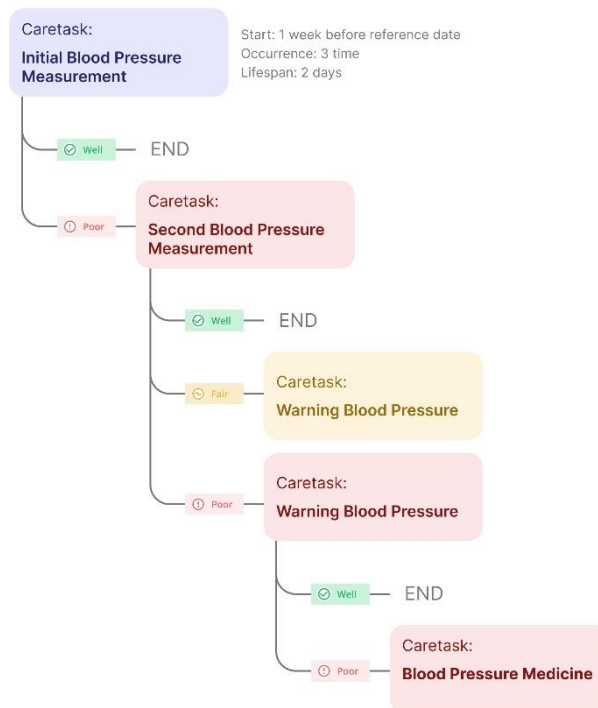
Healthcare professionals are allowed to establish connections between any caretask and each of the health indicator categories assigned to the Parent Caretask. If the linked caretask also features the "Categorization via health indicator" functionality, the healthcare professional can add another layer of linked caretasks. This multi-tiered linkage can extend up to three levels.

Linked caretasks or assessments have a configurable lifespan and occur only once.



Healthcare professionals are unable to directly edit a caretask containing links. Instead, to edit the caretask, all links within the care pathway need to be removed beforehand.

Adjacent to the card of the linked caretask, a delete icon is conveniently located. Upon clicking this icon, the selected linked caretask is deleted.



The parent caretask has the 'Categorization via Health Indicator' feature activated. If a patient falls into the 'Poor' health category after responding to this task, it triggers the second 'Blood Pressure Measurement' caretask. Similarly, the second 'Blood Pressure Measurement' caretask also has the 'Categorization via Health Indicator' feature enabled. After the patient answers this task, if they fall into either the 'Well' or 'Poor' health categories, they will be assigned the 'Warning Blood Pressure' caretask. Continuing the process, if the patient falls into the 'Poor' health category after responding to the 'Warning Blood Pressure' caretask, they will receive the 'Blood Pressure Medicine' caretask.

Result View for Linked Caretasks

Patients and healthcare professionals (HCPs) now have the capability to receive caretasks based on the answers of another caretask. This configuration can be set up during the creation of a care pathway.

To access the results of these linked caretasks, the HCP must first expand the care pathway, then expand the parent caretask. If at least one caretask is answered, the "Triggered Results" button will appear adjacent to each configuration row for the respective caretask.

Upon clicking the "Triggered Results" button, the user is redirected to the answer view. In this view, a list of occurrences with answers are displayed, with the latest occurrence automatically selected by default. This view provides an overview of the unexpanded results within the hierarchy of the triggered caretasks.

For each caretask within this hierarchy, the HCP can expand the view to access detailed answers for each individual care task. The hierarchy is visually represented using colored arrows. These arrows are accompanied with icons representing the relevant health indicators of the preceding caretask that triggered it. It's important to note that caretasks triggered but without any associated answers are highlighted in grey and cannot be expanded for further details.

Additionally, linked caretasks within a care pathway that are categorized as "fair" or "poor" based on the health indicator will be distinctly displayed beneath the comprehensive list of all caretasks.















Adding components

By selecting "Add a Component", the interface allows to select the type of component which shall be created. When creating a Caretask or component, the healthcare professional can choose between 14 preset component types. Below is a short description of the individual component types. Each component can contain a question or task-like description.

Answers to components must be confirmed with "Next". Components can also be skipped by the patient if they're not marked as "Required". Patients can return to the previous questions at any time.

Whenever media is included, component types can still apply, for example, when questions are asked about a video, image, or other document. Media can be attached within the settings bar on the right after clicking on the respective component.



	Free text: allows patients to answer in their own words to the corresponding question. Scores will only count towards this component being answered. The maximum number of characters that can be used for the answer is 250.
	Single Choice: patients can choose exactly one option while answering the question or task.
	Multiple Choice: patients may choose multiple selections for responding to the component.
	Numeric range: will display a scale on which patients are asked to drag the slider into a position which reflects their answer to the question raised. The possible value range and the labels of the scale ends are adjustable.
	Numeric value: allows patients to enter a numeric value to respond to the component. This type will recognize commas and decimal values. Activating the “float-point numbers” toggle button will allow for decimal values to be entered.
	Yes / No: this component type allows healthcare professionals to build decision trees within the Caretask (i.e., if the answer to a question is “YES”, the patients will receive a follow-up question which would be skipped if the answer was “NO”). The current limit of decision tree levels is 1. Further possibilities to show / skip screens can be found at the Jumps.
	Pain location charts: it opens a silhouette of a human on which patients can locate their primary pain point. Note: No score can be assigned to individual pain locations; thus, scores will only count towards this component being answered.
	Ranking: enables patients to sort answer options according to their own preference / ranking, while the primarily applicable item shall always be on the top. The preset of answer options can be changed by dragging them into the desired position. This component type will also feature the “Evaluation Line”, which is an additional aspect exclusively available for the “Ranking” component type, indicates the answer option after which lower ranked items are no longer considered for the calculation, i.e., if “Evaluation Line” is set to “2” with 8 ranking items, only the first two answer options will be regarded for the calculation.
	Information: features a description of a task which the patient is asked to fulfill. This component type shall be the primary type featuring media.
	Section: allows to describe ensuing components with a longer text than the regular component description allows for. May be used as an introductory text. With this type of component, no interaction of the patient is intended, apart from viewing the information.
	File Request: allows the healthcare professionals to request a file within the Caretask so that the patient or the HCP can upload a file while answering the Caretask. This file can be reviewed either in the results view or in the files of the respective patient. Note: The patient can only upload files up to 10 MB in size, and the file will be compressed to enable speedy file transfer. Therefore, the quality of the file might vary. myoncare Careplan Manager does not provide any imaging or diagnostic service based on the file.
	Date Request: allows the patient or healthcare professional in the medical staff to enter a specific date within the conduction of a Caretask. The healthcare professional can also define a threshold depending on the reference between the submitting date and the answered date of the Caretask.
	BMI: this feature will calculate a BMI (Body Mass Index) based on the input data (height and weight). While adding the component to the Caretask, the healthcare professional can define a score or threshold for the answer based on the predefined categories (“Underweight”, “Normal weight”, “Overweight” and “Obesity”). Note: The definition of the categories is referring to the categorization of the “World Health Organization” refer to: https://www.who.int/europe/news-room/fact-sheets/item/a-healthy-lifestyle---who-recommendations
	Blood Pressure: firstly, this component allows healthcare professionals to request blood pressure measurements from patients, supporting the monitoring of their health status. Secondly, besides displaying the raw answer values, it uses the ESC-ESH Guidelines 2018 to classify patients into distinct hypertension categories based on their blood pressure values. Blood pressure categories and conditions:

Categories	Condition
Optimal	Systolic < 120 and Diastolic < 80
Normal	(Systolic between 120-129 and Diastolic < 84) OR (Systolic < 129 and Diastolic between 80-84)
High normal	(Systolic between 130-139 and Diastolic < 89) OR (Systolic < 139 and Diastolic between 85-89)
Grade 1 hypertension	(Systolic between 140-159 and Diastolic < 99) OR (Systolic < 159 and Diastolic between 90-99)
Grade 2 hypertension	(Systolic between 160-179 and Diastolic < 109) OR (Systolic < 179 and Diastolic between 100-109)
Grade 3 hypertension	(Systolic >= 180 and Diastolic < 110) OR (Systolic < 180 and Diastolic >= 110)

Note: The hypertension classifications are sourced from the ESC-ESH Guidelines of 2018.

Components Settings

By clicking on the added component, the settings that only apply to this component will open in the right part of the screen. The following options are available:

- Add a description (e.g., of the question or task)
- Attach file (e.g., image, URL or document)
- Add jumps
- Set the rating of individual answers
- Activate scoring
- Activate the required field (making the component mandatory and ensuring the patient cannot skip it without providing an answer).

All these aspects must be actively selected by the healthcare professional via the corresponding sliders in the right sidebar. Within the medical variant, the healthcare professional also has the possibility to add thresholds and adjust the details of the set thresholds.

Besides the questions / information and the settings, the answer options must be defined for some components. This applies to single and multiple choices as well as the ranking component. All other component types do NOT require the definition of answer choices.

To create answer choices, click on "Show Contents" under the appropriate component. The menu for entering the answer choices now opens. You can then enter the possible answers for this question.

myoncare Careplan Manager offers the option of displaying individual components only under certain conditions. There are two options for this, decision trees with yes/no components or jumps.

Decision trees can be created using "Yes/No" components by arranging individual questions one below the other. Using "Drag and Drop", the component that should follow the yes/no question can be "dragged" under it until a connection appears. Questions which should only be asked if answered with "Yes" are inserted by the regular Caretask sequence. If the answer is "No", these questions will be skipped and the Caretask will continue with the next question outside the insertion. The current depth of the decision trees is one.

To ensure optimal performance and provide patients with the best user experience, it is advised to limit the number of components in a caretask to 30. Not all parameters are available or required for each component type.



Deleting a component will remove it from the myoncare Careplan Manager entirely, i.e., for all healthcare professionals having access to a site's components. Deleted components cannot be restored.

Activate Scoring

Assigning scores to components and / or answer options allows healthcare professionals to introduce a multi-level factoring of how to rank or value single components and their corresponding individual answer options. Under Component settings (right side of the screen), the slider must be activated to start an evaluation.

For various component types, the scoring system is tailored to ensure accuracy and relevance.

Free Text, Yes/No, Pain Location Chart, and Section Components: these components have a single score, determined by the healthcare professional, and are considered upon answering them.

Single Choice and Multiple-Choice Components: Each choice option can have an individual score which is set by the healthcare professional. The score is determined by the chosen option's score.

BMI and Blood Pressure Components: these components contain predefined categories, for which scores can be assigned individually. When the patient responds to the caretask, their responses are categorized accordingly, and the score is determined based on the category.

Ranking Components: each option in a ranking component can be assigned a score. The healthcare professionals set an evaluation line. When the patient ranks all the options, the scores of the options above this evaluation line are factored in the calculation of the overall score.

Numeric Range and Numeric Value Components: The score corresponds to the value entered by the patient or healthcare professionals when answering the caretask.

Information, File Request & Date Request Components: Scores cannot be activated for these components.



The Numeric value component can contain a decimal score, which may lead to a decimal overall score of a caretask. In such instances, the overall score of a caretask is rounded to the nearest whole number. E.g., overall scores of 4.2, 4.5, and 4.7 for different caretasks are rounded to 4, 5, and 5 respectively.

Healthcare professionals (HCPs) now have the option to input negative values for the minimum or maximum value in Numeric Range and Numeric Value components. When a negative value is entered, it is important to note that configuring scores for this component will be disabled.

The scoring being defined here will also be the input taken for the corresponding "health indicator" displayed around the profile picture of the patient.

The scores corresponding to a "well", "fair", "poor" and "neutral" patient condition must be defined in the Caretask settings. Whether the highest or lowest rating defines a good or bad condition can be decided here per Caretask. If a Caretask with activated scoring is created, a value range must be defined, which corresponds to a "well" and which to a "poor" condition - the value range of a "fair" condition can be defined optionally.

Note: A plausibility check of the calculated maximum value can help to identify potential errors in the scoring of individual components.

Interface to OncoBox

In case you want to import patient information from the OncoBox into myoncare, myoncare Careplan Manager facilitates an interface which allows you to import the following data:

- Master data (without any patient personal information)
- Case information
- Diagnosis
- Tumor board
- Surgery
- Surgery course
- Post operative histology staging
- Radio therapy and process.

To import the above-mentioned information, click the 'Action'-button within the patient list and select the import button. Select the .xml-file you want to import and click on 'Import'. The information will be added to the respective patient, in the patient overview under the section 'Imported Data'. The imported information will only be displayed and is not processed by any means. The mapping of patient data works via the Patient-ID. In case data is already being imported and will be imported once again, the old data will be overwritten with the new import information.

Furthermore, you can export the patient information via clicking the 'action'-button and use the functionality of exporting patient data. A CSV-file with the above-mentioned data will be generated and downloaded to your files.

Note: This functionality is not available by default and can be requested to be activated within your instance.

Assigning Care Pathways and Caretasks

myoncare Careplan Manager allows healthcare professionals to assign Care Pathways and Caretasks in three ways:

- Assigning within the patient overview of a specific patient
- Assigning from the Care Manager to specific patients
- Assigning a Care Pathway or a Caretask via QR-Code

Assigning within the patient overview of a specific patient:

In the workflow from the patient overview page, healthcare professionals need to select “Assign Care Pathway” or “Assign Caretask” from the action menu (appearing after clicking the “+”-button), which will redirect them to the “assignment modal”, which details the four steps necessary to assign a Care Pathway or Caretask to a patient.

- **Step 1 – Choose a Care Pathway or Caretask:** Choose a Care Pathway, which shall be sent out to the patient. Note: The search functionality only searches for a match within the name.
- **Step 2 – Settings:**
For **Care Pathways:** In the second step you need to define the reference date. Based on the date chosen within this step, all Caretask occurrences of the Care Pathway will be scheduled to be sent out to the patient. On the right side of the modal, you can view the scheduled occurrences. Note: In case “Unspecified” is chosen as a time, the default reference time will be defined as 12 pm. By default, the functionality of sending out Care Pathways on already existing patient appointments is disabled. In case you wish to use this functionality, please contact the myoncare support. In case this functionality is enabled, be aware that the assignment of the Care Pathway to the patient via an existing appointment uses the most recently created appointment to schedule the Care Pathways Caretask occurrences to the patient.
For **Caretasks:** define the scheduling of the occurrence of the Caretask by defining the start date, number of occurrences and lifespan of the occurrences. Within the medical variant the healthcare professional also has the possibility to set individual thresholds (or remove all preset thresholds from the template.)
- **Step 3 – Components Configurations:** In this step, make sure that all scores, thresholds and jumps have been verified. In addition, at no time should a score lead to the sole basis of an intervention, relevant medical action, or prioritization of individual patients. Within the medical variant the healthcare professional is also requested to review the set thresholds. Furthermore, the thresholds shall also not be used as the sole basis of an intervention, relevant medical action, or prioritization of individual patients.
- **Step 4 – Assign / Send out:** Within the last step the healthcare professional can review the planned assignment.

Assigning from the Care Manager module to specific patients

Assigning Care Pathways or Caretasks from myoncare Caretask Manager module is the most efficient way to assign a Care Pathway or a Caretask to multiple patients at once. After clicking on the “Assign” icon on the right side of the template overview screen, an “assignment modal” will appear. Healthcare professionals are required to select patients to whom this Care Pathway or Caretask shall be sent and assign according to the workflow outlined above.

Note: Settings can still be changed in the assignment screen. Only the previously selected Caretask, i.e., the Caretask displayed in the row in which “Assign” was selected, can be assigned.

Caretasks can only be assigned to patients in whose Careteam the current healthcare professional is included. Further, only those patients will be displayed by filters. To assign a Care Pathway or Caretask efficiently to a specific patient group, the healthcare professional can use the filter functionality within the first assignment step within the Care Manager. This allows bulk to assign the Care Pathway or Caretask to a filtered patient group.

Assigning a Care Pathway or Caretask via QR-Code or Deeplink

Clicking on the QR-Code symbol within the Care Manager on the respective Care Pathway or Caretask will open a modal on the right side of the myoncare Careplan Manager healthcare professional interface. This modal shows a QR-Code, a Deeplink, a button to export the QR-Code as well as an opportunity to activate or deactivate the QR-Code and Deeplink.

To use the functionality of assigning Care Pathways or Caretasks via the exported QR-Code or Deeplink, the respective QR-Code or Deeplink must be activated. This can be done via the toggle button within Modal. This is not possible for Care Pathways with occurrences in the past as well as for Caretasks which should be conducted by healthcare professionals.

By letting a patient scan the shown QR-Code or open Deeplink, the Care Pathway or Caretask will be assigned and sent out to the patient. In case the patient scans a QR-Code or open Deeplink of a Care Pathway, the time of the scanning will define the reference date and time. All Caretasks included within the Care Pathway will be scheduled based on this date and time. Scanning a QR-Code or opening Deeplink of a Caretask will send out one single occurrence of the Caretask to the patient.

To enable the healthcare professional to create individual invitation or registration letters, the QR-Code can be exported as a PNG or JPG.

All patients scanning the QR-Code or opening Deeplink, who are not enrolled to the site of the healthcare professionals, will be asked to connect to the site. Therefore, the self-registration process will be triggered.

Exporting or importing a Care Pathway or Caretask

Templates offer various options to collaborate among teams or sites by enabling ex- or import of templates of any size.

"Export" will automatically trigger the download of the selected Care Pathway or Caretask and compress it into a .zip folder ([Name of Caretask].zip) with the .care file included to save disk space.

Exported files can be imported to different sites by selecting "Import Caretask/Care Pathway" from the action menu on the Care Manager screen. Besides following the on-screen instructions, healthcare professionals must select a .care file, since this will be the only data format accepted by the myoncare Careplan Manager. Once imported, the template is available to be assigned and edited for healthcare professionals of the site as a regular template.

PDF Report

myoncare Careplan Manager allows healthcare professionals to decide if their patients get a PDF report of conducted Caretasks. Through the report, the patients can review the results and forward the information to another doctor to assess it, if needed.

The PDF Report contains a generic first page which includes general information about the patient like name, Patient-ID, date of birth, ICD-Code, gender, the institution name and address of the institution. Also, it includes the name of the Caretask, the description of the Caretask - if given -, the date when the report was generated, total recurrences and lifespan of the Caretask. The following pages of the report include a header with the name of the Caretask and when the report was generated. Besides that, it always contains the components and the given answers. The components are including an index number and the title, as well as all answer options (depending on the type of component).

Note: Only the components that were displayed to the patient while answering the caretask are available in the report. Components which include a defined jump for one or more options will include an indicator which displays which option leads to which of the following components.

To generate the PDF-Report, the healthcare professionals have to activate the option 'Create a Caretask report for the patient' within the Caretask settings. Once activated, additional settings will open. The healthcare professional has to decide, if the report should be generated every time a patient or healthcare professional answers a caretask or only if a threshold is exceeded. Besides that, the healthcare professional has to decide in which language the Caretask report should be generated. Per default the language is set in the same way as the healthcare professional has set the myoncare Careplan Manager. The language setting will only affect the generic information of the report, while the content will not be translated. Additionally, healthcare professionals can review the report by enabling the "Report Review" toggle. They also have the option to select a default "Review Caretask" that will automatically be associated with the generated reports. These reports can be easily accessed by clicking on the "Ready-to-Review Reports" notification icon located at the top right of the screen.

The patient gets a push notification, through the Mobile, when a report is generated. The patient can access the report either clicking on the push notification, or going to the file section, within the Mobile. The generated report will be also found within the file tab of the patient profile in the myoncare Careplan Manager.

Note: Reports that require review are not available in the file sections and are not visible to the patients.

7. Rights & Roles

Adding and editing roles

In case your setup has been adjusted and you have received the rights to also add, edit and delete roles the following instructions will help you to understand how this can be done.

"Add new role" will open a configuration menu which allows to tailor roles according to the desired permissions. It is required to set a role name and select permissions for modules and actions. Changes must be saved to be effective.

Note: (De-) selecting the button on the left of the module name will automatically set or remove all permissions for this module.

The attributes reflect the following permissions:

- **"Read"** defines the function of viewing the individual pages, but not the history, which describes when, who, and what changes have been made.
- **"Show"** defines the function of viewing history, which describes when, who, and what changes have been made.
- **"Send"** defines the function of assigning. If a healthcare professional shall be able to assign Caretasks, assessments, care pathways, appointments or medications, this function is required. ONCARE recommends that all healthcare professionals with this right should also be able to "unassign".

- **"Unassign"** allows the healthcare professional to revoke content that has already been sent, making it unavailable to the patient.
- **"Share"** allows to import and export Caretasks and Assessments. Additionally, it allows sharing media files with other sites.

If an adjustment of a role is necessary, this can be done within the tab "Roles & Rights" in the administration section. To edit a role, click on the "edit"-symbol and an edit mask will be opened.

Furthermore, it is possible to hide all demographic data for a specific healthcare professional group by enabling the option "This role does not have access to demographic data of patients' within the roles and rights matrix". In case this option is enabled, all demographic data is hidden as well as the exporting functionality for the system is limited to only non-demographic data.

In case the healthcare professional is assigned with a role which cannot access demographic data, the healthcare professional will not receive push notification within the myoncare Careplan Manager in case a threshold is exceeded. Neither this healthcare professional will have access to mail notifications.

Deleting a role

Before deleting a role and its corresponding permission set, admins need to ensure that no active healthcare professionals of the system are still associated with this role. Deletions require double confirmation by means of a dialogue popup. Deleting a role will automatically render all logins associated with this role invalid. Healthcare professionals of this role / permission set will no longer be able to log in.

8. Troubleshooting & Reporting

- **Were you connected to the internet?**
If NO, connect to the internet and retry.
- **Which browser and operating system are you using?**
The browser as well as the version do have an impact on the functionality of myoncare Careplan Manager. Please, refer to Section 4 – Technical requirements for myoncare Careplan Manager.
- **What is your role?**
If the assigned role does not have permissions to perform the operation which causes the error/inconvenience to occur, ask the site administrator to change the role restrictions.
- **Since when does the issue persist?**
If it happened once, restart the browser, clear the browser's cache, and try again.
- **Does the issue persist for multiple healthcare professionals of different roles?**
If YES, report the issue to ONCARE.

Incident reporting

Healthcare professionals shall report any serious incident which has occurred in relation to myoncare Careplan Manager, to ONCARE (service@myoncare.com) as well as the competent authority of the member state in which the user is established. Healthcare professionals are required to also inform patients of this procedure prior to their use of myoncare (Mobile).

Only applicable if you are a Healthcare professional Facility located in the United States of America:


If you are a healthcare professional facility, please note that the reporting requirements of Title 21, CFR Part 803 apply to this device. Please make sure to submit individual adverse events to vigilance@myoncare.com regarding:

- **Device-related deaths**
- **Device-related serious injuries**

Please further note the reporting requirements of Title 21, CFR Part 803 including to the FDA.

Site Admin

The defined role "Site Admin" reflects a role within your institution with the most rights for the Webapplication myoncare and should therefore be assigned to IT-Admins or personal within your organization responsible for the administration of myoncare.

Page	 Delete	 Update	 Read	 Create	 Show	 Send	 Unassign	 Share
Patients	✓	✓	✓	✓	✓			
Users	✓	✓	✓	✓	✓			
User Roles		✓			✓			
Sites								
Satellite	✓	✓	✓	✓	✓			
Custom Filters	✓	✓	✓	✓	✓	✓	✓	
Appointments	✓	✓	✓	✓	✓	✓	✓	
Medications	✓	✓	✓			✓		
Tele Medicine	✓	✓	✓	✓	✓	✓	✓	✓
Careplan Templates	✓	✓	✓	✓	✓	✓	✓	
Careplans	✓	✓	✓	✓	✓	✓	✓	
Care Pathways	✓		✓	✓	✓	✓	✓	
Care Pathway Templates	✓	✓	✓	✓	✓	✓	✓	✓
Files	✓	✓	✓	✓	✓	✓		✓
Standard Data Mapping			✓		✓			

Doctor

The defined role "Doctor" has all rights to edit, delete or do further actions with the essential features of this product. This role is foreseen for doctors or medical staff which should be able to assign medical content to patients.

Page	 Delete	 Update	 Read	 Create	 Show	 Send	 Unassign	 Share
Patients	✓	✓	✓	✓	✓			
Users		✓	✓		✓			
User Roles								
Sites								
Satellite			✓		✓			
Custom Filters			✓		✓			
Appointments	✓	✓	✓	✓	✓	✓	✓	
Medications	✓	✓	✓	✓	✓	✓	✓	
Tele Medicine	✓	✓	✓			✓		
Careplan Templates	✓	✓	✓	✓	✓	✓	✓	✓
Careplans	✓	✓	✓	✓	✓	✓	✓	
Care Pathways	✓		✓	✓	✓	✓	✓	
Care Pathway Templates	✓	✓	✓	✓	✓	✓	✓	
Files	✓	✓	✓	✓	✓	✓	✓	✓
Standard Data Mapping			✓		✓			









Nurse

The defined role "Nurse" is foreseen for medical staff which should have the permissions to view relevant content but not edit it. This role has the rights to work on administrative tasks within myoncare.

Page	 Delete	 Update	 Read	 Create	 Show	 Send	 Unassign	 Share
Patients		✓	✓	✓	✓			
Users		✓			✓			
User Roles								
Sites								
Satellite			✓		✓			
Custom Filters			✓					
Appointments	✓	✓	✓	✓	✓	✓	✓	
Medications			✓		✓	✓		
Tele Medicine	✓	✓	✓			✓		
Careplan Templates			✓		✓			
Careplans		✓	✓		✓			
Care Pathways			✓		✓			
Care Pathway Templates			✓		✓			
Files	✓	✓	✓	✓	✓			
Standard Data Mapping			✓		✓			



External HCP

External HCP: The defined role 'External HCP' is designated for healthcare professionals "external" to the institution, granting them limited access to patient data associated only with their assigned satellite for efficient patient management within myoncare.

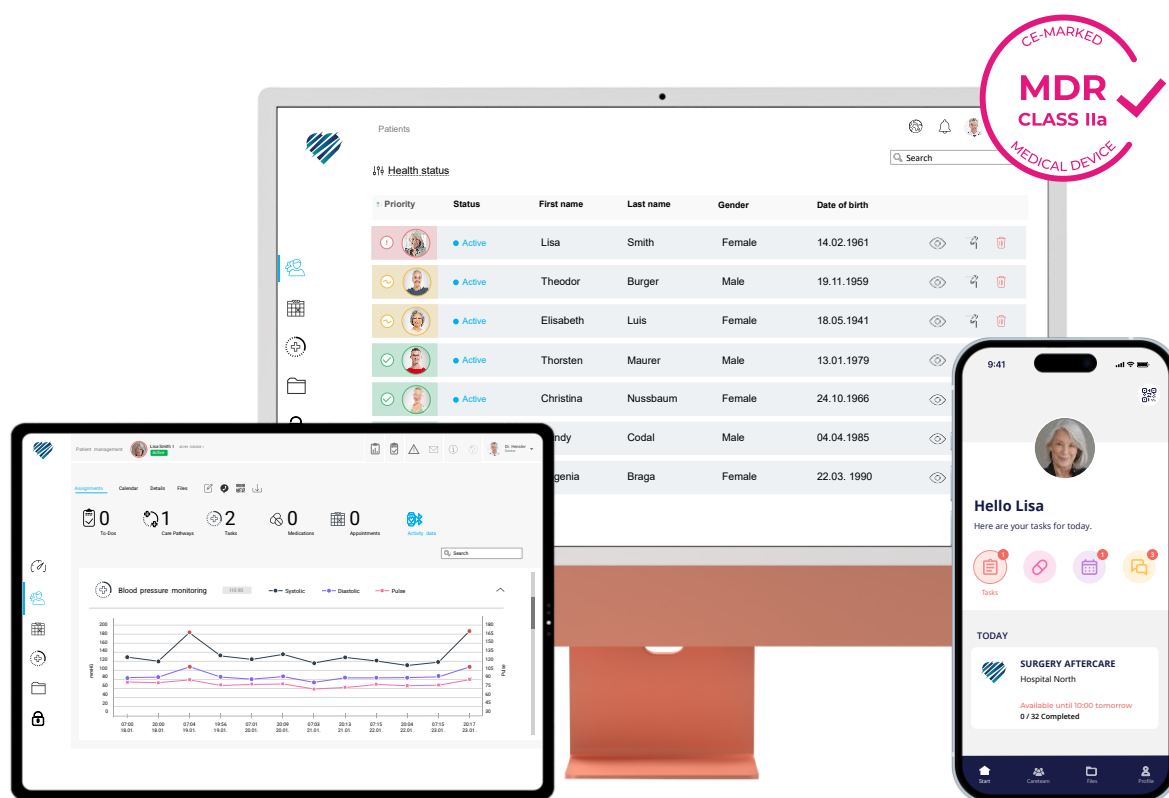
Page	 Delete	 Update	 Read	 Create	 Show	 Send	 Unassign	 Share
Patients			✓		✓			
Users		✓			✓			
User Roles								
Sites								
Satellite								
Custom Filters			✓		✓			
Appointments			✓		✓			
Medications			✓		✓			
Tele Medicine			✓			✓		
Careplan Templates			✓		✓			
Careplans			✓		✓			
Care Pathways			✓		✓			
Care Pathway Templates			✓		✓			
Files			✓		✓			
Standard Data Mapping			✓		✓			

Author

The defined role "Author" primarily focuses on managing the association of components with analytics labels. This role is intended for users who are responsible for creating, editing, and linking medical content or system components to analytics labels for tracking and reporting purposes.

Page	 Delete	 Update	 Read	 Create	 Show	 Send	 Unassign	 Share
Patients	✓	✓	✓	✓	✓			
Users		✓	✓		✓			
User Roles								
Sites								
Satellite			✓		✓			
Custom Filters			✓		✓			
Appointments	✓	✓	✓	✓	✓	✓	✓	
Medications	✓	✓	✓	✓	✓	✓	✓	
Tele Medicine	✓	✓	✓			✓		
Careplan Templates	✓	✓	✓	✓	✓	✓	✓	✓
Careplans	✓	✓	✓	✓	✓	✓	✓	
Care Pathways	✓		✓	✓	✓	✓	✓	
Care Pathway Templates	✓	✓	✓	✓	✓	✓	✓	
Files	✓	✓	✓	✓	✓	✓		✓
Standard Data Mapping	✓	✓	✓	✓	✓			

THE DIGITAL HEALTH PLATFORM



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