♥myoncare

General Information

Version 1.12

MDR
CLASS IIa
CE-MARKED
MEDICAL DEVICE

ISO
27001
CERTIFIED
INFORMATION SECURITY MANAGEMENT

ISO
13485
CERTIFIED
QUALITY MANAGEMENT

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.

Medical device of class IIa

myoncare is available as a medical device (class IIa), but can also be provided as a non-medical device variant (which does not allow users to set thresholds or utilize the health indicator functionality).

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 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.

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.

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.

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).

Warnings ⚠️

• 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: "Filter applied!".

• Users and medical professionals are hereby advised not to 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.

Warnings ⚠️

- 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.

- 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.

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 e 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.

Precautions ⚠

- 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 oversees 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.

Precautions ⚠️

- 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 professionals seek permission from the patient before utilizing this option.

Undesirable 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.