

SC1-PHE-CORONAVIRUS-2B

ENVISION

Intelligent plug-and-play digital tool for real-time surveillance of COVID-19 patients
and smart decision-making in Intensive Care Units

Project No. 101015930

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Abstract

Within only six months, over 7.4 million people have been diagnosed with SARS-CoV-2. In the most severely hit countries, more than 10% of infected patients have received treatment in Intensive Care Units (ICUs). Insufficient data and limited knowledge on the disease as well as the lack of tools to support the intensivist in making accurate, timely and informed decisions have led to high mortality rates.

Continuous surveillance, the collection and intelligent analysis of data from many sources, including ventilators and electrical impedance tomography, would allow intensivists to decide on the best suitable treatment to accelerate the recovery of the often-comorbid COVID-19 patients, while reducing the burden on clinical staff and healthcare costs. This information would also increase our understanding of the yet unknown course of disease, supporting other stakeholders in the quest for new therapies.

In ENVISION, our multidisciplinary public-private consortium will advance an innovative digital tool, Sandman.MD, a real-time and plug-and-play monitoring app, to an intelligent decision-support system for monitoring, prediction and treatment of COVID-19 patients in ICUs – the Sandman.ICU – reaching Technology Readiness Level 9 and ready for CE marking by the end of the project. The app has been developed by our SME partner app@work and was successfully introduced by several hospitals in Germany for use during the perioperative period. Sandman.ICU will be integrated into an AI-driven data analytics suite with predictive modelling tools and enhanced with a smart alert functionality. The digital tool will be validated and demonstrated in 13 hospitals across Europe. Our Health Technology Assessment expert partner will demonstrate the economic and societal value of Sandman.ICU, while an experienced SME will manage the innovation process in view of an immediate market uptake. The rollout will be supported by the European Society of Anaesthesiology and Intensive Care (ESAIC).



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Partner short names

AAW	app@work GmbH
accelCH	accelopment Schweiz AG
accelDE	accelopment Deutschland GmbH
CCHT	Spitalul Clinic Judetan De Urgenta Pius Brinzeu Timisoara
CHUC	Centro Hospitalar e Universitario de Coimbra E.P.E.
DPT	Central Hospital of Southern Pest National Institute of Hematology and Infectious Disease
ESAIC	European Society of Anaesthesiology and Intensive Care
GUF	Johann Wolfgang Goethe Universität Frankfurt am Main
ICS-HUB	Institut Catala de la Salut – Bellvitge University Hospital
iDA	Intelligent Data Analytics GmbH & Co. KG
KC	Lietuvos Sveikatos Mokslu Universiteto Ligonine Kauno Klinikos
LMI	Löwenstein Medical Innovation GmbH & Co. KG
SE	Semmelweis Egyetem
TAU	Tampereen Korkeakouluosaatio SR
UCL	University College London
UMCG	Universitair Medisch Centrum Groningen
UMCL	Univerzitetni Klinicni Center Ljubljana
UMCM	Univerzitetni Klinicni Center Maribor
UMFCD	Universitatea de Medicina si Farmacie Carol Davila din Bucuresti
UNIPG	Università degli Studi di Perugia
UNITO	Università degli Studi di Torino

Abbreviations

D	Deliverable
EC	European Commission
H2020	Horizon 2020
ICU	Intensive care unit
M	Month
MS	Milestone
SOP	Standard operating procedure
WP	Work package



Revision history

Date	Authors	Revision
16.07.2021	GUF: BG, MK, LG	Draft version
19.07.2021	GUF: BG AAW: DW, RB, JW ESAIC: CW, JR, JD	Revision 1
21.07.2021	GUF: BG ESAIC: JD	Revision 2
28.07.2021	GUF: BG AAW: DW, RB, JW ESAIC: CW, JR, JD	Revision 2
29.07.2021	GUF: BG	Final version
28.03.2022	GUF: BG AAW: DW, RB, JW ESAIC: JW, CW	Final version 2

Executive Summary

This deliverable is part of **Work Package 4 (WP4), Task 4.2: Sandman.IC user guide and trainings material** and it describes which work packages have been defined and implemented to ensure the correct functional handling and data collection through Sandman.IC at all clinical partners with the correct provision of training materials.

Need for the Deliverable

In the ENVISION project, for artificial intelligence (AI) training purposes, all clinical partners across Europe collect vital data from COVID-19 patients during their stay in the intensive care unit (ICU). The data recording is done using Sandman.IC which directly extracts the vital data from the connected medical devices (in the current scenario vital monitors and ventilators), pseudo-anonymises it and then stores it in K-anonymised form on the big data hub (server) of the European Society of Anaesthesiology and Intensive Care (ESAIC).

However, it must be ensured by the app@work (AAW) software experts together with the project coordinator (GUF) and ESAIC, that the medical professionals can record the data through Sandman.IC to a high-quality standard. With this in mind, training materials that are easy to understand and adapted to the different clinics across Europe are necessary and the medical staff that will be collecting data through Sandman.IC need to be properly trained.

In addition to the data acquisition, Sandman.IC functions similarly to a typical patient data management system in the ICU. Sandman.IC, an innovative and at the same time a cost-effective tool, is intended to be used in intensive care worldwide. Also in this sense, a comprehensive training of the medical staff is mandatory for meaningful further development of Sandman.IC in this area.

Outcomes

The aim of this document is to create training materials including a comprehensive user guide to ensure data of high quality is collected during the project lifespan and also that the full functionality of the Sandman.IC tool can be utilised by the medical experts across Europe. The latter also enables better feedback of the tool due to the extensive use of Sandman.IC by many medical professionals in order to create more optimised functions.



Related documents:

- D4.1 Study protocol and standard operational procedures.
- D2.2 Unsupervised long-term documentation.
- D4.3 Site initiation and installation report.
- D6.3 eLearning materials (30.11.2021).

1 Introduction

Sandman.IC, the software to be developed in the ENVISION project, is intended to assist healthcare personnel in accurate and timely decision-making when treating COVID-19 patients in ICUs. In order to provide this help effectively, the planned predictive models have to be created using high-quality data. Thus, it is imperative to ensure the proper use of Sandman.IC during the data collection period. The smart app is also intended to be used as a patient management system in the future. Therefore, as well as overall training in the use of the app, information about the benefits offered by the app is also required.

The Deliverable 4.2 - Sandman.IC user guide and trainings material, constitutes a part of Work Package 4, which overall deals with the implementation of Sandman.IC at the clinical partners.

1.1 Purpose of this deliverable

The purpose of this deliverable is to:

- Describe the training materials and their contents.
- Explain the purpose of all training materials.
- Describe what is planned for the future and an assessment of the effectiveness of the training materials provided (outlook).

This deliverable is therefore structured as follows:

- Discussion of the training material is divided into two parts: data recording and patient management system;
 - Data recording part discusses the specific training tools intended to enable the collection of high-quality data;
 - Functional part of Sandman.IC - Comparable with a typical patient management system. Discussion of the training tools for providing the clinical partners with a thorough overall training in use of and benefits offered by Sandman.IC;
 - Summary of the training materials used, assessment of the effectiveness and an outlook on outstanding work packages (and deliverables).
 - Outlook and assessment of the effectiveness of the training materials.

2 Training materials

The training materials are divided into two distinct categories and through a series of meetings between the partners involved in this deliverable, the associated tasks were divided to best match the skills and expertise of the partners.

The two categories are as follows:

- Data recording:
 - The main focus was to ensure clinical partners could record data as soon as possible. This meant that clear, easy to use instructions were required;



- It is crucial that high data quality is collected and so instructions needed to be detailed enough to minimise any human error;
- Materials will comprise of a pictogram and a short tutorial videos.
- Patient management system:
 - The aim of this is to provide a clear explanation of the functionalities and benefits offered by Sandman.IC;
 - Materials will comprise of a comprehensive user guide and a general training presentation. This part will give the clinical staff to ask any specific questions and look at any centre specific issues or problems.

The diagram below shows an overview of the training materials (figure 1):

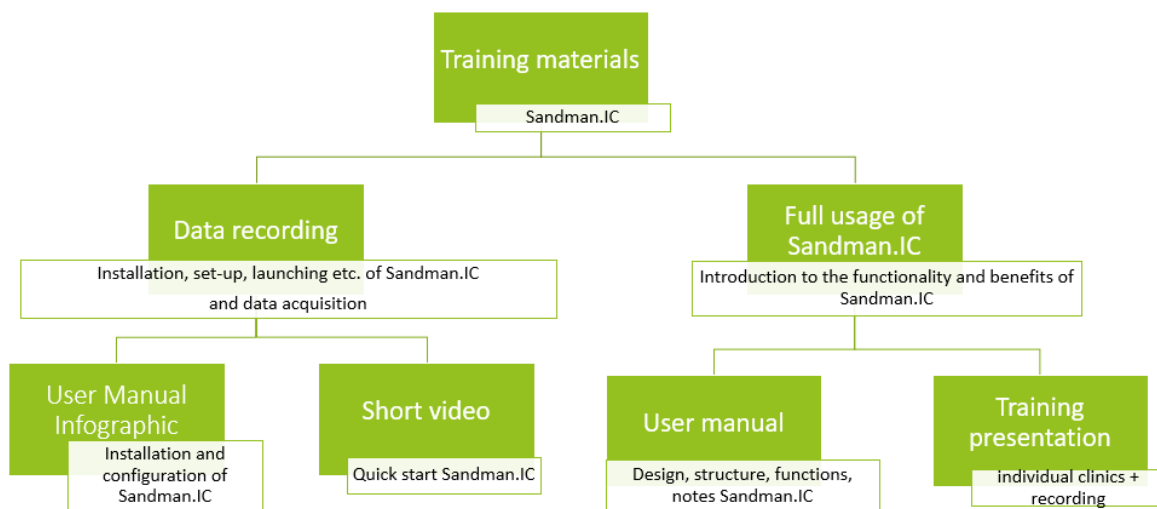


Figure 1: Overview of training materials.

Regardless of the corresponding training categories, operational support for Sandman.IC is divided into the following stages:

- Stage 1: Installation;
- Stage 2: Machine communication;
- Stage 3: Complete professional use;
- Stage 4: Support.

These four levels of support are described below, along with an overview of the materials used.

In the following, the training categories are described in more detail in the first instance and the operational support is described in more detail in the second instance.

2.1 Categories of training materials

The training materials are divided into two categories:

- Training materials for data recording;
- Training materials for using Sandman.IC as a patient management system.

The different training materials are described in more detail below.

2.1.1 Category 1 - Data recording

2.1.1.1 User infographic

The infographic (figure 2) is a compact and simplified schematic representation that describes the necessary functions of Sandman.IC. This document is attached as Appendix 1: User Infographic and is also available on the ENVISION cloud (accelCLOUD): https://cloud.accelopment.com/index.php/apps/files/?dir=/ENVISION/03_Deliverables/Revision%20deliverables/D4.2&fileid=147697. This website can be accessed only by authorised users.

There is often a need for great flexibility in the ICU, which can often mean a changeover of medical equipment. However, this means that Sandman.IC must be connected to the now "new" medical devices and the clinical staff must be able to do this quickly and efficiently.

It is therefore necessary to include the most important key points within the user info graphic, as well as how the process of creating a new patient record (when changing patients) works. With the first delivery of the Sandman.IC Kits, each clinical partner received two user infographics that can be attached to the vital monitors, for example, so that in addition to experienced medical staff, new staff can also ensure continuous data recording.



Figure 2: User infographic.

2.1.1.2 Training videos

These training videos contain similar information to the info graphic but demonstrates each of the steps with short and simple instructions. The videos have background music but no recorded speech as text is expected to be easier to understand, especially given that it will be used in 13 medical

institutions in multiple countries. The videos are approximately two minutes long and they were purposefully kept short in order to make it a tool that is quick and easy to access at the point of use.

Below is a description of the contents of the videos:

- How to connect the device;
- How to log in;
- How to search for a patient and start data recording;
- How to disconnect device when data recording is complete;
- Contact details in case of questions or feedback.

The training videos are available on the ENVISION cloud (accelCLOUD): https://cloud.accelopment.com/index.php/apps/files/?dir=/ENVISION/09_Work%20Packages/Other/Trainingmaterial&fileid=78541. This can be accessed only by authorised users.

Below are several screenshots from the training videos which show simple instructions with a 'live' demonstration (figures 3, 4 and 5).



Figure 3: Connection between Sandman.IC and a medical device.

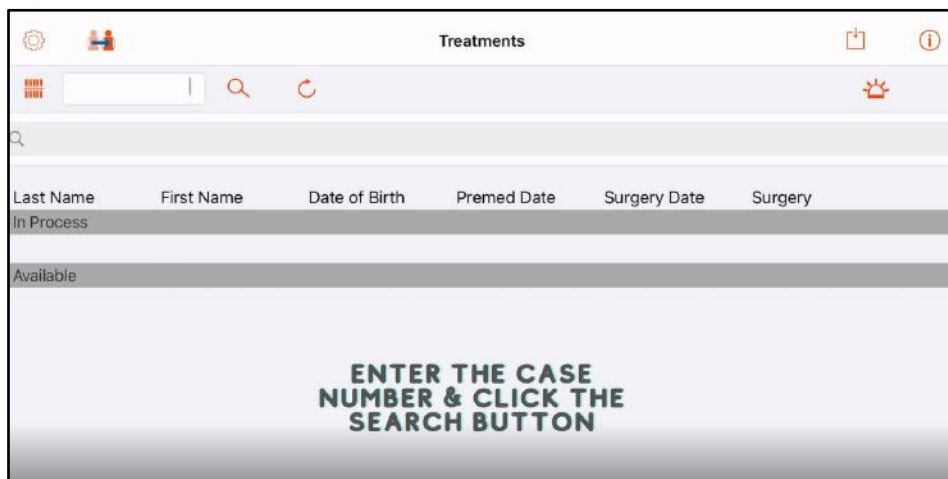


Figure 4: Treatment interface in the Sandman.IC app.

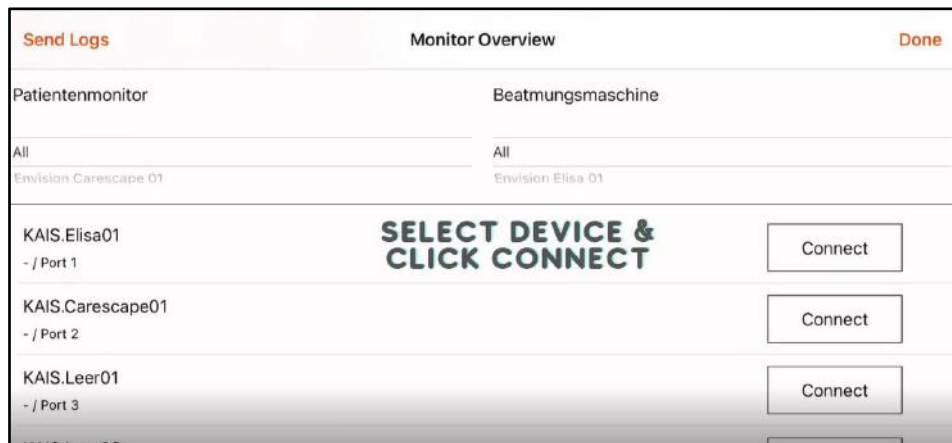


Figure 5: Overview of available medical devices for connection as shown in Sandman.IC.

2.1.2 Category 2 - Use of Sandman.IC as a patient management system

In addition to ensuring data capture, Sandman.IC has many useful features to help medical staff simplify their day-to-day work in the ICU.

The functions of Sandman.IC are comparable to a comprehensive patient management system, where the recorded vital parameters of the patient are automatically documented and which at the same time enables a mobile and comprehensive planning of the treatment of the patient and allows continuous monitoring of the patient's health status.

In this sense, extensive training of the medical staff is necessary to cover the full functionality of Sandman.IC. The following training materials will make this possible:

- User manual;
- Training presentations
- Training videos.

2.1.2.1 User manual

The user manual (figure 6) describes the most important functions, structures and interfaces of Sandman.IC. The guide is divided into the following parts:

- Treatments;
- Course of treatment;
- Structure Sandman.IC;
- Patients;
- Medical History;
- Post ICU.

This document is attached as Appendix 2: User manual and is also available on the ENVISION cloud (accelCLOUD):

https://cloud.accelopment.com/index.php/apps/files/?dir=/ENVISION/03_Deliverables/Revision%20deliverables/D4.2&fileid=147697. This website can be accessed only by authorised users.

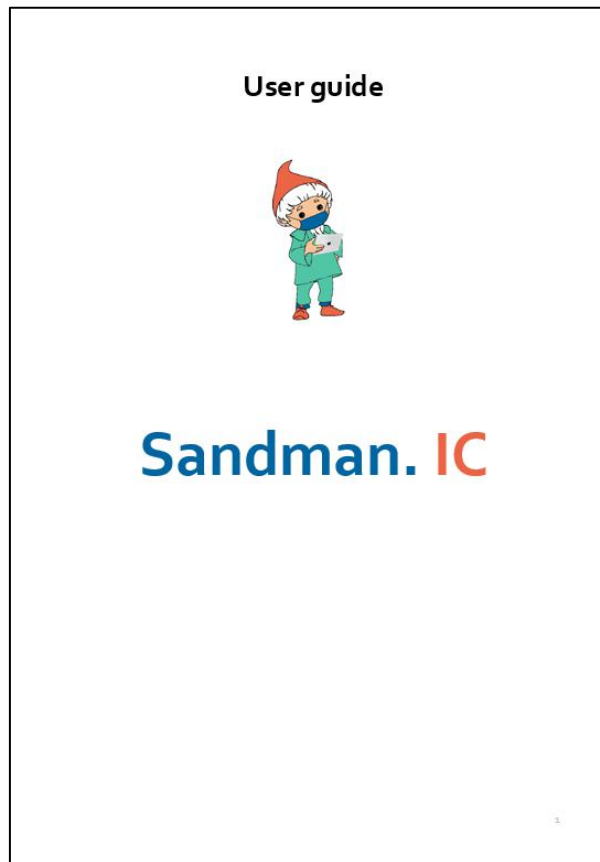


Figure 6: User manual Sandman.IC.

Even for healthcare professionals with little experience in working with a "typical" patient management system, the user manual with its structured illustrated presentations is an easy and quick to use guide.

2.1.2.2 Training presentation

In order to address the questions and needs of each clinical partner individually, training sessions with the individual clinical partners are offered by AAW. In addition, AAW also provides a presentation (as multiple short videos) and makes this available to all the clinical partners, in order to give the medical staff an understanding of how Sandman.IC works in a visualised way. The content of the presentation is similar to the topics in the user guide.

The training videos are uploaded to the ENVISION Cloud (accelCLOUD) so that the training material is freely available to everyone. ENVISION partners are also allowed to upload the training materials to their respective hospital's internal website at any time.

2.2 Operational support steps for training

2.2.1 Stage 1: Installation

Sandman.IC is an intuitive system that does many things automatically and can be operated using current standard procedures for handling smartphones and tablets. Nevertheless, there is a very complex information system in the background, which is necessary since the documentation of manual

and machine data in the intensive care process is an extremely complex procedure. Furthermore, the installation of Sandman.IC and its components requires the cooperation of experts from the ICU departments as well as experts from IT, especially those responsible for the network, and possibly also employees from medical technology.

The following components are part of the Sandman.IC system:

- The Sandman app, which is used to perform all documentation of patient data and is the clinical staff's only documentation tool when treating ICU patients;
- The iPad on which this app is installed and which is installed at each ICU bed for monitoring;
- The ComBox, which enables communication between Sandman and its components;
- The medical intensive care equipment, such as patient monitors and ventilators, whose data is documented via the ComBox on the iPad in the Sandman;
- The Sandman server, which makes treatment cases available to Sandman.IC on the iPads, which are then documented there and whose data is then stored again on the Sandman server. The Sandman server is also the link between the data-producing components (Sandman and medical devices) and the data-processing or analysing components, the analysis database and the AI system.

In order for the Sandman.IC system to function properly (including the communication between the individual components, see also figure 7), it must be carefully installed and put into operation.

Each individual clinic has its own infrastructure for this as they have their own intensive care equipment (including monitors) from different manufacturers that may not be used in other clinics.

Not all clinics use the Elisa 600 ventilators from Löwenstein Medical Innovation (LMI) that were offered to all the clinical experts during the early beginning of the ENVISION project. Furthermore, the clinics have different ways of providing networks and specific procedures for including devices in these networks. It may be possible to carry out data communication via a LAN or a WLAN but this is likely to involve different approval procedures and technical considerations at the different clinics.





Figure 7: ComBox, installed system.

Installation of Sandman.IC is all the more difficult because the Sandman.IC components used in the clinics are not installed by the developers of these components, but have been shipped to the clinics and are installed by the staff on site with the support of the experts.

To support such remote installations, appropriate information material for the staff on site is required. However, this is unlikely to be sufficient as it is impossible to foresee the individual issues that may occur in each clinic. Means, this first phase of installation must be supported personal communication by telephone and video.

What materials are available to individuals on site at the clinics?

There is a standard operating procedure (SOP) that shows the basic wiring of the different components with pictures (see figure 2).

The basic installation of the system, which is shown in the SOP with a few pictures, is initially very simple. It is necessary to keep the process easy to understand since installation must also be carried out by any member of clinical staff (using only the photos and instructions in the SOP) when changing the position of the system to another bed or another machine.

Installation involves simply the following plugging in:

- Of a cable into the patient monitor;
- Of a cable into the ventilation machine;
- Of a cable into the iPad;
- Of a power supply unit into the socket and, if necessary;
- Of a cable into the LAN socket.

These cables can all be plugged in and unplugged at any time without any risk of affecting the data collection or the functioning of the machines. Installation of Sandman in the clinic's IT infrastructure, on the other hand, is more complicated and must be coordinated with the technical and IT experts on site. In order to do this, several workshops will be held with the relevant clinic staff using video conferencing.

The first workshop should make it clear to those involved what the procedure is to carry out the installation and what activities are involved in the process. All details that have been previously exchanged in advance should be checked and questioned (i.e. whether they are still as reported or have changed, any misunderstanding of the requirements, whether some components do not exist in the form in which they were reported and intended). In the workshop any open questions are discussed and clarified and the necessary persons and roles are identified. It is also agreed what preliminary work is to be carried out by the clinic and a date is set for carrying out the installation.

During the workshop, it is determined if the clinic infrastructure is different than planned and if a modification of the ComBox is therefore necessary. For example, it may be that communication with the Sandman server in the clinic is not carried out via a LAN access, as planned, but via a WLAN (or vice-versa). It may also be possible that the clinic's medical devices do not have the appropriate interfaces or other medical devices from other manufacturers must be connected. The workshop will be an opportunity to discuss these issues and agree the steps required for any changes.

2.2.2 Stage 2: Machine communication

After the installation of the Sandman.IC system, stage 2 is about the documentation of the data from the machine. As in stage 1, a SOP is available to describe the procedure. After starting the transfer of the data, it can be tracked in the Sandman.IC app on the iPad.

The user manual explains the operation of the interface in Sandman.IC, the possibilities to move the data, how to access detailed views and how to add or delete data manually.

This user manual describes the most important functions, structures and interfaces (for further detail please refer to section 2.1.2.1).

The user manual also describes how the data is then restored to the server and at what intervals this should be done. This means that the first data supplied by the medical devices can then be documented and made available in the analysis tool.

2.2.3 Stage 3: Complete professional use

In stage 3, the entire functionality of Sandman.IC is presented, including all the options for manually entering all the patient's treatment data. For this purpose, in addition to the user manual (as discussed in stage 2), multiple videos are used, as well as the direct contact with the users via video conferencing. These videos are available on the ENVISION cloud (accelCLOUD): https://cloud.accelopment.com/index.php/apps/files/?dir=/ENVISION/09_Work%20Packages/Other/T_rainingmaterial/Sandman/Videos&fileid=125682 This can be accessed only by authorised users.

The videos are recordings of how to use the Sandman.IC app: from logging in to logging out. The videos are short to allow faster access to the



required. The videos enable users to see what can be done in the different areas of the app and have a voice recording to explain each step and function. The videos therefore contain the same information as a presentation that would be done live in front of users in a training session. As scheduling appointments with so many clinics from different countries would be extremely difficult, the videos are available to all clinics instead of a live presentation. This means that users can access the videos when it is convenient to them. Any questions that the clinic staff may have will be answered by referring to the user manual. In addition, appointments for video conferences are offered to the clinics in the follow-up to the training materials being sent to them and this will be an opportunity to answer any remaining questions. During this training, the clinics are given a demonstration of the app.

Through a combination of the training materials, support from the AAW team and the fact that Sandman.IC is an extremely intuitive app, the clinical staff should all be appropriately trained for the purpose of ENVISION.

2.2.4 Stage 4: Support

Even with the training materials and workshops, it is highly likely that there will be new questions or issues that arise. This is to be expected as this is a research project and the app is in a constant state of development and will not be able to achieve real product maturity within the relatively short project duration. Therefore, the users as well as the on-site administrators (who installed and deployed the app) must still have the possibility to ask their questions to the development team during the project.

For this purpose, a Europe-wide standardised telephone number is available for urgent cases. This means that users should have the possibility to speak immediately with a person from the development team during normal office hours. For non-urgent questions, there is an E-mail address. The E-mails are sent to members of the development team to ensure a quick response.

For central administration, E-Mails are also automatically transferred to a ticket system that stores all requests from all clinics and all users together. The requests are prioritized and processed by the development team accordingly. Through this central recording, it is possible to gather information about the nature of the questions which can then be incorporated into future versions of the training materials (such as the user manual, videos, SOP, etc.) to ensure they are continuously improved and updated.

This ticket system is also directly available to the business administrators, belonging to the medical staff of the clinics. They can enter their inquiries or suggestions and ideas for improving the Sandman system in a structured form. The direct use of the ticket system should be reserved for the administrators, as this requires more explanation than writing an E-Mail and thus a filter function can also be used by the administrators, with which the non-urgent inquiries or notes of the users in the clinic are initially collected via a one-point channel.

As the Sandman.IC system continues to evolve as part of the ENVISION research project and will most likely undergo updates, it will be necessary to update the training material accordingly. As it is not always possible to quickly update materials such as longer videos, SOPs or the user manual, release notes by Sandman.IC will be published and sent to all the clinics. These will explain the changes made to Sandman.IC and summarise the information that users need to know.



3 Summary

As previously discussed, the purpose of this Deliverable is to provide tools and materials to ensure that intensivists and other clinical staff are trained on using Sandman.IC. The training materials are split into two categories: data recording and full training of Sandman.IC.

The data recording part (comprising of an infographic and training video) aims to enable clinical partners to start recording data as quickly as possible. The training materials are therefore relatively short and quick to use. The full training part is in a depth explanation of the functionality and benefits of Sandman.IC and consist of user manual and training presentation.

The combination of the different training materials should ensure that medical professionals can record data through Sandman.IC quickly and to a high standard. Furthermore, this should result in meaningful further development of Sandman.IC in intensive care.

All materials and documents described in this deliverable (the videos as well as the texts), should be available on the iPad to ensure quick access at the point of use. It will be ensured that all documents can be downloaded and viewed on any iPad. The text documents will be available as ePub files and can therefore be opened using the standard Apple app "Books". Of course, the app's own functionalities, such as bookmarks, search, zoom in and out, etc., and will also be available.

With these materials and the additional support offered, it is expected that Sandman.IC will be applied in all clinics very quickly and without great difficulty, especially given that s this solution supports the important work in the treatment of patients and does not hinder it. This is crucial given that this is an additional documentation to be prepared for the research project parallel to the original documentation in the clinic.

4 Outlook and assessment of the effectiveness of the training materials

In view of the goals set by ENVISION and the limited time frame of the project, the implemented work packages and the subdivision of the training materials into documents for data acquisition and later on the full training of the functionality of Sandman.IC were targeted. Due to the unpredictable course of the COVID-19 pandemic and the resulting fluctuating COVID-19 patient numbers, it was essential that the clinical partners were able to acquire data on Sandman.IC as early as possible. Particularly with regard to the achievement of Milestone 13 ("Clinical partners are prepared for data acquisition through Sandman.IC"), the distribution of training materials as described in the deliverable was necessary.

First feedbacks from the Steering Committee meeting in June 2021 have shown that the training materials for data acquisition (info user graphic and short training video) are welcomed and accepted by all partners. Later in the project, the clinical experts will be taught the full functional capabilities of Sandman.IC through intensive training (user guide and virtual training presentations).

Also the experts at AAW are available to answer questions about the set-up, functioning and data recording by Sandman.IC. An E-Mail account has been opened exclusively for this purpose:

AAW service hotline envision@appatwork.com

This account is linked to a ticket system where requests from clinical partners are processed and answered in a timely manner.



With all the corresponding measures implemented and work packages processed, there is a confident positive assumption of high data quality by clinical experts across Europe.

In the future, in addition to the described training materials, e-learning materials will also be produced within the framework of the project duration, which will also be finalised by the end of November 2021 according to Deliverable D6.3. In this context, the first measures are currently being taken to make the user guide available to the ENVISION partners in e-format. For similarly structured EU research projects, the approach described in this deliverable can be adapted and implemented in a similar way.

5 Appendices

Appendix 1: User infographic

Appendix 2: User manual



CHECK CABLE CONNECTIONS



iPad



Power supply



Elisa (slot 1-4)

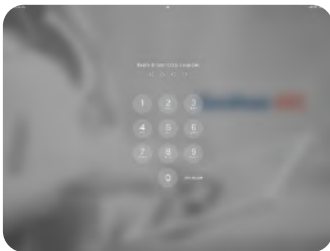


LAN connection

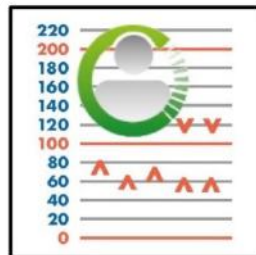


GE Monitor (slot 1-4)

START SANDMAN.IC



Enter code on iPad



Start Sandman.ICU app




Enter user and password



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101015930.

CREATE TREATMENT



Click on the icon  to create a new case



Enter the required data and click on "Create"

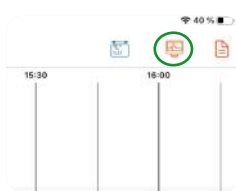


Click on the arrow pointing up

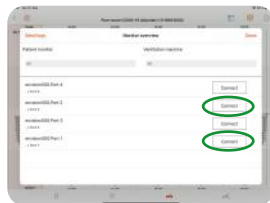


Enter ICU area

ESTABLISH DEVICE CONNECTION



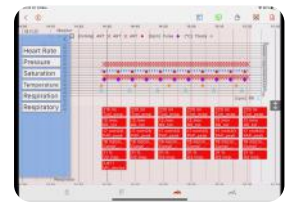
Press 



Select devices and press „connect“

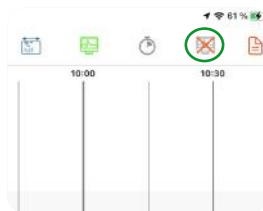


Press „Done“ when entries are green



Data is recorded

DISCONNECT DEVICE




Press 



Confirm warning

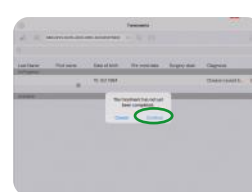
SAVE TREATMENT



Go to treatment list by pressing 



Press 



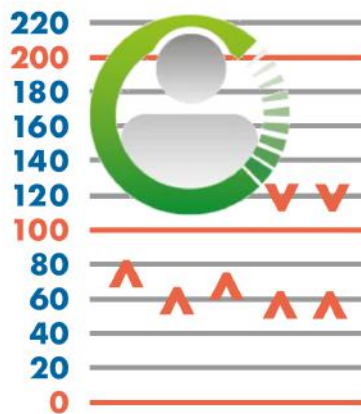
Confirm warning



Wait until treatment appears in „available“ list

Sandman.MD

Sandman ICU User manual



Version 4

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II. Preliminary remarks

This user manual describes the everyday usage of the Sandman ICU app. It is structured in the same way as the process in the app and the patients stay in the Intensive Care Unit. It starts with the creating of a case, followed by the entering of personal and medical data of the patient. After that the patient can be admitted to the ICU and the treatment data, for example drug administration, is documented. The vital parameters from the patient monitor, as well as the respiratory data from the ventilator, are transferred automatically. In the end the discharge of the patient is documented.

In order to achieve a better understanding, screenshots of the app are incorporated into this manual. In some cases a hand pointer is added, to visualize the processes described in the text.

1. General

The main user interface is divided into four sections which are shown in the navigation bar at the bottom. These tabs are in chronological order of the patients stay in the ICU. First the patient data (height and weight) is documented and the anamnesis is conducted. The documentation of the treatment in the Intensive care unit is performed in the ICU tab. In the end the discharge of the patient is reported in the Post-ICU tab.

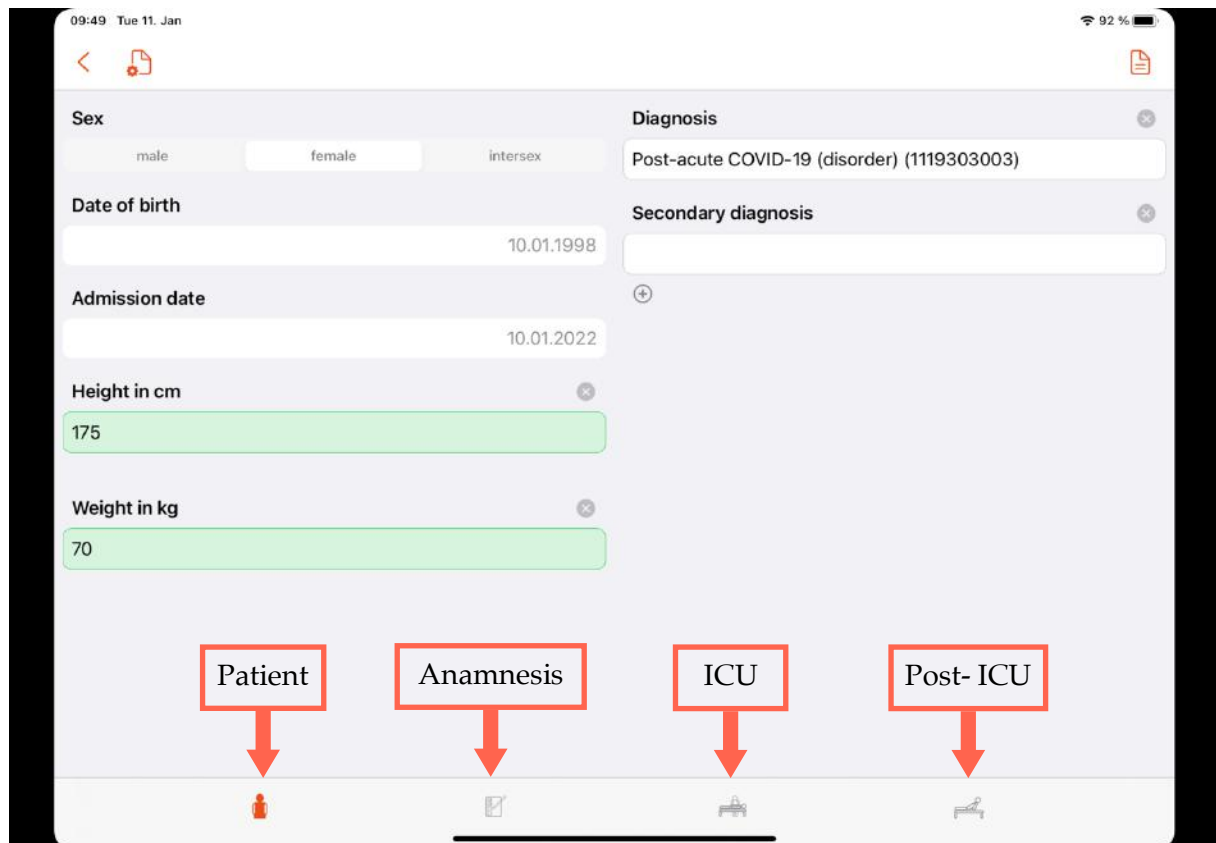


Figure 1: Main user interface

2. Open a case

Before you can start to document, you need to create a new case or reopen an existing one.

Please note:

The Case ID is given by the system and cannot be changed.

2.1. Create a new case

If you want to create a new case, click on the bed icon with the blue cross and fill in “Sex”, “Date of birth” and “Admission date”. Click on create. The treatment then appears on the screen in the category “Available”. To open it click on the red arrow pointing up on the right-hand side.

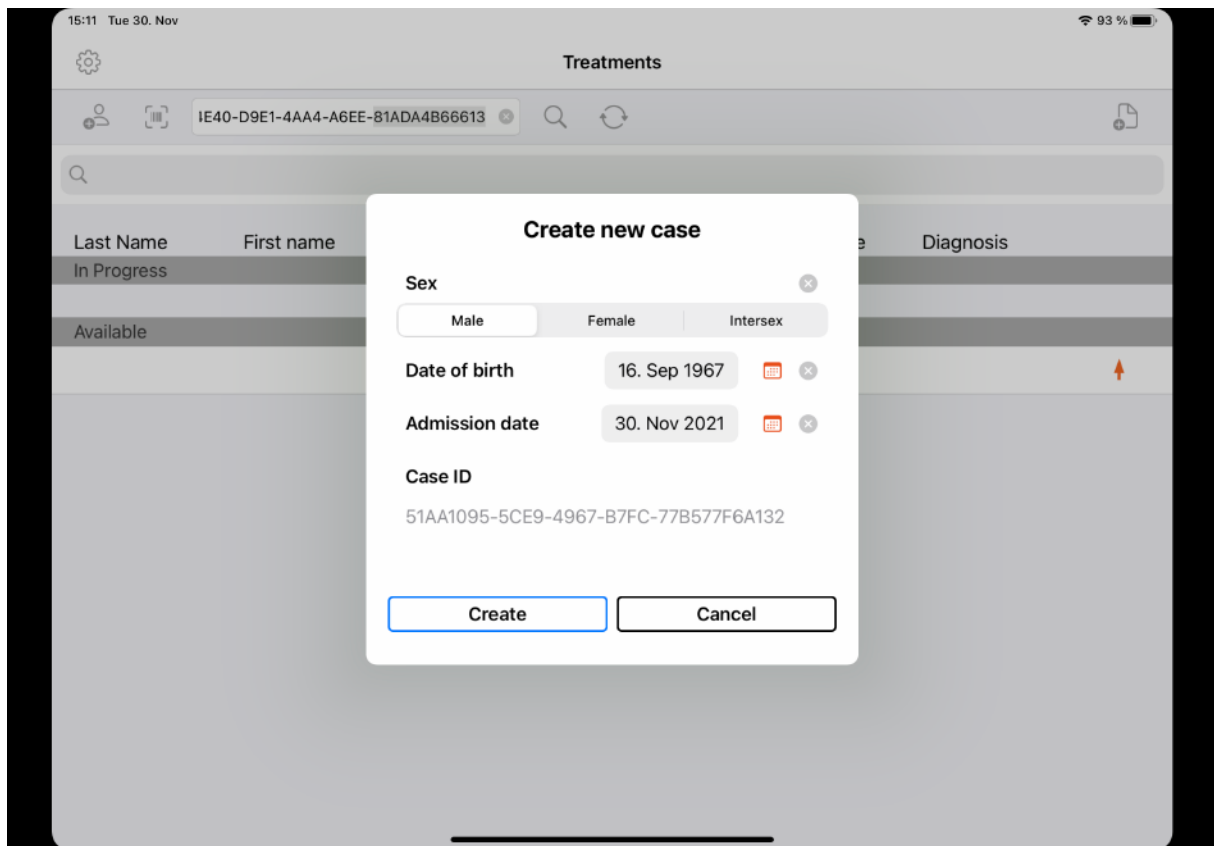


Figure 2: Creating a new case

2.2. Reopen an existing case

In order to search for an already existing case, you can click on the magnifying glass with an empty search bar. You will then see a list of the available cases. Load the requested case by clicking on the red arrow pointing up.

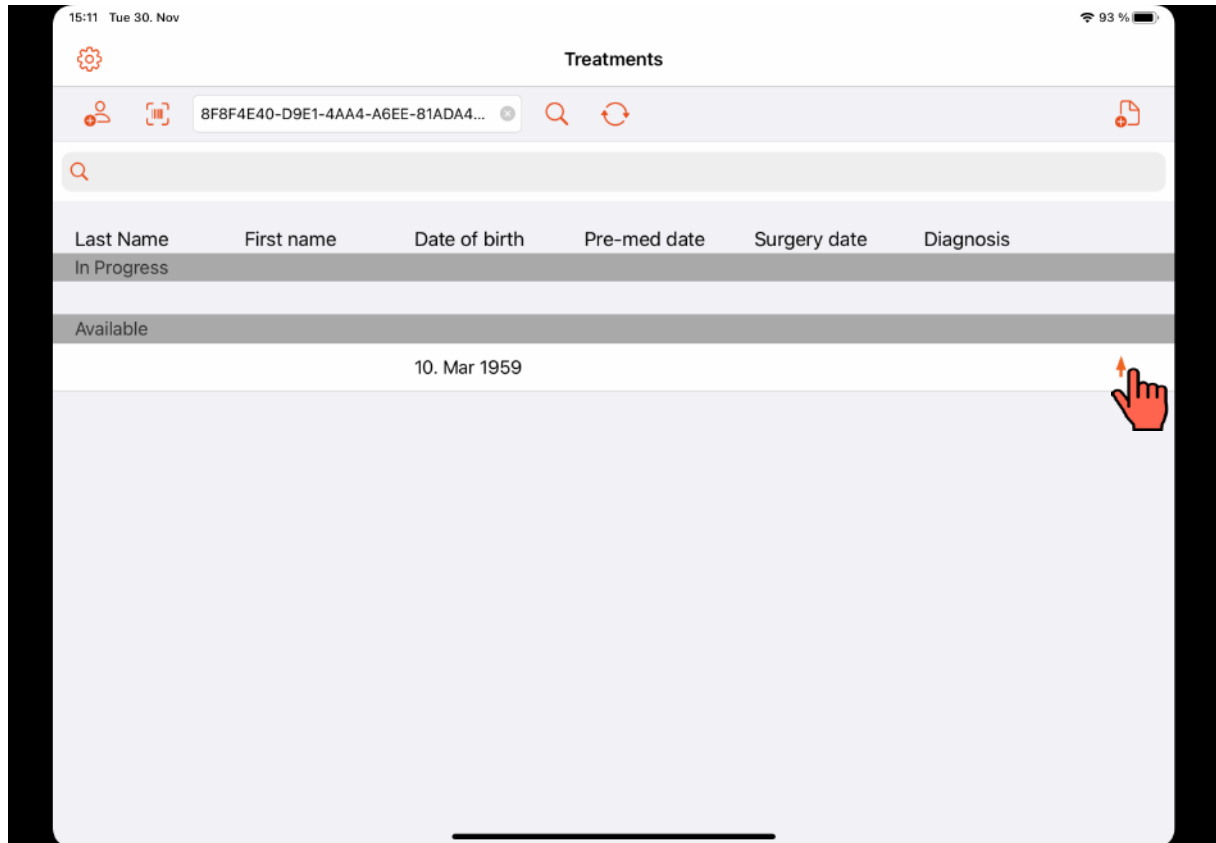
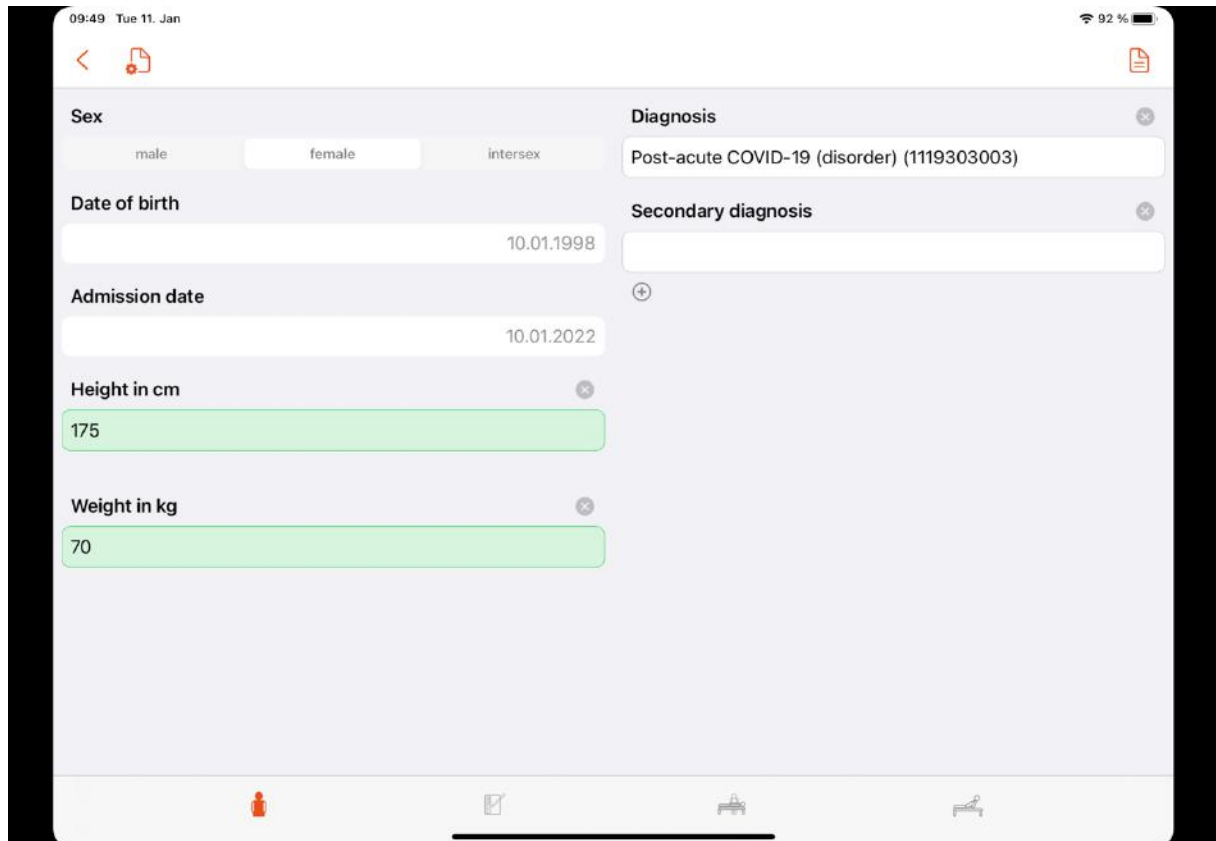


Figure 3: Loading an existing case

3. Document patient data

The first interface that is opened after a case is loaded is the patient tab. In this tab you can fill in the fields "Height in cm" and "Weight in kg". If a numeric value is detected, the fields will be highlighted in green. If an invalid character is detected, the fields will be highlighted in red.

Additionally the main diagnosis can be documented. This can be done by typing in the field "Diagnosis". Based on the inserted text (at least three characters) a list of diagnosis from the SNOMED terminology is shown. From this list you can choose the correct one. A secondary diagnosis can be filled in in the field below. Clicking on the little plus adds additional fields for further diagnosis.



The screenshot displays a mobile application interface for entering patient data. The top status bar shows the time as 09:49 on Tuesday, January 11th, with a 92% battery level. The interface is divided into several sections:

- Sex:** Three radio button options: "male", "female", and "intersex".
- Diagnosis:** A text input field containing "Post-acute COVID-19 (disorder) (1119303003)".
- Date of birth:** A date picker field showing "10.01.1998".
- Secondary diagnosis:** An empty text input field with a plus sign icon below it for adding more.
- Admission date:** A date picker field showing "10.01.2022".
- Height in cm:** A text input field containing "175", highlighted with a green border.
- Weight in kg:** A text input field containing "70", highlighted with a green border.

The bottom navigation bar contains four icons: a person, a clipboard, a hospital bed, and a person in a bed.

Figure 4: Patient tab

4. Anamnesis documentation

4.1. Documentation of medical data

In the Anamnesis tab you can fill in medical information about the patient. Select one of the groups on the lefthand side. There you can mark the conditions which the patient suffers from and other medical data by clicking on the correct entries. They will then be marked with a little checkmark. There are also fields where you can fill in numeric values. If at least one of the submenus is filled in the exclamation mark is highlighted in yellow. You can click on a yellow exclamation mark in a group, to reset all entries in this group.

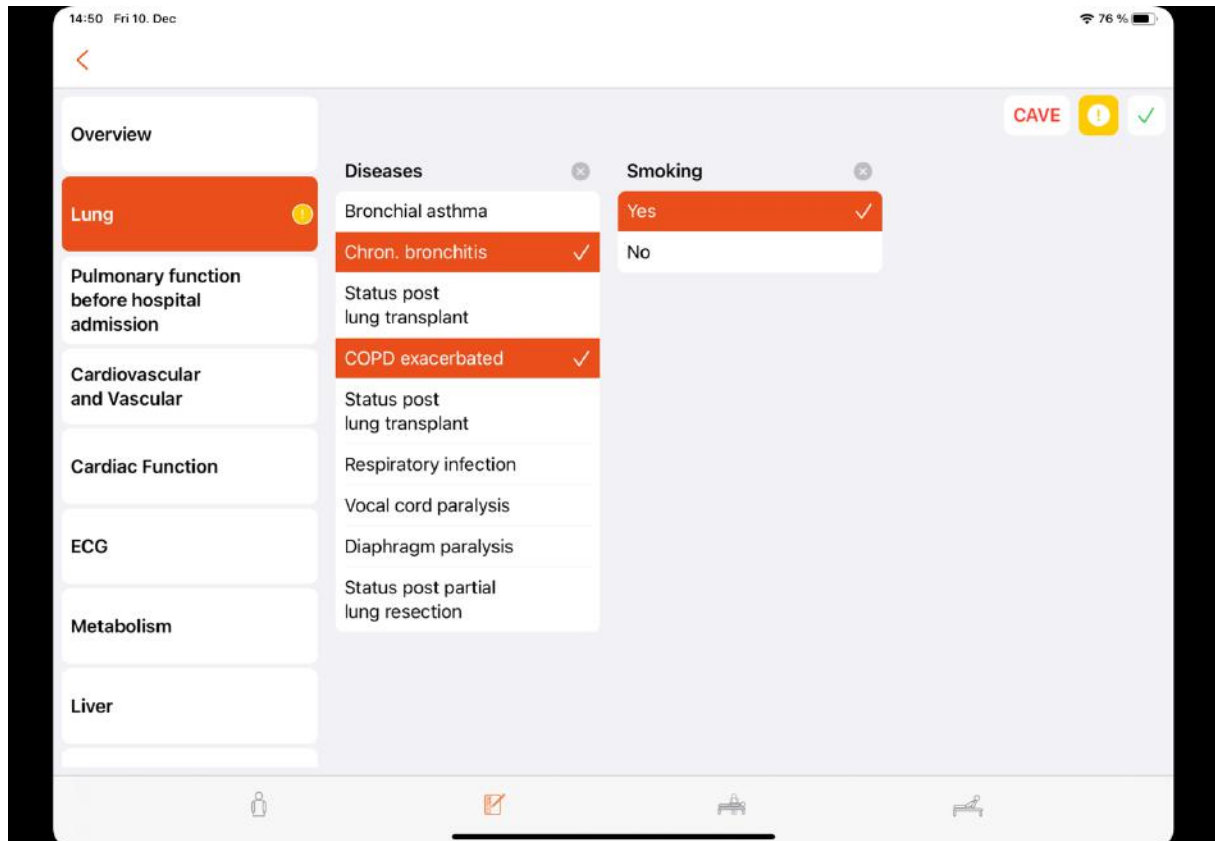


Figure 5: Anamnesis tab: Indicator edited

4.2. Green check mark as indicator: Completed

The group can be marked as completed, by clicking on the checkmark in the right upper corner. It will then turn green in the group menu and in the left column. The next group is opened automatically.

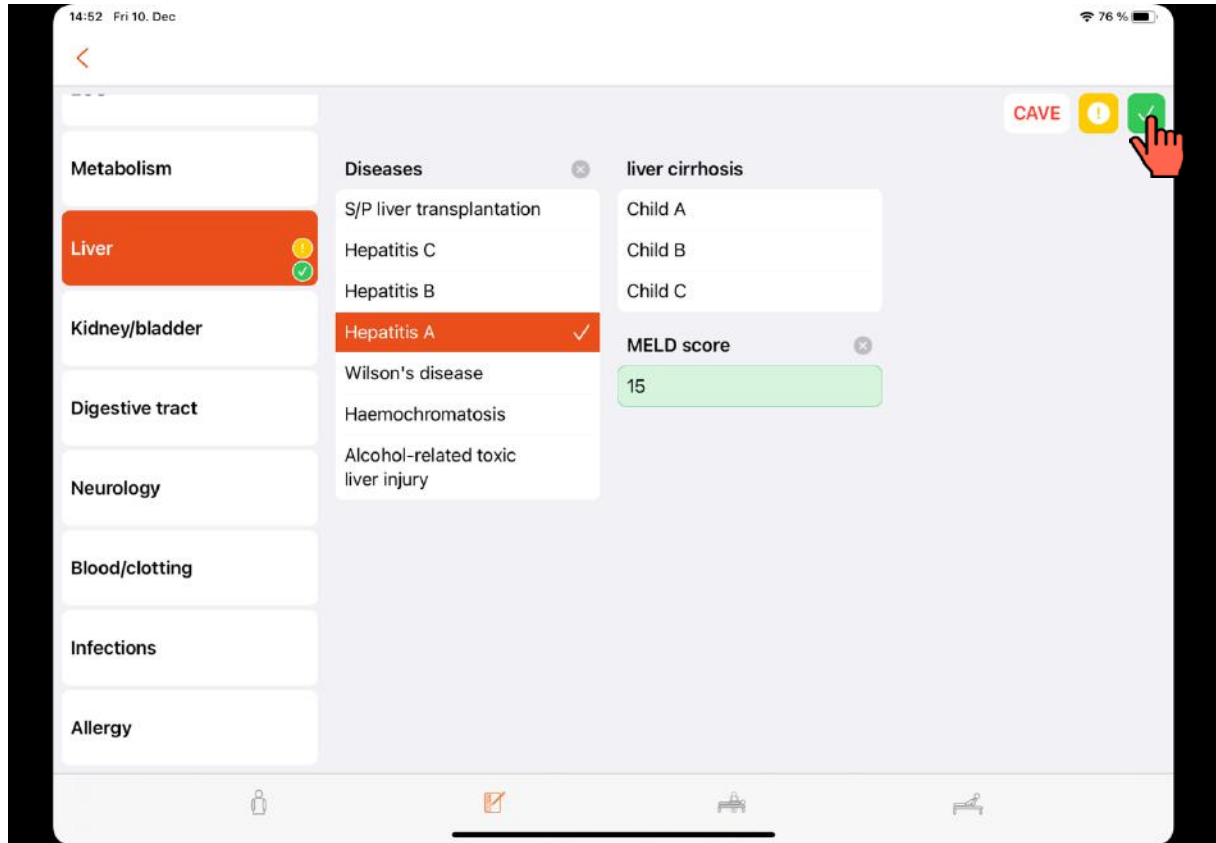


Figure 6: Anamnesis tab: Indication completed

4.3. CAVE as indicator: Critical entry

In case a condition may cause critical effects during the treatment and should be observed carefully, it is possible to set the flag CAVE. For this, click on CAVE in the right upper corner. The selected group will then be highlighted in red in the left column as well as the CAVE logo itself.

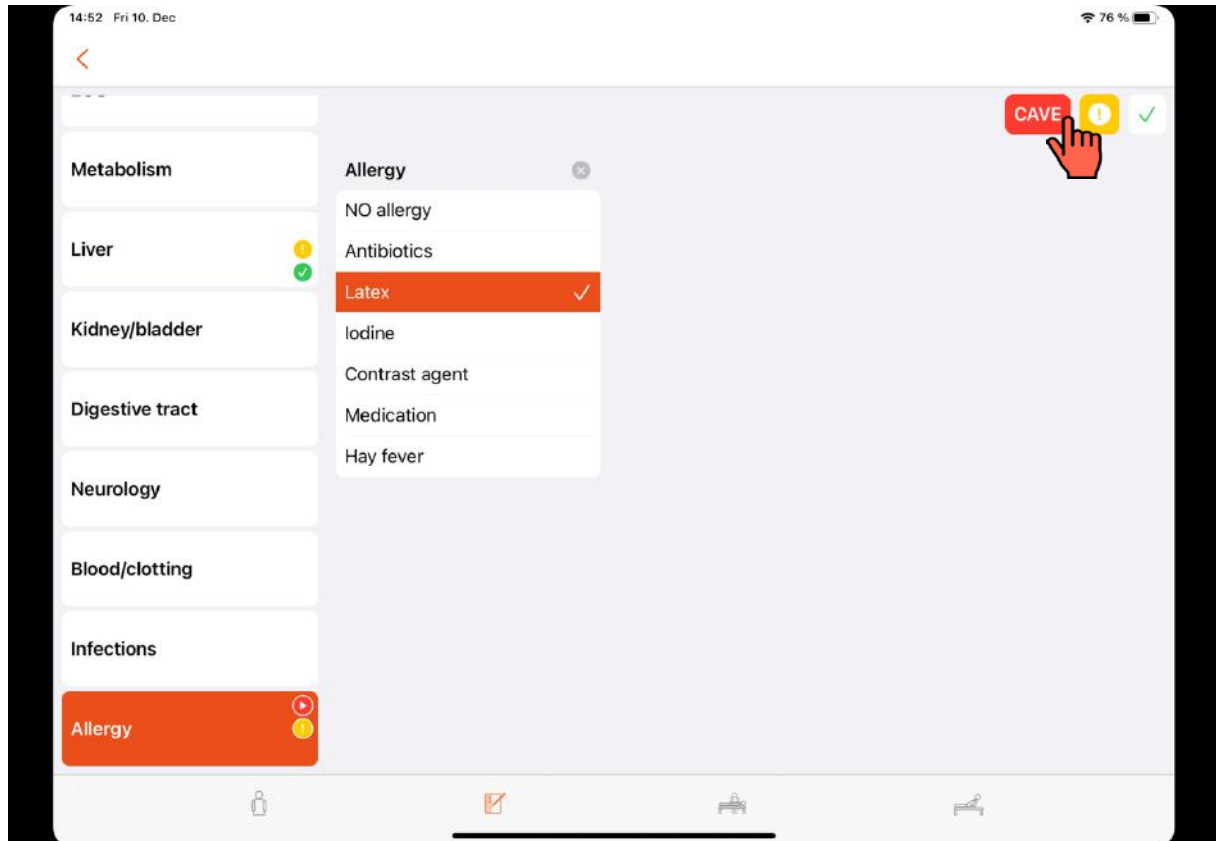


Figure 7: Anamnesis tab: Indication critical entry

4.4. Overview

All the filled in data is listed in the category “Overview”. In case CAVE was activated it is also shown here.

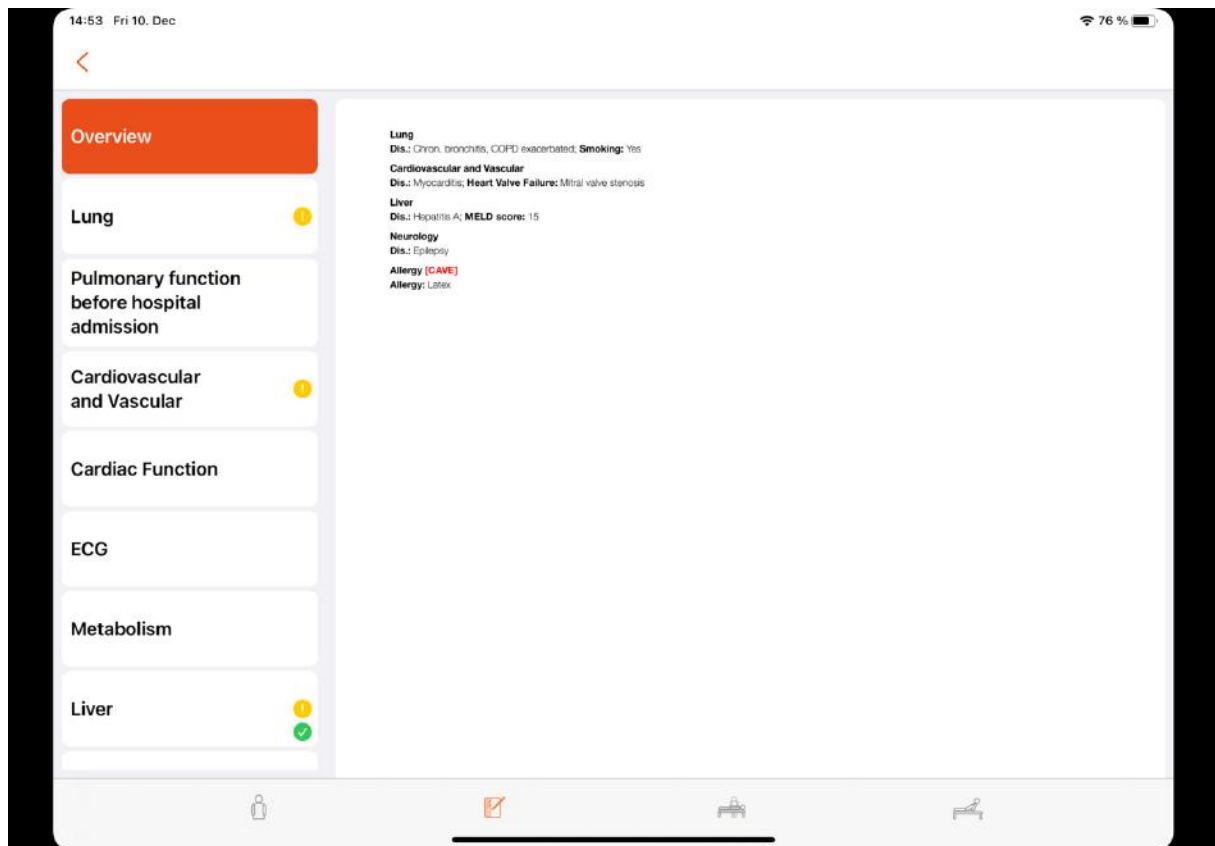


Figure 8: Anamnesis tab: Overview

5. Documenting the treatment in the ICU

At the top of the grid a timeline and the vertical red line represents the current point of time. The display in the ICU Tab is divided into two grids. In the upper half the given drugs and executed activities can be documented. In the lower half the data from the monitor and the ventilator is displayed and can be entered manually. The two sections can be enlarged by double-clicking in the desired section.

The list icon in the upper bar shows the overview of the anamnesis, as filled in before. If a group was marked with the CAVE flag, the icon is marked in red.

The timetable icon allows to jump to different positions on the timeline. Namely, the first entry, the last entry and the current point of time.

The monitor icon opens the window "Monitor overview". There you can connect the app to patient monitor and ventilator.

The page icon opens the "protocol selection" with the "Envision Form". This protocol can be printed and contains the case ID and other information about the case.

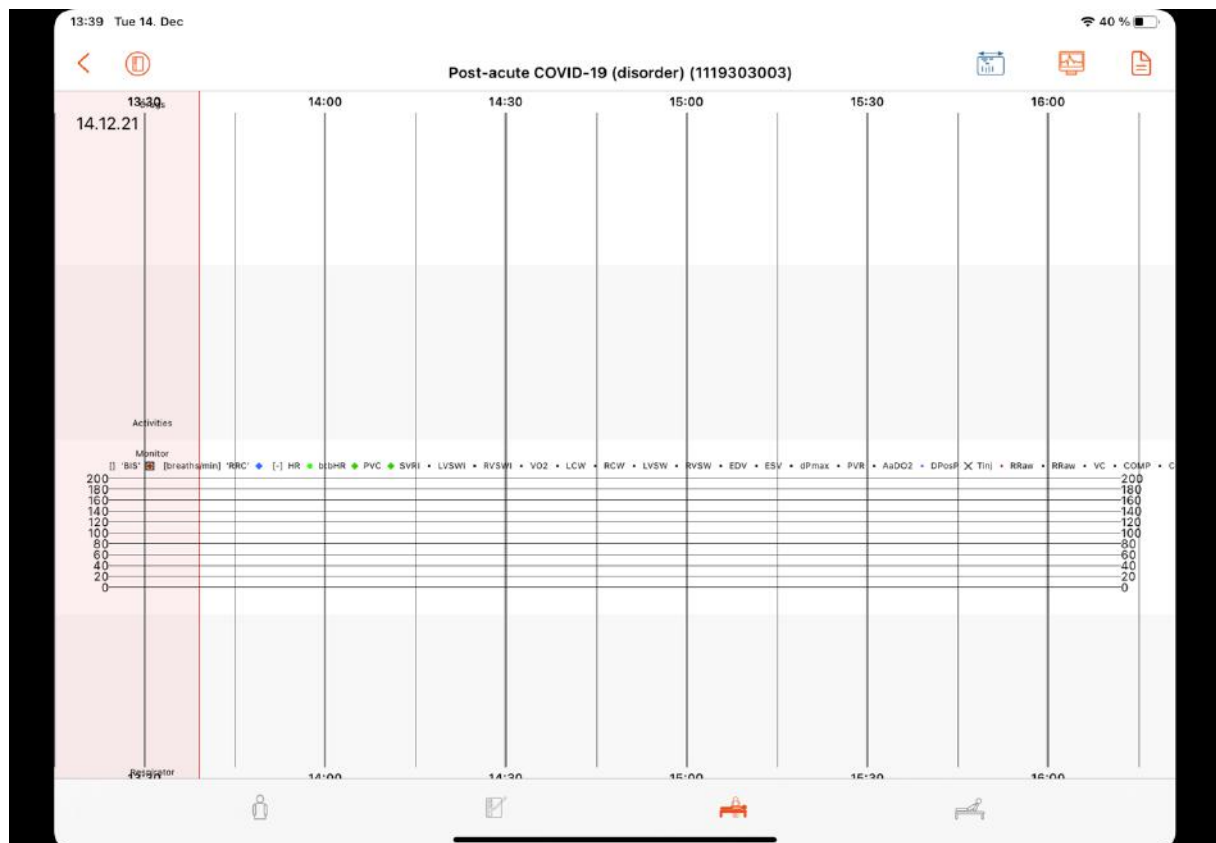


Figure 9: Overview ICU tab

5.1. Connect to medical devices

The medical devices can be connected with the App by clicking on the monitor icon in the upper bar. In the dialogue window the correct medical device can be chosen and selected by clicking on “Connect”. Please select the devices named with “envisionXXX Port 1” and “envisionXXX Port 2”. The number XXX can be found on the ComBox which the iPad is connected with.

Once the medical device is connected it is highlighted in green. After that you can click on “Done”. In the lower section you should then see parameters from the devices. The monitor icon in the upper bar is then coloured green.

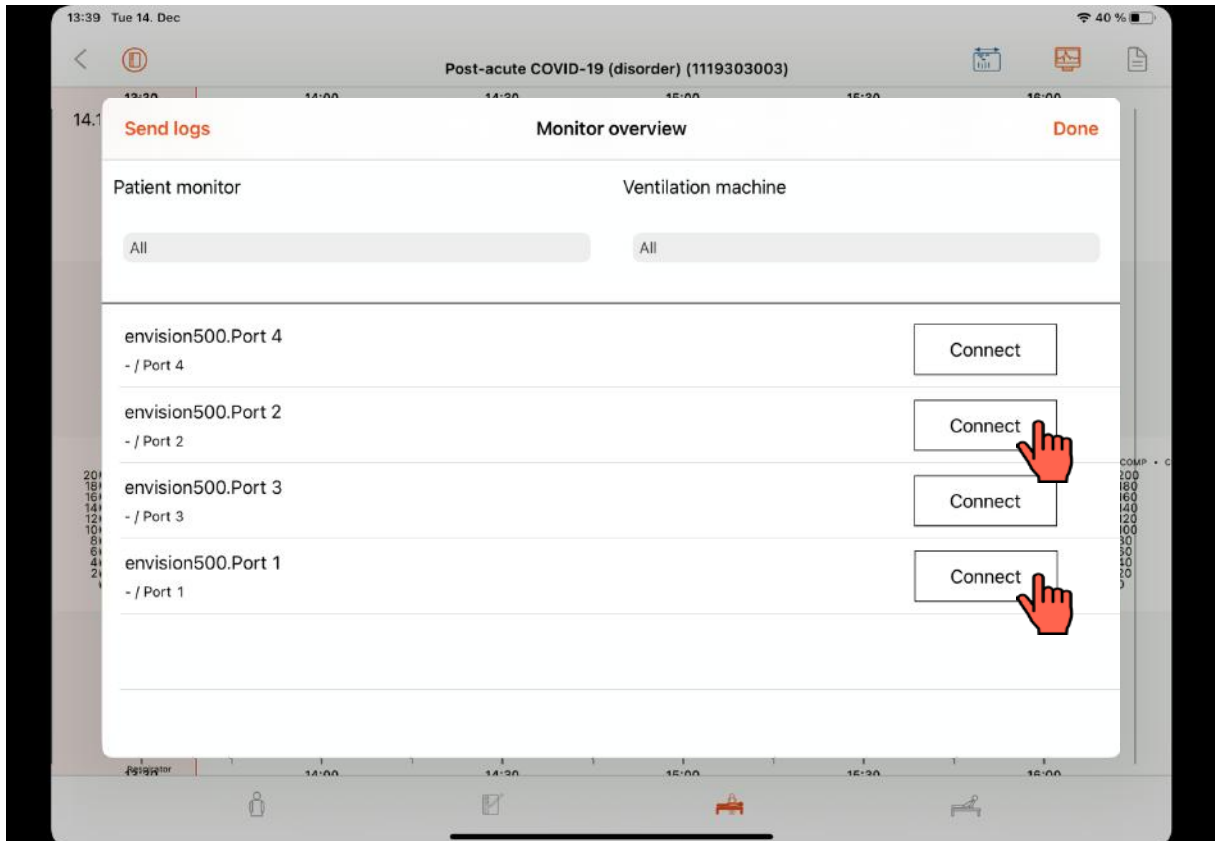


Figure 10: Connecting medical devices in the Monitor overview

5.2. Drug documentation

5.2.1. Documenting drug administration

Start the documentation by dragging the box “Drugs” into the grid. The left edge of the box represents the time of administration. After releasing the box a window is opened where you can first choose a type of drug, then select a certain drug and assign the amount.

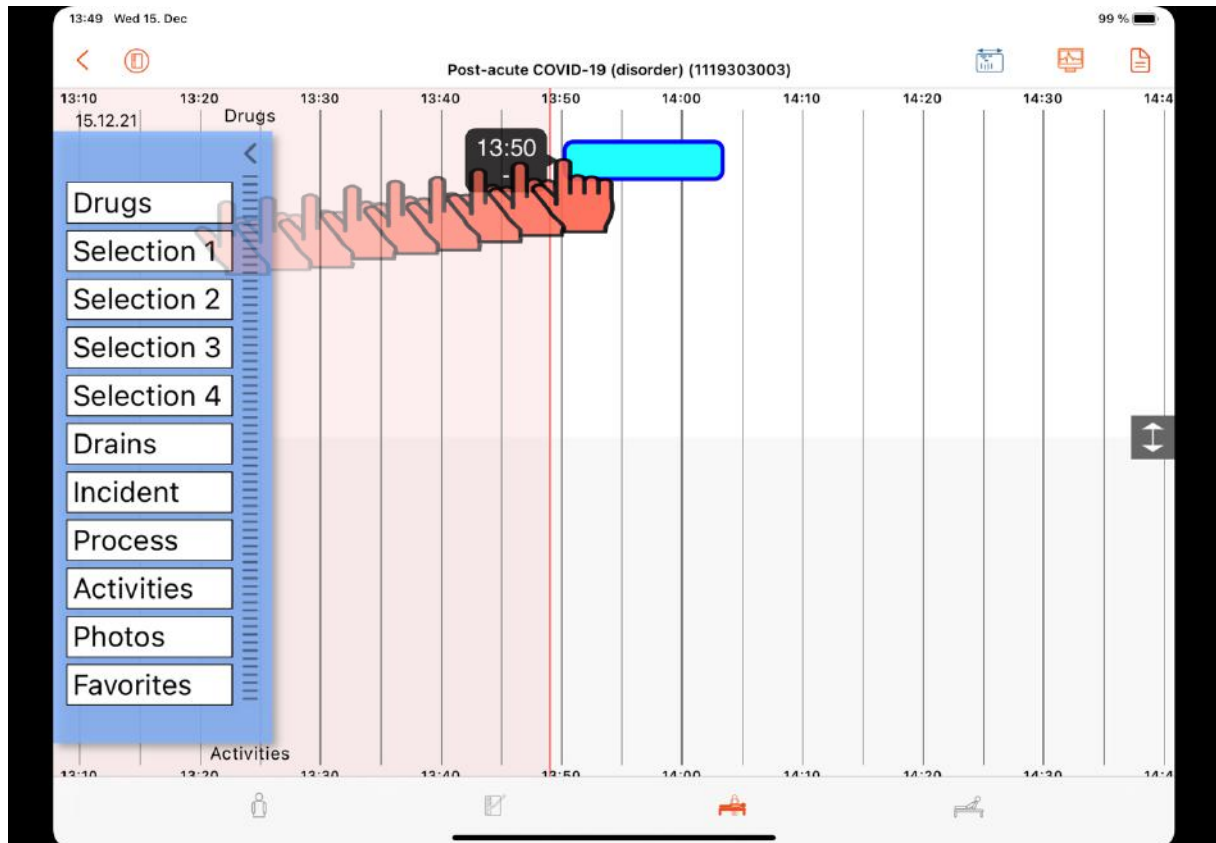


Figure 11: Documenting drug administration

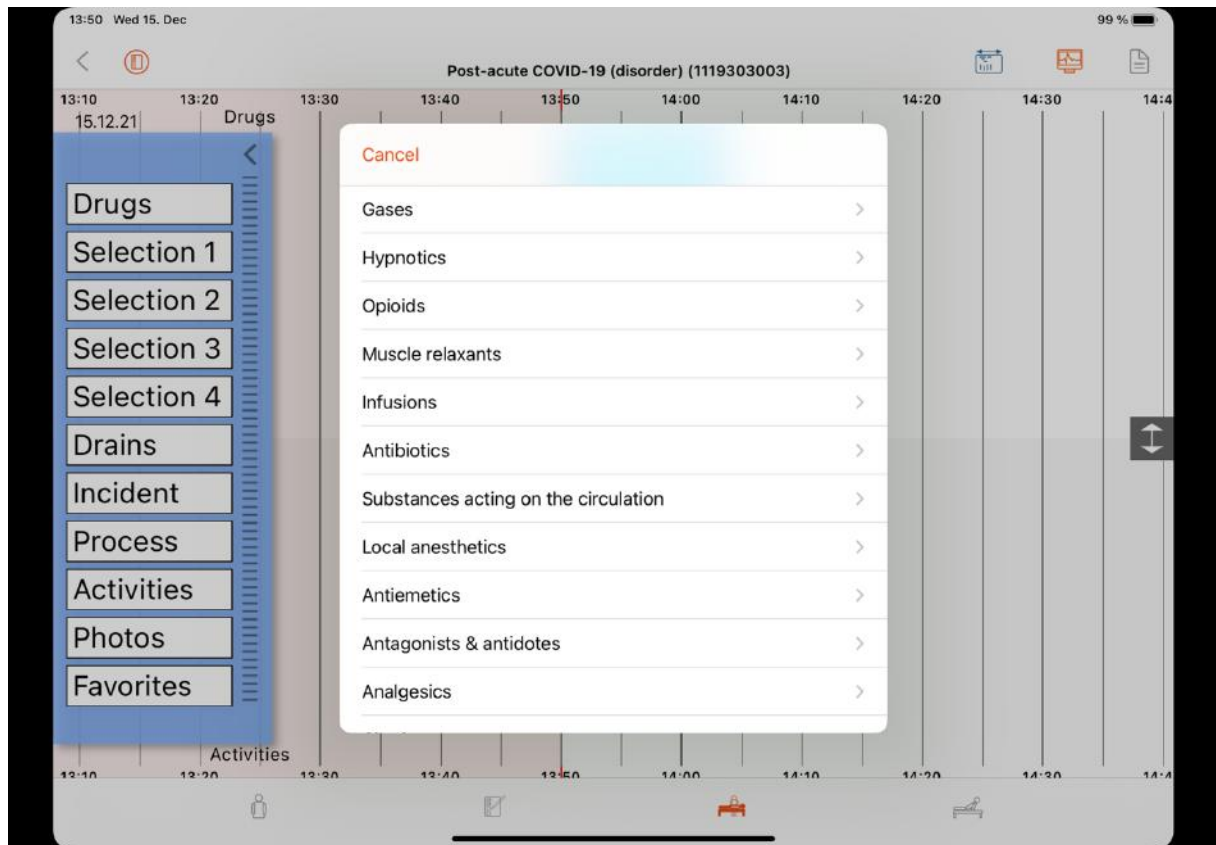


Figure 12: Types of drugs

5.2.2. Types of drug administration

You can also specify the way in which the drug is administered. Bolus, continuously or as infusion. Each drug has a default way of administration, but it can be changed by clicking on the correct type. Based on the way of administration the window has slightly different options.

“Bolus”: Assign the total amount administered to the patient

“Continuous”: Assign the amount administered to the patient per hour

“Infusion”: Assign the size of the infusion bag

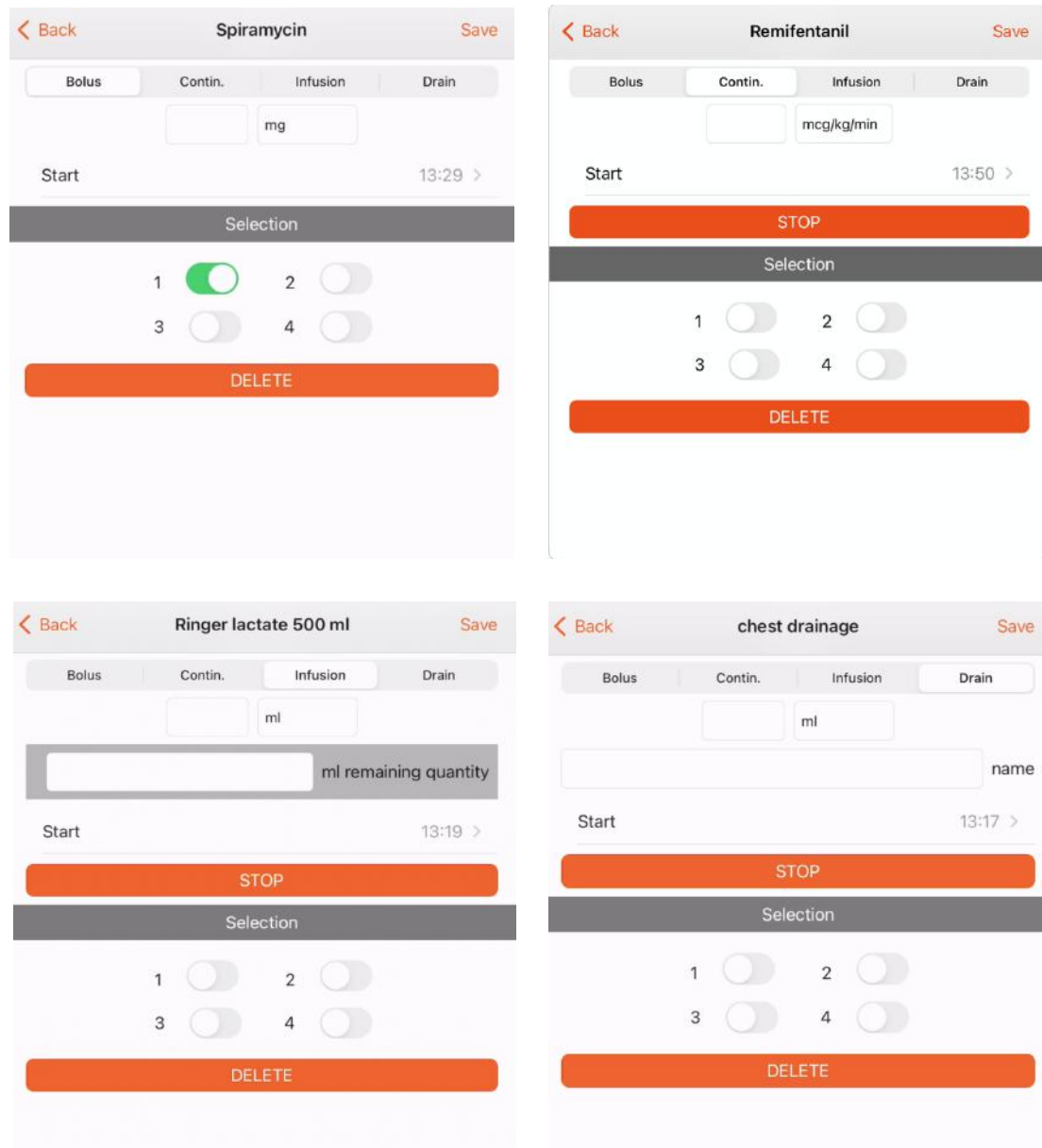


Figure 13: Types of drug administration and drain

Documenting a drain can be done analogously, by dragging the box “Drains” into the grid.

5.2.3. Grouping drugs and drains

Drugs and drains can be grouped in Selections to allow a faster access. This can be done by setting one or multiple selection flags. In order to access this selections drag the requested one into the grid. All the selected items will then appear in the grid. However, as their amount is set to 0, you need to open each drug administration and assign an amount.

5.2.4. Change settings in the drug detail window

You can click on an entry, hold it and then drag it to another point of time on the timescale. A drug administered as bolus is moved as a whole, whereas in case of continuously administered drugs, infusions or drains only the start time is changed. The end time is the current point of time.

Clicking on one of the entries opens its detail window. Based on the way of administration the window has slightly different options. In every case the entry can be deleted here. Additional options are described in the following:

“Continuous”: The flow can be changed and stopped.

“Infusion”: The exchange of the infusion bag can be documented with “Bottle change”. Then you need to fill in the remaining quantity in the old bag. The consumed amount will be calculated automatically. The infusion can also be stopped.

“Drain”: The exchange of the collection bag can be documented with “Container change”. You will be asked to state the withdrawn amount. The drain can also be stopped.

The change of flow, the exchange of an infusion bag or a collection container can also be done by placing two fingers next to each other on the entry and moving them to the time of change. In the appearing window you can then document the change.

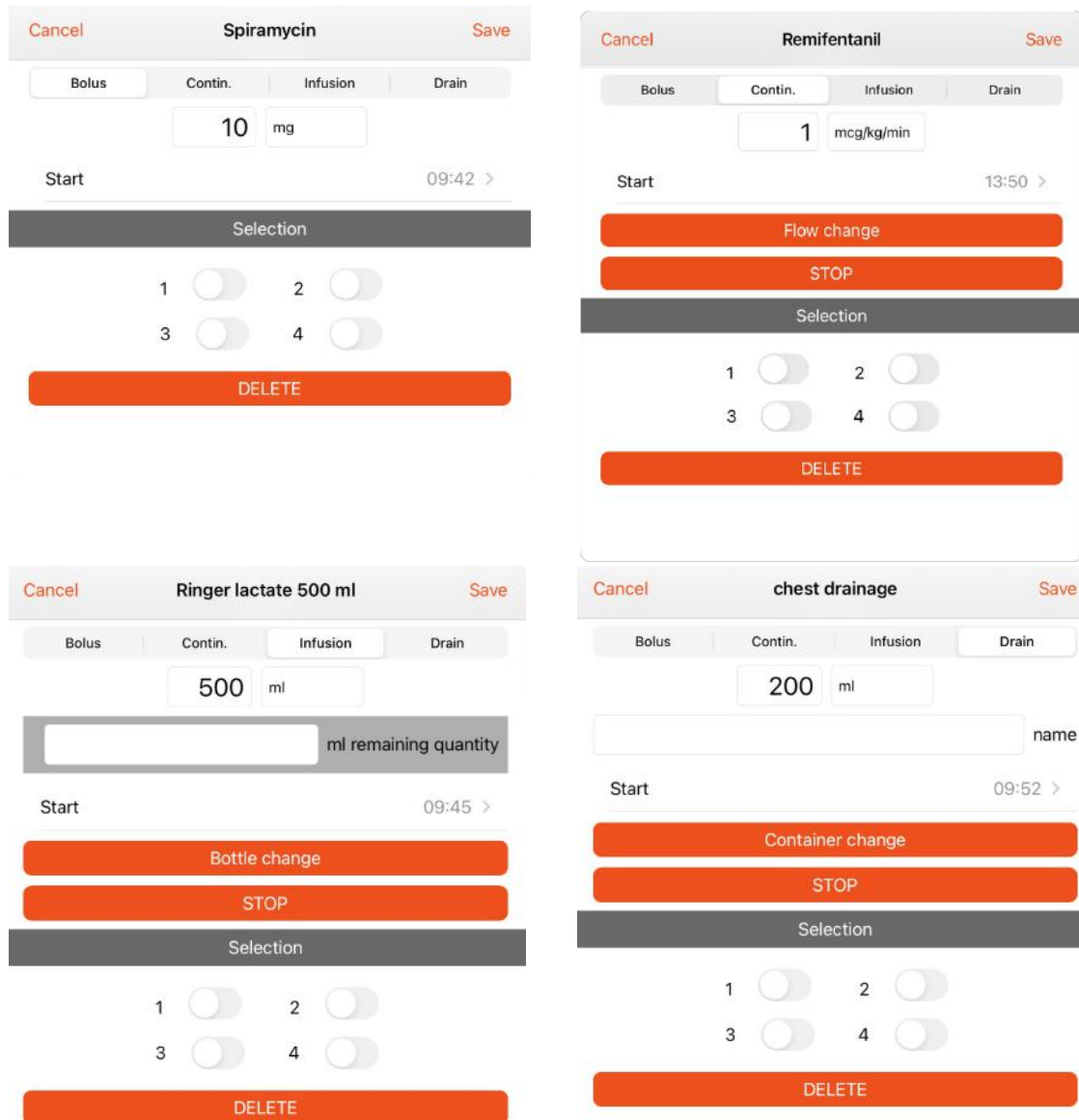


Figure 14: Detail windows for different types of drug administration and drains

5.3. Activity documentation

5.3.1. Documenting processes

Start the documentation by dragging one of the boxes (“Incident”, “Process”, “Activities”) into the grid. The left edge of the box represents the time of the activity.

Logistical events, such as transports are grouped in “Process”. There you can also document the discharge or the death of the patient. The processes “ICU admission” and “ICU discharge” are mandatory before closing the documentation. “ICU admission” should be documented as soon as the documentation has been started.

“BTM destruction” and “chief medical” are special in that regard, that an authentication is needed to document these two processes. It must be predefined who is allowed to authenticate these. The other processes do not require any further information.

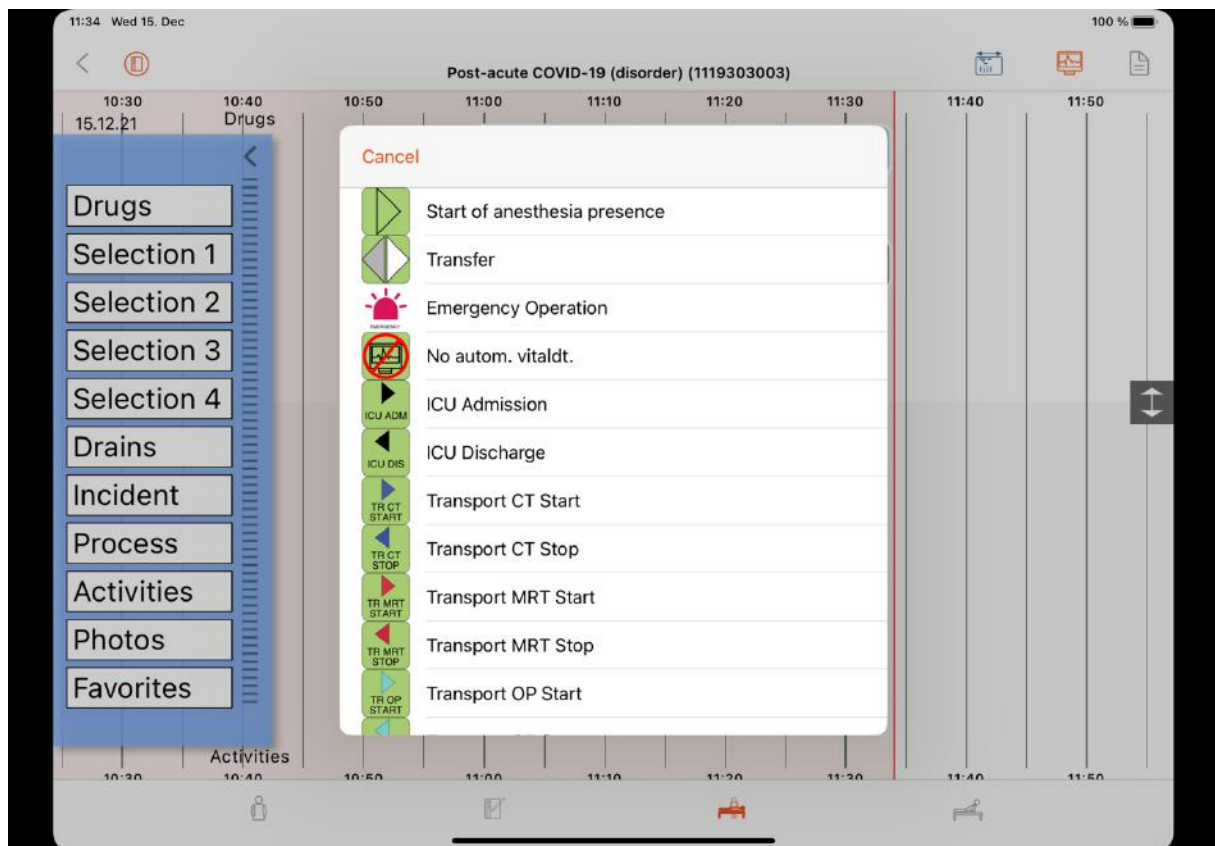


Figure 15: Category "Process"

5.3.2. Documenting activities

“Activities” comprise other events, like positioning the patient or monitoring. If the patient is ventilated and/or anesthetized, it can be documented here. Furthermore, diagnosis during the treatment can be documented in the subgroup “SNOMED CT”, analogously to the patient tab.

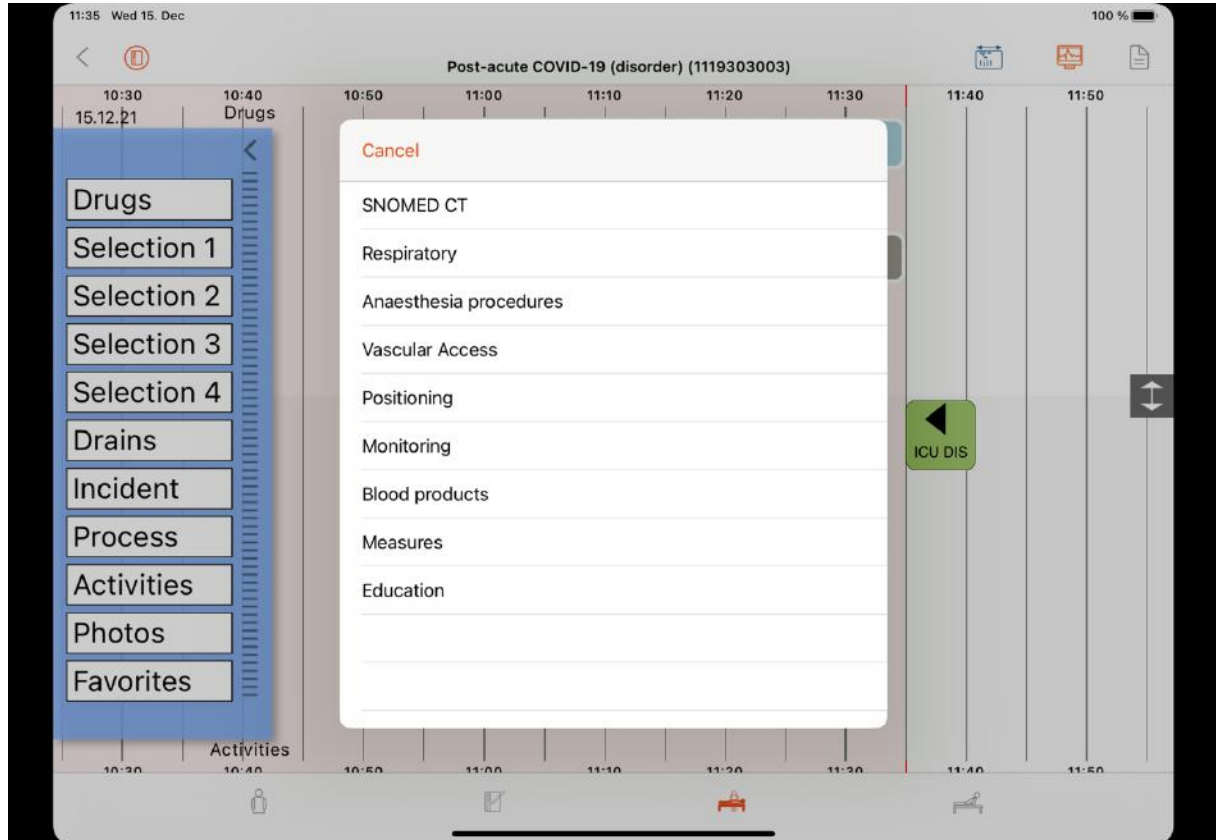


Figure 16: Category "Activities"

5.3.3. Documenting incidents

In the group "Incident" critical events during the ICU can be documented.

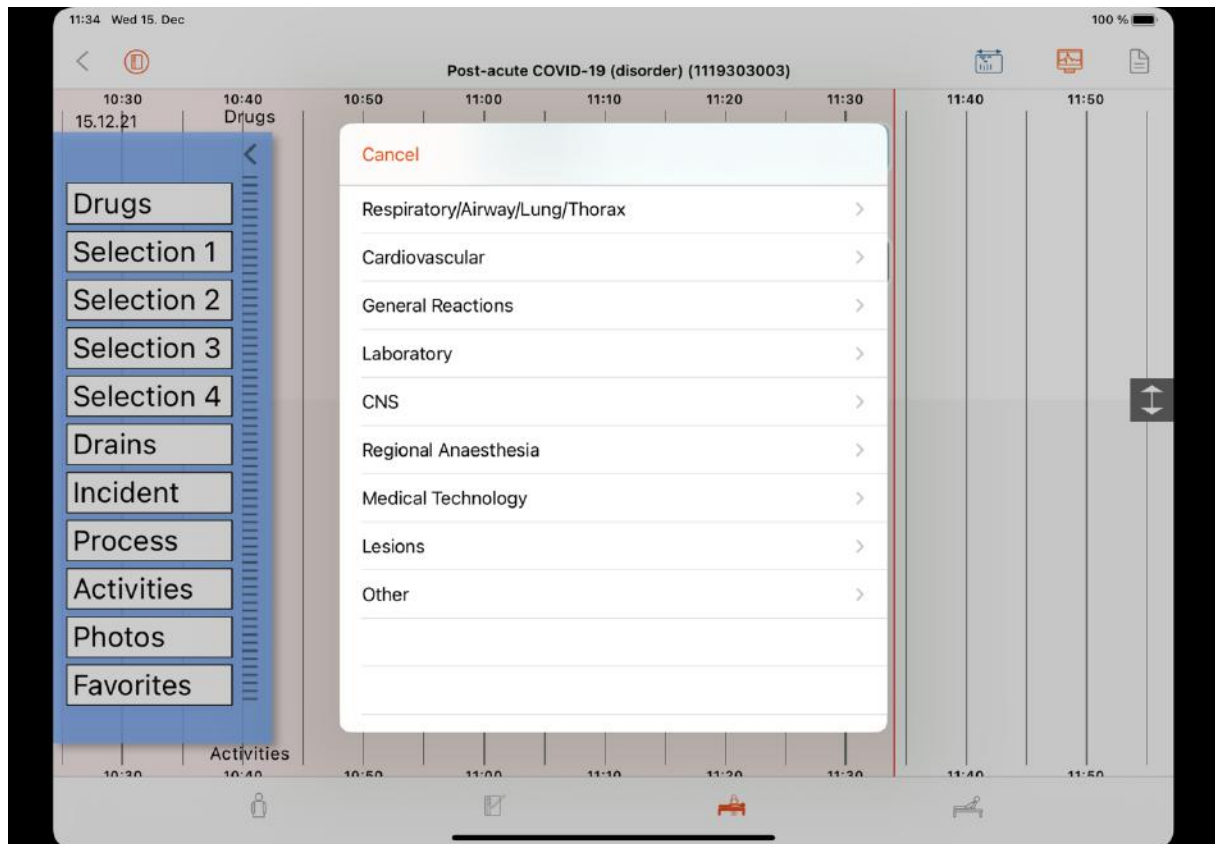


Figure 17: Category "Incident"

5.3.4. Setting Favorites

You can add entries to favorites. If you drag the group “Favorites” into the grid, a menu will be opened with all these entries.

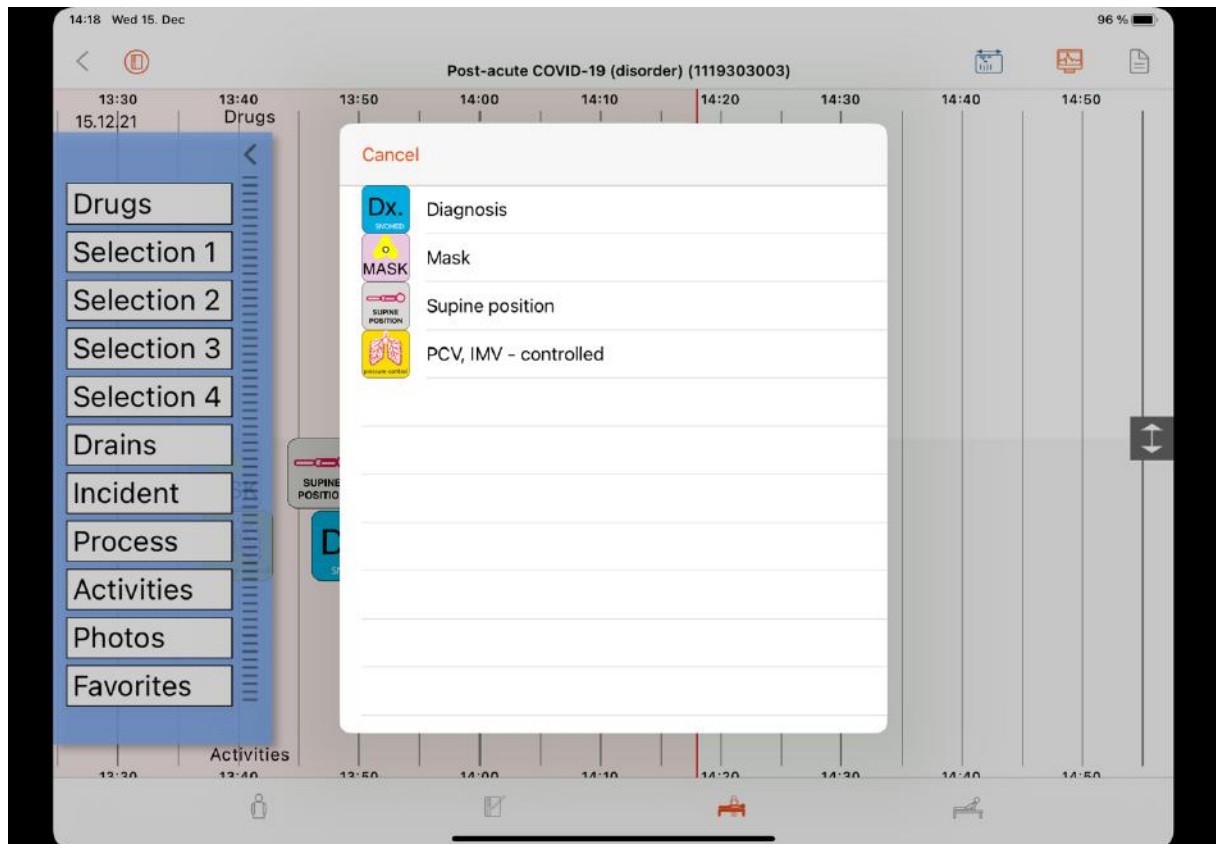


Figure 18: Category "Favorites"

5.4. Documentation of vital parameters and respiratory data

5.4.1. Automated data documentation

Once the medical devices are connected the data is displayed. In the upper half the data from the patient monitor is plotted and below that the respiratory data. Each value is saved every minute, but not necessarily displayed every minute. The time interval in which the values are displayed can be configured.

Patient monitor

The grid in the upper half shows the parameters of the monitor. The x-axis shows the time and the y-axis contains two scales. One of the scales is shown on the left hand side of the grid and the parameters are listed above. The other scale is plotted on the right hand side and the parameters of that scale are shown below. The value range of the scales, as well as the symbols and colours of each parameter can be configured. The time interval in which the data is displayed differs for different parameters.

Ventilator

The data from the ventilator is shown in the lower half. The data there is also displayed on the time axis. The rectangle with the values is located in such manner that the left edge represents the time of data collection. The vertical position of the entries has no further meaning. The data is displayed every ten minutes in the default setting.

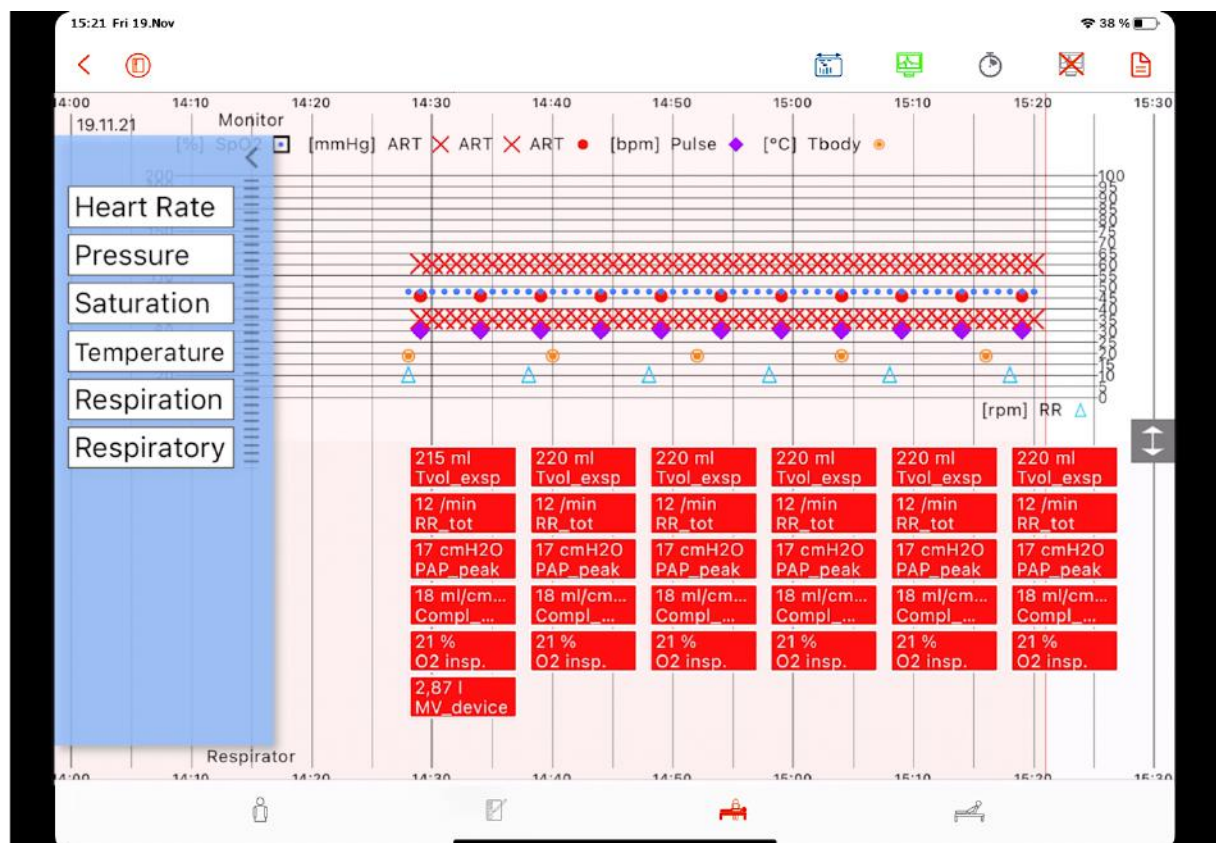


Figure 19: Automated data documentation

5.4.2. Manual data documentation

In addition to the automated documentation data can also be added manually. In order to do this drag the requested group into the grid and assign the value. Then click on save.

An already existing entry can be changed either in the detail window by clicking on it, or by moving it in the grid. The time can be changed by clicking on the entry and moving it horizontally to the correct point of time. The parameters of the patient monitor can also be moved vertically, to change their value according to the respective scale. This cannot be done with the respiration data. After releasing the entry at the desired place, a window will pop up. You have to confirm the moving, to prevent the unintended changing of entries.

An entry can be deleted in the detail window.

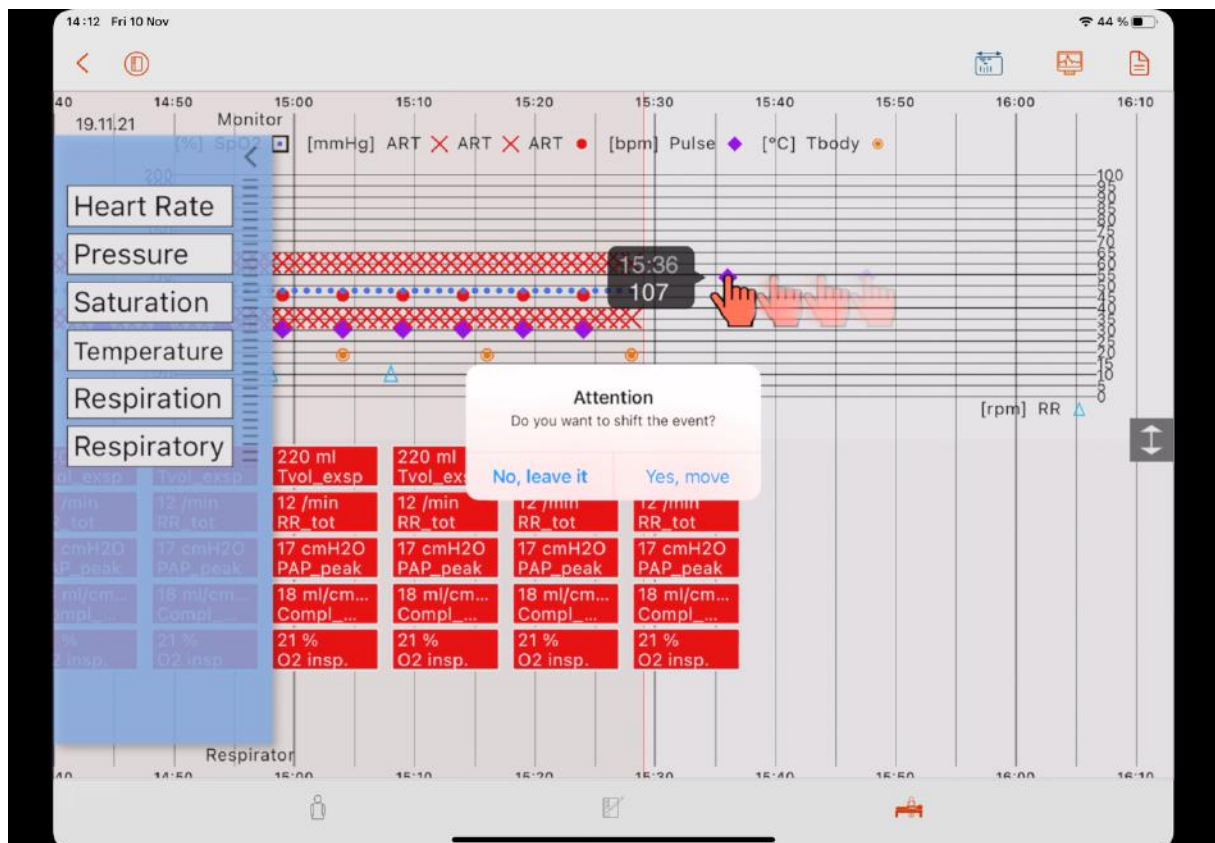


Figure 20: Moving of entries

5.5. Saving the treatment data

The treatment data shall be saved at least every 24 hours. For this the medical devices need to be disconnected. Then the treatment can be uploaded to the server and immediately afterwards downloaded again.

5.5.1. Disconnecting medical devices

Disconnecting the medical devices can be done in two ways. You can end the connection for every medical device individually. For this go to “Monitor Overview” by clicking on the green monitor icon in the upper bar of the ICU tab. You can then click “Stop” for every device. In order to disconnect all devices you can click on the crossed out monitor.

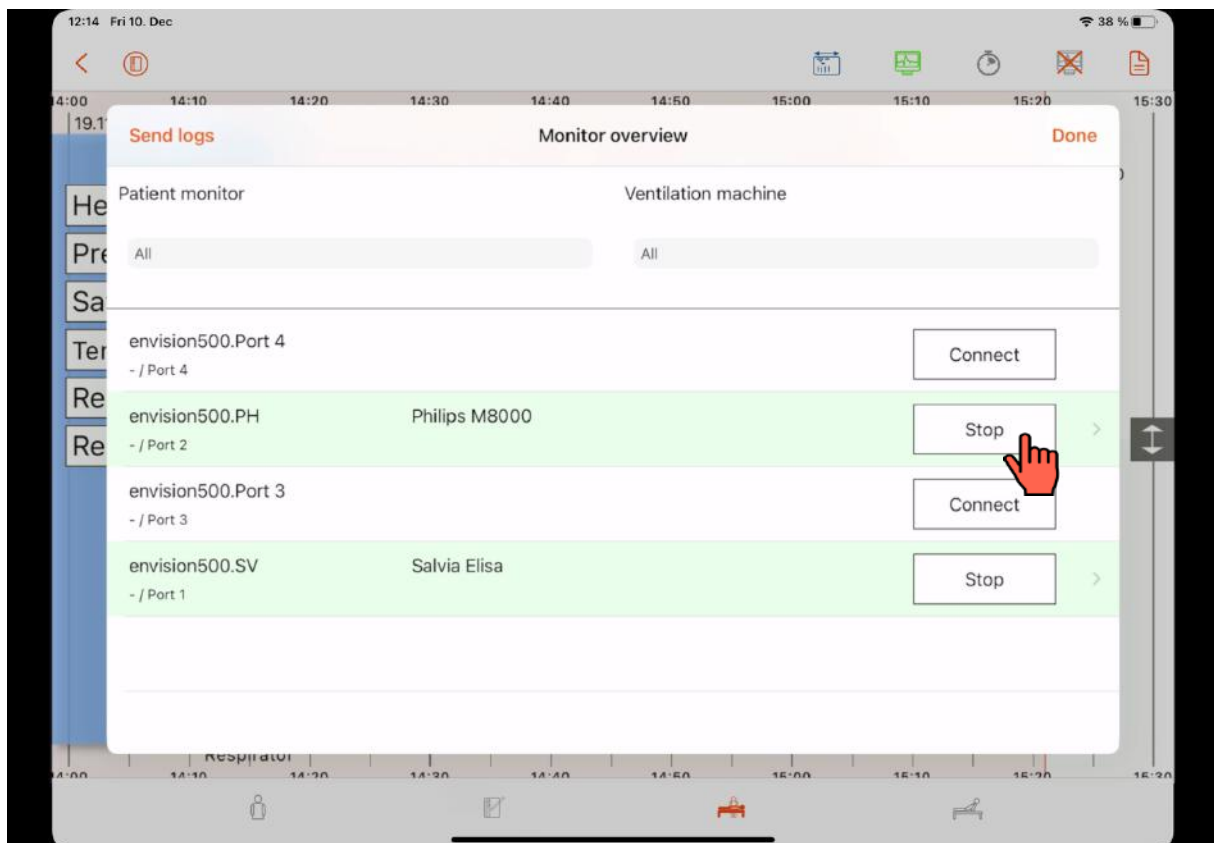


Figure 21: Disconnecting medical devices in the Monitor overview

5.5.2. Uploading treatment

After disconnecting the devices, go back to “Treatments” by clicking on the right arrow in the left upper corner. Load the treatment data onto the server by clicking the red arrow pointing down on the ride side. The treatment changes from “In Progress” to “Available“.

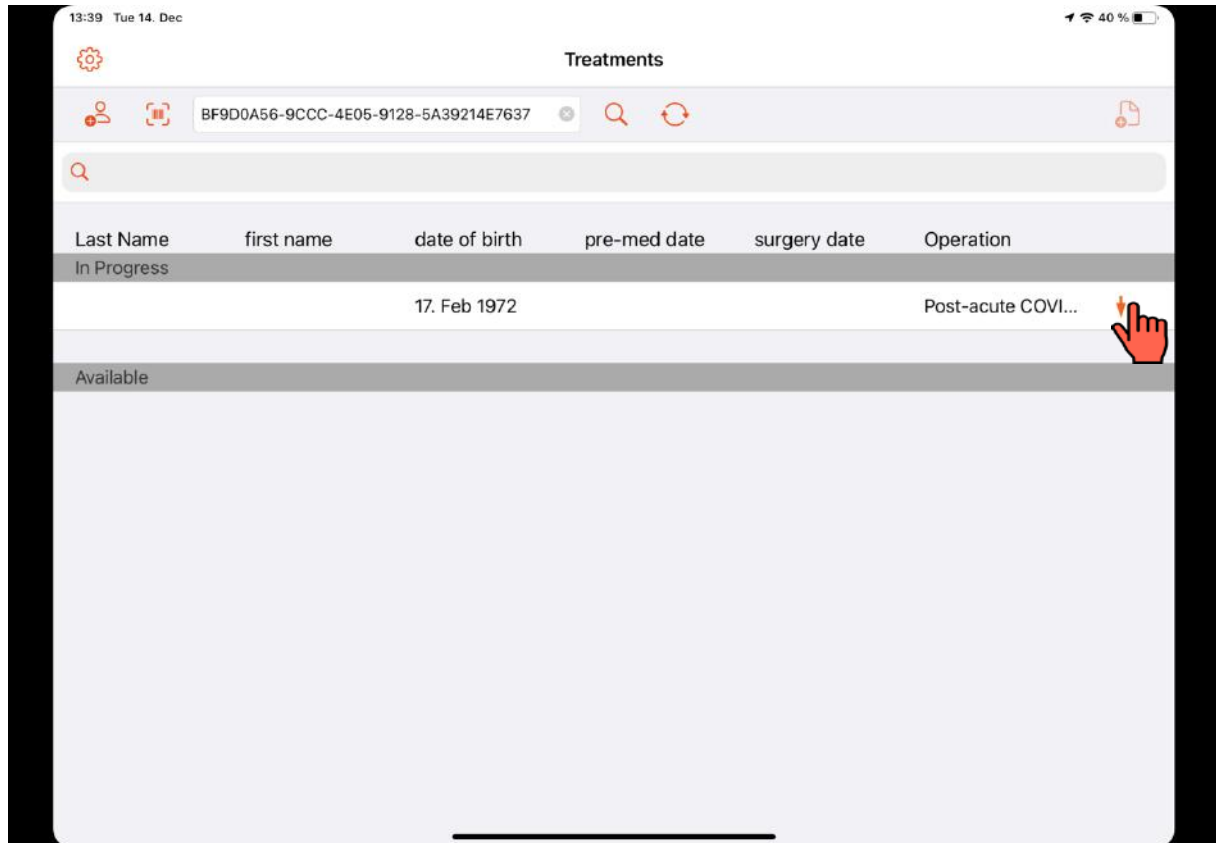


Figure 22: Uploading the treatment to the server

5.5.3. Reloading treatment

After saving the data on the server, you can immediately reload it. Select the red arrow pointing up at the right hand side to open the case again and get to the patient mask. You can then continue the documentation.

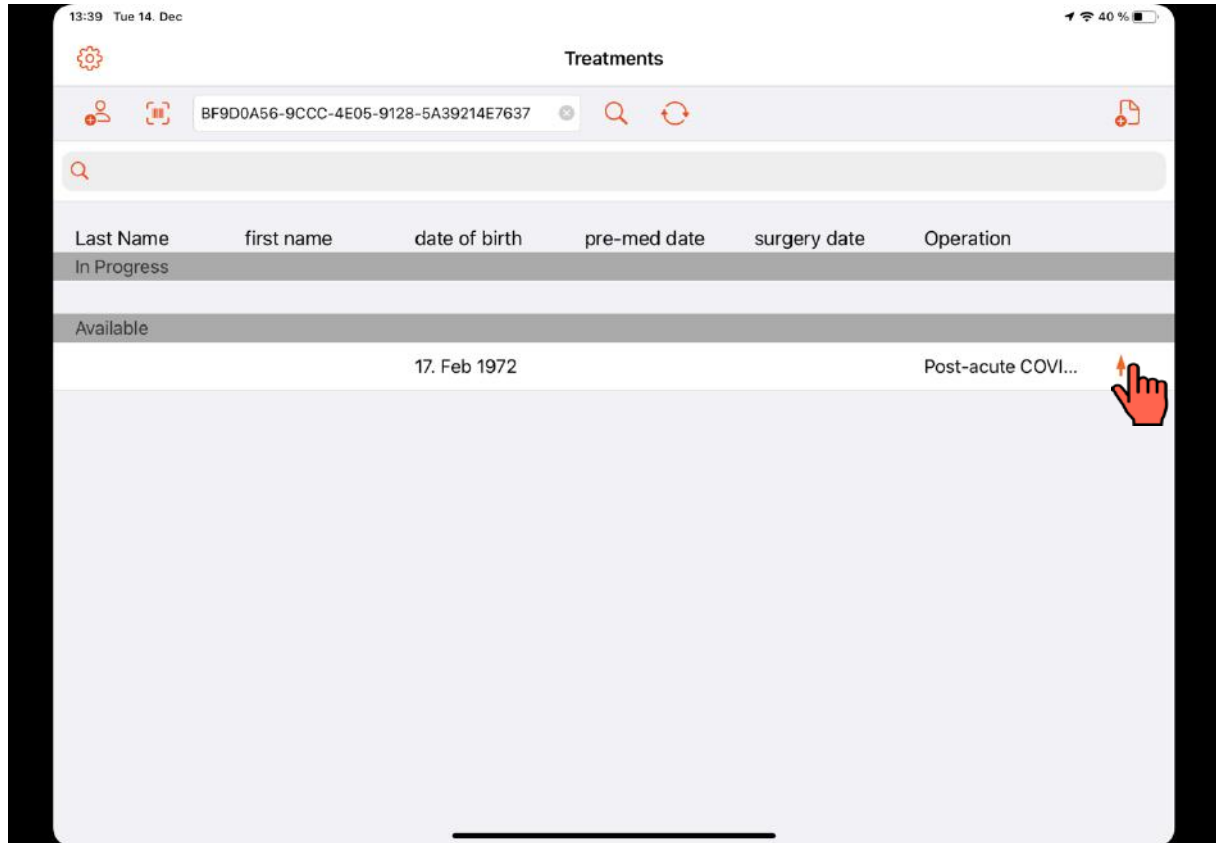


Figure 23: Reloading the current treatment after saving

6. Discharging the patient

Documenting the discharge of the patient requires the closing of the treatment documentation, additional information about the discharge and ends with the upload to the server.

6.1. Information about the discharge

In the fourth tab in the lower navigation bar you can specify the discharge of the patient. Insert the date of discharge. You can also fill in either the date of death or define where the patient is discharged to. In the second category you can note the pulmonary function at the hospital discharge, by documenting the vital capacity of the patient. In the group "Overview" you can see all the data you filled in in this tab.

The indicators in the right upper corner are analogous to the ones in the anamnesis.

If at least one of the submenus is filled in the exclamation mark is highlighted in yellow. A group can be marked as completed, by clicking on the checkmark in the right upper corner. It will then turn green in the group menu and in the left column. CAVE can be activated to mark a critical entry.

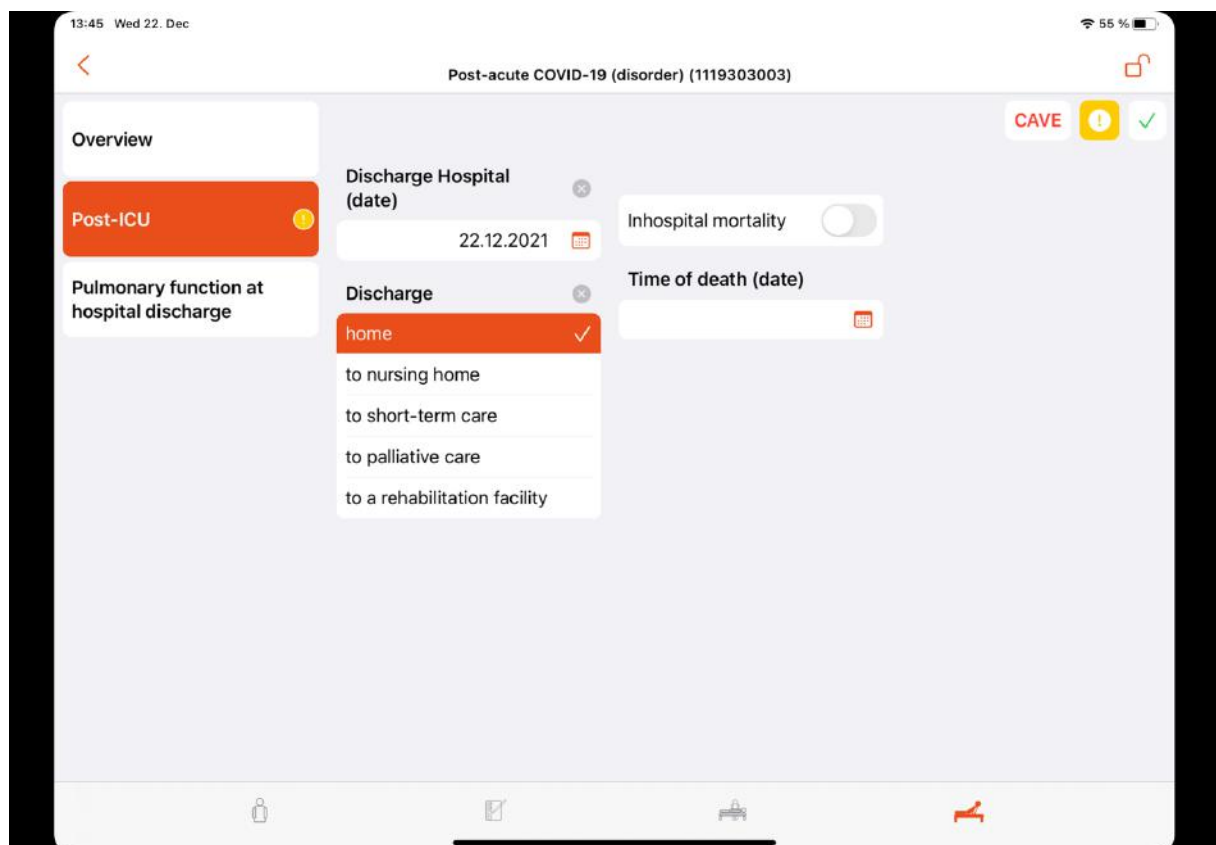


Figure 24: Post ICU tab

6.2. Closing the documentation

The documentation can be closed by clicking on the open lock in the upper bar of the Post-ICU tab. Before that, the process "ICU Discharge" needs to be dragged into the ICU grid. The process "ICU Admission" is mandatory, too. Without this the plausibility check would give a warning and will not allow you to close the documentation.

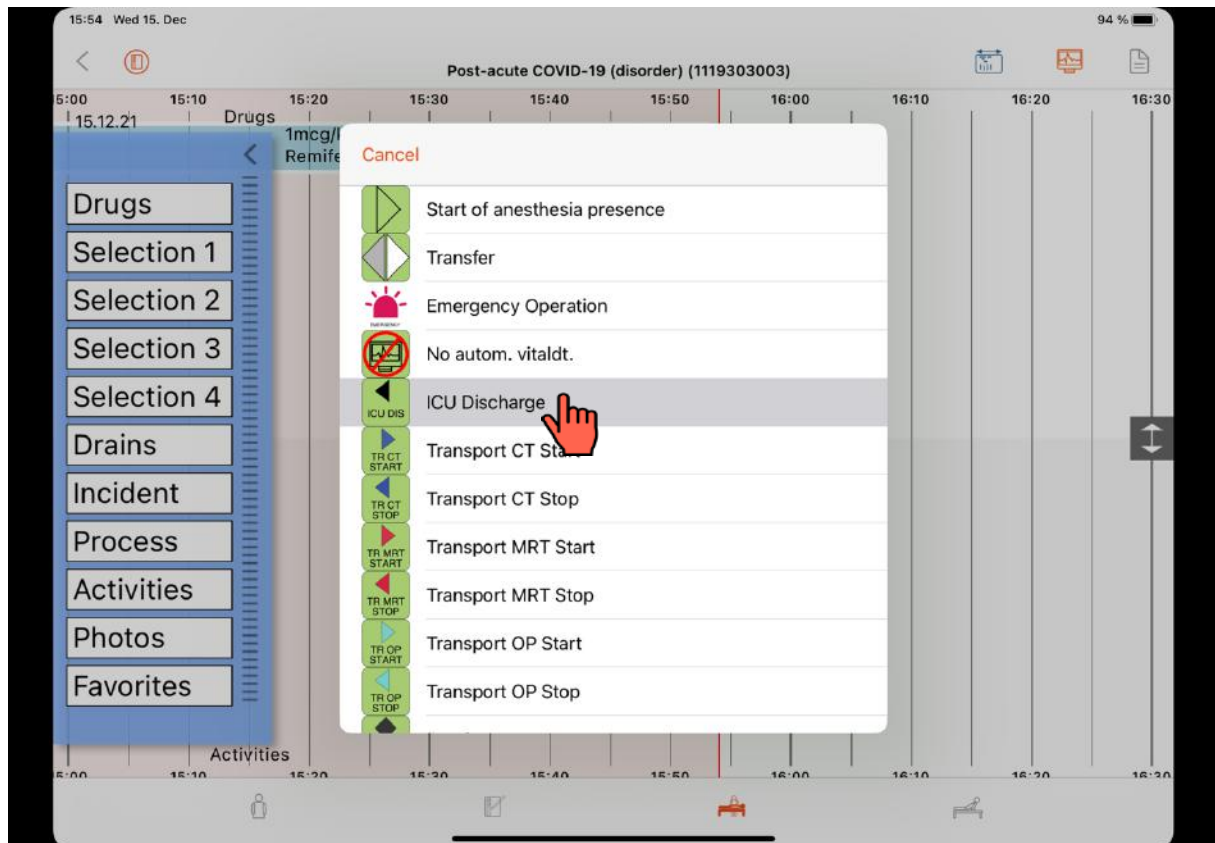


Figure 25: Documenting the process "ICU discharge"

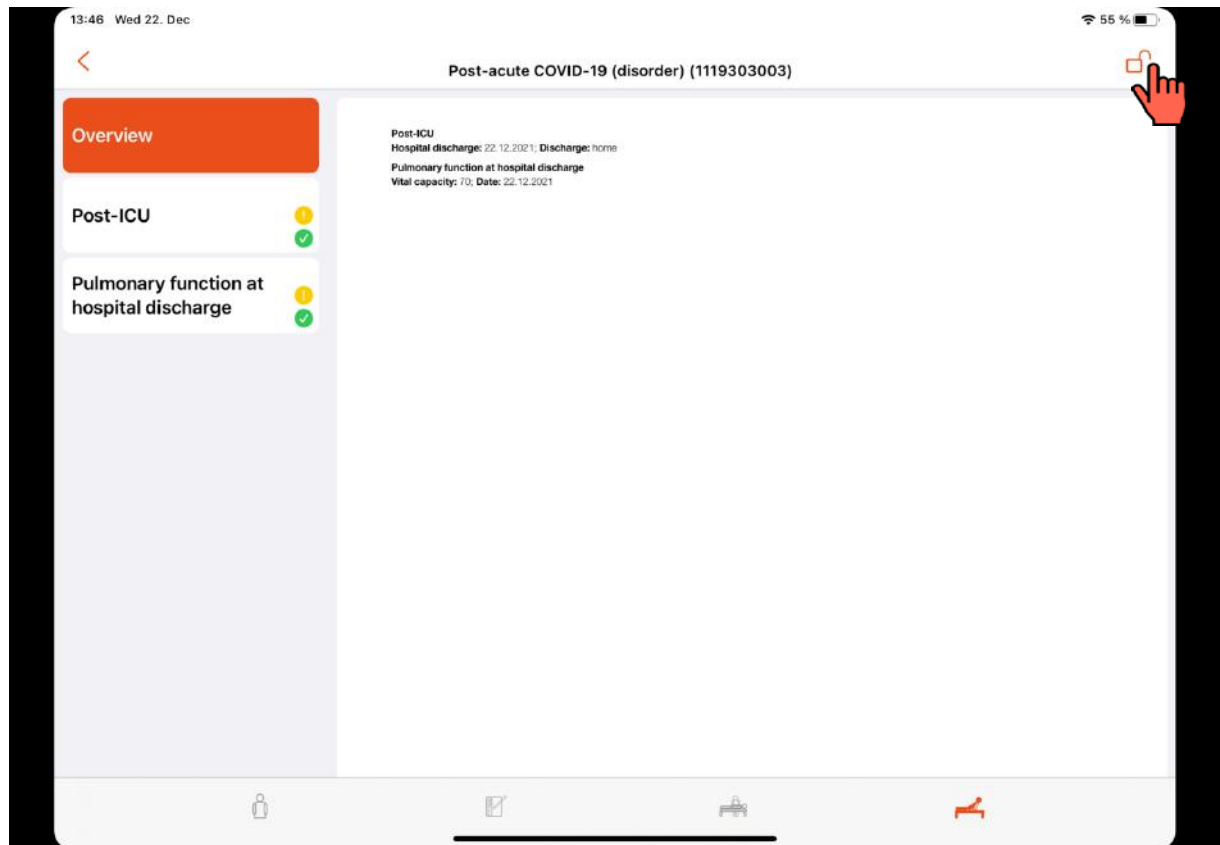


Figure 26: Closing the documentation

After a successful closing the grid will be shaded in gray and the lock icon will change from open to closed. The entries can then no longer be edited, but still be viewed. Should the necessity arise that the documentation needs to be edited it can be unlocked by clicking on the closed lock icon in the Post-ICU tab.

6.3. Uploading the treatment

After closing the treatment and documenting the discharge, the treatment must be stored in on the server. In order to do this, go back to “Treatments” and click on the orange arrow pointing down. The treatment will change from “In Progress” to “Available”. You can then create a new case, by clicking on the icon of the person with a plus.

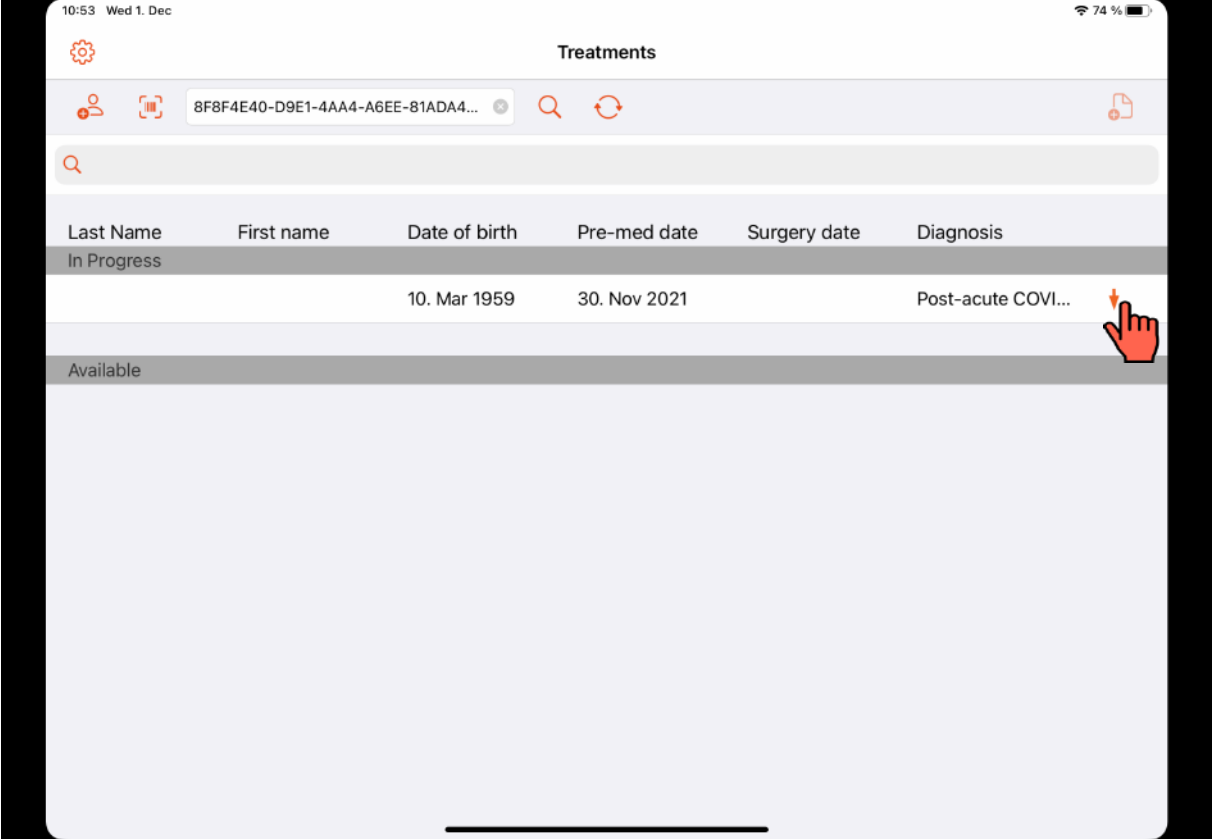
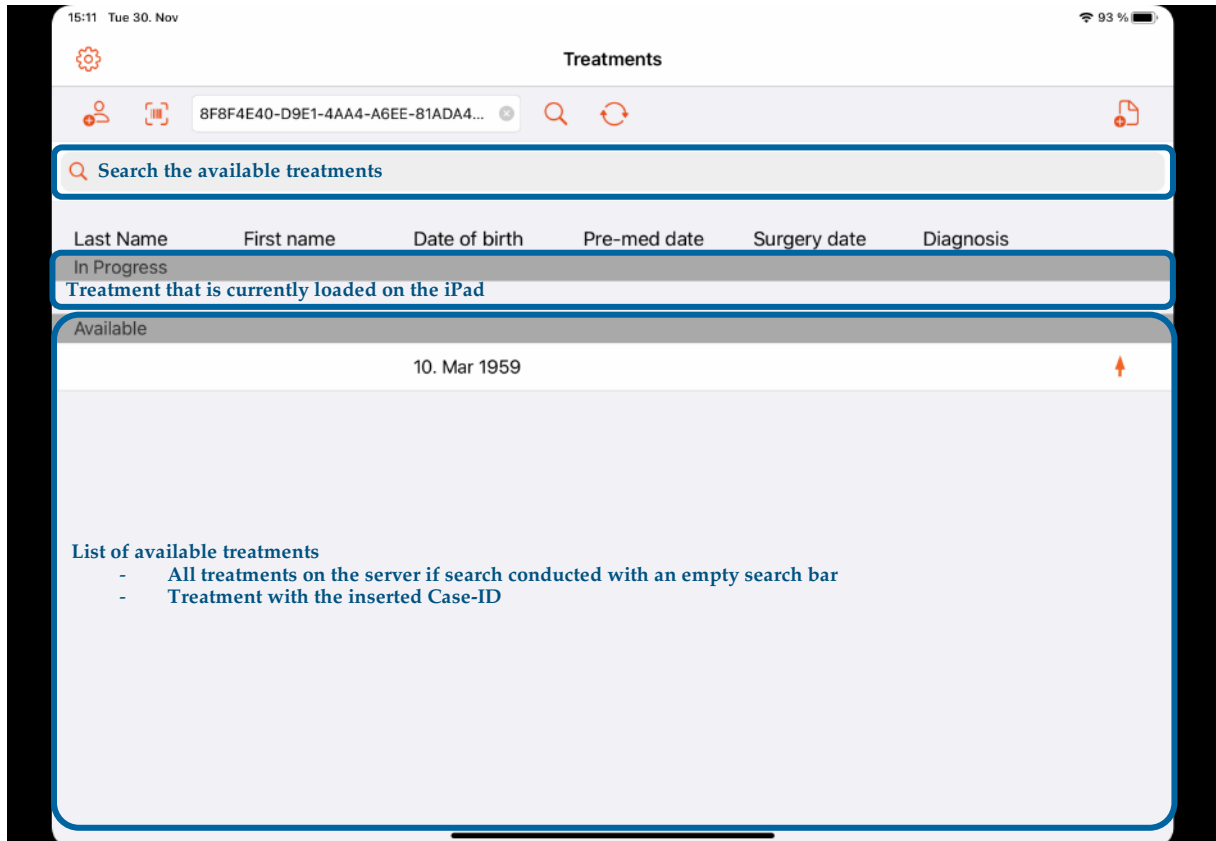









Figure 27: Uploading the treatment

Appendix: Screens and Icons

Treatment overview



Symbol	Name	Description
	Settings menu	Opens Settings: "Change password" , "Configuration" , "Administration" , "App configuration" , "Language selection" , "Send Logs"
	New case	Opens "Create new case" window: "Sex" , "Date of birth" , "Admission date" , "Case-ID"
	Scan Code	Opens camera to scan code of case ID
	Search/ Magnifier	Search for cases with a given case ID
	Reload	Reload the available cases
	Download	Download a treatment onto the iPad
	Upload	Upload a treatment onto the SAS server

Patient Tab

09:49 Tue 11. Jan 92%

< [document icon]

Sex Information filled in at the creation of the case

male female intersex

Date of birth

10.01.1998

Admission date

10.01.2022

Diagnosis

Post-acute COVID-19 (disorder) (1119303003)

SNOMED CT nomenclature of the diagnosis

Secondary diagnosis

+ [plus icon]

Height in cm

175

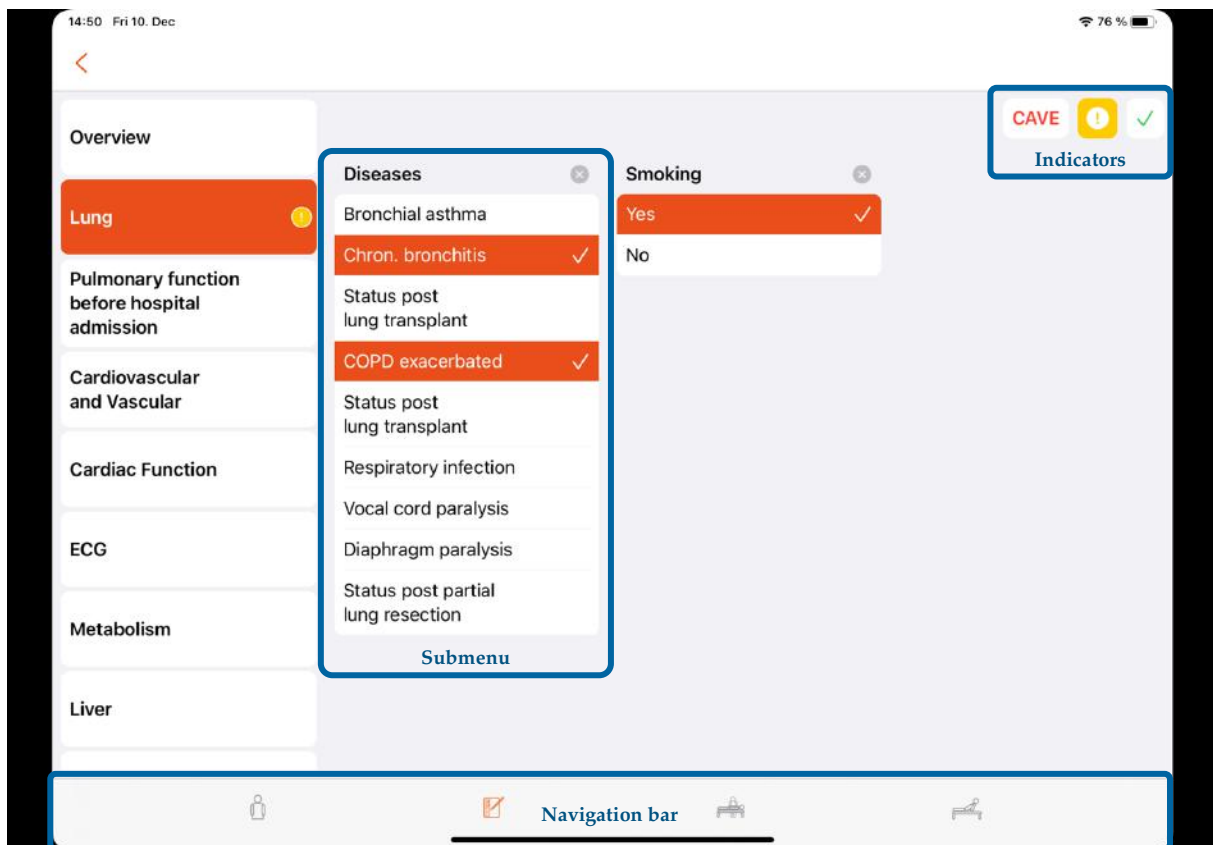
Information filled in in this patient mask



Weight in kg

70

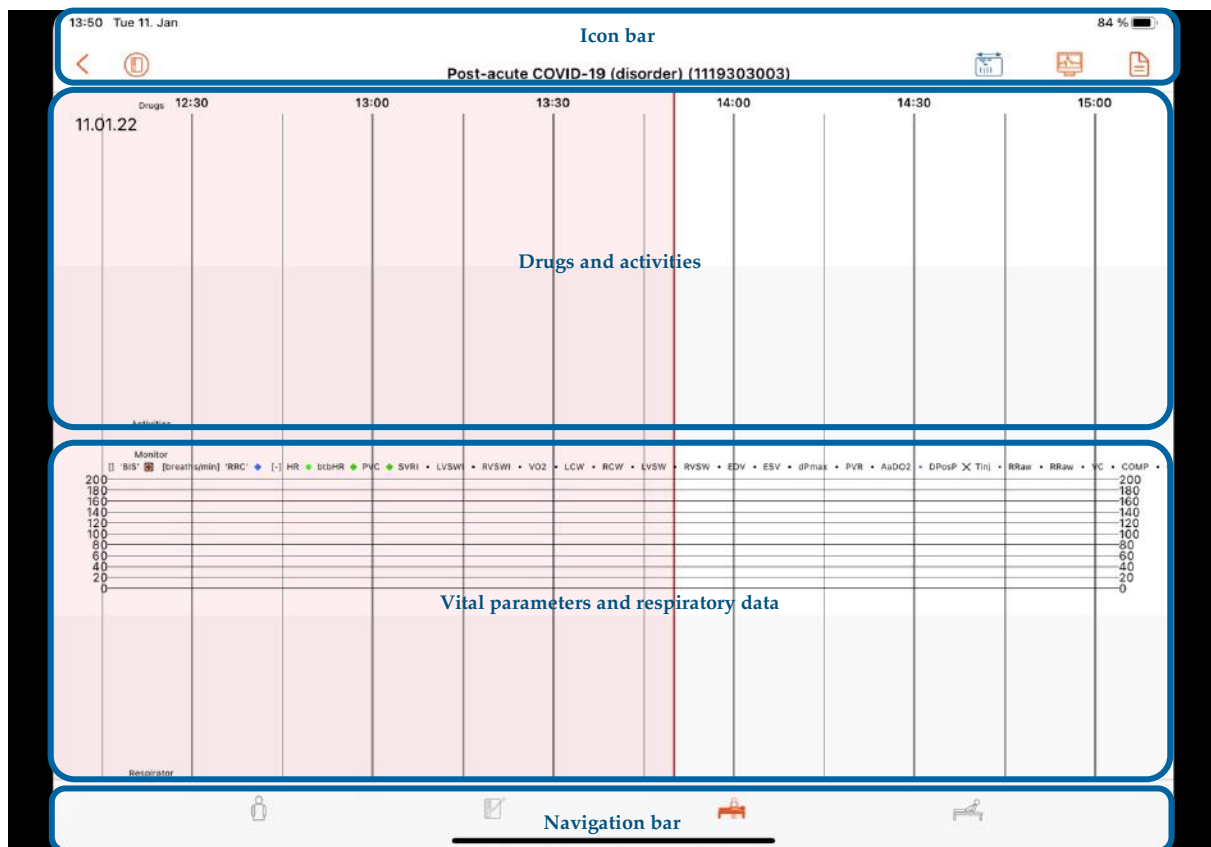
[person icon] [document icon] **Navigation bar** [stretcher icon] [bed icon]







Anamnesis Tab

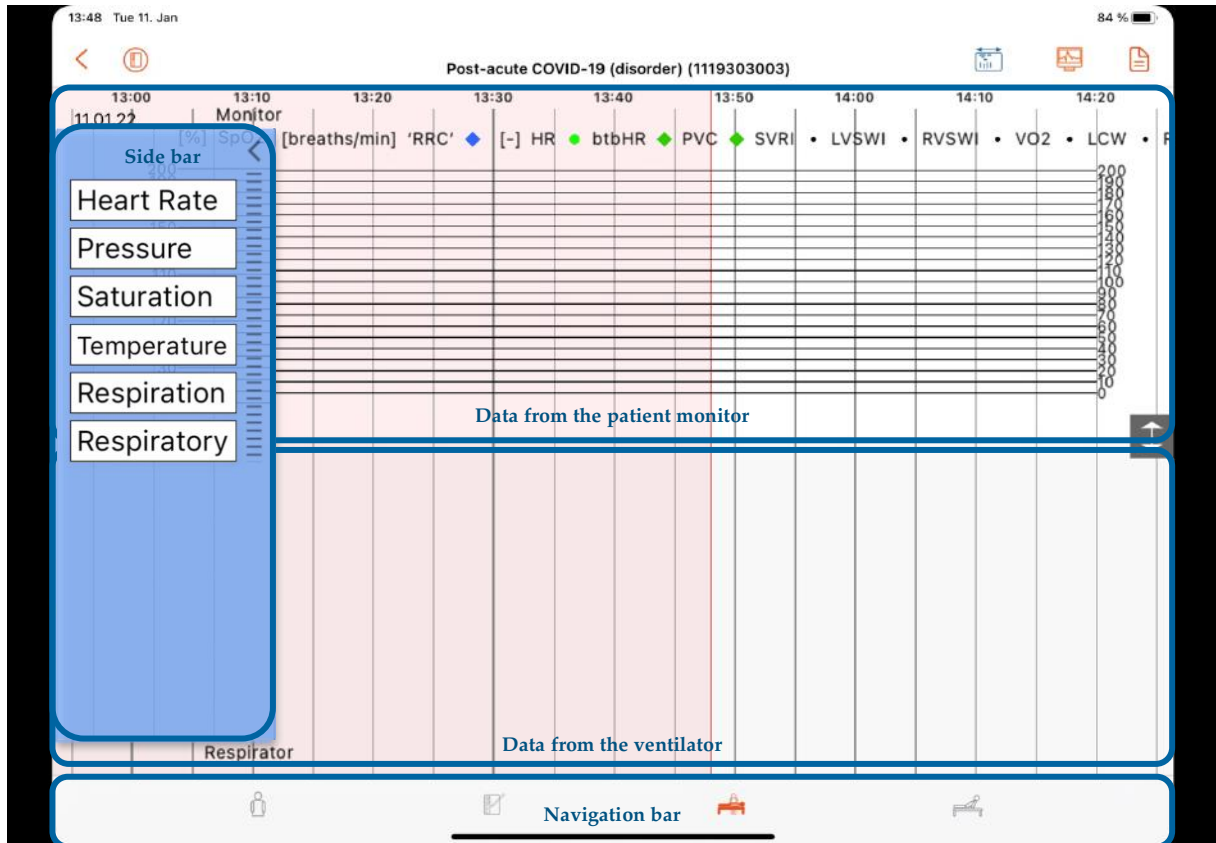
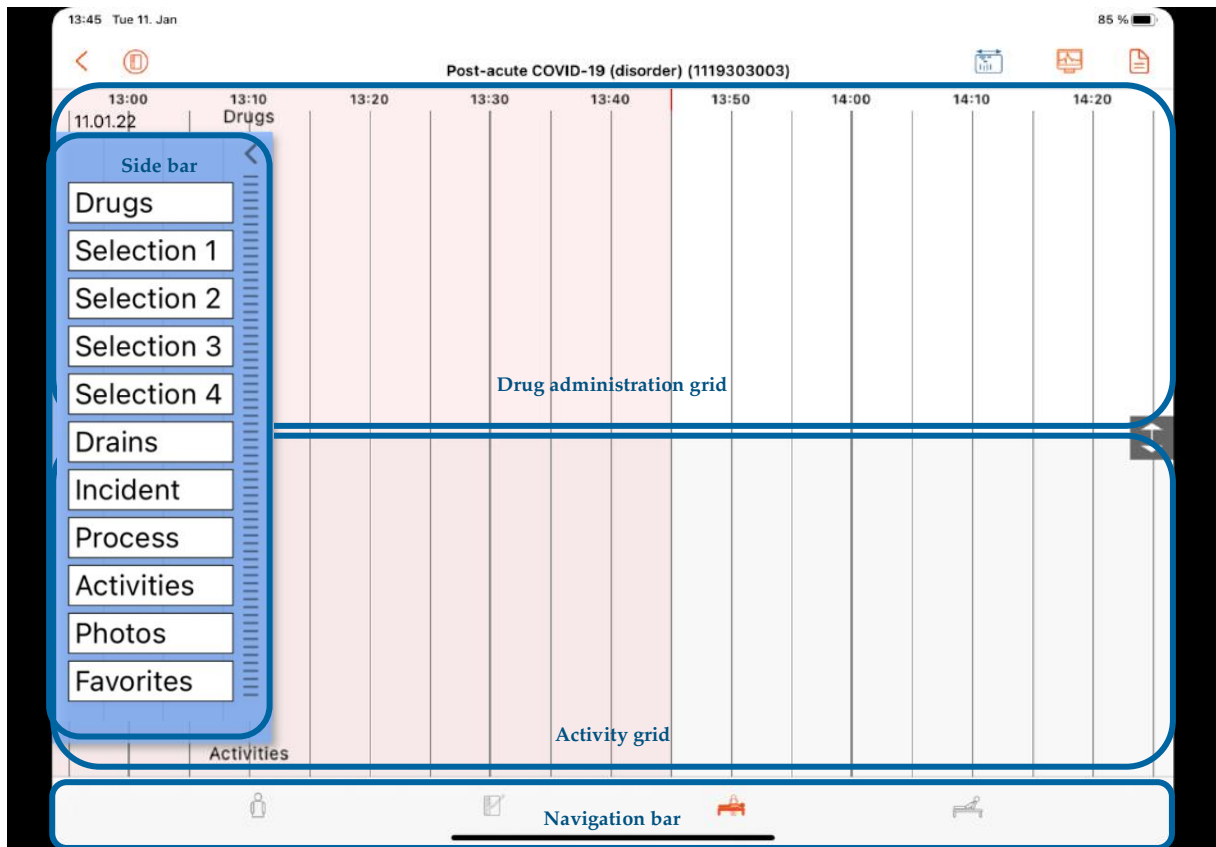


Symbol	Name	Description
CAVE	Indication Critical	Allows to mark a group as critical
	Indication Edited	Automatically highlighted when something is edited
	Indication Completed	Allows to mark a submenu as completed

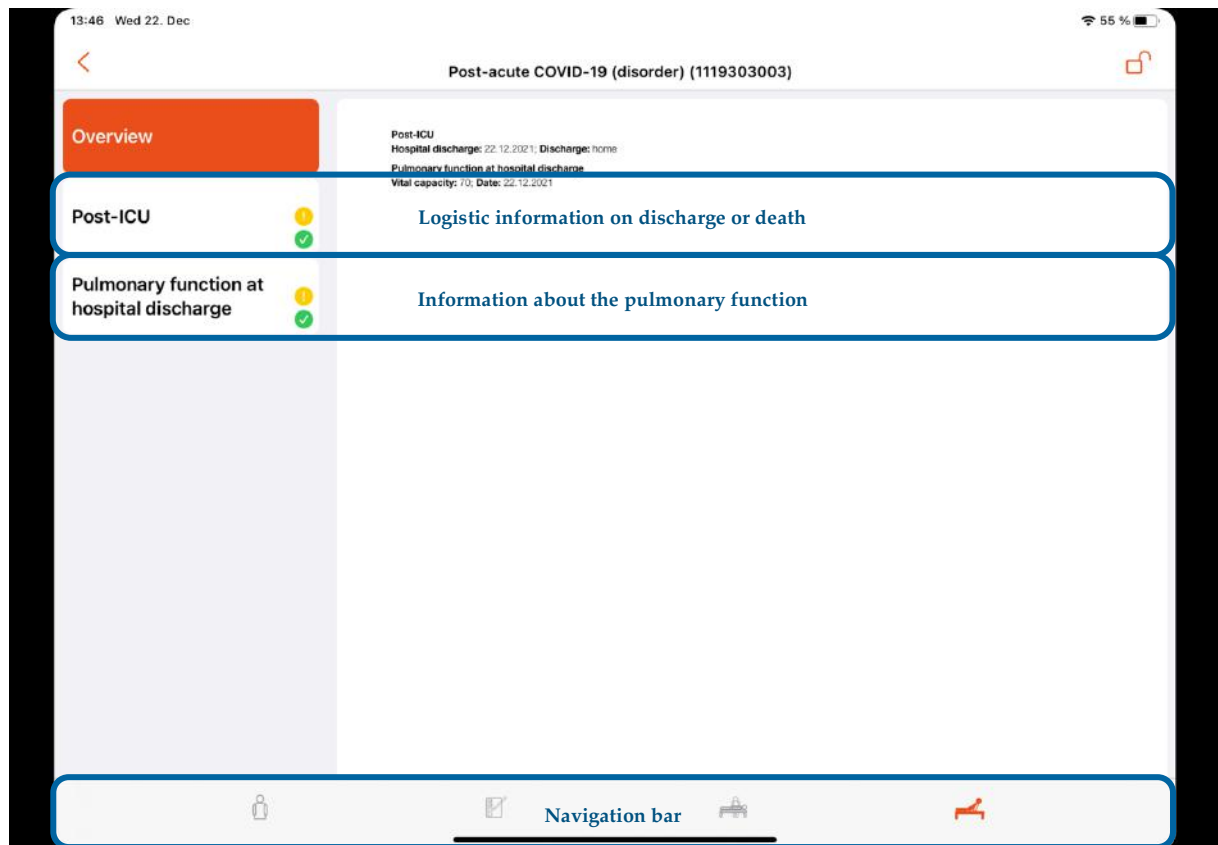
ICU Tab




Symbol	Name	Description
	Anamnesis	Shows anamnesis overview
	Time scale	Allows to jump to the first and last entry, as well as the current time
	Connecting medical devices	Opens "Monitor Overview"
	Monitor Overview	Opens "Monitor Overview" , disconnect individual medical devices
	Disconnect medical devices	Disconnect all medical devices
	Stop watch	Activates a mode in which every vital parameter is displayed every minute



Post- ICU Tab



Symbol	Name	Description
	Lock icon	Closes the documentation, the data can then no longer be edited and if the treatment is saved tot he server it is marked as complete there

The Sandman ICU app is part of the EU project

ENVISION

For more information please visit the website:

<https://www.envision-icu.eu>

