A Personalised Integrated Care Platform

(Grant Agreement No. 689209)

D4.6 Third Version Patient Private Cloud

Date: 2019-07-03

Version 1.0

Published by the PICASO Consortium

Dissemination Level: Public

Co-funded by the European Union's Horizon 2020 Framework Programme for Research and Innovation under Grant Agreement No 689209

Document control page

Document file: D4.6 Third version Patient Private Cloud.docx
Document version: 1.0
Document owner: CNet

Work package: WP4 – Private Patient Cloud with IoT Resource Management
Task: T4.1, T4.2, T4.3
Deliverable type: Demo

Document status: ☒ approved by the document owner for internal review
☒ approved for submission to the EC

Document history:

Version	Author(s)	Date	Summary of changes made
0.1	Matts Ahlsén (CNet)	2019-04-23	Preparation of D4.5 for update
0.4	Matts Ahlsén, Stefan Paulsson, Peter Rosengren (CNet)	2019-05-10	Update of functions & interfaces
0.5	Matts Ahlsén (CNet)	2019-06-10	Requirements review
0.8	Matts Ahlsén, Peter Rosengren (CNet)	2019-06-15	Overall review & update and usage statistics
0.95	Matts Ahlsén, Peter Rosengren (CNet)	2019-06-24	Version for internal review
1.0	Matts Ahlsén, Peter Rosengren (CNet)	2019-07-03	Final version submitted to the European Commission

Internal review history:

Reviewed by	Date	Summary of comments
Armanas Povilionis (INUIT/BOSARC)	2019-06-27	Approved

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1 Executive Summary

The Patient Private Cloud implements the PICASO Patient Self-Monitoring Framework, which supports the following functions,

- A user interface for patients and informal carers with scheduled care-plan activities and compliance feedback.
- Continuous data, vital signs and behaviour monitoring.
- Patient reported outcomes through questionnaires.
- User feedback: Overview and summary of data in graphs and tables.
- Clinician feedback: aggregated patient data available over time, for controlled integration with clinical back-end systems.

This deliverable describes the third (final) version of the PICASO Patient Private Cloud (PPC) demonstrator. The PPC includes the set of medical devices and the software components that implement the self-monitoring framework of PICASO. The PPC would typically be deployed in a patient´s premises but can also be mobile.

The default configuration of the PPC includes the following components,

- The PPC Gateway
- Monitoring devices
- PICASO software components, private and public cloud.
- Internet access via 3G/4G/LTE/WiFi

The PPC provides user interaction via the Patient Dashboard, a web/app based, device independent, user interface tool that displays patient health data and manages communications with health professionals. Patient data (administrative or clinical) are not stored persistently in the PPC. This data is held remotely in the secure clinical environments, implemented by the PICASO Carers Private Clouds.

This deliverable (D4.6) focuses on the Patient Dashboard part of the PPC Demonstrator.

A sandbox version of the Patient Dashboard UI of the PPC is available at this link,

https://test.picaso.eu:444/pd/en/welcome

with login credentials:

- User: “testpatient4”
- Password: “testpatient4”

2 Introduction

2.1 Purpose, context and scope of this deliverable

This document accompanies the Demonstrator software deliverable D4.6 and describes the configuration for the final third version of the PICASO Patient Private Cloud (PPC). The PPC includes the set of medical devices and the software components that implements the remote monitoring sub system of PICASO. The PPC would typically be deployed in a patient´s premises (usually at home) but can also be mobile (depending on the devices used).

The PPC is implemented in three deliverables,

- D4.1 – Sensor Network and WAN access point: Implements the PPC gateway and device network.
- D4.4 – Second IoT Resource Management Subset: Implements the PPC software components and deployment.
- D4.6 – Third Version of the Patient Private Cloud: Implements the PPC Demonstrator (*this deliverable*).

For descriptions of the PICASO clinical trial protocols and progress, we refer to deliverables D8.7-8.

2.2 Intellectual Property (IP)

The different components of the Patient Private Cloud are subject to open source and commercial licences, which are subject to the licences reflected in the IP repository being created for the project.

2.3 PICASO Architecture

The PICASO architecture is cloud based meaning that the PICASO system functionality is distributed over a set of inter-related secured cloud environments, each of which runs a subset of the PICASO functional components. The cloud environments are agnostic to underlying hardware and operating systems technologies.

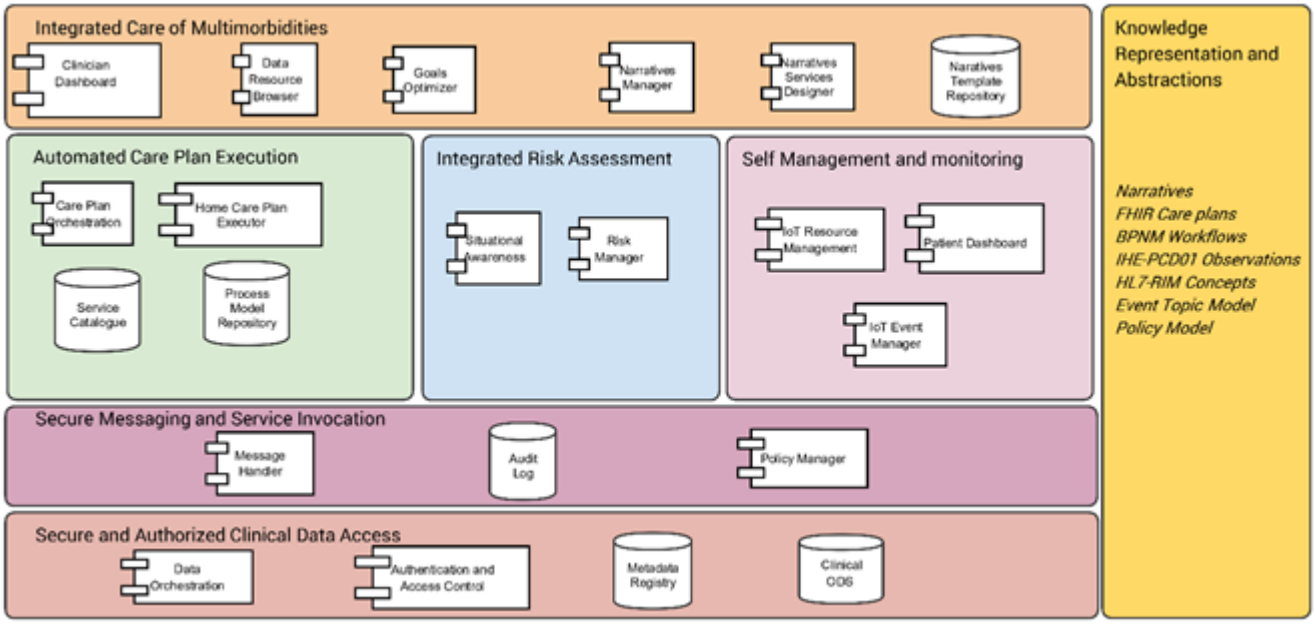


Figure 1: Conceptual architecture

The PICASO Conceptual Architecture with its main functionality blocks is shown in Figure 1. Work Package 4 is devoted to the “Self Management and Monitoring” functionality block. PICASO implements a number of services to allow for patients to be able to self-manage their diseases and monitor different vital signs under the supervision of formal as well as informal carers. This includes software for connecting home monitoring

devices, accessing external cloud services and a Patient Dashboard for visualising vital signs and provide a diary for activities.

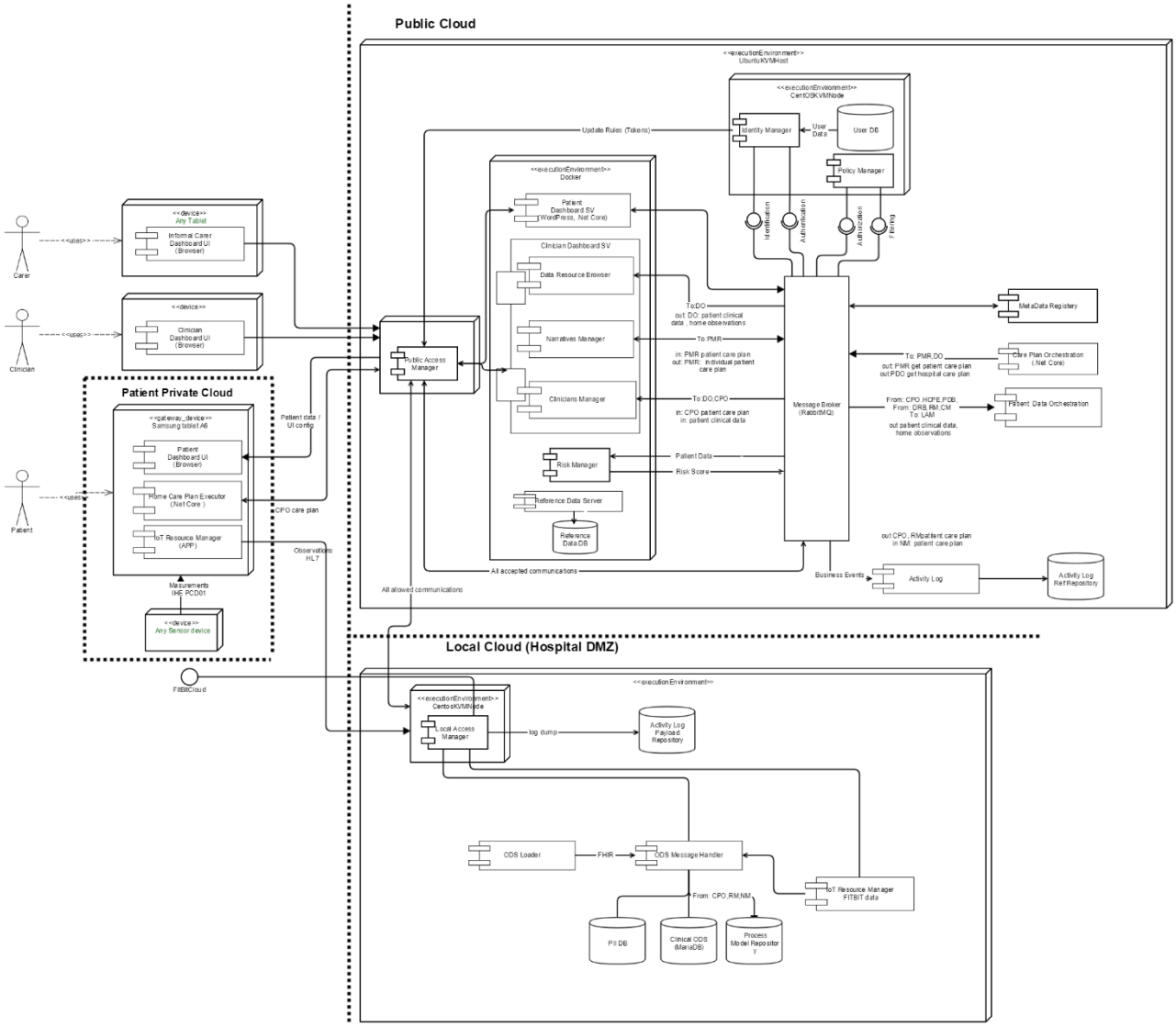


Figure 2: Component deployment diagram of the PICASO platform

The architecture diagram in Figure 2 shows the complete platform with the components deployed in the run-time cloud environments. The PPC in indicated on the left. In addition to the components inside the PPC I the figure, the Patient Dashboard configuration also includes a server-side component (Patient Dashboard SV).

3 Requirements

The following describes the set of PICASO requirements that pertains to the Patient Private Cloud. These are functional user requirements compiled from the requirements workshops involving project clinicians and patients as well as external advisors including the projects Ethical Board.

As a part of the requirements analysis and platform design process, a collection of ”Significant use cases” was specified to cover the overall scenario for the PICASO clinical trials.

Below is the subset of Jira Requirements that pertains to the PPC, remote monitoring and the use of the Patient Dashboard, grouped under use cases. These use cases were developed during the Trial requirements process including a series of end-to-end solution design workshops (c.f. corresponding deliverables in WP2).

3.1 Use case 3a: Patient receives tasks to-do

ID	Description	Rationale	Fit Criterion
PIC-15	PICASO provides an adaptable reminder system for patients and/or carers	Patients should have the option to receive reminders for, e.g., proper medication intake, doing home monitoring measurements and/or self-recording of symptoms.	Reminders as defined by patients, physicians or therapists are related to, e.g., the medication plan, home monitoring measurements and/or patient diary of the patient. In addition to date and time, the mode of presentation (text, image, sound) can be selected.
PIC-46	PICASO provides a patient diary for self-recording.	A recorded history of daily self-diagnostics is an important tool for PD patients in regard to self-assessment and discussion with, e.g., physicians.	A patient diary is available where patients can record their daily well-being on a scale from 1 to 6. The recorded rating is presented to the user relative to the schedule for medication intake.
PIC-67	Patients are provided an overview of their daily tasks and progress of fulfilment.	Patients need to be informed on daily base about what tasks they are expected to fulfil, what tasks they have achieved already and which ones are open. This may also support motivation to achieve all tasks.	Patients are provided daily an overview of the tasks they are expected to achieve and their progress of fulfilment. In case PICASO cannot detect automatically when a task is fulfilled, the patients are asked to confirm by other means.
PIC-113	Patients are provided constantly available material with instructions on how to use sensors, devices, and the applications on the Patient Dashboard.	For the trials patients need to have information constantly available, e.g., in form of a ‘handbook’, video clip or the like, on how to use properly sensors and device for the home monitoring platform and applications of the Patient Dashboard, e.g., for self-recordings.	Patients are provided constantly available material such as a handbook with instructions on how to use sensors and devices for home monitoring and applications on the Patient Dashboard properly.
PIC-173	Patients should be able to document drug intake when differing from their	In case patients’ drug intake differs from the defined medication plan, e.g. because they have been advised to adjust the dose of a certain drug according to their well-being or	Patients shall be able to document drug intake when differing from the defined medication plan. The documented drug intake shall be stored and displayed along the

ID	Description	Rationale	Fit Criterion
	defined medication plan.	decided to take in an additional drug, they shall be able to document this.	medication history in relation to date and time of recording or as the user has specified the date/time, also when looking at the medication history in retrospective.
PIC-113	Patients are provided constantly available material with instructions on how to use sensors, devices, and the applications on the Patient Dashboard.	For the trials patients need to have information constantly available, e.g., in form of a 'handbook', video clip or the like, on how to use properly sensors and device for the home monitoring platform and applications of the Patient Dashboard, e.g., for self-recordings.	Patients are provided constantly available material such as a handbook with instructions on how to use sensors and devices for home monitoring and applications on the Patient Dashboard properly.

3.2 Use case 3b: Patient is presented overview of home monitoring measurements and self-recordings

ID	Description	Rationale	Fit Criterion
PIC-17	The patient diary provides a graphical presentation of the patient's recordings	Graphical presentation is an effective way to get an overview of the progression of the disease for patients as well as for physicians.	A graphical presentation of recordings is available that allows selection of the time frame presented (daily, weekly or monthly).
PIC-105	Patients need to be able to fill out questionnaires FFbH/HAQ and RADAI.	To monitor the development of RA disease, it is important that patients are able to fill out the questionnaires FFbH/HAQ and RADAI according to a set schedule.	Patients are able to fill out the questionnaires FFbH/HAQ and RADAI and are reminded to do so according to a schedule as defined by the RA specialist.
PIC-175	Patients need to be able to fill out the Morisky scale.	In order to estimate the risk of medication non-adherence patients have to be able to fill out the Morisky scale at a predefined time.	Patients are able to fill out the Morisky scale. They are asked to do so at a time predefined by a physician.
PIC-176	Patients should be presented an integrated view on drug intake, activity, and well-being ratings also in retrospective.	Patients should be supported in understanding/judging about their health status particularly by looking at it in retrospective. This is an important part of patient empowerment.	Patients should be presented an integrated view on drug intake, outcome of home monitoring measurements and well-being ratings. Patients shall be able to see historical data for activity values (e.g. walking distance), drug intake and well-being ratings. For both views it shall be possible to show/hide certain information types, e.g. activity results or well-being ratings to ease overview.

ID	Description	Rationale	Fit Criterion
PIC-177	Patients should be presented an integrated view on drug intake, activity, and well-being ratings also in retrospective.	Patients should be supported in understanding/judging about their health status particularly by looking at it in retrospective. This is an important part of patient empowerment.	Patients should be provided an integrated view on their drug intake, outcome of home monitoring measurements and self-recordings unless it is marked in the patient's care plan that a certain measurement or self-recording shall not be presented (see PIC-208).
PIC-202	When presenting an integrated view on results from, e.g., home monitoring and self-recordings to patients it shall be possible to hide/show certain types of results, e.g. heart rate measurements.	In order to ease overview for patients when looking at an integrated view of results from different home monitoring measurements, self-recordings etc., it needs to be possible to hide and show any of the presented data types such as heart rate measurements or well-being ratings.	In an integrated view for patients on results from, e.g., home monitoring and self-recordings, it is possible to hide/show types of results such as heart rate measurements and/or well-being ratings.
PIC-203	An optional alternative view shall be provided for patients when presented a complex integrated view on results from, e.g., many different home monitoring measurements and self-recordings.	Rationale: Integrated views on personal health data are an important source of information for patients, because it allows them to understand correlations between different health parameters and their well-being. However such integrated views can be rather complex when presented for instance in one graph and thus might impede comprehension. In such cases it is necessary to provide an optional simplified version. A design solution for this purpose could be for instance to condense the information from the integrated graph into a table and only indicate measurements out-of-expected values by a red dash while showing pain ratings and drug intake as recorded by the patient. Such a view will support patients in understanding, e.g., correlations between drug intake, activity and pain.	If more than 4 different types of patient data from self-recordings (e.g. drug intake differing from medication plan, pain ratings) and home monitoring measurements (e.g., blood pressure, heart rate, step counter) are presented in an integrated view for patients, an optional simplified version shall also be provided.
PIC-208	Presentation as well as visualisation of results from home monitoring measurements and self-recordings for patients should be adjustable to patients' needs.	During discussions about PICASO user trials it turned out that particularly for UTV trial, care needs to be taken that patients are not overburdened by being confronted with unfavourable results from home monitoring measurements and self-recordings. Therefore, clinicians need to have the possibility to define whether or not results from home monitoring measurements and self-recordings	Presentation of values from home monitoring measurements and self-recordings to patients shall be configurable to patients' needs.

ID	Description	Rationale	Fit Criterion
		should be presented retrospectively to patients.	

3.3 Use case 3c: Home monitoring measurements are out-of-expected range (e.g. blood pressure is above threshold)

ID	Description	Rationale	Fit Criterion
PIC-98	Information must be provided for patients on how to interpret results of measurements and self-recordings	Patients need to be supported in understanding what results of their measurements and self-recordings mean to judge better about their current health status.	In case physicians have defined for a patient when results of vital sign measurements are out-of-expected range this shall be indicated in the graphs on the Patient Dashboard as agreed on with trial owners. Beyond this, a legend is provided for health questionnaires to support patients in interpreting their questionnaire results.
PIC-106	Graphical presentation of a patient's sensor platform measurements indicates out-of-expected-range incidents.	Measurements of vital parameters below or above defined thresholds need to be indicated to patients to inform them about out-of-expected-range incidents.	In the graphical presentation of a patient's sensor platform measurements, measurements above/below defined thresholds are highlighted, e.g., by a line representing the maximum/minimum expected measurement, also when presented in combination with patient's self-recordings (see PIC-45).

3.4 Use case 3d: Patient can adjust personal preferences.

ID	Description	Rationale	Fit Criterion
PIC-15	PICASO provides an adaptable reminder system for patients and/or carers.	Patients should have the option to receive reminders for, e.g., proper medication intake, doing home monitoring measurements and/or self-recording of symptoms.	Reminders as defined by patients, physicians or therapists are related to, e.g., the medication plan, home monitoring measurements and/or patient diary of the patient. In addition to date and time, the mode of presentation (text, image, sound) can be selected.
PIC-22	Participants can control devices and technologies used for home monitoring	Participants must feel in control of what goes on in their home even if they have agreed to home monitoring.	Participants can switch off equipment or choose not to send data.
PIC-174	Patients should be able to create	In case patients participating in the user trials will not be able to use the	Patients participating in the user trials are able to create a ‚leave

ID	Description	Rationale	Fit Criterion
	a ‚leave of absence' message during the user trials.	home monitoring platform, because they are, e.g., on vacation, they should be able to send a ‚leave of absence' message to PICASO indicating the period of time they will be away, so clinicians are informed about why no data are coming in from this patient and for how long this will be.	of absence' message indicating the period of time they will be absent.
PIC-205	Patient can choose not to send a measurement.	When a patient has taken a measurement which is then transferred automatically to the PICASO App, e.g. weight and blood pressure, the patient should have the option in the App to "not send" or "delete" the data to the patient dashboard. This functionality is useful in case other people use the device to take a measurement; the patient must therefore be able to delete it so that it doesn't become confused with the patient's own data.	A "delete" option is available in the PICASO App. The option is displayed next to the "send" option.

4 Patient Dashboard functionality

4.1 Devices and Use

The Patient Dashboard is deployed on a local gateway in the PPC. For the PICASO Trials a tablet PC was selected.

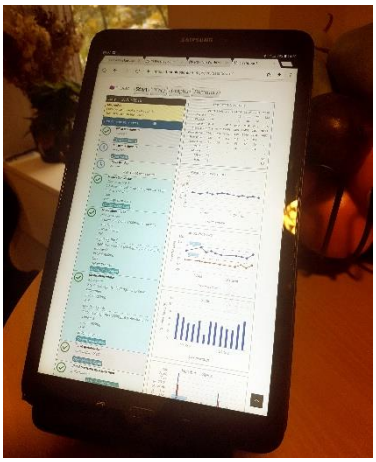


Figure 3: PPC gateway tablet

We refer to Deliverable D4.1 for details on the PPC gateway and the associated devices. The Patient Dashboard can in addition to patients also be used by informal carers, i.e., non-professional carers such as relatives or friends. The self-monitoring process is depicted below, from the patient's point of view.

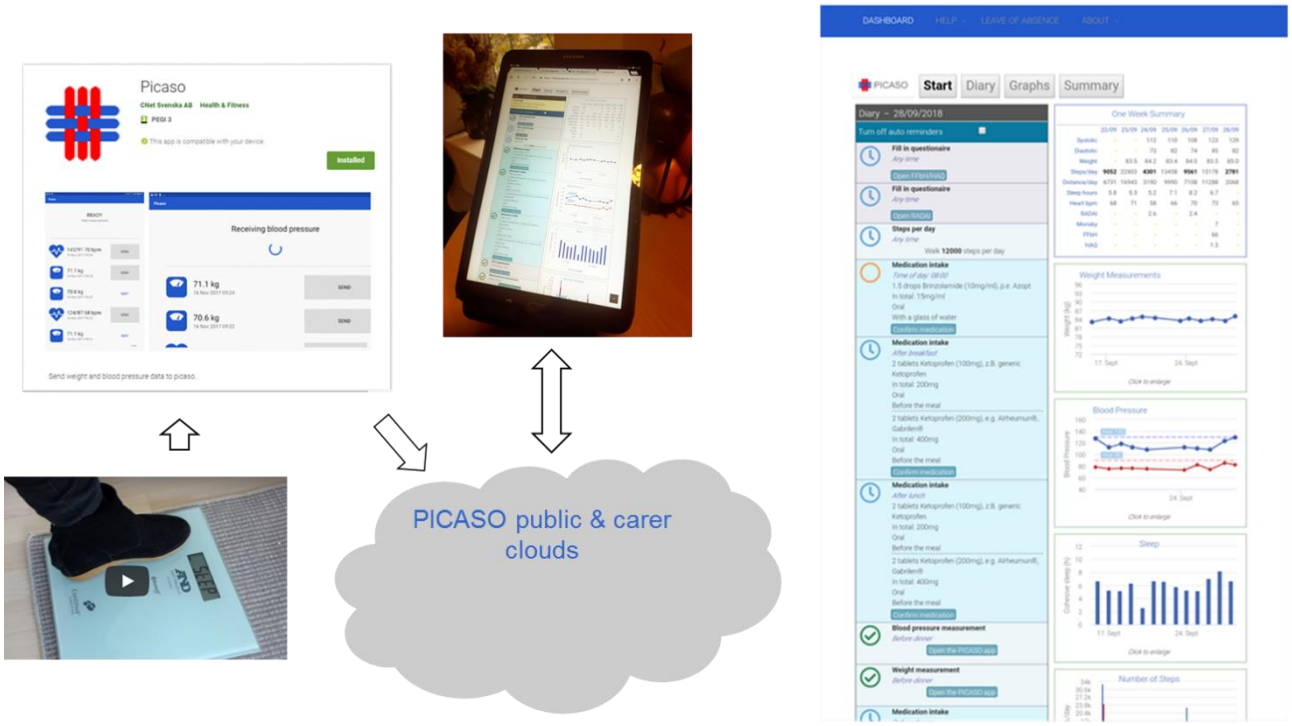


Figure 4: PICASO self-monitoring workflow, patient perspective.

For privacy purposes, patient users will be able to restrict access for informal carers to the dashboard contents. Informal carers may access the dashboard over the web from other devices rather than the PPC gateway (tablet). However, the measurement app and the remote monitoring devices, can only be used from the PPC

gateway since this requires a local installation of the IoT Resource Manager and the corresponding measurement app.

4.2 Dashboard User views

The Patient Dashboard UI supports multiple languages (currently Italian, German and English), this also applies to the user guidelines and patient information.

The following UI screen shots are in English.

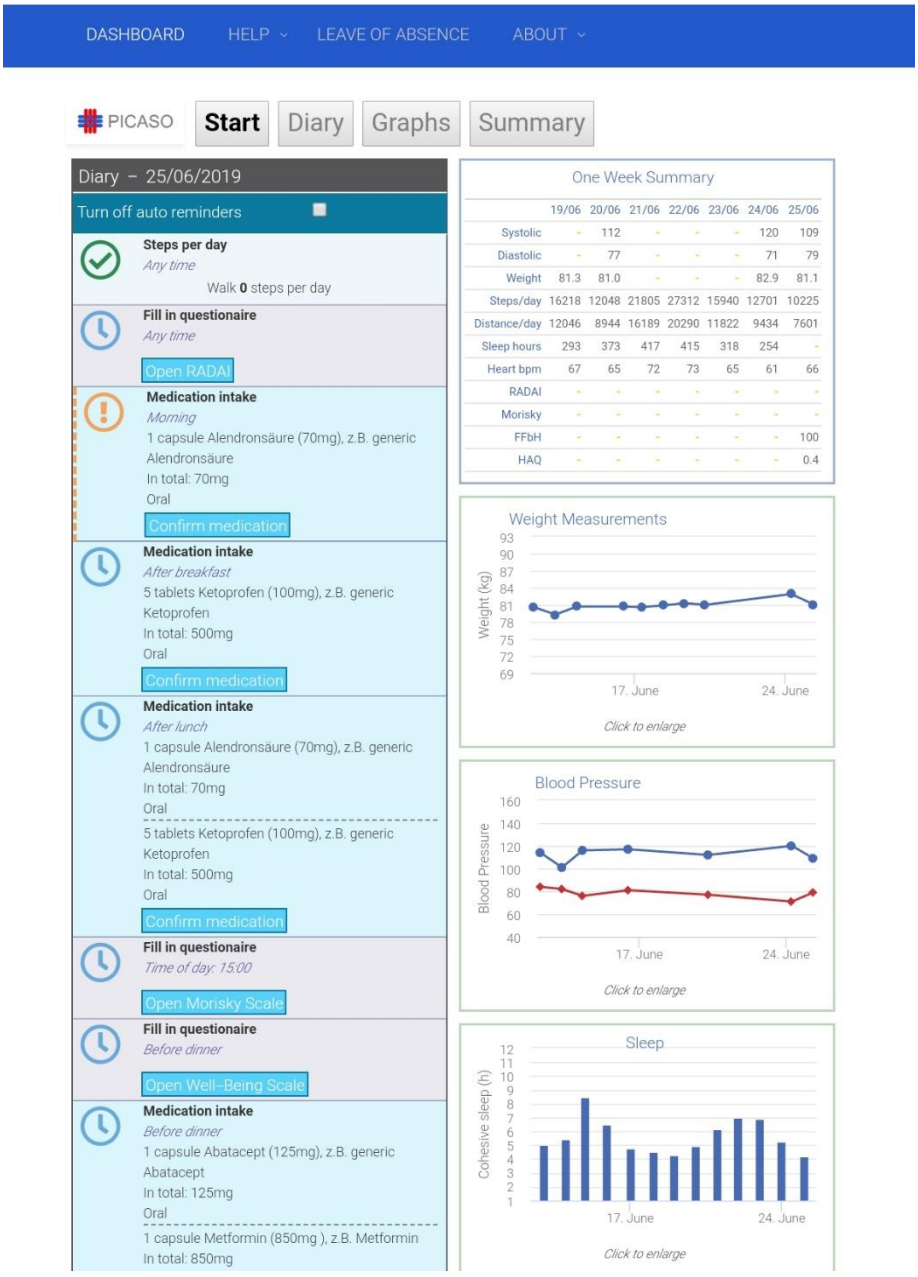


Figure 5: Patient Dashboard start screen

A patient user of the Dashboard or an informal carer (subject to authorization) can easily navigate between the different views of the Dashboard. Strictly speaking the “Dashboard” refers to the Start screen which combines the Diary and all measurements in a single page overview. However, in order to improve readability and prepare for future extensions, several page views were introduced, projecting the same content but in different detail and time resolutions.

4.3 Patient Diary/Activity List

The Patient Diary is a list of scheduled activities for a patient. The activities and schedule are generated from the PICASO care plans, created and maintained with the Care Plan Manager component in the Clinicians Dashboard (see Deliverable D7.6). PICASO care plans are represented in the FHIR format, an interoperability standards framework created by HL7[1].

The Diary example (Figure 5) shows the scheduled actions for a specific patient on a particular date. The entries include scheduled medication intakes and the filling out of questionnaires (RADAI, Morisky Scale, see below).

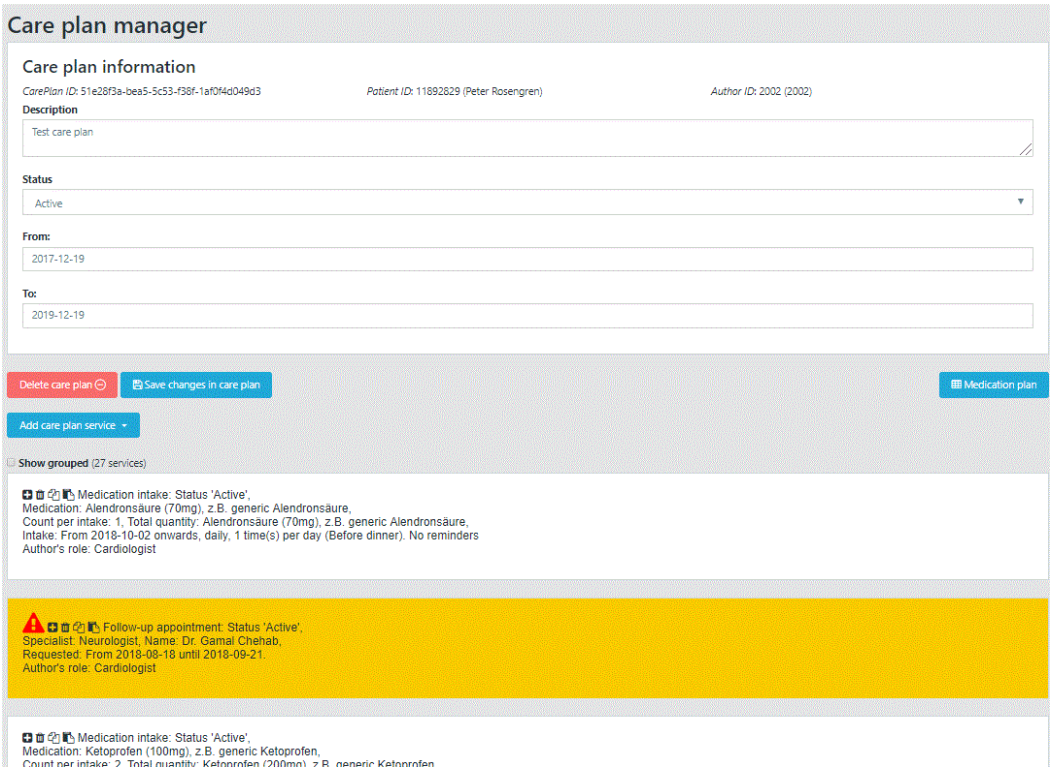


Figure 6: A Care Plan specification

The clinicians view of a Care Plan specification is shown in Figure 6 in the Care Plan Manager user interface.

4.3.1 Symbols and actions used in the Diary

The Diary contains a small set symbols associated with tasks and appointments, for attention and information.

[1] https://www.hl7.org/fhir/summary.html

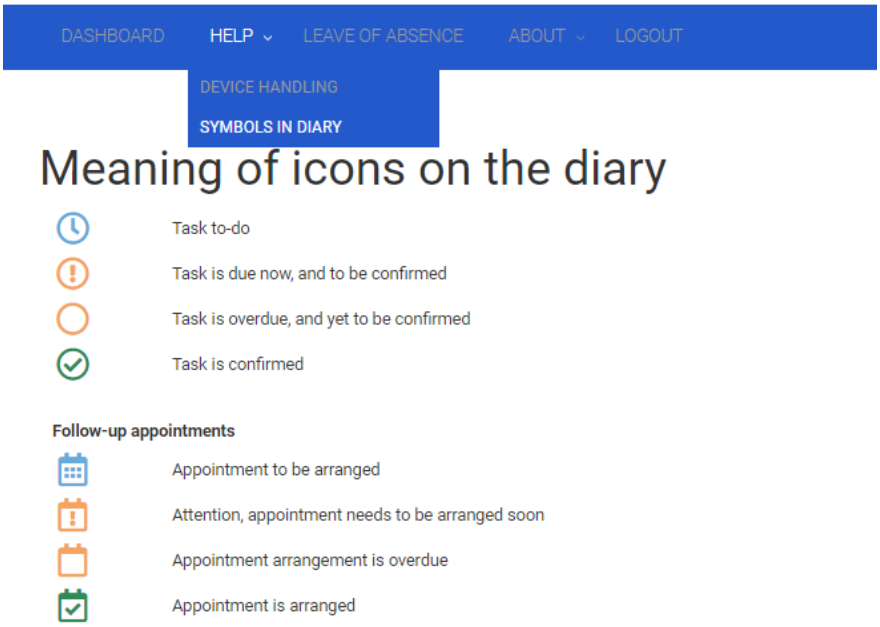
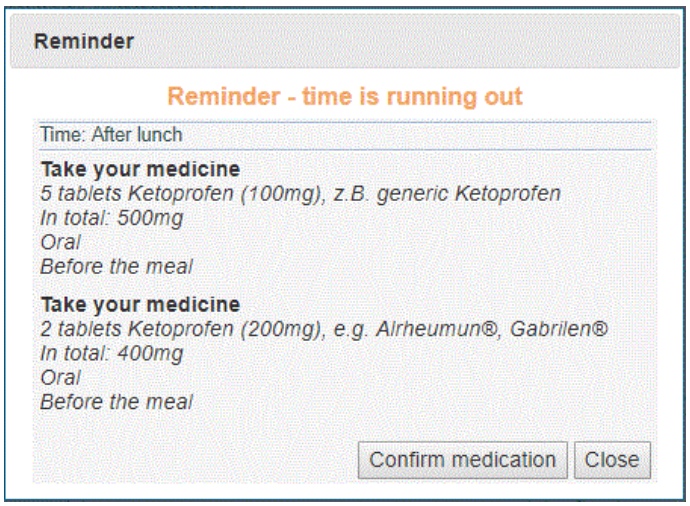


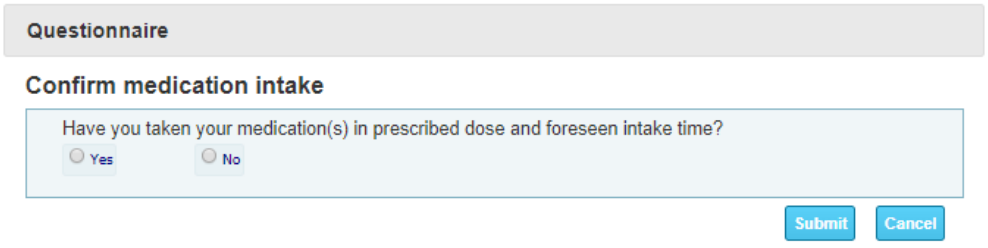
Table 1: Symbols in the Patient Diary

Most actions may be associated with reminders which can be automatically issued to the patient.

4.3.2 Reminders and Push Notifications

The reminders are specified in the Clinician Dashboard. The reminders will appear on the Patient Dashboard when a scheduled action (such as measurements, questionnaires, medication intakes) is approaching, is due or has recently passed.





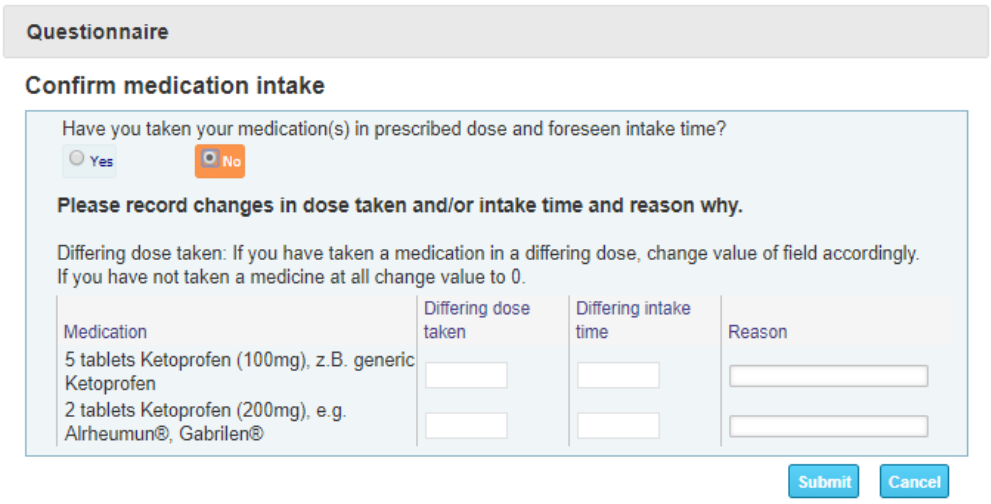


Figure 7: Medication intake reminder and confirmation pop-ups with option to record deviations

Reminders are issued for those actions associated with a certain time interval during the day, not for actions which can be performed anytime.

- Time intervals are expressed in relation to meals, which are associated to the corresponding hours (see Table 2).
- The time intervals are very broad. Meal intake varies among individuals and may depend on culture. Thus, the time intervals will be configurable.

Table 2 summarizes the reminder scheme for the Patient Dashboard.

FHIR Code	Meaning	Part of Day	From Hour	To Hour	Order No
ACM	Before breakfast	Morning	4	11	1
CM	During breakfast	Morning	4	11	2
PCM	After breakfast	Morning	4	11	3
ACD	Before lunch	Midday	11	15	4
CD	During lunch	Midday	11	15	5
PCD	After lunch	Midday	11	15	6
ACV	Before dinner	Afternoon	15	20	7
CV	During dinner	Afternoon	15	20	8
PCV	After dinner	Evening	15	24	9

Table 2: Reminder scheme

In the current demonstrator set-up, reminders are triggered 1 hour before an action is due. The reminder is only shown once, per day and action. Thus, if blood pressure measurements are scheduled for three times a day, at most three reminders will be triggered We refer to the Clinician Dashboard and the Care plan Manager tool for the different options available to a clinician when setting up reminders.

For details on the functionality and specification of care plan reminders, we refer to the Care Plan Manager in the Clinician Dashboard.

Push Notifications are used as a complement to the regular reminders. Whereas the latter require the Patient Dashboard application (web browser) to be open(ed) on the user tablet device for the user to be alerted, Push Notifications can be sent to alert a user device regardless of this.

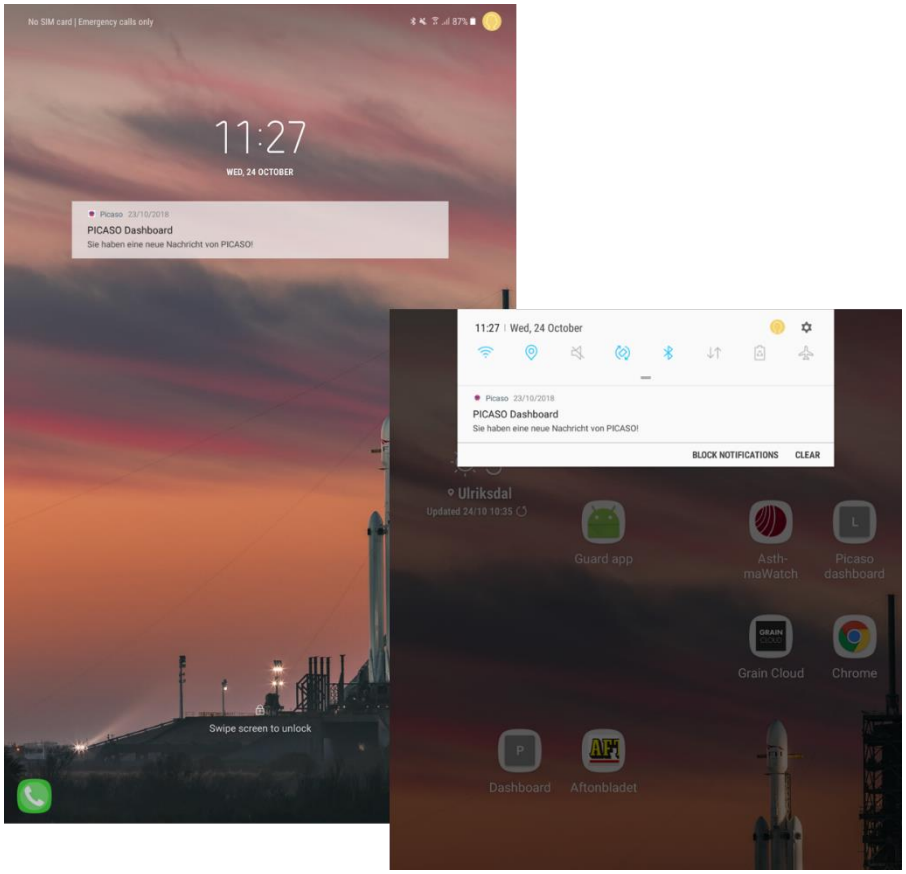


Figure 8: Push notifications on a user Android tablet device.

The current notification solution can be used with Android tablet devices and is based on the Google Cloud Messaging service Firebase[2] (see the accompanying Deliverable D4.4 for technical details).

4.4 The Measurement App

The Patient Dashboard is associated with a separate app[3] which is used to obtain the measurements from the wirelessly connected devices.

The Measurement app is launched from the Diary, by the user selecting a measurement activity entry.

[2] https://firebase.google.com/
[3] This app implements the IoT Resource Manager component, see D4.4.

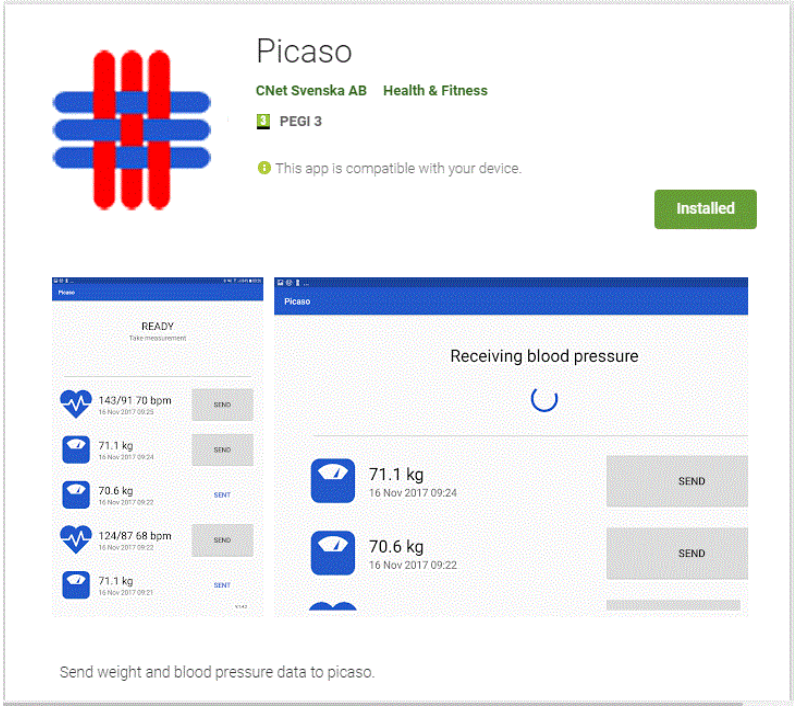


Figure 9: PICASO app (Google Play[4] screen capture)

The App connects standard medical devices and pushes data to the clinical cloud.

Note that observations from the activity monitoring device (FitBit) are retrieved (pseudonymized) from an external cloud service. See Deliverable D4.1 for details on device connectivity and the measurement app.

4.5 Behaviour monitoring

A complement to patient controlled measurements, patients can wear an activity bracelet (Fitbit) which provides continuous recording of

- sleep hours
- walking distance and number of steps per day
- heart rate

Figure 10: Activity bracelet

Data is automatically reported to the PICASO platform (no patient action is required). A third-party cloud service is used to relay data from the bracelets and patient tablet, to the PICASO platform. Data is transferred in pseudonymized form.

During the PICASO trials a total of 33 000 000 steps were recorded.

4.6 Viewing observations

The Dashboard views provide alternative visualizations of the patient's observation data (measurements), individually and in an integrated summary.

[4] https://play.google.com/store/apps/details?id=se.cnet.picasoble

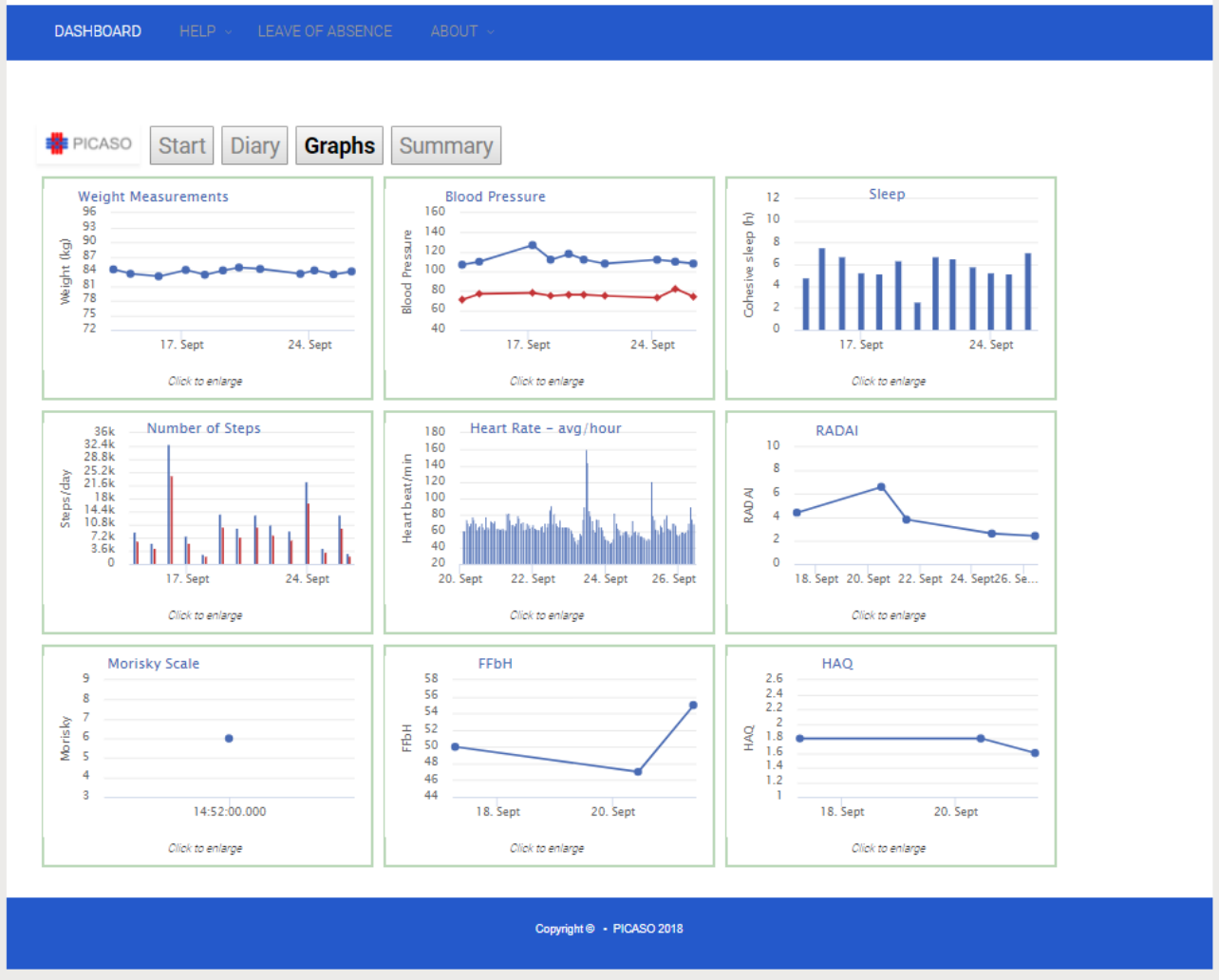


Figure 11: Main observation graphs page

The main graph page shows the diagrams for all monitored observation types. The current observation types include: weight, blood pressure, sleep hours, number of steps/day with distance, and, heart rate.

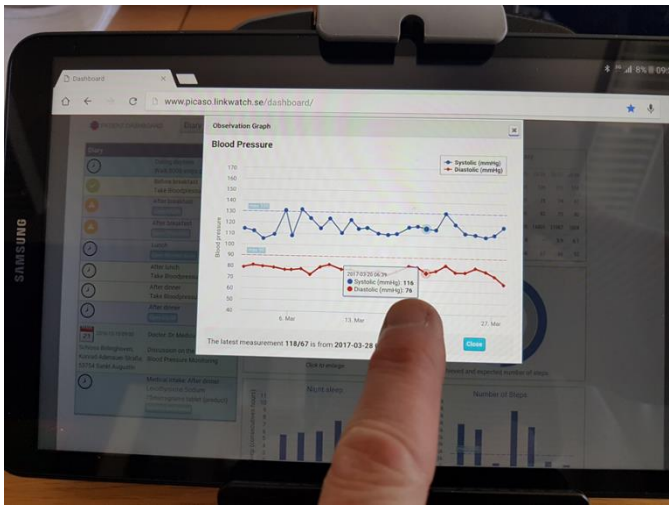


Figure 12: Enlarged view of blood pressure graph

By selecting (pointing at) a specific graph, an enlarged version will be displayed which can be used to browse the individual data points.

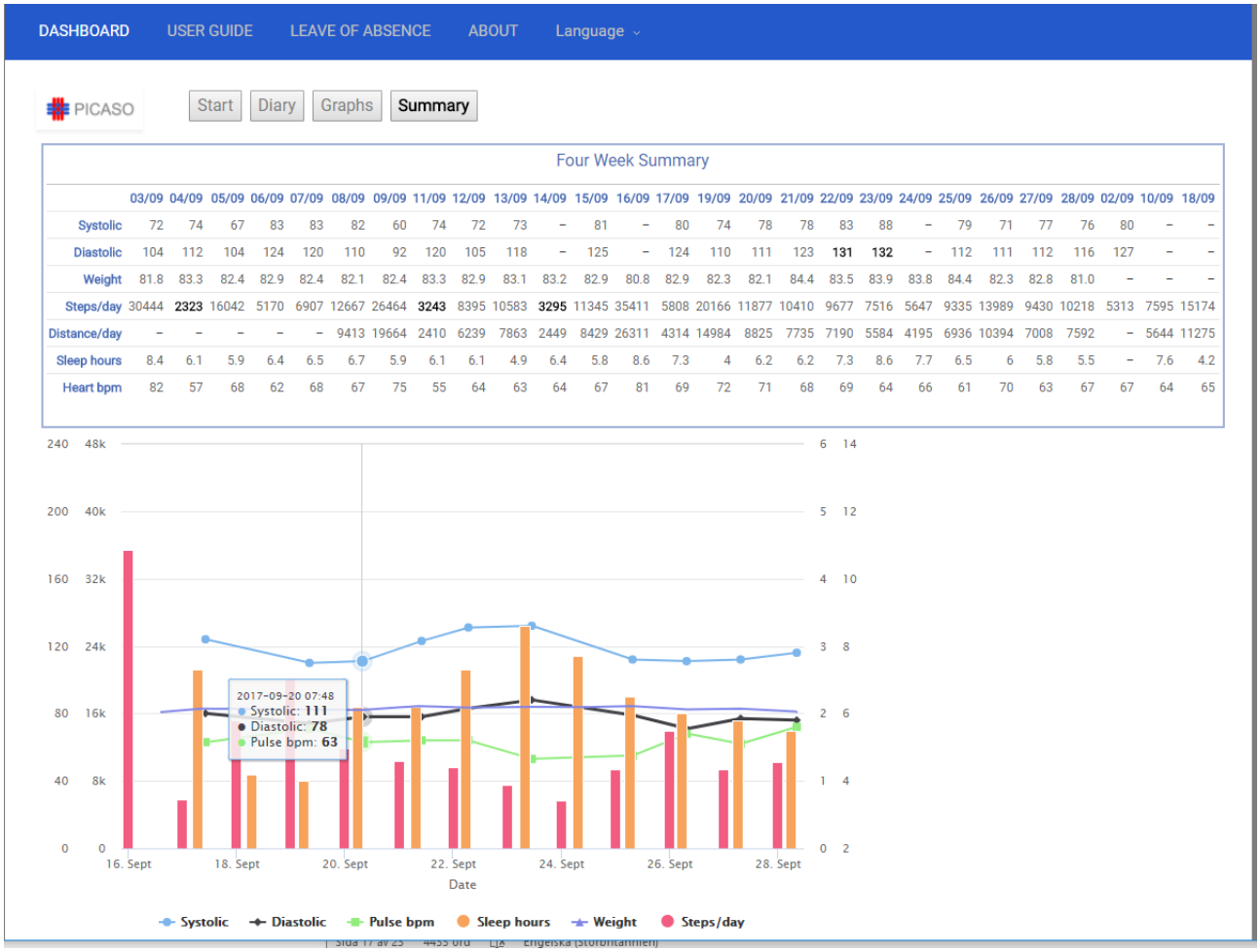


Figure 13: Summary page with Integrated view

The choice of which graphs and measurements to display is dependent on the clinicians choice. Thus in certain cases only a subset of the observation types monitored, will be shown on the Patient Dashboard. The full set will however be available to the clinician in the Patient Data Viewer of the Clinician Dashboard (see Deliverable D6.7).

4.7 Patient reported outcomes by questionnaires

The main objective of the Patient Private gateway in combination with the Patient Dashboard is to give carers and patients an efficient way to monitor vital signs using the various types of medical and well-being devices (c.f. Deliverable D4.1).

However, in order to provide additional data acquisition capabilities, the PICASO platform also allows carers to collect patient data via different types questionnaires. Questionnaire fill-out is scheduled as one type of activity in the Diary of the Patient Dashboard.

The structure and contents of questionnaires range from fairly complex multiple-choice forms, to fairly simple input frames (Figure **14**).

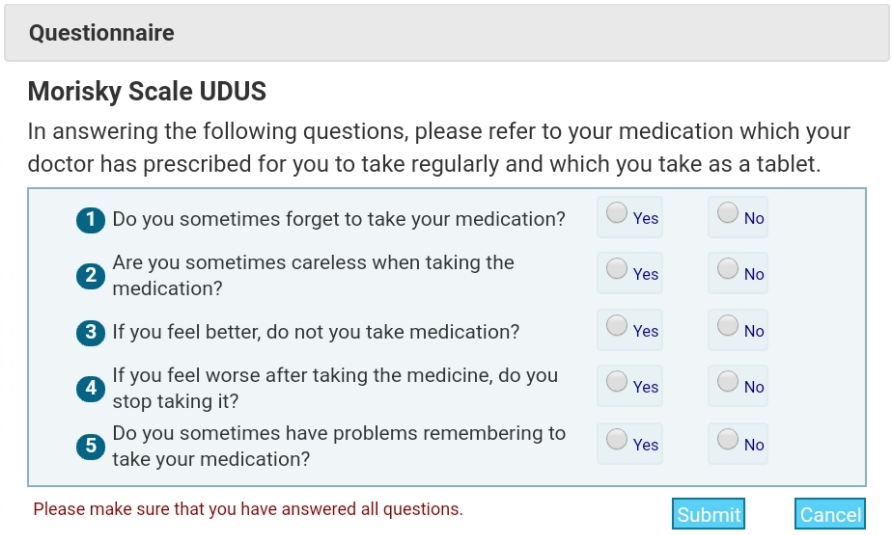


Figure 14: A questionnaire for recording medication compliance

When a patient has completed and submitted a questionnaire, it will be transferred to the back-end clinical system (carers private cloud and the ODS), for display in the Clinician Dashboard. Questionnaire meta data includes the context in which it was filled out which is either the patients or the carers premises.

The Questionnaires are structured following the FHIR Questionnaire[5] format.


```
{
  "resourceType": "Questionnaire",
  "status": "draft",
  "date": "2019-06-18",
  "version": "1",
  "meta": {
    "profile": [
      "http://hl7.org/fhir/us/sdc/StructureDefinition/sdc-questionnaire|2.0"
    ]
  },
  "title": "Morisky scale",
  "name": "Morisky",
  "description": "In answering the following questions, please refer to your
  medication which your doctor has prescribed for you to take regularly
  and which you take as a tablet",
  "identifier": [
    {
      "system": "http://www.picaso-project.eu/fhir/questionnaire",
      "value": "Morisky",
      "display": "Morisky scale"
    }
  ],
  "code": [
    {
      "system": "http://www.picaso-project.eu/fhir/questionnaire",
      "code": "Morisky",
      "display": "Morisky scale"
    }
  ],
  "subjectType": [
    "Patient",
    "Person"
  ],
  "item": [
    {
      "extension": [
        {
          "url": "http://hl7.org/fhir/StructureDefinition/questionnaire-minOccurs",
          "valueInteger": 1
```


Figure 15: PICASO Questionnaire in FHIR format

The clinical trials included questionnaire/form types for,

[5] https://www.hl7.org/fhir/questionnaire.html

- Assessment of functional capacity for RA patients (FFbH/HAQ)
- Calculation of disease activity for RA patients (RADAI-5)
- Medication Compliance (Morisky Scale)
- Self-assessment of well-being

The completed questionnaires and their calculated scores (see appendix) are made available to clinicians in the Clinician Dashboard for subsequent analysis, e.g., by plotting questionnaire results in combination with other collected patient data. Clinicians may also decide to make questionnaire scores available in the graphs of the Patients Dashboard.

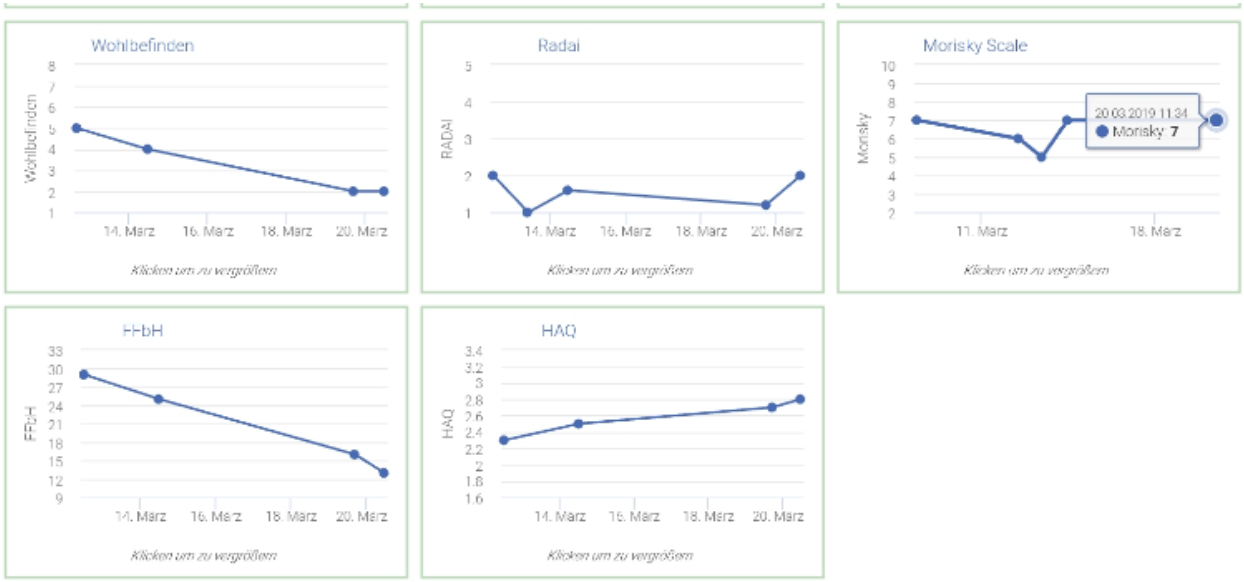


Figure 16: Completed forms are stored (in the ODS) and calculated results (scores) may be plotted in patient graphs.

The different types of questionnaire calculations implemented in the PICASO trial are described in the appendix.

4.8 Privacy and security

In order to comply with the requirements on privacy and ethical guidelines, patient data is not stored persistently on the Patient Private Gateway device (tablet), and is protected when in transit.

Further, all data are pseudonymized, in that PICASO system-generated PICASO patient IDs (tokens) are used to represent actual users. The mapping between such IDs and actual individual patients is maintained in the secured Carers (hospital) Private Clouds.

The following devices and data paths are pseudonymized and protected:

Data from monitoring devices

- BT Connected devices
- Cloud based devices, like the FitBit activity monitor

Manual input by patients/informal carers,

- Questionnaires
- Acknowledgement of reminders

The publicly downloadable PICASO app[6] is associated with a privacy policy (see appendix) as required by the service provider.

4.9 User guidelines and support

The Dashboard top menu bar provides access to on-line user guides and contact data for personal support. The guides are presented in the form of instructional videos complemented by fact documents.

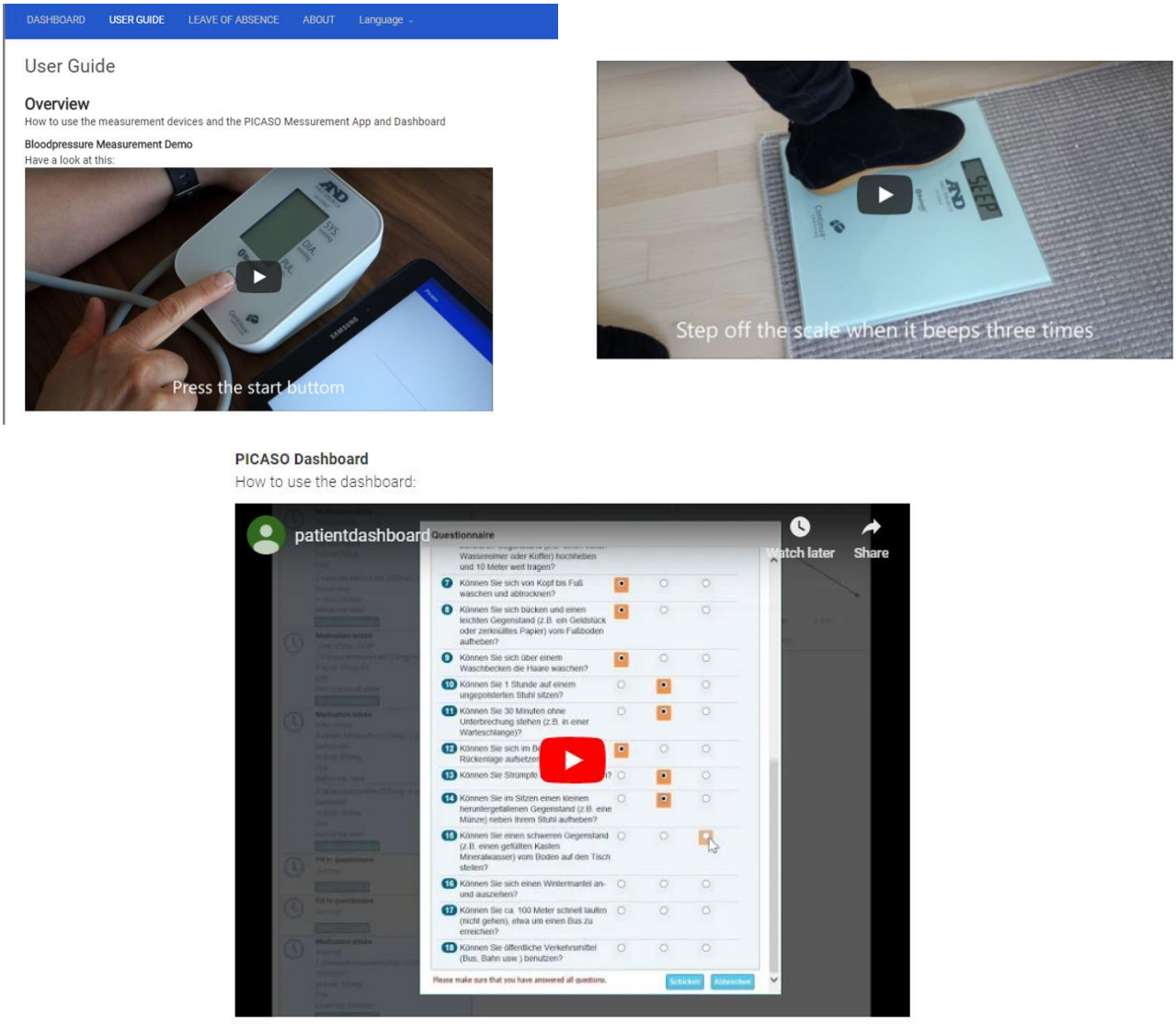


Figure 17: Instructional videos for measurements

For the PICASO trials all video and document materials are available in the users' native language.

[6] https://play.google.com/store/apps/details?id=se.cnet.picasoble

5 Usage statistics

Below we summarize the usage statistics from the German trial (including 30 patients).

The median value per patient during the trial

Observations	Median	Max	Average
Questionnaire FFbh	21	83	24
Questionnaire HAQ	21	83	24
Questionnaire RADAI	22	84	29
Daily Distance Measurement	150	268	152
Daily Steps Count	150	268	152
Heartrate	155	268	152
Heartrate resting	151	266	143
Weight	150	256	149
Diastolic	307	478	276
Systolic	307	478	276
Pulse rate	307	478	276
Activity			
Total number of steps during trial	1012314	3104342	1203094
Reporting frequency			
Number of days reporting BPM	149	186	148
Number of days reporting weight	146	177	142
Number of days reporting medication	134	182	108

Adherence to scheduled activities

The total number of performed activities (Measurements, Medication Confirmation, Questionnaires)

Communication Request	late	129	
Communication Request	on-time	1254	
Device Request	late	2783	
Device Request	on-time	9124	
Medication Request	late	1	
Medication Request	on-time	13628	
Total		26919	
Total On-time		24006	89,2%
Total Late		2913	10,8%

6 Summary

The Patient Private Cloud and the Self-monitoring framework,

- Enable continuous patient data collection
- Support (FHIR) care-plan compliance
- Facilitate patient – clinician communication
- Promote patient empowerment, involvement and self-care
- Support mobility and ease of use

The current version of was subject to validation within the PICASO clinical trials. The following points summarizes usage statistics,

- 47000 patient interactions registered
    - Device measurements, Filling out Questionnaires, Confirming Medications
- 8000 Blood pressure measurements registered
- 4300 Weight measurements registered
- 2000 Health Questionnaires filled out
- Adherence (degree to which patients followed the schedule): 90%
- 33 Million steps have registered by the patients activity bracelets
- 3200 Activity days registered (steps, heart rate)

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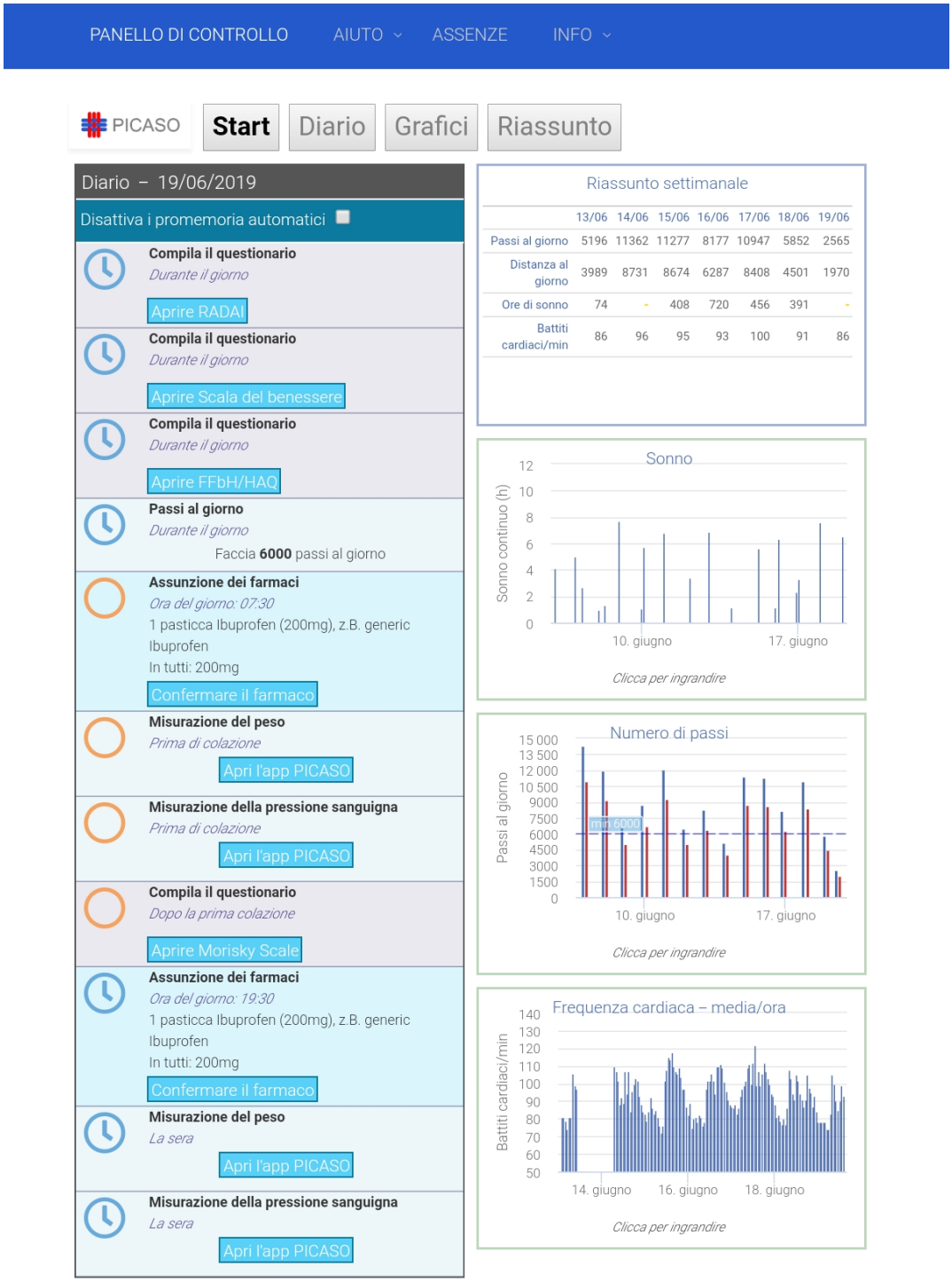
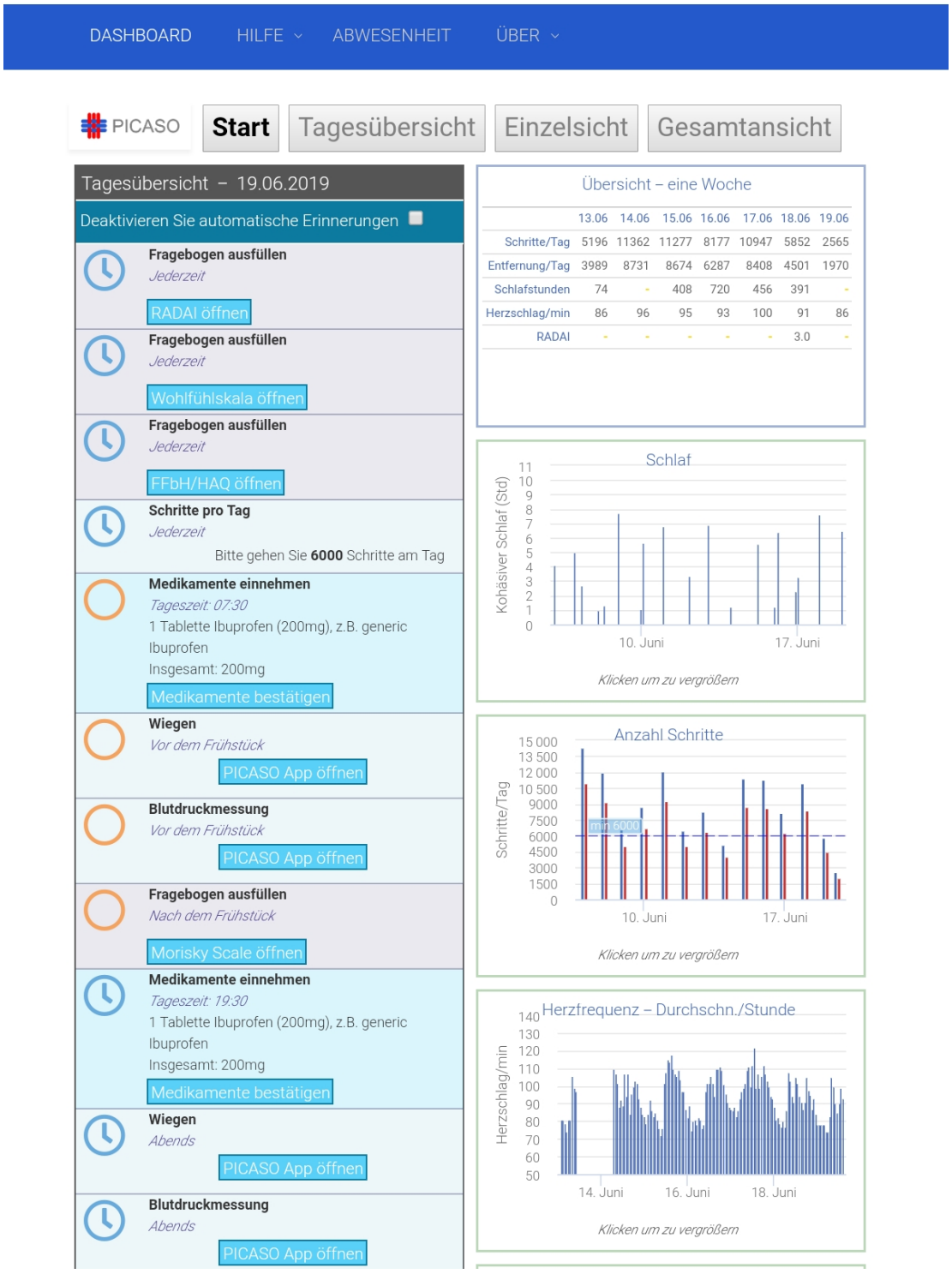
Appendix 1: Sample screens: Italian and German

The language adaptations in PICASO have been developed by the projects´ clinicians in collaboration with the UI designers.




DASHBOARD
HILFE
ABWESENHEIT
ÜBER
PICASO
Start
Tagesübersicht
Einzelsicht
Gesamtansicht
Tagesübersicht – 19.06.2019
Deaktivieren Sie automatische Erinnerungen
Fragebogen ausfüllen
Jederzeit
RADAI öffnen
Fragebogen ausfüllen
Jederzeit
Wohlfühlskala öffnen
Fragebogen ausfüllen
Jederzeit
FFbH/HAQ öffnen
Schritte pro Tag
Jederzeit
Bitte gehen Sie 6000 Schritte am Tag
Medikamente einnehmen
Tageszeit: 07:30
1 Tablette Ibuprofen (200mg), z.B. generic Ibuprofen
Insgesamt: 200mg
Medikamente bestätigen
Wiegen
Vor dem Frühstück
PICASO App öffnen
Blutdruckmessung
Vor dem Frühstück
PICASO App öffnen
Fragebogen ausfüllen
Nach dem Frühstück
Morisky Scale öffnen
Medikamente einnehmen
Tageszeit: 19:30
1 Tablette Ibuprofen (200mg), z.B. generic Ibuprofen
Insgesamt: 200mg
Medikamente bestätigen
Wiegen
Abends
PICASO App öffnen
Blutdruckmessung
Abends
PICASO App öffnen
Übersicht – eine Woche
13.06 14.06 15.06 16.06 17.06 18.06 19.06
Schritte/Tag 5196 11362 11277 8177 10947 5852 2565
Entfernung/Tag 3989 8731 8674 6287 8408 4501 1970
Schlafstunden 74 - 408 720 456 391 -
Herzschlag/min 86 96 95 93 100 91 86
RADAI - - - - - 3.0 -
Schlaf
Kohäsiver Schlaf (Std)
10. Juni
17. Juni
Klicken um zu vergrößern
Anzahl Schritte
Schritte/Tag
min 6000
10. Juni
17. Juni
Klicken um zu vergrößern
Herzfrequenz – Durchschn./Stunde
Herzschlag/min
14. Juni
16. Juni
18. Juni
Klicken um zu vergrößern

Appendix 2: Questionnaires used in PCASO trials

The following questionnaire types have been selected and specified by the clinical partners of PICASO for use in the trials:

- FFbH/HAQ – Assessment of functional capacity for RA patients.
- RADAI-5 – Calculation of disease activity categories for RA patients.
- Morisky Scale – Medication Compliance for PD and RA patients.
- Well-being – Self-assessment of well-being for PD patients.

Once completed and submitted by a patient, the full questionnaire content is transferred to the carers private cloud and stored in the ODS, together with a calculated overall result (if applicable). Calculation of results per questionnaire type is as follows:

- FFbH

$$FFbH = \text{Functional capacity (\%)} = \frac{points\ scored\ x\ 100}{2x\ number\ of\ valid\ responses}$$

  Interpretation shall be provided in the legend as follows:
  FFbH: Functional capacity (%)

- HAQ value has to be calculated from FFbH result:

  HAQ= 3,16-0,028x FFbH

  Interpretation shall be provided in the legend as follows:

  HAQ: Functional limitation (0 to 3.0)

  0 to 1: Mild to moderate

  >1 to 2: Moderate to severe

  >2 to 3: Severe to very severe

- RADAI-5 shall be used in user trials. Calculation is:

$$RADAI = \frac{(Q1+Q2+Q3+Q4+Q5)}{5}$$

  - Disease activity categories (de: krankheitsaktivitätskategorien) according to the RADAI-5 which should be listed in the legend:

	Remission	mild	moderate	high
RADAI-5 value	0.0-1.4	1.6-3.0	3.2-5.4	5.6-10.0

- Morisky scale results shall be presented in form of a line graph. On mouse-over, the actual result (number between 0-4) should be shown and where it was taken (UDUS_Rh, RA_home, SLucia, PD_home). The header of this graph shall be 'Morisky Scale results', with the following interpretation:
  - 4 points = high compliance; 2-3 points = medium compliance; 0-1 = low compliance
- Well-Being (PD patients/Italy) ratings shall be shown as numbers between 1 - 5 (1= very bad, 2 = bad, 3 = OK, 4= good, 5 = very good) which shall be explained in the legend of all views).

Appendix 3: PICASO app Privacy Policy

October 2018

Privacy Policy

CNet Svenska AB built the PICASO App as a Free app (referred to as the “App”). The App is provided by CNet Svenska AB at no cost and is intended for use as is.

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info@cnet.se

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The App does NOT collect any log data.

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