A Personalised Integrated Care Platform

(Grant Agreement No. 689209)

D4.3 First version of the Patient Private Cloud

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1 Executive Summary

This deliverable describes the demonstration of the first version of the PICASO Patient Private Cloud (PPC). The PPC includes the set of medical devices and the software components that implement the remote monitoring sub system 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
- 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 communications with health professionals. Patient data (administrative or clinical) is not persistently stored in the PPC, but held remotely in secure clinical environments, represented by the PICASO Carers Private Clouds.

This deliverable (D4.3) focuses on the Patient Dashboard part of the PPC Demonstrator.

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

http://www.picaso.linkwatch.se/dashboard/

with login credentials:

- User: “picasodemo”
- Password: “password”

2 Introduction

2.1 Purpose, context and scope of this deliverable

This document accompanies the Demonstrator software deliverable D4.3, and describes the configuration for the first 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
- D4.2 – First IoT Resource Management Subset: Implements the PPC software components and deployment.
- D4,3 – First Version of the Patient Private Cloud: Implements the PPC Demonstrator (*this deliverable*)

For detailed descriptions of the PICASO clinical trial protocols, we refer to deliverables D8.1-3.

2.2 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.

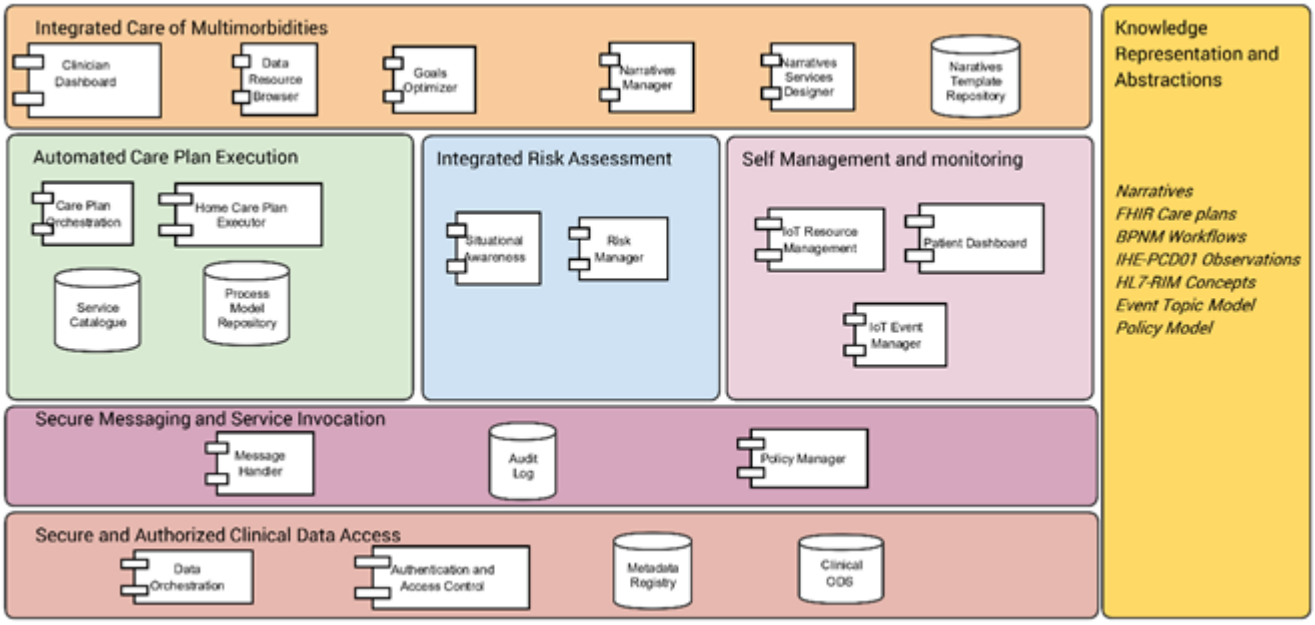


Figure 1: Conceptual architecture

The PICASO Conceptual Architecture with its main functionality blocks is shown in Figure 1. Workpackage 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.

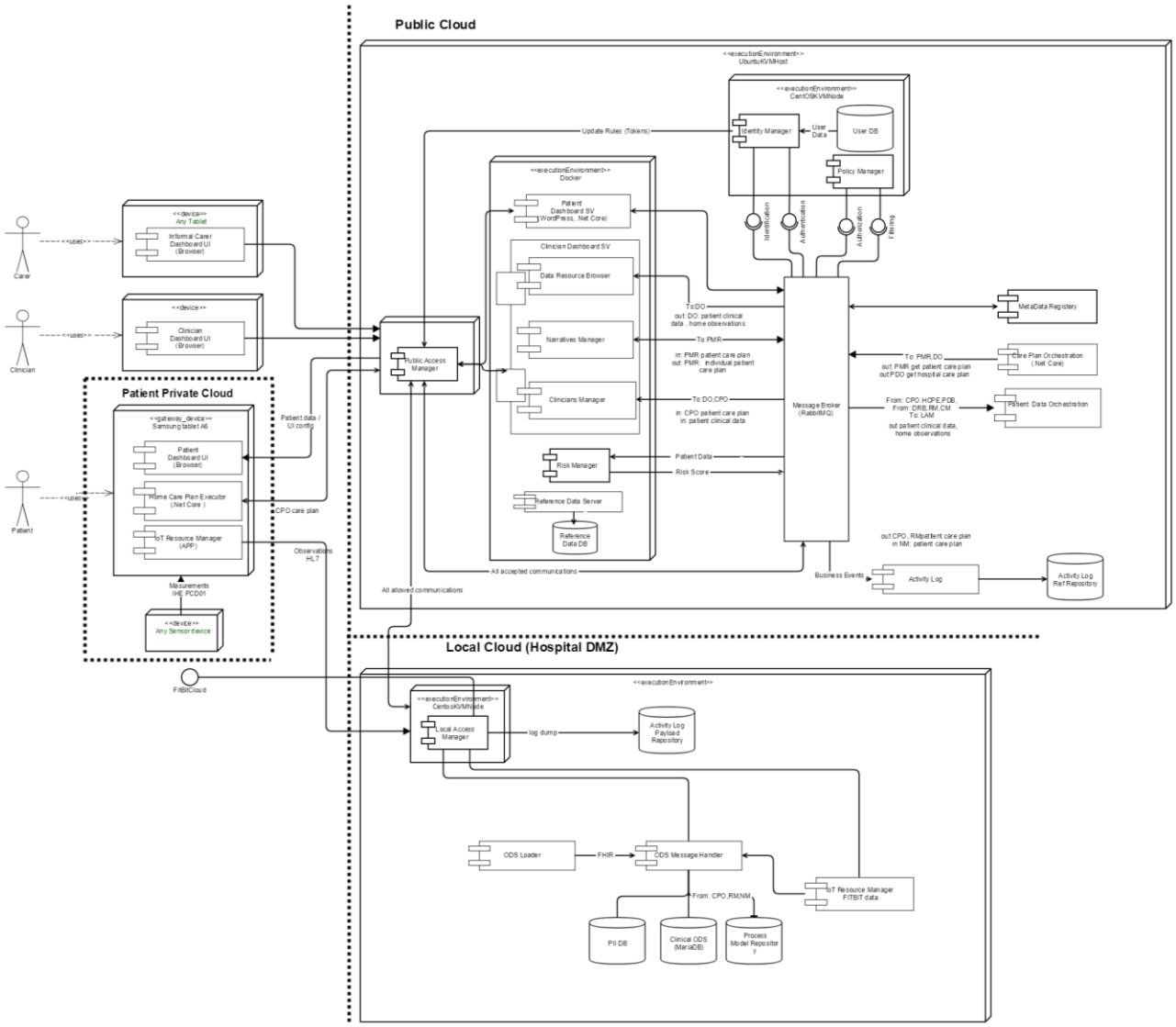


Figure 2: Component deployment diagram of the PICASO platform

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 PICASO clinical trial 1.

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 1 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-16	PICASO provides a patient diary for self-recording of symptoms.	A recorded history of daily self-diagnostics is an important tool for RA patients in regard to self-assessment and discussion with, e.g., physicians.	A patient diary is available where patients can indicate affected joints on the body and record their daily level of pain on a 10 point rating scale.
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 fulfillment.	Patients need to be informed on daily base about what tasks they are expected to fulfill, 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 fulfillment. In case PICASO cannot detect automatically when a task is fulfilled, the patients are asked to confirm by other means.
PIC-173	Patients should be able to document drug intake when differing from their defined medication plan.	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 decided to take in an additional drug, they shall be able to document this.	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 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-207	Patient provides informed electronic consent.	Particularly when asked to provide consent in an electronic form, i.e. without having the possibility to directly communicate with the professional asking for the consent, it should be ensured that a patient is providing an informed consent.	In order to provide informed consent on the Patient Dashboard about which formal/informal carers shall have access to a patient's health data during the user trials, information in text is available explaining the opt-in/opt-out procedure as well as what the

			consent encompasses.
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-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.
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). The integrated view on home monitoring measurements and self-

			recordings shall be offered in a graph, e.g., as on the Clinician Manager, but also in a simplified version meaning that all results are presented in a table and measurements out-of-expected range are indicated, e.g., in bold. Drug intake shall be presented above or below the mentioned table/graph, so patients can easily relate medication intake and results of their measurements and recordings. For this purpose time period selected for measurements and recordings will also be applied to the recorded history of drug intake.
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.

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 available for patients providing explanations and advice on what to do, if home monitoring presents out-of-expected-range measurements to patients.	In order to avoid patients becoming afraid about their health status in case out-of-expected-range measurements are highlighted to them, information material has to be presented providing explanation of the situation and advice on what to do.	Information is presented to patients in case out-of-expected-range measurements are highlighted to them providing an explanation of the situation and advice on what to do.
PIC-106	Graphical presentation of a patient's sensor platform measurements indicates 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~~).	Measurements of vital parameters below or above defined thresholds need to be indicated to patients to inform them about out-of-expected-range incidents.

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-174	Patients should be able to create a ‚leave of absence' message during the user trials.	In case patients participating in the user trials will not be able to use the 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.	Patients participating in the user trials are able to create a ‚leave of absence' message indicating the period of time they will be absent.
PIC-205	Patient can choose not to	When a patient has taken a measurement which is then transferred	A "delete" option is available in the PICASO App. The option is

	send a measurement.	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.	displayed next to the "send" option.

4 Patient Dashboard functionality

4.1 Devices and User Categories

The Patient Dashboard is deployed on a local gateway in the PPC. For PICASO Trial 1 a tablet PC has been selected.

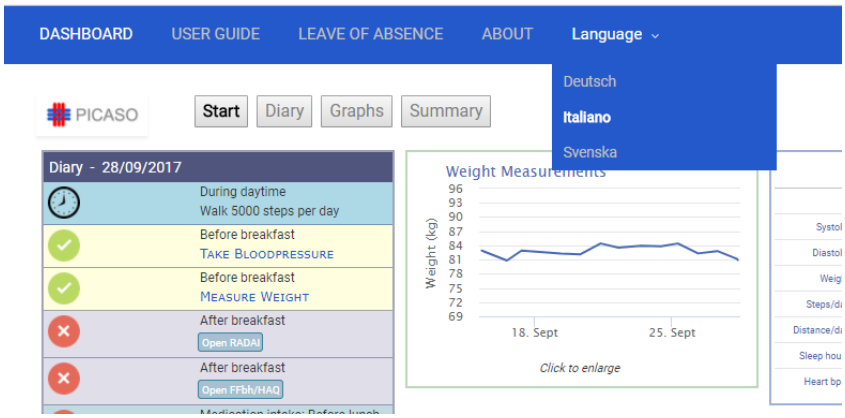
Figure 3: PPC gateway tablet

We refer to Deliverable D4.1 for details on the PPC gateway and devices. The Patient Dashboard will in addition to patients also be used by the so called informal carers, i.e., non-professional carers such as relatives or friends.

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 eng, ger, ita, swe). The following descriptions below will be in English (se appendix for sample screens in other languages).



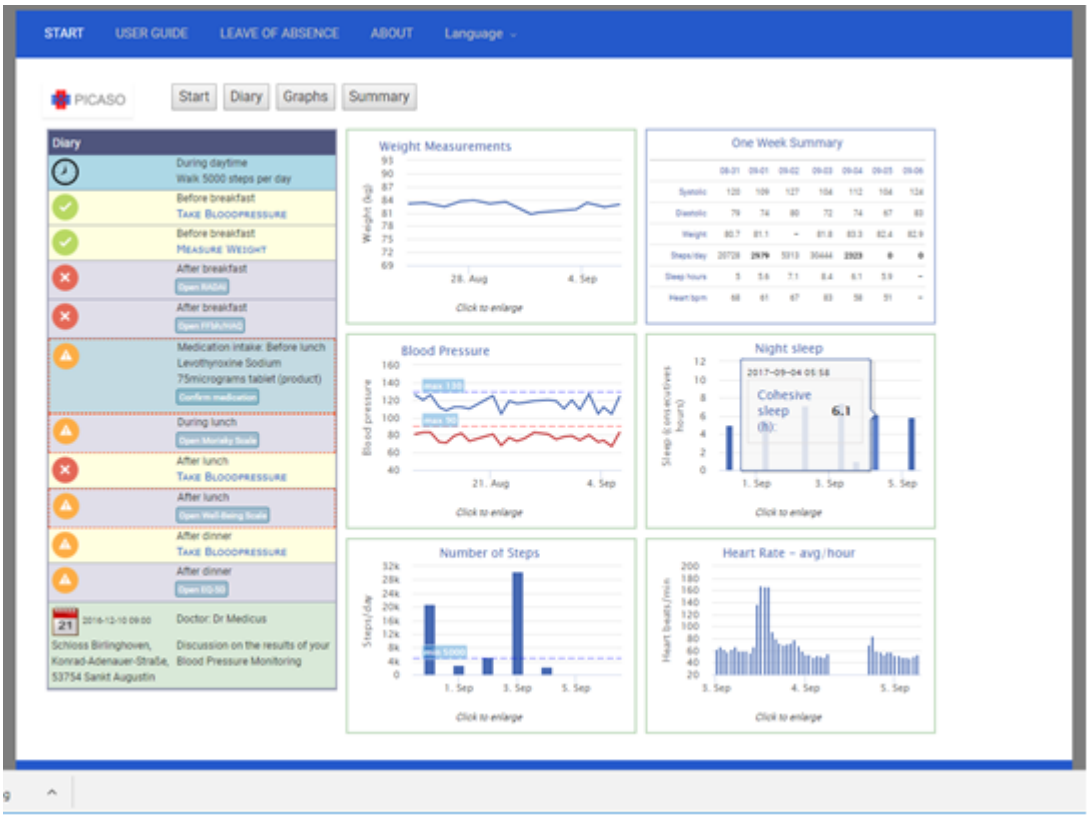


Figure 4: Patient Dashboard start screen

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 Dairy 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 Dairy/Activity List

4.3.1 PICASO Care Plans and the Dairy

The Patient Dairy 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 Narratives Manager component in the Clinicians Dashboard (see Deliverables D7.1/D7.2). PICASO care plans are represented in the FHIR format, an interoperability standards framework created by HL7[1].

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

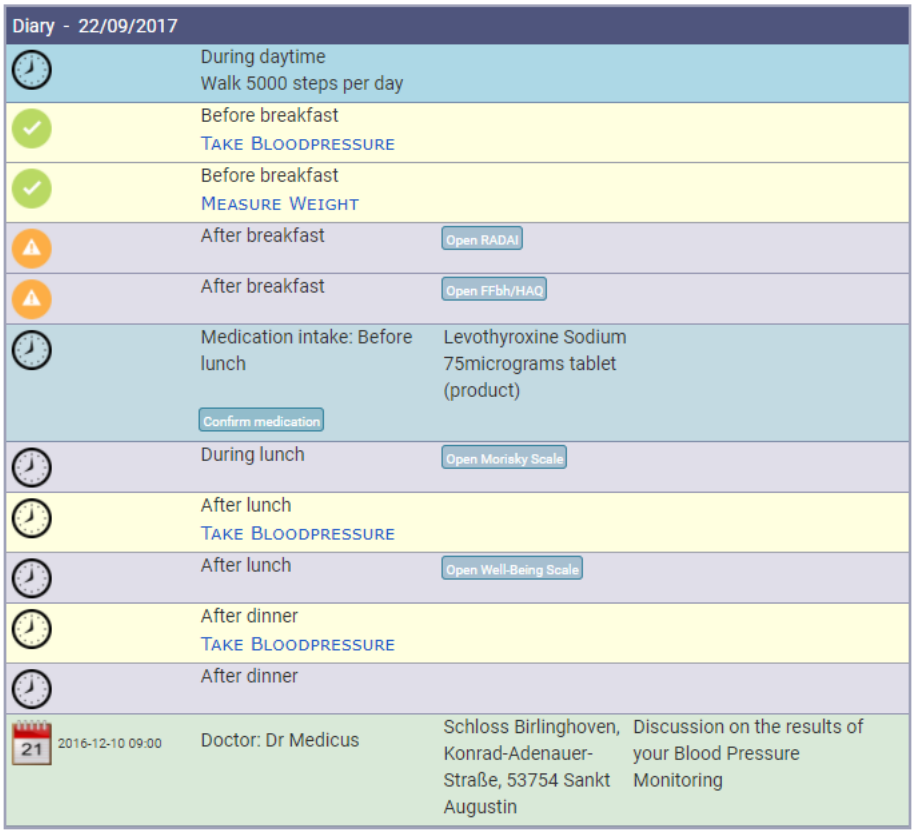
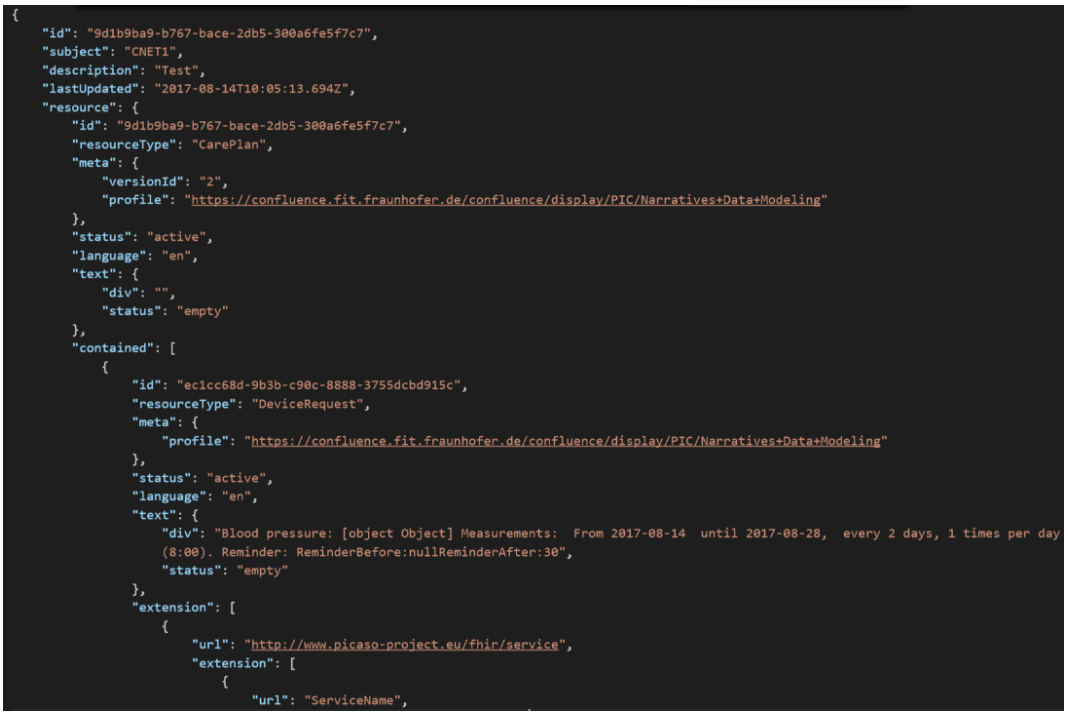


Figure 5: Dairy rendered from a PICASO FHIR care plan

The Dairy example (Figure 5) shows the scheduled actions for a specific patient on a particular date (todays date).

The first entry is a recommendation for daily physical exercise, followed by two actions for blood pressure and weight measurements respectively. The “After Breakfast” actions include the completion of two different questionnaires: RADAI and FFbH/HAQ (explained below). A “Medication Intake” is to be done before lunch, and has a corresponding Confirmation action for user input. The last entry in this Dairy is a scheduled doctors appointment.



```
{
    "id": "9d1b9ba9-b767-bace-2db5-300a6fe5f7c7",
    "subject": "CNET1",
    "description": "Test",
    "lastUpdated": "2017-08-14T10:05:13.694Z",
    "resource": {
        "id": "9d1b9ba9-b767-bace-2db5-300a6fe5f7c7",
        "resourceType": "CarePlan",
        "meta": {
            "versionId": "2",
            "profile": "https://confluence.fit.fraunhofer.de/confluence/display/PIC/Narratives+Data+Modeling"
        },
        "status": "active",
        "language": "en",
        "text": {
            "div": "",
            "status": "empty"
        },
        "contained": [
            {
                "id": "ec1cc68d-9b3b-c90c-8888-3755dcbd915c",
                "resourceType": "DeviceRequest",
                "meta": {
                    "profile": "https://confluence.fit.fraunhofer.de/confluence/display/PIC/Narratives+Data+Modeling"
                },
                "status": "active",
                "language": "en",
                "text": {
                    "div": "Blood pressure: [object Object] Measurements:  From 2017-08-14  until 2017-08-28,  every 2 days, 1 times per day
                    (8:00). Reminder: ReminderBefore:nullReminderAfter:30",
                    "status": "empty"
                },
                "extension": [
                    {
                        "url": "http://www.picaso-project.eu/fhir/service",
                        "extension": [
                            {
                                "url": "ServiceName",
```


Figure 6: PICASO FHIR Care Plan in JSON format.

An excerpt of a corresponding FHIR care plan is shown in Figure 6. This is an internal structure and format not to be seen by PICASO end-users.

4.3.2 Symbols and actions used in the Dairy

The Dairy contains a small set symbols associated with actions, for attention and information.

Symbol	Meaning	Actions
	Instruction: A scheduled action or recommendation	Any dashboard action such as performing measurements, medication intake, complete questionnaires.
	Notification: Action duly performed	An action is acknowledged. The related patient data has been transferred to the PICASO clinical systems.
	Reminder: An action is overdue	A reminder pop-up will be issued. Overdue actions can still be performed.
	Alert: Time to perform an action	An action should be performed. A reminder pop-up will be issued.
	Instruction: A scheduled calendar event, such as an appointment	For information.

Table 1: Symbols in the Patient Dairy

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

4.3.3 Time and reminders

Reminders will appear when a scheduled action (measurements, questionnaires, medication intake) is approaching.

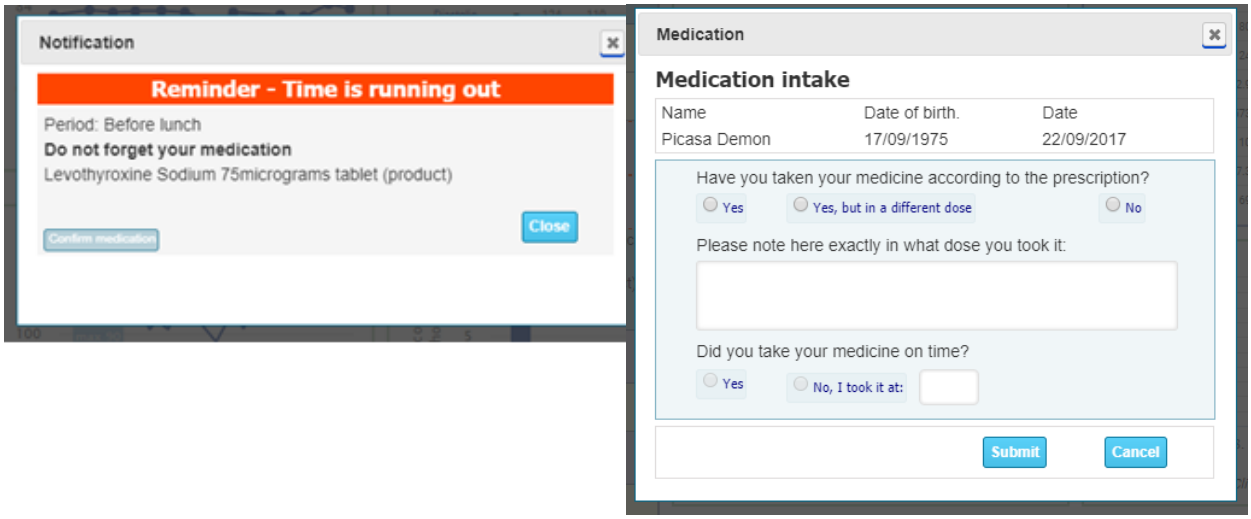


Figure 7: Reminder pop-up and confirmation for medication intake.

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. The reminder solution is subject to further extensions e.g., concerning adaptability.

NB: If a Dashboard is re-started, a number of reminders may occur in a sequence, however this excludes any overdue actions ( ).

4.4 The Measurement App

The Patient Dashboard is associated with a separate App[2] which is used to obtain the measurements from the wirelessly connected devices.

The Measurement App is launched from the Dairy, by the user selecting a measurement activity entry.

[2] This App implements the IoT Resource Manager component, see D4.2.

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

4.5 Viewing observations

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

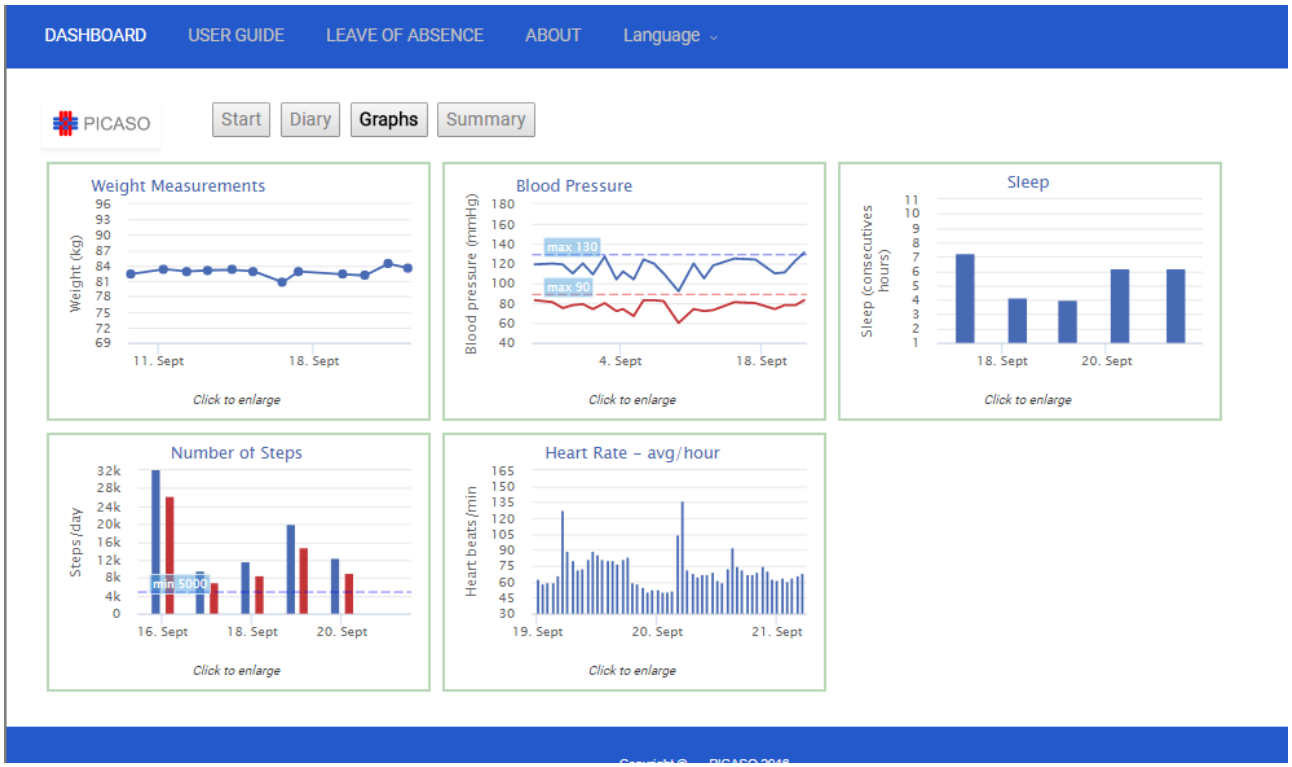


Figure 8: Main observation graphs page

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 9: 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.

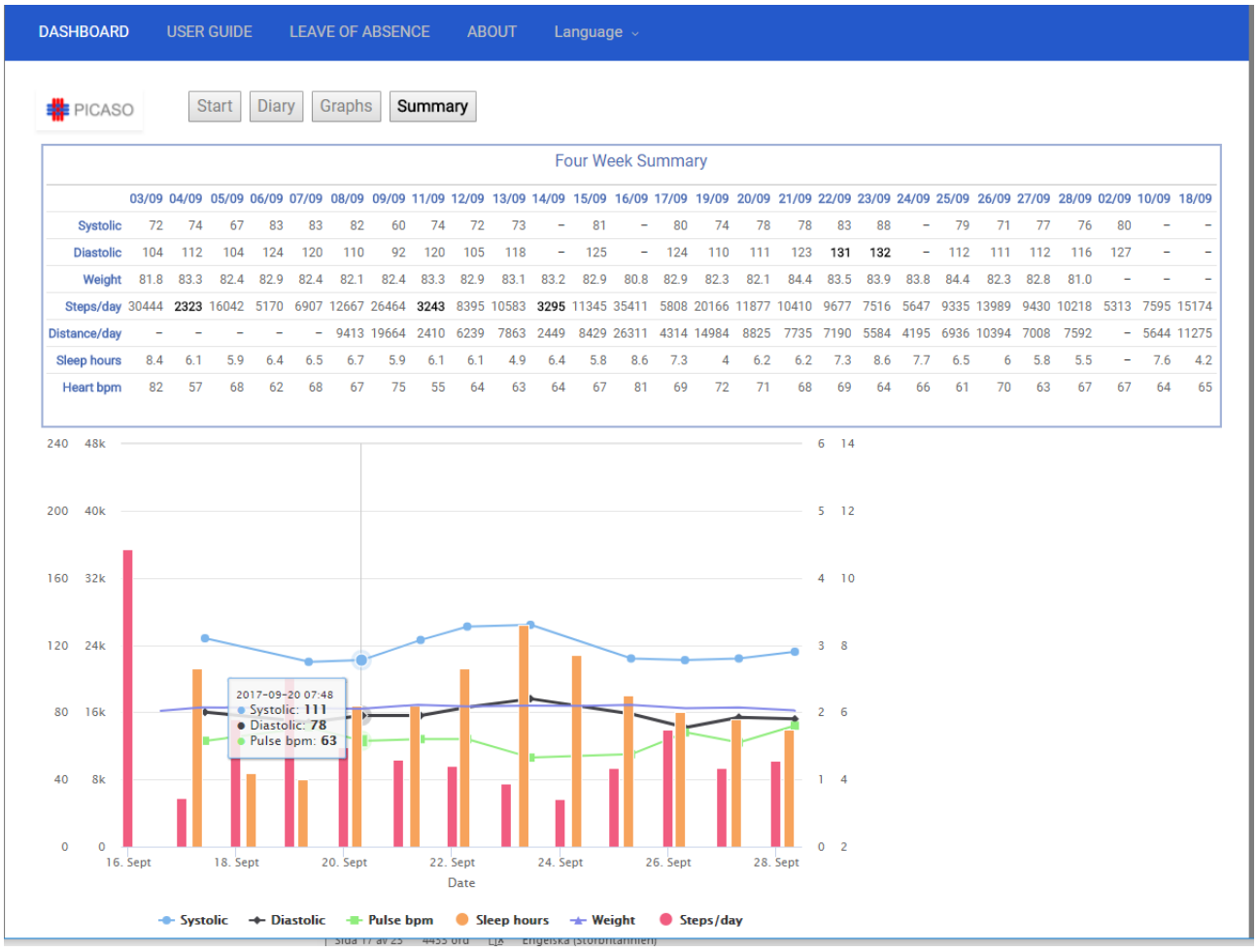


Figure 10: Summary page with Integrated view

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 Clinician Manager user interface (see Deliverable D5.4).

4.6 Providing data 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 Dairy of the Patient Dashboard.

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 structure and contents of questionnaires range from fairly complex multiple choice forms, to fairly simple input frames (**Figure 11**).

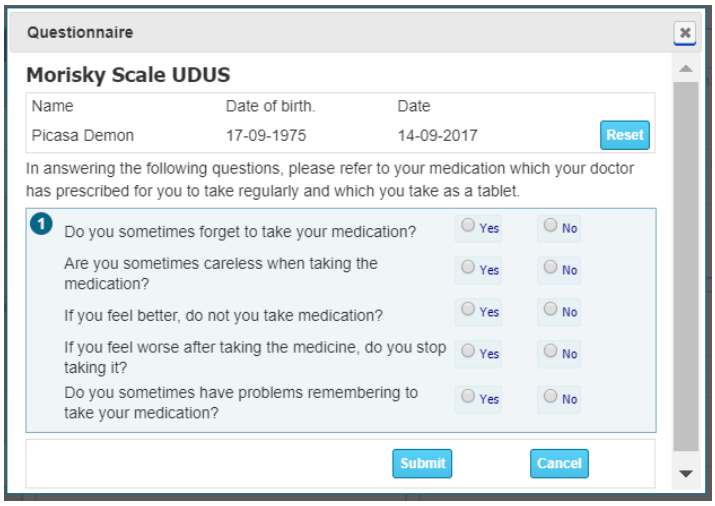


Figure 11: A simple questionnaire for medication compliance

The computed questionnaire results (see Appendix) are made available to clinicians for subsequent analysis, e.g., by plotting questionnaire results in combination with other collected patient data. Clinicians may also decide to make questionnaire results available in the Patients Dashboard.

The different types of questionnaires implemented in the first PICASO trial are described in the appendix.

4.7 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 anonymized, in that PICASO system-generated 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 anonymized 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

4.8 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.

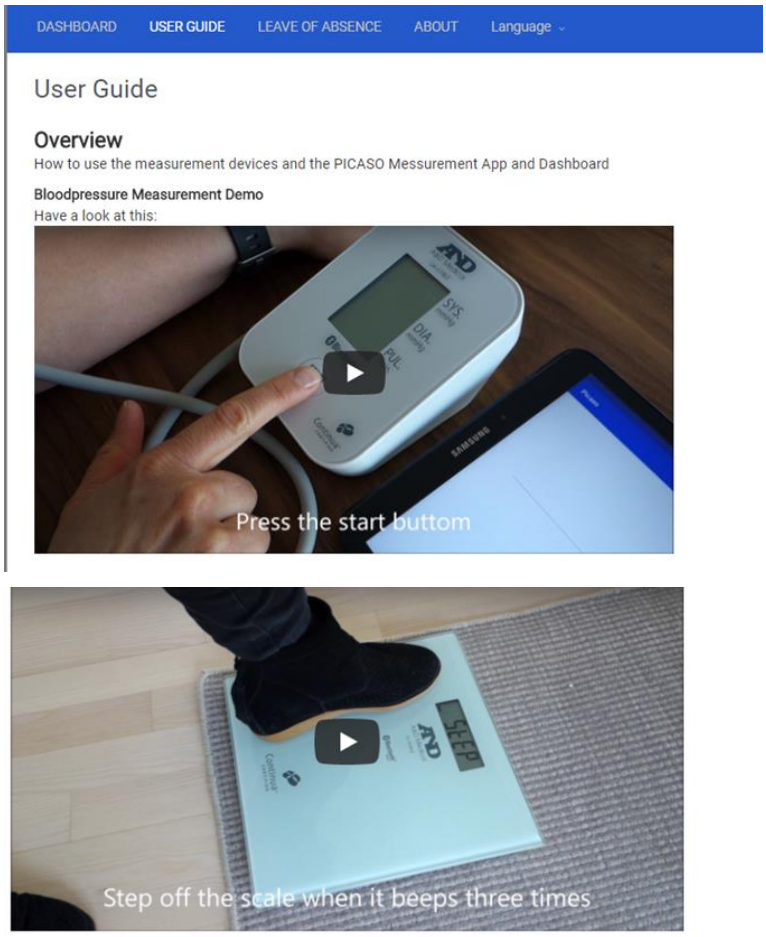


Figure 12: Instructional videos for measurements

For the PICASO trials all video and document material is available in the users' native language.

5 Forthcoming Development

The current version of the Patient Private Cloud is subject to validation within the first PICASO clinical trial (T1). Future work will address new requirements and change requests as a result of the user trial, as well as yet unresolved requirements in the JIRA database.

Currently known future effort are in the following subjects:

For the Patient Dashboard

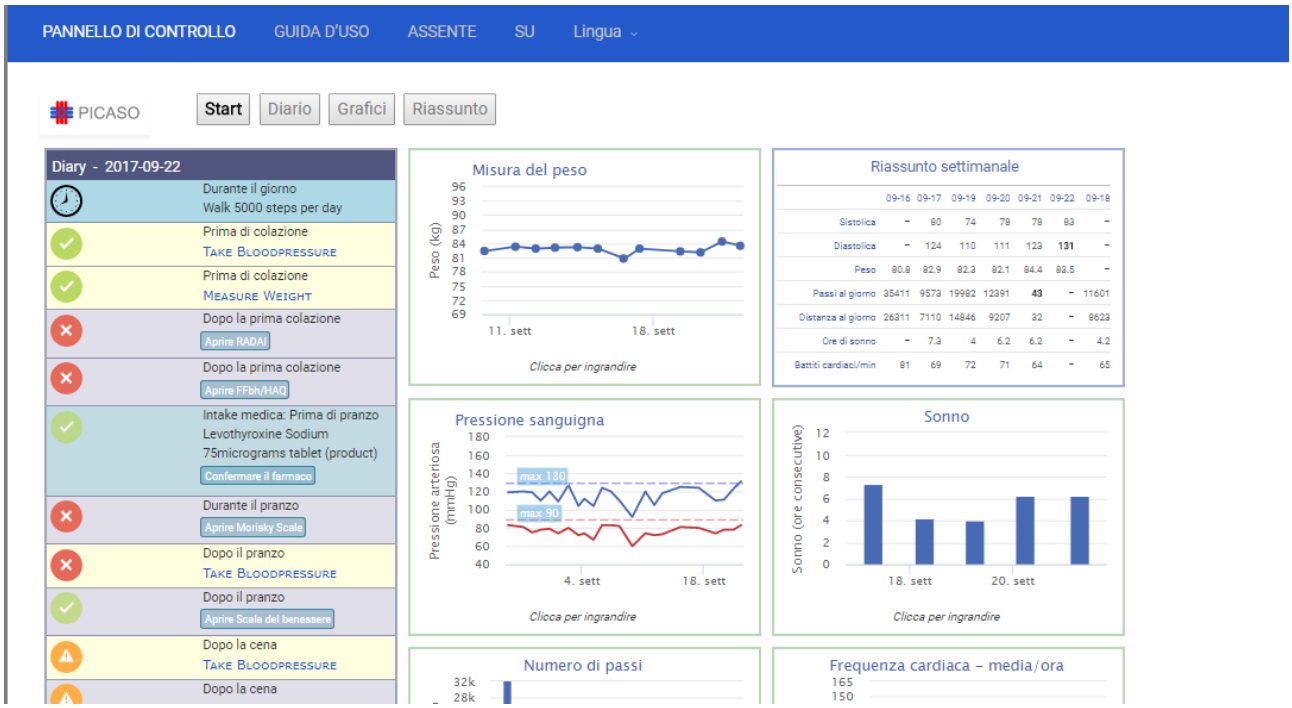
- Management of medication plans
- Elaboration of Informal Carers interface including access restrictions
- User configurable graph and table displays

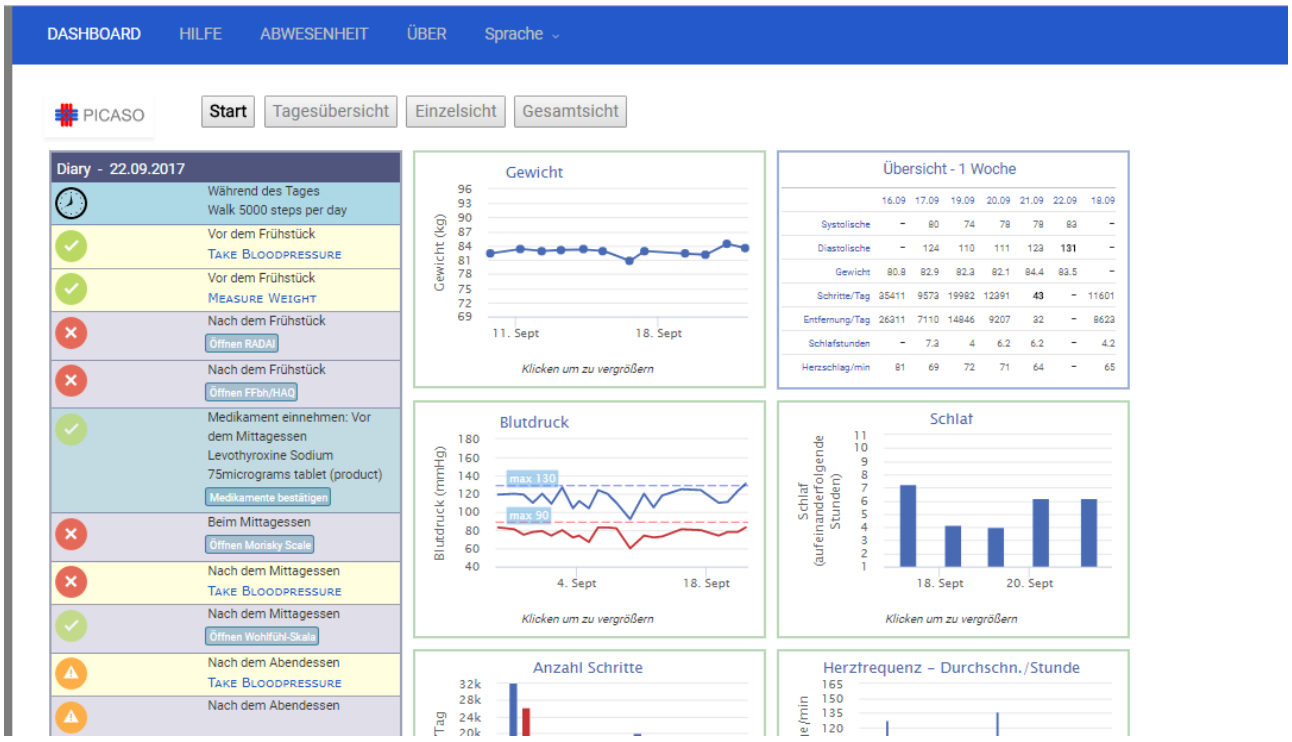
For the Gateway and devices:

- Device management by carers/administrators

Appendix 1: Sample screens: Italian and German

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





Appendix 2: Questionnaires used in PCASO trial 1

The following questionnaire types have been selected and specified by the clinical partners of PICASO for deployment in trial 1:

- FFbH/HAQ – Assessment of functional capacity for RA-patients.
- RADAI-5 – Calculation of disease activity categories for RA-Patients.
- Morisky Scale – Medication Compliance.
- 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).