PROTOCOL FOR THE VIRTUAL MANAGEMENT OF FOLLOW-UP VISITS IN PATIENTS WITH HEART FAILURE

DOCUMENT READING INSTRUCTIONS

The following document is a **protocol sample** drafted on the virtual visit model defined by a working group of clinical service representatives from 4 Pilot Centers of national relevance for the management of Heart Failure.

The various sections of the document can be customized or deleted, based on the virtual visit model of choice implemented at your center, considering the needs of each center and your clinical practice.

This document is designed to facilitate your interaction with your Health Department and/or other internal functions involved in the virtual visit service approval process:

- a first section aims to frame the need for an alternative tool to traditional visits, highlighting the opportunity and expected benefits;
- a second section is aimed at providing the structure of the model and supporting tools.

You will find some indications in yellow, to help you to identify the sections of the protocol that can possibly be customized and modified based on the needs of your HF center and the virtual visit model to be adopted in your clinical practice.

You will find the fields in blue to fill in and update with your information and the virtual visit template that can be implemented in your HF center.

Bip shall have no liability whatsoever for the consequences of the application of the proposed model and tools in clinical practice, nor for the choices related to them, which shall be at the discretion of the clinical team.

INTRODUCTION

Patients diagnosed with Heart Failure (HF) are regularly treated at the HF center with a program of care that includes frequent doctor-patient interaction.

Follow-up cardiology visits for patients with HF are critical in order to:
- follow the clinical evolution of the disease;
- monitor clinical effects, tolerability and occurrence of adverse events related to drug therapy;
- catch the onset of symptoms related to the course of the disease early on.

The need for new innovative models for managing HF patients process can be linked to several factors:
- high frequency of follow-up visits;
- saturation of available outpatient appointments;
- different criticality levels in patients requiring different monitoring frequencies.

The virtual visit model for monitoring HF patients proposed in this protocol was developed with a patient process based on the following steps:
- analysis and decomposition of the management processes of cardiology visits of patients with HF (activities, parties involved, roles, support tools);
- scouting of available technological solutions for remote doctor-patient communication;
- scouting of the instruments to detect the parameters functional to the clinical evaluation before and during the visit;
- analysis of implementation challenges related to the introduction of a virtual visit mode.

OPPORTUNITIES AND URGENCY OF A DIGITAL EVOLUTION

For years now, the National Health System (NHS) has been experiencing a constant tension linked to an increased need for assistance against substantially stable resources.
This situation, transversal to the different pathological areas, is particularly critical for HF given the large pool of patients and the clinical and organizational burdens that impact on patients, clinicians and facilities.

Technological evolution has progressively increased the availability and accessibility of advanced, low-cost solutions that can improve the quality of patient care and simplify the management and organizational burden of the facility. Among the technological solutions mostly adopted in recent years are telemedicine, wearable devices, connected diagnostics and patient behavioural support Apps.

The opportunity to leverage these technologies to optimize the management of outpatients becomes urgent in the face of the COVID-19 pandemic impact on the NHS.
Against this backdrop of slowly resuming outpatient activities, with the introduction of new COVID-19 safety regulations that greatly prolong visit times, and the prospect of a full return only in a few months' time, innovative approaches to the management of visits are seen as critical to managing a transitional phase of the pandemic in which it will be necessary to:
- recover a significant volume of outpatient activities postponed in the emergency phase;
- preserve already fragile patients as much as possible, preventing unnecessary travel;
- rethink the management of waiting rooms to avoid overcrowding in diagnosis and treatment facilities, in order to safeguard the health of patients, caregivers and health workers;
- efficiently use available resources and health workers' time.

It is hoped that the evolution of health services induced by the pandemic will be subsequently maintained and enhanced, also in a post-emergency phase, through review and adaptation of the model based on the type of visit and the patient's profile.

EXPECTED BENEFITS

The implementation of a new model of conducting virtual visits will prove beneficial to all the parties involved in the process of managing HF patients (Table 1).

Table 1. *Expected benefits of virtual visits for different stakeholders*

BENEFIT	PATIENT	CLINICIAN	FACILITY
Simplified logistics (travel reduction)	✔		
Minimization of the risk of infection	✔	✔	
Potential reduction in burden and clinical time		✔	
Continuity of patient care	✔	✔	✔
Effective management of visit processes (delegation, automation)		✔	
Use of innovative solutions for the management of admission and treatment	✔	✔	✔
Increased activity volumes (for the same resources)			✔
Formalization of informal doctor-patient contacts		✔	
Possible reduction of direct and indirect costs (social costs)	✔		✔

VIRTUAL VISIT ORGANIZATION

Section to be validated/customized according to patients management models in your center (frequency of visits, type of patients) and to your clinical practice.

Eligible Patients

Below is a proposal for the categories of patients eligible for a virtual visit. Validate or modify the type of patients according to the model you want to implement in your center.

The type of patients who could benefit most from remote follow-up visits has been identified after several comparisons among the main clinical service representatives of the HF patient process:

- ✓ Patient with known diagnosis
- ✓ No age limit for patients
- ✓ Support of a caregiver during the virtual visit (family member, friend, RSA staff, home-care nurse)
- ✓ Cognitive self-sufficiency status *(in the absence of a caregiver)*
- ✓ Good familiarity of the patient or caregiver with the technology
- ✓ Availability of a PC and/or smartphone, webcam and internet connection
- ✓ Availability of devices for the measurement of certain clinical parameters:
  - o Scale
  - o Sphygmomanometer
  - o Oximeter

The applicability of the above parameters will have to be assessed on a case-by-case basis. For example, to provide for the possible inclusion of other categories of patients unable to access the facility (e.g. self-isolation, out of region).

Below is a proposal of activities that can be replicated in virtual mode. Validate or modify the type of patients according to the model you want to implement in your center.

Activities and Tools to Support the Visit

In order to assess the feasibility and clinical validity of the cardiology visit new virtual model, all activities performed during the outpatient visit were mapped in detail, so as to confirm new model replicability.

As detailed in Table 2, all activities carried out in the outpatient clinic can be transferred to the virtual clinic, with the exception of diagnostic activities, for which physical access to the facility continues to be necessary. It is, therefore, deemed reasonable to evaluate the virtual visit for patients with Heart Failure as equivalent to a physical examination carried out in outpatient settings.

Table 2. *Activities of the outpatient cardiology visit that may be transposed to the Virtual Visit*

TRADITIONAL EXAMINATION ACTIVITIES	ACTIVITIES THAT MAY BE PROVIDED IN VIRTUAL MODE
Weight (Kg)	✔
Heart Rate (HR)	✔
Blood Pressure (BP)	✔
Fluid intake	✔
Narrative medicine (e.g. daily activities)	✔
Peripheral saturation	✔
ECG test administered	X
ECHO test administered	X
Blood chemistry tests evaluation	✔
Diagnostic tests evaluation	✔
Verification/Check of Implanted Devices	✔
Evaluation/revision of drug therapy and Therapeutic Plan	✔
Prescription of in-depth diagnostic tests, if necessary	✔
Information/training on the disease, therapy and lifestyle	✔
Comparison of patient concerns/doubts	✔
Report drafted and submitted	✔
Scheduling the next appointment	✔

A follow-up visit for patients with HF was scheduled allocating the implementation of activities into the following blocks:

- Collection of clinical parameters

- Evaluation of clinical parameters and discussion of reports

- Review and training

- End of visit

The sequence and activities to be performed by the patient during the visit will be defined at the discretion of the clinician, also depending on the clinical picture of each individual patient.

Below is a proposal of the tools that can be used, both by the patient and the clinician, during a virtual visit. Validate or modify according to the needs of your clinical practice.

Table itemizes the different evaluation modes specific to each activity of the follow-up visit, validated during sharing and comparing with different clinical service representatives within the scope of Heart Failure at the national level, which confirmed the selection of the methods listed below.

Table 3. *Virtual cardiology examination activities*

BLOCK	ACTIVITY	EVALUATION MODES
COLLECTION OF CLINICAL PARAMETERS AND QUALITY OF LIFE	Weight (Kg)	Patient Diary
	Heart Rate (HR)	
	Blood Pressure (BP)	
	Fluid intake	
	Narrative medicine (e.g. daily activities)	
	Peripheral saturation (Optional)	
EVALUATION OF CLINICAL PARAMETERS AND DISCUSSION OF REPORTS	Evaluation of clinical parameters collected from the patient	Patient Diary
	Discussion of blood chemistry tests report	Reading the report
	Discussion of diagnostic tests report	
REVIEW AND TRAINING	Evaluation/revision of drug therapy and Therapeutic Plan	Virtual interview
	Prescription of in-depth diagnostic tests, if necessary	
	Information/training on the disease, therapy and lifestyle	
END OF VISIT	Discussion of patient's concerns/doubts	Virtual interview
	Scheduling the next appointment (in virtual mode or in person, according to the criticality level assessed during the VV)	Clinical assessment of the case
	Compilation and submission of VV report	Virtual interview

Organization Aspects

In order to optimize the time-span of the visit, maximizing direct interaction time between the clinician and the patient, certain activities may be performed before the virtual visit, not requiring direct doctor-patient interaction but, for example, through the active involvement of a nurse and/or a caregiver. Activities itemization is outlined in

Table based on the specific phase of the activity.

Table 4. Virtual visit organization for patients with Heart Failure

BEFORE THE VISIT	DURING THE VISIT

1. Collection of **clinical parameters** and **quality of life***:
  - Weight
  - Blood Pressure (BP)
  - Heart Rate (HR)
  - Water intake
  - Daily activities
  - Peripheral saturation *(Optional)*
2. Evaluation of **clinical parameters** and **medication reconciliation**.
	1. Discussion of **clinical parameters** collected (e.g. weight, BP, HR etc.)
	2. Discussion of **blood test results and diagnostic findings**
	3. Verification/Check of Implanted Devices
	4. Evaluation/revision of drug **therapy** and Therapeutic Plan
	5. Prescription of in-depth **diagnostic tests**, if necessary
	6. **Information/training** on the disease, therapy and lifestyle
	7. Discussion of patient's **concerns/doubts**
	8. Compilation and submission of **VV report**
	9. Scheduling the **next appointment** (in **virtual** mode or **in person**, according to the criticality level emerged during the VV)

Activity carried out by 👨‍⚕️ *Doctor* 👩‍⚕️ *Nurse* *Caregiver*
* Collected from the patient and evaluated by the nurse for subsequent

TECHNOLOGY

The following section is intended to present the range of free solutions currently available and most widely used in the field of telemedicine.

In case of a dedicated platform available at your facility, the section should be drafted through discussion with the center's IT department, requesting from the latter the platform specifications in terms of:

- o Functionality (e.g. call, document exchange, etc.)
- o Technology requirements and equipment
- o Security

Required equipment

Below is a list of the equipment that must be available in the outpatient clinic, so that the doctor may carry out a visit in virtual mode:

- o PC
- o Microphone (to be connected to the PC if not already integrated)
- o Audio system (to be connected to the PC if not already integrated)
- o Webcam (to be connected to the PC if not already integrated)
- o Stable Internet connection
- o No Firewall installed (for connection to free platforms)

Platform used for the Virtual Visit

A number of free digital platforms are already available on the market for the management of visits in virtual mode.
To identify the most suitable solution for the project, the required functionalities were first defined and, on the basis of these features, some of the available platforms were evaluated (Table).
Some platforms are already widely used for personal video calls, online meetings, etc. (e.g. Skype, Zoom, Teams), increasing the likelihood that callers and recipients are already aware on how these platforms work.

Table 5. Features and comparison of digital video calling platforms

Category	Function	Priority level	Skype (1st)	Teams (1st)	Cisco Webex (1st)	Meet (2nd)	Zoom (3rd)	Jitsi (3rd)
CONNECTION	Reduced bandwidth optimization	✔	N/A	N/A	N/A	N/A	N/A	✔
	HD Quality		✔	✔	✔	✔	✔	N/A
USER EXPERIENCE	Intuitive interface	✔	✔	✔	✔	✔	✔	✔
	Italian language	✔	✔	✔	✔	✔	✖	✔
	Web access	✔	✔	✔	✔	✔	✖	✔
	Access without plug-ins or clients		✖	✖	✖	N/A		N/A
	Mobile App for patient		✔	✔	✔	✔	✔	✖
SECURITY	Privacy guarantee (encryption)	✔	✔	✔	✔	✔	✔	✔
	Direct access with links	✔	✔	✔	✔	✔	✔	✔
	Video recording		✔	✔	✔	✖	✔	✔
ACCESS MANAGEMENT	Waiting room management	✔	✖	✖	✖	✖	✖	✖
	Master records	✔	✔ [1]	✔	✔	✔	✔ [1]	✔
	Program	✔	✔	✔	✔	✔	✔	✖
	Booking a visit		✖	✖	✖	✖	✖	✖
CONNECTIVITY	Document sharing	✔	✔	✔	✔	✖	✔	✔
	Document archiving		✔	✖	✖	✖	✔	✖
	EHR databases integration		✖	✖	✖	✔	✖	✖
	Devices connection		✖	✖	✖	✔	✖	✖
OTHER	Unlimited number of video sessions	✔	✔	✔	✔	✔	✔	✔
	No strings attached call duration	✔	✔	✔	✔	✔	✔	✔
	Chat		✔	✔	✔	✖	✔	✔
Percentage of features present			**67%**	**67%**	**67%**	**62%**	**57%**	**57%**

✔ function present; ✖ function not present; N/A data not available
Notes: [1]Through external plugin (contact management with Outlook);

[name of the chosen platform] has been selected for the execution of virtual visits, based on the following characteristics that make it the most suitable platform for immediate start-up:

- o free to use
- o already known and used on a daily basis
- o user-friendly
- o the patient is able to access the call without needing to signup
- o the web-based version may be accessed and used without the need to download additional software
- o Document sharing supported

The use of the platform does not involve the sharing and storage of sensitive data. Information on privacy protection and data security relating to the use of the platform can be found in the privacy policy on the platform website.

VIRTUAL VISIT IMPLEMENTATION PLAN

The activation process of the Virtual Visit service for patients with Heart Failure will follow a step-by-step logic, in order to guide the definition of a virtual visit model that is most in line with the purposes conceived for the tool.

The approach defined for implementation is subdivided into the following phases:

- **Step 0 – Start of activities and communication to the Health Department:** Request to the Health Department to start with the implementation of the Virtual Visit in the Outpatient Clinic and to involve the relevant offices of the structure:
    - o Meeting with the Health Department to define the scope of application (e.g. Outpatient Clinics involved, dedicated resources)
    - o Establishment of a clinical (doctors and nurses at the outpatient clinic) and administrative (selected Representatives of the DPO, IT, Health Department offices) work group

- **Step 1 – Organization Model:** Definition and customization of the Virtual Visit implementation mode:
    - o Validation of the eligible patient profile
    - o Definition of the visit implementation timeline (before or during the actual meeting with the patient)
    - o Selection and definition of documents to share with the patient (e.g. brochure of the disease, self-assessment questionnaire)
    - o Definition of the parties to be involved in each phase of the process

    Useful paragraphs: Sect. Eligible Patients, Sec. Activities and tools to support the Visit, Sect. Organization aspects

    Professionals involved: Doctors and nurses of the Heart Failure outpatient clinic

- **Step 2 – Choice of digital technology:** Selection of the digital platform to perform the Virtual Visits:
    - o Contact your IT department and check if there is a proprietary platform for your facility*
    - o Organize training for the outpatient team on the use of the platform
    - o Request any information material on the platform operation to be shared with the patient
    - o Schedule the test/launch phase with the support of the IT department

    *In the absence of such phase, select with the IT department the free digital solution best suited to your purposes of use

    Useful paragraphs: Sect. Technology

    Professionals involved: Doctors and nurses of the Heart Failure outpatient clinic, IT department

- **Step 3 – Administrative and legal aspects:** Once the model and channel have been defined, administrative and medical-legal aspects shall be duly considered with the competent offices:
    - o If the topic has not been defined before, contact your Primary Care and/or the Health Department to clarify the procedures for reporting and remuneration of the visits
    - o Define with the DPO the tools necessary for the patient's acceptance of the service (patient information disclosure, information on data processing)

    Useful paragraphs: Sect. Annexes – Patient information disclosure

    Professionals involved: Doctors and nurses of the Heart Failure outpatient clinic, DPO office

- **Step 4 – Customizing the support tools for the execution of the visit:** At this point, the support tools should be populated with data processed in the previous steps. **Table 6** shows the activities to be carried out and the professionals to be involved during tools customization:

Table 6. Activities and roles in support tools customization

Patient Guide	Outpatient Clinic Team	IT	DPO
Adjusted patient information disclosure	✔		✔
Information on the processing of personal data	✔		✔
Visit implementation steps	✔		
Instructions on how to use the chosen digital solution	✔	✔	
Patient diary	✔		
Brochure of the disease	✔		
Clinician Support Kit			
Virtual Visit process steps	✔		
Visit implementation mode	✔		
Activities check-list	✔		

Useful paragraphs: Sect. Annexes – Clinician Support Kit and Patient Guide

Professionals involved: Doctors and nurses of the Heart Failure outpatient clinic, IT department, DPO office

- **Step 5 – Model validation with the Health Department:** Preparation for discussion with the Health Department to receive authorization to start the service:

    o This document (Protocol for the Virtual Management of Follow-up Visits in Patients with Heart Failure) should be adjusted, customizing it with the *ad-hoc* model and information disclosure for your center.

    o Once the Protocol has been finalized, it must be submitted to the Health Department to obtain authorization to start the service.

Professionals involved: Doctors and nurses of the Heart Failure outpatient clinic, the Health Department

- **Step 6 – Test and go live:** Once the support tools have been completed and the necessary approvals have been obtained from the IT, DPO and Health Department offices, it is possible to start with a pilot group of patients, who will be enrolled in the service, so as to anticipate any criticalities in the grounding of the protocol:

    o Define the test execution parameters (patients that may be enrolled, number of visits, timing)

    o Follow the steps of the virtual visit process (patients enrolment, documents sharing, preliminary assessments)

    o Virtual Visit Testing

    o Model evaluation (sending out patient and outpatient team evaluation questionnaires for consideration of possible corrective action)

If deemed appropriate after the testing phase, adapt the model and/or tools in view of final implementation of the service.

Professionals involved: Doctors and nurses of the Heart Failure outpatient clinic

VIRTUAL VISIT SERVICE CONSENT

All eligible patients must be informed of the purpose of the project and must obtain a written information document explaining the nature, purpose and course of the project. The clinician will have to illustrate the initiative to the patient and to any of the patient caregivers, answering possible questions and informing the patient that his/her acceptance of the virtual visit service is absolutely voluntary.

The patient shall have the opportunity to discuss his/her consent with trusted individuals and the appropriate time for a full assessment before agreeing to participate. The patient will be able to express his/her willingness to participate in the service by telephone and will then receive a "Patient Guide" via e-mail (see Sect. Annexes), containing a copy of the service information and instructions for implementation of the virtual visit. The patient may express his/her wish to discontinue the service at any time.

PRIVACY

The data on the participants joining the project will be confidential and used in compliance with current legislation on the protection of sensitive data (including sensitive data obtained by electronic means) and privacy legislation as indicated in Regulation 679/2016/EU and Legislative Decree 196/2003, as amended by Legislative Decree 101/2018. The Center will process the personal data of the project participants as Independent Data Controller, pursuant to and for the purposes of Regulation 679/2016/EU and Legislative Decree 196/2003, as amended by Legislative Decree 101/2018, each to the scope of its competence, exclusively insofar as project execution.

The data and personal information collected during the virtual visit are to be considered equivalent to those collected during a traditional visit at a hospital facility. The patient will be provided with a copy of the information on the processing of personal data related to the service offered, integrated with information on the security of data transmission on the platform used for the visit.

SUPPORTING ANNEXES

Below is a proposal of the tools that can be used, both by the patient and the clinician, during a Virtual Visit. Validate and customize them. After customization, report the instruments selected as images in the protocol, in order to provide a complete document to the Health Department.

IMPLEMENTING A VIRTUAL VISIT
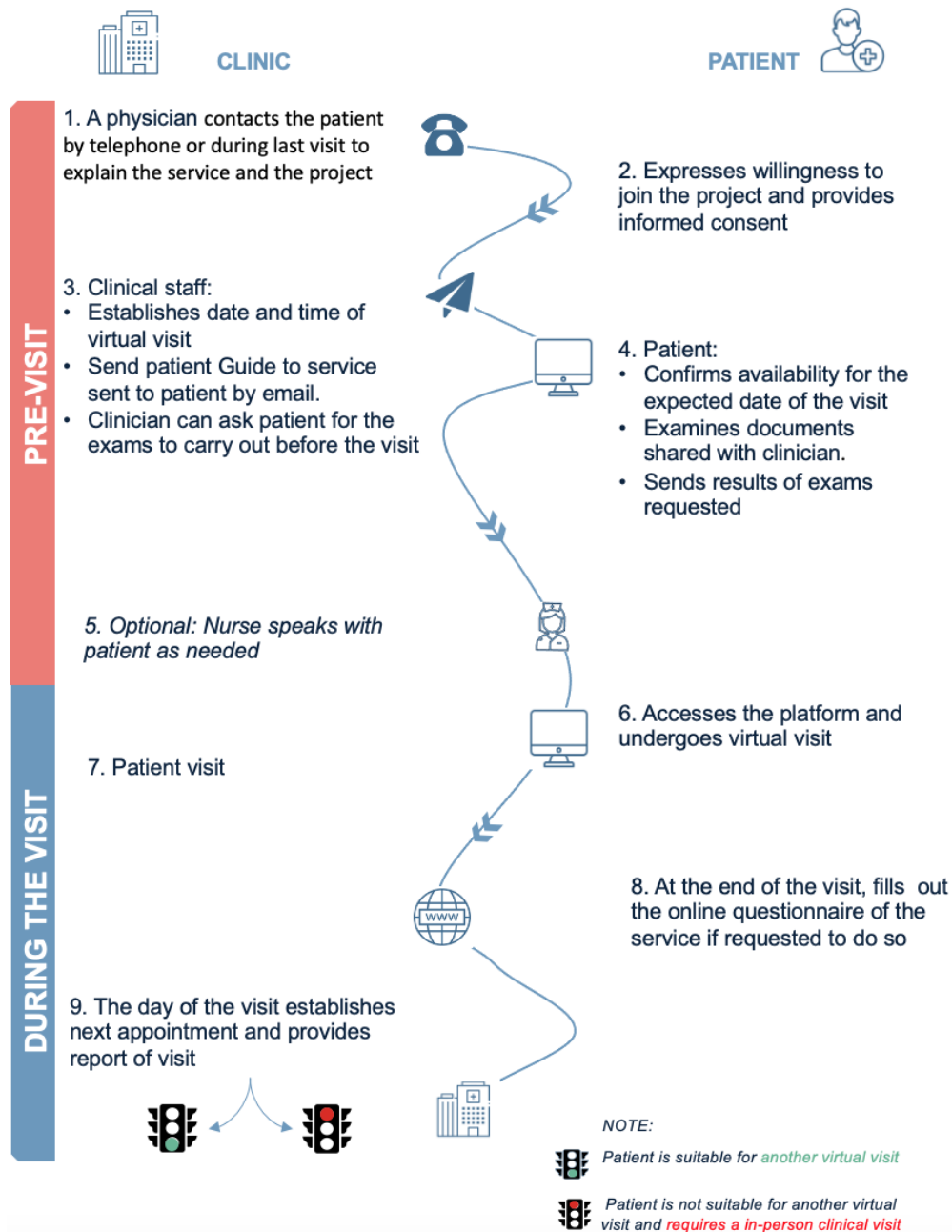
Dear Heart Failure Outpatient Clinic Representative,

below you will find the itemization of the activities planned and how to carry out a virtual visit.
For time optimization purposes, the visit is sub-divided into three subsequent phases:

1. ***Pre-visit activities:*** *Completion of the Patient Diary by the patient. This will be discussed during the visit*

2. ***Implementing a "live" visit:*** *interview with the patient to discuss the evidence gathered and the patient's health condition*

3. ***Post-visit activities:*** *sharing and archiving the virtual visit report.*

Then you will find a detailed outline of the activities provided in the 3 phases, on the page "Virtual visit follow-up activities".

VIRTUAL VISIT PROCESS STEPS

CLINIC

PATIENT

PRE-VISIT

1. A physician contacts the patient by telephone or during last visit to explain the service and the project

2. Expresses willingness to join the project and provides informed consent

3. Clinical staff:
- Establishes date and time of virtual visit
- Send patient Guide to service sent to patient by email.
- Clinician can ask patient for the exams to carry out before the visit

4. Patient:
- Confirms availability for the expected date of the visit
- Examines documents shared with clinician.
- Sends results of exams requested

5. Optional: Nurse speaks with patient as needed

DURING THE VISIT

6. Accesses the platform and undergoes virtual visit

7. Patient visit

8. At the end of the visit, fills out the online questionnaire of the service if requested to do so

9. The day of the visit establishes next appointment and provides report of visit

NOTE:

Patient is suitable for *another virtual visit*

Patient is not suitable for another virtual visit and *requires a in-person clinical visit*

VIRTUAL VISIT PROCESS FOR PATIENTS WITH HF

BEFORE THE VISIT

1. Collection of **clinical parameters** and **quality of life***:
   - Weight
   - Blood Pressure (BP)
   - Heart Rate (HR)
   - Water intake
   - Daily activities
   - Peripheral saturation *(Optional)*

2. Evaluation of **clinical parameters** and **medication reconciliation**

DURING THE VISIT

1. Discussion of **clinical parameters** collected (e.g. weight, BP, HR etc.)
2. Discussion of **medical reports**:
   - Blood chemistry tests
   - Diagnostic tests
3. Verification/Check of Implanted Devices
4. Evaluation/revision of drug **therapy** and Therapeutic Plan
5. Prescription of in-depth **diagnostic tests**, if necessary
6. **Information/training** on the disease, therapy and lifestyle
7. Discussion of patient's **concerns/doubts**
8. Compilation and submission of **VV report**
9. Scheduling the **next appointment** (in **virtual** mode or **in person** according to the criticality level emerged during the VV)

Activity carried out by Doctor Nurse Caregiver

* Collected from the patient and evaluated by the nurse for subsequent examination by the doctor

VIRTUAL VISIT ACTIVITIES CHECKLIST FOR PATIENTS WITH HEART FAILURE

Below are all the areas of assessment that can be investigated during a virtual visit. The method of evaluation is indicated for each area. Depending on the patient's clinical condition, activities may be fully or partially implemented.

VIRTUAL VISIT ACTIVITIES	MODES

☐ Detection of **clinical parameters** and **quality of life**:
   ❑ *Weight*
   ❑ *Blood Pressure (BP)*
   ❑ *Heart Rate (HR)*
   ❑ *Water intake*
   ❑ *Narrative Medicine (daily activities)*
   ❑ *Peripheral saturation (Optional)*
	Patient diary

☐ Evaluation of **clinical parameters** collected (e.g. weight, BP, HR, etc.)
☐ Discussion of **medical reports**:
   ❑ *Blood chemistry tests*
   ❑ *Diagnostic tests*
☐ Verification/Check of **Implanted Devices**
☐ Evaluation/revision of **drug therapy** and **Treatment Plan**
☐ Prescription of in-depth **diagnostic tests**, if necessary
☐ Discussion of patient's **concerns/doubts**
	Virtual interview

☐ **Information/training** on the disease, therapy and lifestyle	Patient brochure
☐ Scheduling the **next appointment** ☐ Compilation and submission of the virtual visit **report** ☐ Archiving the virtual visit **report**	Virtual interview

VIRTUAL VISIT EVALUATION QUESTIONNAIRE

Dear Doctor,

at the end of your visit, we ask you to take a few minutes to complete a questionnaire. Your opinion is important to us and will help us evaluate and improve this service.

The questionnaire is completely anonymous.

Please enter the icon that best reflects your level of satisfaction:

NOT SATISFIED 🙁   SATISFIED 🙂   VERY SATISFIED 😎

General information

1. Virtual visit date _____

2. Patient age group

<18	18-35	36-55	56-64	>65
○	○	○	○	○

3. Presence of the caregiver   YES ○   NO ○   Active role during the visit   YES ○   NO ○

Technology assessment

4. Did I have connection problems during the call?   YES ○   NO ○

5. The instructions I was given for using the technology were adequate   🙁 🙂 😎

6. I didn't need support...

a. ... in managing the technical side of the visit (e.g. accessing the visit)   🙁 🙂 😎

b. ... to exchange documents   🙁 🙂 😎

Evaluation of appointment times

7. The scheduled connection time for the visit was respected   🙁 🙂 😎

8. The overall duration of the visit was adequate   🙁 🙂 😎

9. How do you rate your virtual visit experience in general?   🙁 🙂 😎

Evaluation of the interaction in virtual mode

10. The patient was able to communicate effectively during the virtual visit   🙁 🙂 😎

11. Communication with the patient through a monitor was not much different from in-person interaction   🙁 🙂 😎

12. I don't think remote interaction is a barrier to assessing a patient's clinical condition   🙁 🙂 😎

Closing assessments

13. Overall assessment of your virtual visit experience

14. I had to refer the patient to an outpatient visit

YES	NO
◯	◯

15. I want to offer the patient other visits in virtual mode

YES	NO
◯	◯

16. Notes

VIRTUAL VISITS MONITORING LOG

Dear Doctor,

at the end of a monthly cycle of virtual visits, we ask for a few minutes of your time to fill out the following log to track your activity.

Date: _____

ACTIVITY VOLUMES

VIRTUAL VISITS PERFORMED

	Number
Total	
Weekly	

DURATION OF VIRTUAL VISITS

	Duration (min)
Live visit	
Patient: pre-visit activities	
Nurse: pre-visit activities	

IMPLEMENTING A VISIT

ROLE OF THE CAREGIVER

	%
Present during the visit	
Active role during the visit	

PRE-VISIT ACTIVITIES

	%
Patient use of devices available at home	
Scale	
Sphygmomanometer	
Oximeter	
Shared documents: Patient Guide	
VV Service Information Disclosure	
Data processing information	
Visit implementation instructions	
Skype instructions	
Patient Diary	
Brochures	
VV evaluation questionnaire	

VIRTUAL INTERVIEW

	%
Patient: respected visiting hours	
Doctor: respected visiting hours	
Effective communication with the patient	
Patient: experienced technical difficulties	
Doctor: experienced technical difficulties	
Patients referred for a virtual visit	
Patients referred for an outpatient visit	

VIRTUAL VISITS MONITORING LOG

How did the patient evaluate his/her virtual visit experience?

Critical issues that emerged during the course of the Virtual Visit:

Suggestions for improving the Virtual Visit service:

Patient Tools

Foreword: The parts highlighted in blue should be customized with the required information before sharing them with the patient

INFORMATION DISCLOSURE FOR THE "VIRTUAL FOLLOW-UP VISIT IN PATIENTS WITH HEART FAILURE" SERVICE

Dear patient, [name of the Center] has activated a "Virtual Visits" Service, which also allows the provision of remote healthcare services. The virtual visit will be carried out by the [name of the Center] Operating Unit clinicians, under the coordination of Dr. [name of service representative]. The "Virtual Visits" Service will be managed through the platform [name of the chosen platform], selected because it is a free, easy-to-use service whose security standards guarantee the confidentiality and privacy of doctor-patient interactions.
The Service consists of several phases that are briefly illustrated below.
In order to be able to use this service, in light of the information on the processing of personal data that we annex herein, we need you to provide your express authorization.
1. **Virtual visit proposal**
   * Your doctor at [name of the Center] offers to the patient already admitted at [name of the Center], the provision of visits in virtual mode, through the use of [name of the chosen platform].
   * The doctor explains to the patient the disclosure statement on the processing of personal data.
   * The doctor collects the (patient) acceptance to use the Service.

2. **Virtual visit patient acceptance**
   * If the patient accepts to take advantage of this new Service, he/she will be entered in a special calendar dedicated to the virtual outpatient clinic, in which the patient's personal data will be noted in a special slot of the calendar (day and time slot) along with the patient e-mail address, which is indispensable to later contact the patient for the virtual visit.
   * The patient receives by e-mail:
     o A Patient Guide containing information and instructions for connecting to the platform [name of the chosen platform] and how to use it for the visit;
     o Diary for initial grading;
     o Sharing a questionnaire for a possible anonymous evaluation of the Service.

3. **Sharing doctor-patient documents**
   A few days before the visit, if requested by the doctor, the patient shares via (insert the document exchange mode according to the chosen platform) any preliminary documents (e.g. blood chemistry tests and diagnostic tests reports, Patient Diary) useful for the evaluation of the patient's state of health.

4. **Virtual visit access**
   On the day and at the time set for the virtual visit, the doctor initiates the video call to the patient.

5. **Visit implementation and risks minimization**
   The doctor speaks with the patient and inquires on his/her health condition through a series of targeted questions.
   In the final phase of the visit, the doctor tells the patient about his/her assessment of the patient health condition and any therapy suggestions or requests for further evaluation.
   A report will be drafted and shared with the patient (insert report sharing mode provided by the Center).

6. **End of the Virtual Visit**
   If requested, the patient will fill out an anonymous online questionnaire evaluating his/her visit by accessing the link received via e-mail.

INFORMATION ON THE PROCESSING OF PERSONAL DATA FOR THE PURPOSE OF DIAGNOSIS, TREATMENT AND REHABILITATION ACTIVITIES

"VIRTUAL FOLLOW-UP VISIT IN PATIENTS WITH HEART FAILURE" SERVICE

(pursuant to Art. 13 and 14 (EU) Regulation 2016/679)

[name of the Center], located in [location of Center], as the Data Controller, informs you that a new Service has been adopted, "Virtual follow-up visits in patients with Heart Failure", through which health services can be provided even when the patient cannot be physically present at the facilities of the [name of Center].

With this Service, which uses the [name of the chosen platform] tool, the Doctor and the patient may have a virtual conversation and exchange documents useful for the evaluation of the patient's health condition.

[name of the platform] is the digital platform chosen for implementing virtual visits, as it is a free, easy-to-use tool whose security standards guarantee the confidentiality and privacy of doctor-patient interaction.

The virtual dialogue between Patient and Doctor involves personal data being captured in streaming mode and document sharing. [name of Center] will not store virtual visits videos and interviews will, therefore, be managed in the same way as those which take place when the patient is physically present at his/her outpatient clinic. A report will be drawn up for virtual visits according to the ordinary procedures, which will be sent to the patient according to the methods defined by the facility.

DATA PROCESSING PURPOSE

The processing of personal data carried out by [name of the Center] through the Virtual Outpatient Clinic Service is aimed at ensuring the provision of healthcare services for diagnosis and treatment.

LEGAL GROUNDS

The legal grounds for the lawful processing operations is the acquisition of a specific consent from the patient in accordance with Article 6, par. 1, letter a) of EU Regulation 2016/679.

In this regard, it should be noted that the specific processing of personal data is discretionary and failure to provide processing consent thereof, does not affect the provision of ordinary healthcare services.

THE SOURCE OF PERSONAL DATA

The personal data processed by the Facility is provided to it by the data subjects, or by their legal representatives.

RECIPIENTS OR CATEGORIES OF RECIPIENTS TO WHOM PERSONAL DATA MAY BE DISCLOSED

[name of the Center] may communicate, if specifically provided for by law, the personal data, of a public or private nature, of the data subjects to third parties, who will subsequently process them as Independent Data Controllers.

PERSONAL DATA PROCESSING METHODS

Personal data processing activities relating to the Virtual Outpatient Clinic Service are carried out electronically and/or manually by specifically authorized individuals, in accordance with the provisions of Articles 28 and 29 of the GDPR. Personal data will be processed subject to the adoption of technical and organizational measures, in compliance with the principles of necessity, lawfulness, fairness, accuracy, proportionality, relevance and non-excessiveness pursuant to Article 5 of the GDPR.

With regard to the specific adoption of the [name of the platform] tool, we point out that this tool was chosen because it operates according to encryption protocols that guarantee the communications security with respect to the risk of third-party interception.

It is important to underline that, as indicated by ISS in the document "Interim indications for telemedicine services during the COVID-19 health emergency", in order to facilitate as much as possible the adoption of telemedicine services in the emergency phase, it may be necessary to leverage on devices and tools already present at the patients' home, addressing at best the possible risks related in terms of data security, balancing these risks in relation to the system that is used and the huge advantages that remote service can offer. Therefore, by agreeing to participate in the Service, you acknowledge the benefits of virtual visits and accept any risk related to the management of personal data related to the Service.

TRANSFER OF PERSONAL DATA

Data is not transferred outside of the European Union.

DATA RETENTION PERIOD

Personal data processed to ensure that Virtual Outpatient Clinic Service operations are stored, excluding those acquired by video, by [name of the Center] for the time necessary to achieve the purposes for which they are processed, except for any longer time necessary to comply with legal or regulatory obligations due to the nature of the data, also taking into account the provisions of the Company Document Retention Plan (so-called mandatory retention period) to protect the documentary database.

DATA PROTECTION OFFICER

The Data Protection Officer appointed by the [name of the Center] can be contacted at this e-mail address: [DPO representative e-mail]

EXERCISE OF RIGHTS

The Data Subjects may exercise their right to obtain access to personal data, rectify inaccurate data, integrate incomplete data and, in the cases established by law or regulation, to limit, delete or oppose data processing (Articles 15 to 22 of the GDPR), by sending an e-mail to [DPO representative's e-mail], or sending a letter to the above address.

RIGHT TO FILE A COMPLAINT

If you believe that your personal data is being processed in breach of the law, you have the right to lodge a complaint with the personal data protection Authority.

Further information regarding the processing of personal data, including how to exercise your own rights, is available on the website: [insert Center's website], under the Privacy section [customize based on the location of the Center's website].

The Data Controller

[name of Center]

WHAT WILL HAPPEN DURING YOUR VIRTUAL VISIT

DOCTOR

Your doctor **suggested** to conduct your next **visit in virtual mode**. Look over the **documents provided** by the doctor (e.g. service information disclosure and information on data processing) and ask for information if anything is unclear

DIARY

Prior to your scheduled virtual visit, be sure to **fill out the Patient Diary** as often as your doctor prescribed to you during your last visit

ON THE DAY OF THE VISIT

On the previously agreed day and time, **you will receive a call from your doctor** (NB: If you are late, the doctor will call you as soon as possible. Do not initiate the call if you are late):

1. **Answer** the call prompt that will appear on your smartphone or computer screen

2. **Place** your mobile phone or computer in a position so that the doctor may clearly see your face

During the visit, the doctor may ask you to perform certain activities during which you will have to remain in the frame of your screen
If you are experiencing any difficulties using your computer or smartphone, make sure you have someone with you who can help (family member, caregiver, friend, etc.)

REPORT

The doctor will share the **report** of the visit as soon as it is completed

QUESTIONNAIRE

At the end of the visit, the doctor may ask you to fill out a **questionnaire to evaluate** your virtual visit experience

DIGITAL SOLUTION INSTRUCTIONS

INSTALLING SKYPE ON YOUR COMPUTER

Access the following link from your browser:
https://support.skype.com/it/faq/FA11098/come-posso-iniziare-a-utilizzare-skype or follow the instructions below:

❶ Search for "download Skype" on Google or another browser

❷ Click on the first result

❸ Select the download option for Windows, Mac OS or Linux and follow the instructions
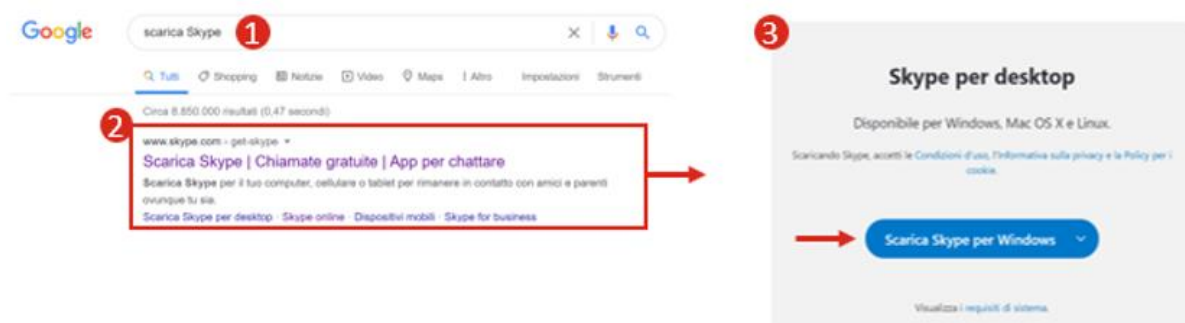
INSTALLING SKYPE ON YOUR SMARTPHONE

❶ From your smartphone, open the Google Play application or App Store (for iPhone)
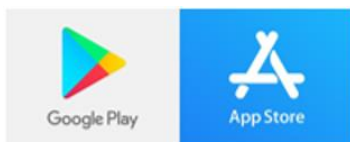
❷ Search for the "Skype" application

❸ Download the application on your smartphone

❹ Open the Skype App by clicking on the Skype icon

❺ Log in with your credentials (or create an account by following the instructions)

(continued on next page)

Add /'Heart Failure Outpatient Clinic' to your Skype contacts

❶ Look up the name assigned to you by your doctor

❷ Send a contact request

❸ Wait for the confirmation that will arrive in the chat in the following days

❶ Search here for the name received by e-mail
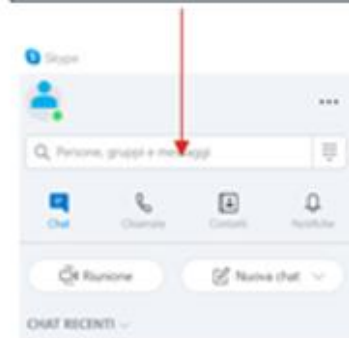
❷ Click on the contact name and then click on "Greet" to send a contact request
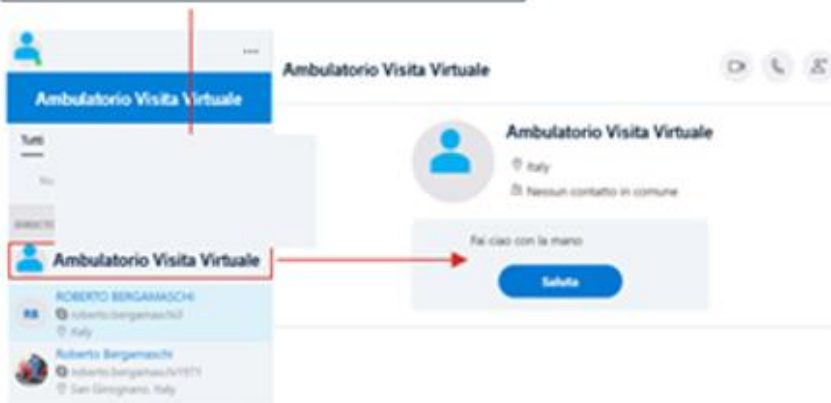
❸ Wait for the acceptance of the contact request in the following days

DIGITAL SOLUTION INSTRUCTIONS – TEAMS

Once you have received the e-mail confirming your appointment, to access your visit:

❶ Click on the text
Click here to join the meeting
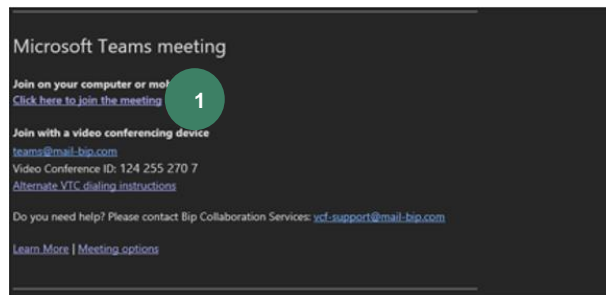
❷ Click cancel on the window that opens

❸ Click on Web attendance
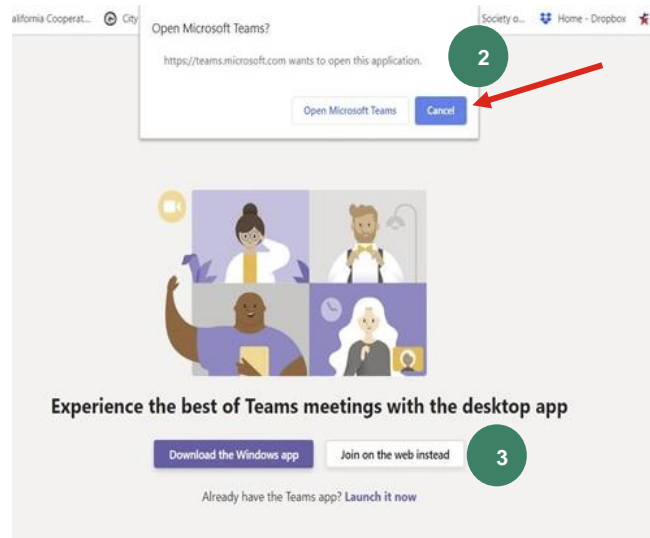
❹ Enter your name

❺ Activate microphone and camera

❻ At the exact time and date of your visit, click attend now
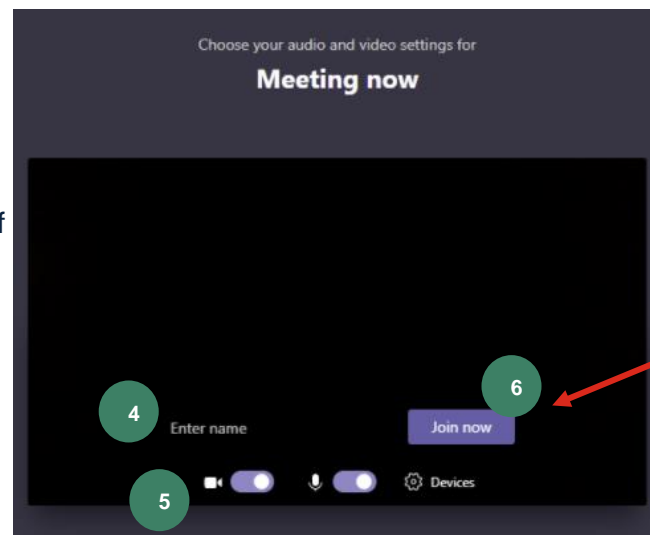
DIGITAL SOLUTION INSTRUCTIONS – ZOOM
INSTALLING ZOOM ON YOUR COMPUTER

❶ Search "Download Zoom" on Google or other search engine

❷ Click on the first result

❸ Select the download option "Zoom Client for Meetings" and follow the instructions to create an account

❹ On the day of your visit, open the App and click Join

❺ Enter the meeting ID you received by e-mail

❻ Make sure all options are unchecked and that you entered your name

❼ Click on Join
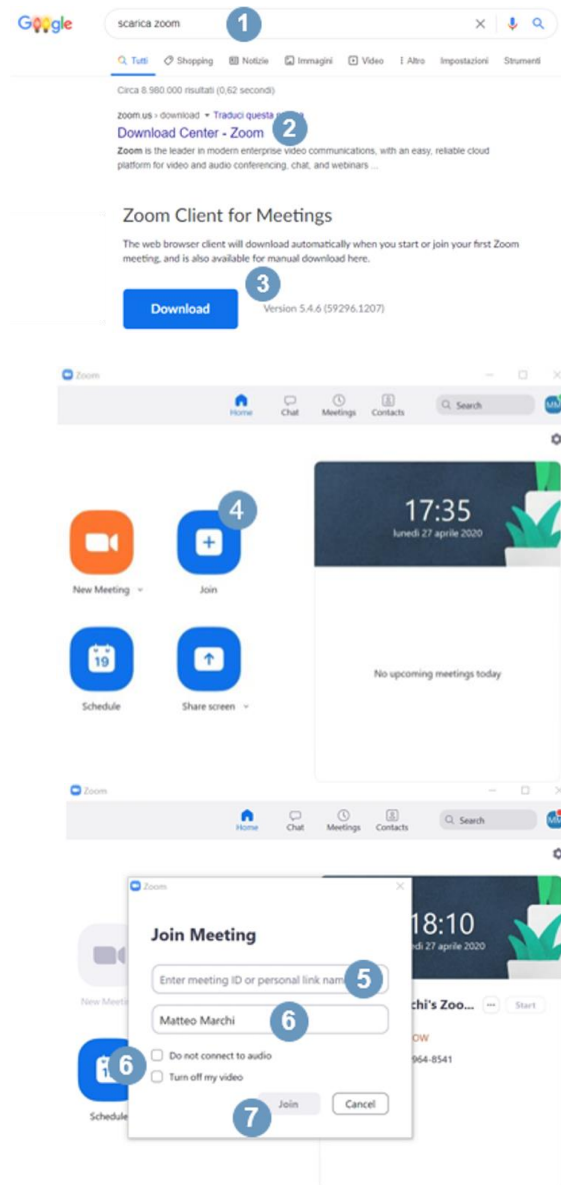
PATImient DIARY

PATIENT DIARY

Records the parameters shown in the table to monitor the course of the disease

Fill in the various fields according to the frequency prescribed by your doctor. Report your Weight, Blood Pressure and Heart Rate upon awakening

First and Last Name: _____   To be completed each: _____

DATE	WEIGHT (morning after urinating and before breakfast)	Blood Pressure (Always measure upon awakening)		Heart Rate (Always measure upon awakening)	Fluid intake (Estimate intakes in liters)	Notes Use this field to report any special or abnormal events to share with the doctor during the visit
		B.P. Minimum	B.P. Maximum			

Evaluate whether there has been an improvement or deterioration in the activities indicated in the following table as compared to the previous visit

Select the option that most closely reflects your opinion, Start filling out the questionnaire 2 weeks before the visit

First and Last Name: _____

WEEKS	WALK			SWOLLEN LEGS/FEET	SLEEP QUALITY	HOW MANY PILLOWS DO YOU SLEEP ON?
2 weeks before the visit	😊 😐 ☹️		😊 😐 ☹️	😊 😐 ☹️	😊 😐 ☹️	Ex. 2
The previous week	😊 😐 ☹️	😊 😐 ☹️	😊 😐 ☹️	😊 😐 ☹️	😊 😐 ☹️	

Legend: Condition improved 😊, Condition unchanged 😐, Condition worsened ☹️

DRUG NAME	ACTIVE INGREDIENT	DOSAGE	REASON	MORNING	LUNCH	AFTERNOON	DINNER	EVENING	STARTED ON	STOPPED ON

Taking Care of My Heart Failure

WHAT IS **HEART FAILURE**?

A condition in which the heart is no longer able to pump blood throughout the entire body adequately to meet the demands of the body

It is a chronic disease that can be managed effectively by learning to recognize and control its main symptoms

WHAT ARE THE SYMPTOMS AND HOW RECOGNIZE THEM?

Feeling extremely tired and weak

Swelling of belly, legs, ankles and feet

Shortness of breath

Rapid weight changes

Feeling dizziness

Irregular heartbeat

WHAT YOU CAN **MONITOR**?

Monitor the following parameters on a daily basis and promptly notify your doctor in case of any changes

BODY WEIGHT – Weigh yourself every morning on an empty stomach at the same time and ask yourself the following questions:

1. My weight has increased more than 2 kg in two days?
2. Do I have sock marks on my ankles after a few hours?
3. I can't sleep lying down (I have difficulty breathing)?

If you answer YES to only one of these questions please inform the doctor

Taking Care of My Heart Failure

DIFFICULTY BREATHING – Ask yourself the following questions:
1. Do I struggle to breathe more when performing daily activities?
2. Do I feel more tired even if I'm at rest?
3. Do I need an extra pillow to sleep on?
4. Do I wake up at night because I have an irritating dry cough?

If you answer YES to only one of these questions please inform the doctor

HEART RATE – Ask yourself the following questions:
1. Do I feel a fast heartbeat even when I'm at rest?
2. Does the heartbeat seem irregular or strange to me?

If you answer YES to only one of these questions please inform the doctor

HOW CAN YOU INTERVENE?

1. Take your medications as directed by your doctor
2. Try to have a healthy diet
3. Reduce your salt intake
4. Stop smoking
5. Exercise

We recommend that you start a diet eating foods that you like and gradually change your eating habits

Food recommended:
✓ Low-fat milk and cheese
✓ Olive oil
✓ Fresh fish
✓ White meat (chicken, turkey, etc.)
✓ Lean meats
✓ Legumes
✓ Fresh fruit

Food not recommended:
- Cold cuts and sausages
- Fatty cheeses
- French fries
- Canned or salted fish (anchovies, mackerel, sardines, etc.)
- Sweets and chocolate
- Dried and oily fruits and nuts

SERVICE EVALUATION QUESTIONNAIRE

Dear Patient,

at the end of your visit, we ask you to take a few minutes to complete a questionnaire. Your opinion is important to us and will help us evaluate and improve this service.

The questionnaire is completely anonymous.

Please enter the icon that best reflects your level of satisfaction:

NOT SATISFIED 😞　　SATISFIED 🙂　　VERY SATISFIED 😎

	<18	18-35	36-55	56-64	>65
1. Age group	○	○	○	○	○

	<18	18-35	36-55	56-64	>65
2. Caregiver age group	○	○	○	○	○

	0-30 MIN	30-60 MIN	1-2 HOURS	>2 HOURS
3. Time generally necessary to go to a regular outpatient clinic visit in person	○	○	○	○

	YES	NO
4. Did you have any connection problems during the call?	○	○

5. I was provided adequate instructions for using the technology 😞 🙂 😎

6. I didn't need support...

a. ... in managing the technical side of the visit (e.g. accessing the visit) 😞 🙂 😎

b. ... to proceed with the visit and understand the doctor 😞 🙂 😎

c. ... to exchange documents 😞 🙂 😎

7. The overall duration of the visit was adequate 😞 🙂 😎

8. How do you rate your virtual visit experience in general? 😞 🙂 😎

9. Communication with the doctor through the screen was not much different from in-person interaction 😞 🙂 😎

10. The benefits of remote management of the visit, avoiding access to the hospital, are high 😞 🙂 😎

11. Notes

[ ]